

111TH CONGRESS  
1ST 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, and Mr. ISAKSON) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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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,*

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

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

7 (b) **REFERENCES.**—Except as otherwise specified,  
8 whenever in this Act an amendment is expressed in terms  
9 of an amendment to a section or other provision, the ref-

1 erence shall be considered to be made to a section or other  
 2 provision of the Federal Food, Drug, and Cosmetic Act  
 3 (21 U.S.C. 301 et seq.).

4 (c) TABLE OF CONTENTS.—The table of contents for  
 5 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 during 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 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. 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 350c(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  
17 to be affected in a similar manner,” after “relating  
18 to such article”;

19 (3) by striking the last sentence; and

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

21 “(2) USE OF OR EXPOSURE TO FOOD OF CON-  
22 CERN.—If the Secretary believes that there is a rea-  
23 sonable probability that the use of or exposure to an  
24 article of food, and any other article of food that the

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

20 “(3) APPLICATION.—The requirement under  
21 paragraphs (1) and (2) applies to all records relating  
22 to the manufacture, processing, packing, distribu-  
23 tion, receipt, holding, or importation of such article  
24 maintained by or on behalf of such person in any

1 format (including paper and electronic formats) and  
2 at any location.”.

3 (b) CONFORMING AMENDMENT.—Section  
4 704(a)(1)(B) (21 U.S.C. 374(a)(1)(B)) is amended by  
5 striking “section 414 when” and all that follows through  
6 “subject to” and inserting “section 414, when the stand-  
7 ard for record inspection under paragraph (1) or (2) of  
8 section 414(a) applies, subject to”.

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

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

13 (1) in paragraph (2), by—

14 (A) striking “conducts business and” and  
15 inserting “conducts business, the e-mail address  
16 for the contact person of the facility or, in the  
17 case of a foreign facility, the United States  
18 agent for the facility, and”; and

19 (B) inserting “, or any other food cat-  
20 egories as determined appropriate by the Sec-  
21 retary, including by guidance)” after “Code of  
22 Federal Regulations”;

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

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

3           “(3) BIENNIAL REGISTRATION RENEWAL.—  
4           During the period beginning on October 1 and end-  
5           ing on December 31 of each even-numbered year, a  
6           registrant that has submitted a registration under  
7           paragraph (1) shall submit to the Secretary a re-  
8           newal registration containing the information de-  
9           scribed in paragraph (2). The Secretary shall pro-  
10          vide for an abbreviated registration renewal process  
11          for any registrant that has not had any changes to  
12          such information since the registrant submitted the  
13          preceding registration or registration renewal for the  
14          facility involved.”.

15          (b) SUSPENSION OF REGISTRATION.—

16                 (1) IN GENERAL.—Section 415 (21 U.S.C.  
17                 350d) is amended—

18                         (A) in subsection (a)(2), by inserting after  
19                         the first sentence the following: “The registra-  
20                         tion shall contain an assurance that the Sec-  
21                         retary will be permitted to inspect such facility  
22                         at the times and in the manner permitted by  
23                         this Act.”;

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

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

3 “(b) SUSPENSION OF REGISTRATION.—

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

12 “(2) HEARING ON SUSPENSION.—The Secretary  
13 shall provide the registrant subject to an order  
14 under paragraph (1) with an opportunity for an in-  
15 formal hearing, to be held as soon as possible but  
16 not later than 2 days after the issuance of the order,  
17 on the actions required for reinstatement of registra-  
18 tion and why the registration that is subject to sus-  
19 pension should be reinstated. The Secretary shall re-  
20 instate a registration if the Secretary determines,  
21 based on evidence presented, that adequate grounds  
22 do not exist to continue the suspension of the reg-  
23 istration.

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

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

11           “(B) VACATING OF ORDER.—Upon a de-  
12 termination by the Secretary that adequate  
13 grounds do not exist to continue the suspension  
14 actions required by the order, or that such ac-  
15 tions should be modified, the Secretary shall va-  
16 cate the order or modify the order.

17           “(4) EFFECT OF SUSPENSION.—If the registra-  
18 tion of a facility is suspended under this subsection,  
19 such facility shall not import food or offer to import  
20 food into the United States, or otherwise introduce  
21 food into interstate commerce in the United States.

22           “(5) REGULATIONS.—The Secretary shall pro-  
23 mulgate regulations that describe the standards offi-  
24 cials will use in making a determination to suspend  
25 a registration, and the format such officials will use



1 to explain to the registrant the conditions found at  
2 the facility.

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

8 (2) IMPORTED FOOD.—Section 801(l) (21  
9 U.S.C. 381(l)) is amended by inserting “(or for  
10 which a registration has been suspended under such  
11 section)” after “section 415”.

12 (c) CONFORMING AMENDMENTS.—

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

15 (2) Section 415(d), as redesignated by sub-  
16 section (b), is amended by adding at the end before  
17 the period “for a facility to be registered, except  
18 with respect to the reinstatement of a registration  
19 that is suspended under subsection (b)”.

20 **SEC. 103. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE**  
21 **CONTROLS.**

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

1 **“SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVEN-**  
2 **TIVE CONTROLS.**

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

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

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

18 “(A) biological, chemical, physical, and ra-  
19 diological hazards, natural toxins, pesticides,  
20 drug residues, decomposition, parasites, aller-  
21 gens, and unapproved food and color additives;  
22 and

23 “(B) hazards that occur naturally, may be  
24 unintentionally introduced, or may be inten-  
25 tionally introduced, including by acts of ter-  
26 rorism; and

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

2           “(c) PREVENTIVE CONTROLS.—The owner, operator,  
3 or agent in charge of a facility shall identify and imple-  
4 ment preventive controls, including at critical control  
5 points, if any, to provide assurances that—

6           “(1) hazards identified in the hazard analysis  
7 conducted under subsection (b) will be significantly  
8 minimized or prevented; and

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

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

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

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

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

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

6           “(3) the owner, operator, or agent is making  
7           appropriate decisions about corrective actions taken  
8           under subsection (e); and

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

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

21          “(h) WRITTEN PLAN AND DOCUMENTATION.—Each  
22          owner, operator, or agent in charge of a facility shall pre-  
23          pare a written plan that documents and describes the pro-  
24          cedures used by the facility to comply with the require-  
25          ments of this section, including analyzing the hazards

1 under subsection (b) and identifying the preventive con-  
2 trols adopted to address those hazards under subsection  
3 (c). Such written plan, together with documentation that  
4 the plan is being implemented, shall be made promptly  
5 available to a duly authorized representative of the Sec-  
6 retary upon oral or written request.

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

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

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

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

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

21       “(l) AUTHORITY WITH RESPECT TO CERTAIN FA-  
22 CILITIES.—The Secretary may, by regulation, exempt or  
23 modify the requirements for compliance under this section  
24 with respect to facilities that are solely engaged in the pro-  
25 duction of food for animals other than man or the storage

1 of packaged foods that are not exposed to the environ-  
2 ment.

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

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

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

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

8           “(c) 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 (c) 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           “(c) 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 paragraph (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 case 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 car-  
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 proc-  
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          (c) 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 car-  
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(c) of  
2 the Elementary and Secondary Education Act of  
3 1965 (20 U.S.C. 6333(c)).

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 car-  
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          “(c) 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          “(c) 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       “(c) 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 (c), 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. 333(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       “(rr) 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.  
19 334(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 (b) REGULATIONS.—Not later than 120 days after  
2 the date of enactment of this Act, the Secretary shall issue  
3 an interim final rule amending subpart K of part 1 of title  
4 21, Code of Federal Regulations, to implement the amend-  
5 ment made by this section.

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

9 **SEC. 208. DECONTAMINATION AND DISPOSAL STANDARDS**  
10 **AND PLANS.**

11 (a) IN GENERAL.—The Administrator of the Envi-  
12 ronmental Protection Agency (referred to in this section  
13 as the “Administrator”), in coordination with the Sec-  
14 retary of Health and Human Services, Secretary of Home-  
15 land Security, and Secretary of Agriculture, shall provide  
16 support for, and technical assistance to, State, local, and  
17 tribal governments in preparing for, assessing, decontami-  
18 nating, and recovering from an agriculture or food emer-  
19 gency.

20 (b) DEVELOPMENT OF STANDARDS.—In carrying out  
21 subsection (a), the Administrator, in coordination with the  
22 Secretary of Health and Human Services, Secretary of  
23 Homeland Security, Secretary of Agriculture, and State,  
24 local, and tribal governments, shall develop and dissemi-  
25 nate specific standards and protocols to undertake clean-

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 (c) 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 (c)  
 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 (c)  
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           (c) CONFORMING TECHNICAL AMENDMENT.—Sec-  
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 “(c) 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 determine 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           “(3) at any time, conduct an onsite audit of  
2           any eligible entity certified by an accredited third-  
3           party auditor or audit agent, with or without the  
4           auditor or audit agent present; and

5           “(4) take any other measures deemed necessary  
6           by the Secretary.

7           “(g) PUBLICLY AVAILABLE REGISTRY.—The Sec-  
8           retary shall establish a publicly available registry of ac-  
9           creditation bodies and of accredited third-party auditors  
10          and audit agents, including the name of, contact informa-  
11          tion for, and other information deemed necessary by the  
12          Secretary about such bodies, auditors, and agents.

13          “(h) LIMITATIONS.—

14                 “(1) NO EFFECT ON SECTION 704 INSPEC-  
15                 TIONS.—The audits performed under this section  
16                 shall not be considered inspections under section  
17                 704.

18                 “(2) NO EFFECT ON INSPECTION AUTHOR-  
19                 ITY.—Nothing in this section affects the authority of  
20                 the Secretary to inspect any eligible entity pursuant  
21                 to this Act.”.

22         **SEC. 309. FOREIGN OFFICES OF THE FOOD AND DRUG AD-**  
23                 **MINISTRATION.**

24                 (a) IN GENERAL.—The Secretary shall by October 1,  
25                 2010, establish an office of the Food and Drug Adminis-

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.

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