

111TH CONGRESS
1ST SESSION

H. R. 1332

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 5, 2009

Mr. COSTA (for himself, Mr. PUTNAM, Mr. PETERSON, Mr. DEAL of Georgia, Mr. CARDOZA, Mr. BARTON of Texas, Mr. FARR, Mr. SHIMKUS, Mr. ENGEL, Mr. RADANOVICH, Mr. THOMPSON of California, Mr. TERRY, Mr. SALAZAR, Mr. BOSWELL, Ms. HERSETH SANDLIN, Mr. WALDEN, Mr. CUELLAR, Mr. KAGEN, Mr. SCOTT of Georgia, Ms. ROS-LEHTINEN, Mr. BURGESS, and Mr. BACA) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Agriculture, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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 “Safe Food Enforcement, Assessment, Standards, and

1 Targeting Act of 2009” or as the “Safe FEAST Act of
2 2009”.

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

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

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

TITLE I—GENERAL FOOD PROVISIONS

Sec. 101. Inspection of records during food-related emergencies.
Sec. 102. Registration of food facilities.
Sec. 103. Mandatory recall authority.
Sec. 104. Hazard analysis and risk-based preventive controls.
Sec. 105. Performance standards.
Sec. 106. Standards for the safety of fruits and vegetables.
Sec. 107. Targeting of inspection resources for domestic facilities, foreign facili-
ties, and ports of entry; annual report.
Sec. 108. Administrative detention of food.
Sec. 109. National agriculture and food defense strategy.
Sec. 110. Food and Agriculture Coordinating Councils.
Sec. 111. Authority to collect fees.

TITLE II—DETECTION AND SURVEILLANCE

Sec. 201. Recognition of laboratory accreditation for analyses of foods.
Sec. 202. Integrated consortium of laboratory networks.
Sec. 203. Building domestic capacity.
Sec. 204. Enhancing traceback and recordkeeping.
Sec. 205. Surveillance.

TITLE III—SPECIFIC PROVISIONS FOR 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. Third-party accreditation of qualified auditors and audit agents.

Sec. 309. Jurisdiction; authorities.

TITLE I—GENERAL FOOD PROVISIONS

SEC. 101. INSPECTION OF RECORDS DURING FOOD-RELATED EMERGENCIES.

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

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

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

“(b) RECORDS INSPECTIONS DURING FOOD-RELATED EMERGENCIES.—If the Secretary has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death to humans or animals, during a food-related emergency, the Secretary—

“(1) may have access to and copy all records relating to such article of food in the same manner and for the same purpose as described in subsection (a); and

“(2) shall, from each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports an article of food related to the article of food referred to under paragraph (1) (such as an article of food pro-

1 duced on the same manufacturing line or any other
 2 article of food that the Secretary reasonably believes
 3 is likely to be affected in a similar manner) at the
 4 request of an officer or employee duly designated by
 5 the Secretary, have permission for such officer or
 6 employee, upon presentation of appropriate creden-
 7 tials and a written notice to such person, at reason-
 8 able times and within reasonable limits and in a rea-
 9 sonable manner, to have access to and copy all
 10 records relating to such article that are needed to
 11 assist the Secretary in determining whether the food
 12 presents a threat of serious adverse health con-
 13 sequences or death to humans or animals.”.

14 (b) CONFORMING AMENDMENTS.—

15 (1) Section 301(e) (21 U.S.C. 331(e)) is
 16 amended by striking “414(b)” and inserting
 17 “414(c)”.

18 (2) Section 704(a)(1) (21 U.S.C. 374(a)(1)) is
 19 amended by striking “414(d)” and inserting
 20 “414(e)”.

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

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

25 (1) in paragraph (2), by—

1 (A) striking “conducts business and” and
2 inserting “conducts business, the e-mail address
3 for the contact person of the facility, and”; and

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

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

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

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

24 (b) SUSPENSION OF REGISTRATION.—

1 (1) IN GENERAL.—Section 415 (21 U.S.C.
2 350d) is amended—

3 (A) in subsection (a)(2), by inserting after
4 the first sentence the following: “The registra-
5 tion shall contain a consent to permit the Sec-
6 retary to inspect such facility.”;

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

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

11 “(b) SUSPENSION OF REGISTRATION.—

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

20 “(2) HEARING ON SUSPENSION.—The Secretary
21 shall provide the registrant subject to an order
22 under paragraph (1) with an opportunity for an in-
23 formal hearing, to be held as soon as possible but
24 not later than 2 days after the issuance of the order,
25 on the actions required for reinstatement of registra-

1 tion and why the registration that is subject to sus-
2 pension should be reinstated. The Secretary shall re-
3 instate a registration if the Secretary determines,
4 based on evidence presented, that adequate grounds
5 do not exist to continue the suspension of the reg-
6 istration.

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

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

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

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

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

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

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

21 (c) CONFORMING AMENDMENTS.—

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

24 (2) Section 415(d), as redesignated by sub-
 25 section (b), is amended by adding at the end before

1 the period “for a facility to be registered, except
2 with respect to the reinstatement of a registration
3 that is suspended under subsection (b)”.

4 **SEC. 103. MANDATORY RECALL AUTHORITY.**

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

7 **“SEC. 418. MANDATORY RECALL AUTHORITY.**

8 “(a) VOLUNTARY PROCEDURES.—If the Secretary
9 determines, based on information gathered through the re-
10 portable food registry under section 417 or through any
11 other means, that there is a reasonable probability that
12 an article of food (other than infant formula) is adulter-
13 ated under section 402 or misbranded under section
14 403(w) and the use of or exposure to such article will
15 cause serious adverse health consequences or death to hu-
16 mans or animals, the Secretary shall provide the respon-
17 sible party (as defined in section 417) with an opportunity
18 to cease distribution and recall such article.

19 “(b) PREHEARING ORDER TO CEASE DISTRIBUTION
20 AND GIVE NOTICE.—If the responsible party refuses to
21 or does not voluntarily cease distribution or recall such
22 article within the time and in the manner prescribed by
23 the Secretary (if so prescribed), the Secretary may, by
24 order require, as the Secretary deems necessary, such per-
25 son to—

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

3 “(2) immediately notify all persons—

4 “(A) manufacturing, processing, packing,
5 transporting, distributing, receiving, holding, or
6 importing and selling such article; and

7 “(B) to which such article has been dis-
8 tributed, transported, or sold, to immediately
9 cease distribution of such article.

10 “(c) HEARING ON ORDER.—The Secretary shall pro-
11 vide the responsible party subject to an order under sub-
12 section (b) with an opportunity for an informal hearing,
13 to be held as soon as possible but not later than 2 days
14 after the issuance of the order, on the actions required
15 by the order and on why the article that is the subject
16 of the order should not be recalled.

17 “(d) POST-HEARING RECALL ORDER AND MODIFICA-
18 TION OF ORDER.—

19 “(1) AMENDMENT OF ORDER.—If, after pro-
20 viding opportunity for an informal hearing under
21 subsection (c), the Secretary determines that re-
22 moval of the article from commerce is necessary, the
23 Secretary shall, as appropriate—

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

1 “(B) specify a timetable in which the recall
2 shall occur;

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

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

7 “(2) VACATING OF ORDER.—If, after such hear-
8 ing, the Secretary determines that adequate grounds
9 do not exist to continue the actions required by the
10 order, or that such actions should be modified, the
11 Secretary shall vacate the order or modify the order.

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

15 “(f) PUBLIC NOTIFICATION.—In conducting a recall
16 under this section, the Secretary shall ensure that a press
17 release is published regarding the recall, as well as alerts
18 and public notices, as appropriate, in order to provide noti-
19 fication of the recall to consumers and retailers to whom
20 such article was, or may have been, distributed. The notifi-
21 cation shall include, at a minimum—

22 “(1) the name of the article of food subject to
23 the recall; and

24 “(2) a description of the risk associated with
25 such article.

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) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331
 9 et seq.) is amended by adding at the end the following:
 10 “(oo) The refusal or failure to follow an order under
 11 section 418.”.

12 **SEC. 104. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE**
 13 **CONTROLS.**

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

17 **“SEC. 419. HAZARD ANALYSIS AND RISK-BASED PREVEN-**
 18 **TIVE CONTROLS.**

19 “(a) IN GENERAL.—Each owner, operator, or agent
 20 in charge of a facility shall, in accordance with this sec-
 21 tion, evaluate the hazards that could affect food manufac-
 22 tured, processed, packed, or held by such facility, identify
 23 and implement preventive controls to significantly mini-
 24 mize or prevent their occurrence and provide assurances
 25 that such food is not adulterated under section 402 or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 “(4) there is documented, periodic reanalysis of
25 the plan under subsection (i) to ensure that the plan

1 is still relevant to the raw materials, as well as to
2 conditions and processes in the facility, and to new
3 and emerging threats.

4 “(g) RECORDKEEPING.—The owner, operator, or
5 agent in charge of a facility shall maintain, for not less
6 than 2 years, records documenting the monitoring of the
7 preventive controls implemented under subsection (c), in-
8 stances of nonconformance material to food safety, in-
9 stances when corrective actions were implemented, and the
10 efficacy of preventive controls and corrective actions.

11 “(h) WRITTEN PLAN AND DOCUMENTATION.—Each
12 owner, operator, or agent in charge of a facility shall pre-
13 pare a written plan that documents and describes the pro-
14 cedures used by the facility to comply with the require-
15 ments of this section, including analyzing the hazards
16 under subsection (b) and identifying the preventive con-
17 trols adopted to address those hazards under subsection
18 (c). High-risk facilities, as determined by the Secretary,
19 shall submit such written plan to the Food and Drug Ad-
20 ministration’s Center for Food Safety and Applied Nutri-
21 tion. The Secretary or a duly authorized representative of
22 the Secretary may review the plan and may make rec-
23 ommendations regarding the effectiveness of the plan in
24 preventing or minimizing the threat of serious adverse
25 health consequences or death to humans or animals. All

1 facilities shall promptly make available such written plan,
2 together with documentation that the plan is being imple-
3 mented, to a duly authorized representative of the Sec-
4 retary upon oral or written request.

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

23 “(j) DEEMED COMPLIANCE OF SEAFOOD, JUICE,
24 AND LOW-ACID CANNED FOOD FACILITIES IN COMPLI-
25 ANCE WITH HACCP.—An owner, operator, or agent in

1 charge of a facility required to comply with 1 of the fol-
2 lowing standards and regulations with respect to such fa-
3 cility shall be deemed to be in compliance with this section,
4 with respect to such facility:

5 “(1) The Seafood Hazard Analysis Critical
6 Control Points Program of the Food and Drug Ad-
7 ministration.

8 “(2) The Juice Hazard Analysis Critical Con-
9 trol Points Program of the Food and Drug Adminis-
10 tration.

11 “(3) The Thermally Processed Low-Acid Foods
12 Packaged in Hermetically Sealed Containers stand-
13 ards of the Food and Drug Administration (or any
14 successor standards).

15 “(k) EXCEPTION FOR FACILITIES IN COMPLIANCE
16 WITH SECTION 420.—This section shall not apply to a
17 facility that is subject to section 420.

18 “(l) AUTHORITY WITH RESPECT TO CERTAIN FA-
19 CILITIES.—The Secretary may, by regulation, exempt or
20 modify the requirements for compliance under this section
21 with respect to facilities that are solely engaged in the
22 storage of packaged foods that are not exposed to the envi-
23 ronment.

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

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

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

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

21 “(A) Sanitation procedures for food con-
22 tact surfaces and utensils and food-contact sur-
23 faces of equipment.

24 “(B) Supervisor, manager, and employee
25 hygiene training.

1 “(C) An environmental monitoring pro-
2 gram to verify the effectiveness of pathogen
3 controls.

4 “(D) An allergen control program.

5 “(E) A recall contingency plan.

6 “(F) Good Manufacturing Practices
7 (GMPs).

8 “(G) Supplier verification activities.”.

9 (b) REGULATIONS.—

10 (1) IN GENERAL.—The Secretary of Health and
11 Human Services (referred to in this Act as the “Sec-
12 retary”) shall promulgate regulations to establish
13 science-based minimum standards for conducting a
14 hazard analysis, documenting hazards, implementing
15 preventive controls, and documenting the implemen-
16 tation of the preventive controls under section 419
17 of the Federal Food, Drug, and Cosmetic Act (as
18 added by subsection (a)).

19 (2) CONTENT.—The regulations promulgated
20 under paragraph (1) shall provide sufficient flexi-
21 bility to be applicable in all situations, including in
22 the operations of small businesses.

23 (3) RULE OF CONSTRUCTION.—Nothing in this
24 subsection shall be construed to provide the Sec-
25 retary with the authority to apply specific tech-

1 nologies, practices, or critical controls to an indi-
2 vidual facility.

3 (4) REVIEW.—In promulgating the regulations
4 under paragraph (1), the Secretary shall review reg-
5 ulatory hazard analysis and preventive control pro-
6 grams in existence on the date of enactment of this
7 Act to ensure that the program under such section
8 419 is consistent, to the extent practicable, with ap-
9 plicable internationally recognized standards in exist-
10 ence on such date.

11 (c) GUIDANCE DOCUMENT.—The Secretary shall
12 issue a guidance document related to hazard analysis and
13 preventive controls required under section 419 of the Fed-
14 eral Food, Drug, and Cosmetic Act (as added by sub-
15 section (a)).

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

19 “(pp) The operation of a facility that manufacturers,
20 processes, packs, or holds food for sale in the United
21 States if the owner, operator, or agent in charge of such
22 facility is not in compliance with section 419.”.

23 (e) NO EFFECT ON HACCP AUTHORITIES.—Noth-
24 ing in the amendments made by this section limits the au-
25 thority of the Secretary under the Federal Food, Drug,

1 and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public
2 Health Service Act (42 U.S.C. 201 et seq.) to revise, issue,
3 or enforce product and category-specific regulations, such
4 as the Seafood Hazard Analysis Critical Controls Points
5 Program, the Juice Hazard Analysis Critical Control Pro-
6 gram, and the Thermally Processed Low-Acid Foods
7 Packaged in Hermetically Sealed Containers standards.

8 (f) EFFECTIVE DATE.—

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

12 (2) EXCEPTIONS.—Notwithstanding paragraph
13 (1)—

14 (A) the amendments made by this section
15 shall apply to a small business (as defined by
16 the Secretary) after the date that is 2 years
17 after the date of enactment of this Act; and

18 (B) the amendments made by this section
19 shall apply to a very small business (as defined
20 by the Secretary) after the date that is 3 years
21 after the date of enactment of this Act.

22 **SEC. 105. PERFORMANCE STANDARDS.**

23 The Secretary shall, not less frequently than every
24 2 years, review and evaluate relevant health data and
25 other relevant information, including from toxicological

1 and epidemiological studies and analyses, to determine the
 2 most significant food-borne contaminants and, when ap-
 3 propriate to reduce the risk of serious illness or death to
 4 humans or animals, to prevent the adulteration of the food
 5 under section 402 of the Federal Food, Drug, or Cosmetic
 6 Act (21 U.S.C. 342), or to prevent the spread of commu-
 7 nicable disease under the Public Health Service Act (42
 8 U.S.C. 201 et seq.), shall issue contaminant-specific,
 9 science-based guidance documents, actions levels, or regu-
 10 lations. Such guidance documents, action levels, or regula-
 11 tions shall apply to products or product classes, take into
 12 account naturally occurring substances in the case of raw
 13 agricultural products, and shall not be written to be facil-
 14 ity-specific.

15 **SEC. 106. STANDARDS FOR THE SAFETY OF FRUITS AND**
 16 **VEGETABLES.**

17 (a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et
 18 seq.), as amended by section 104, is amended by adding
 19 at the end the following:

20 **“SEC. 420. STANDARDS FOR THE SAFETY OF FRUITS AND**
 21 **VEGETABLES.**

22 “(a) DEFINITION.—For purposes of this section, the
 23 term ‘fruits and vegetables’ means raw agricultural prod-
 24 ucts as defined in section 201(r).

1 “(b) IN GENERAL.—Not later than 1 year after en-
2 actment of this section, the Secretary, in consultation with
3 the Secretary of Agriculture and representatives of State
4 departments of agriculture, shall publish a notice of pro-
5 posed rulemaking to establish regulations for the safe pro-
6 duction, harvesting, handling, and packing of those types
7 of fruits and vegetables for which the Secretary has deter-
8 mined that such regulations are necessary to minimize the
9 risk of serious adverse health consequences.

10 “(c) FINAL REGULATION.—Not later than 1 year
11 after the close of the comment period on the notice of pro-
12 posed rulemaking under subsection (a), the Secretary shall
13 adopt a final regulation covering those types of fruits and
14 vegetables for which the Secretary has determined that
15 such regulations are necessary to minimize the risk of seri-
16 ous adverse health consequences. The final regulation
17 shall provide a reasonable period of time for implementa-
18 tion, taking into account the needs of small businesses for
19 additional time to comply. The final regulation shall pro-
20 vide for coordination of education and enforcement activi-
21 ties by the Secretary of Agriculture, appropriate State and
22 local agencies, and appropriate agencies of foreign govern-
23 ments.

24 “(d) COOPERATION.—The Secretary shall work with
25 State and local public health officials in carrying out this

1 section. The Secretary shall coordinate activities with the
2 Secretary of Agriculture related to on-farm requirements
3 for growers including the development of food safety
4 standards and enforcement mechanisms that will address
5 regulations adopted under subsection (c).

6 “(e) CRITERIA.—The regulations adopted under sub-
7 section (b) shall—

8 “(1) set forth such procedures, processes, and
9 practices as the Secretary determines to be reason-
10 ably necessary to minimize the introduction of
11 known or reasonably foreseeable biological, chemical,
12 and physical hazards into fruits and vegetables and
13 to provide reasonable assurance that the fruits and
14 vegetables are not adulterated under section 402;

15 “(2) permit States and foreign governments to
16 seek variances from the requirements of the regula-
17 tions, where the State or foreign government deter-
18 mines that the variance is necessary in light of local
19 growing conditions and that the procedures, proc-
20 esses, and practices to be followed under the vari-
21 ance are reasonably likely to ensure that the fruits
22 or vegetables are not adulterated within the meaning
23 of section 402 to the same extent as the require-
24 ments of the regulation adopted under subsection
25 (b);

1 “(3) require that any State or foreign govern-
2 ment seeking a variance under paragraph (2) shall
3 first notify the Secretary of the intended variance
4 and the basis for it, and the Secretary may grant
5 the variance after 90 days of such notification if
6 Secretary does not communicate objections or modi-
7 fications to the intended variance to the respective
8 State or foreign government prior to the conclusion
9 of the 90-day period; and

10 “(4) provide for publication of notices of re-
11 quests for variances under paragraph (2) at the time
12 they are received.

13 “(f) ENFORCEMENT.—The Secretary shall coordinate
14 enforcement under this section with appropriate State and
15 local agencies and with appropriate agencies of foreign
16 governments. In enforcing any standards for the safety of
17 fruits and vegetables, the Secretary shall, to the maximum
18 extent practicable, use the Department of Agriculture and
19 state agricultural agencies. Such enforcement may be in
20 the form of audit-based verification systems or other
21 methods of inspection.

22 “(g) GUIDANCE FOR GOOD AGRICULTURAL PRAC-
23 TICES.—Not later than 1 year after the date of the enact-
24 ment of this section, the Secretary shall publish updated
25 guidance, in coordination with the Secretary of Agri-

1 culture and representatives of State departments of agri-
2 culture, based on the most currently available scientific
3 evidence, for the safe production, harvesting, handling,
4 packing, and traceability of fruits and vegetables. The Sec-
5 retary shall publish subsequently updated guidance, as
6 necessary.

7 “(h) SCOPE.—This section shall apply to the produc-
8 tion, harvesting, packaging, and traceability of fruits and
9 vegetables intended for human consumption, but not to—

10 “(1) activities involving the further processing
11 of fruits and vegetables which shall be subject to
12 section 419; or

13 “(2) those activities that occur in a retail food
14 establishment (as such term is defined in regulations
15 to carry out section 415(b)(1)).”.

16 (b) PROHIBITED.—Section 301 (21 U.S.C. 331), as
17 amended by section 104, is further amended by adding
18 at the end the following:

19 “(qq) Production, harvesting, handling, and packing
20 of fruits or vegetables not in accordance with the regula-
21 tions under section 419 or a variance issued under section
22 419(e)(2).”.

1 **SEC. 107. TARGETING OF INSPECTION RESOURCES FOR DO-**
2 **MESTIC FACILITIES, FOREIGN FACILITIES,**
3 **AND PORTS OF ENTRY; ANNUAL REPORT.**

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

9 **“SEC. 421. TARGETING OF INSPECTION RESOURCES FOR**
10 **DOMESTIC FACILITIES, FOREIGN FACILITIES,**
11 **AND PORTS OF ENTRY; ANNUAL REPORT.**

12 “(a) IDENTIFICATION AND INSPECTION OF FACILI-
13 TIES.—

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

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

20 “(B) The facility’s history of food recalls,
21 outbreaks, and violations of food safety stand-
22 ards.

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

25 “(D) Whether the food manufactured,
26 processed, packed, handled, prepared, treated,

1 distributed, or stored at the facility meets the
2 criteria for priority under section 801(h)(1).

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

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

8 “(2) INSPECTIONS.—The Secretary shall in-
9 crease the frequency of inspections of all facilities
10 such that—

11 “(A) all facilities registered under section
12 415 are inspected not less than once every 4
13 years; and

14 “(B) all facilities identified under para-
15 graph (1) as a high-risk facility are inspected—

16 “(i) not less than once within a 2-year
17 period after the date of enactment of this
18 section; and

19 “(ii) for each succeeding year, each
20 high-risk facility is inspected not less than
21 once each year.

22 “(b) IDENTIFICATION AND INSPECTION AT PORTS OF
23 ENTRY.—The Secretary, in consultation with the Sec-
24 retary of Homeland Security, shall allocate resources to
25 inspect articles of food imported into the United States

1 according to the risk profile of the article of food, which
2 shall be based on the following factors:

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

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

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

9 “(4) The rigor of the foreign supplier verifica-
10 tion program under section 805.

11 “(5) Whether the food importer participates in
12 the Voluntary Qualified Importer Program under
13 section 806.

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

16 “(7) Whether the food is from a facility that
17 has received a certificate as described in section
18 809(b).

19 “(8) Any other criteria deemed appropriate by
20 the Secretary for purposes of allocating inspection
21 resources.

22 “(c) COORDINATION.—The Secretary shall improve
23 coordination and cooperation with the Secretary of Agri-
24 culture to target food inspection resources.

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

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

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

9 “(1) information about food facilities includ-
10 ing—

11 “(A) the appropriations used to inspect fa-
12 cilities registered pursuant to section 415 in the
13 previous fiscal year;

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

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

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

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

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

8 “(2) information about food imports includ-
9 ing—

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

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

18 “(C) the average cost of physically inspect-
19 ing or sampling a food line subject to this Act
20 that is imported or offered for import into the
21 United States.

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

1 **SEC. 108. ADMINISTRATIVE DETENTION OF FOOD.**

2 (a) IN GENERAL.—Section 304(h)(1)(A) (21 U.S.C.
3 334(h)(1)(A)) is amended by—

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

6 (2) striking “presents a threat of serious ad-
7 verse health consequences or death to humans or
8 animals” and inserting “is adulterated or mis-
9 branded under section 403(w)”.

10 (b) REGULATIONS.—Not later than 120 days after
11 the date of enactment of this Act, the Secretary shall issue
12 an interim final rule amending subpart K of part 1 of title
13 21, Code of Federal Regulations, to implement the amend-
14 ment made by this section.

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

18 **SEC. 109. NATIONAL AGRICULTURE AND FOOD DEFENSE**
19 **STRATEGY.**

20 (a) DEVELOPMENT AND SUBMISSION OF STRAT-
21 EGY.—

22 (1) IN GENERAL.—Not later than 1 year after
23 the date of enactment of this Act, the Secretary of
24 Health and Human Services and the Secretary of
25 Agriculture, in coordination with the Secretary of
26 Homeland Security, shall prepare and submit to the

1 relevant committees of Congress, and make publicly
2 available on the Internet Web site of the Depart-
3 ment of Health and Human Services and the De-
4 partment of Agriculture, the National Agriculture
5 and Food Defense Strategy.

6 (2) IMPLEMENTATION PLAN.—The strategy
7 shall include an implementation plan for use by the
8 Secretaries described under paragraph (1) in car-
9 rying out the strategy.

10 (3) RESEARCH.—The strategy shall include a
11 coordinated research agenda for use by the Secre-
12 taries described under paragraph (1) in conducting
13 research to support the goals and activities described
14 in paragraphs (1) and (2) of subsection (b).

15 (4) REVISIONS.—Not later than 4 years after
16 the date on which the strategy is submitted to the
17 relevant committees of Congress under paragraph
18 (1), and not less frequently than every 4 years there-
19 after, the Secretary of Health and Human Services
20 and the Secretary of Agriculture, in coordination
21 with the Secretary of Homeland Security, shall re-
22 vise and submit to the relevant committees of Con-
23 gress the strategy.

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

4 (A) the National Incident Management
5 System;

6 (B) the National Response Framework;

7 (C) the National Infrastructure Protection
8 Plan;

9 (D) the National Preparedness Goals; and

10 (E) other relevant national strategies.

11 (b) COMPONENTS.—

12 (1) IN GENERAL.—The strategy shall include a
13 description of the process to be used by the Depart-
14 ment of Health and Human Services, the Depart-
15 ment of Agriculture, and the Department of Home-
16 land Security—

17 (A) to achieve each goal described in para-
18 graph (2); and

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

23 (2) GOALS.—The strategy shall include a de-
24 scription of the process to be used by the Depart-
25 ment of Health and Human Services, the Depart-

1 ment of Agriculture, and the Department of Home-
2 land Security to achieve the following goals:

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

6 (i) conducting vulnerability assess-
7 ments of the agriculture and food system;

8 (ii) mitigating vulnerabilities of the
9 system;

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

12 (iv) developing and conducting exer-
13 cises to test decontamination and disposal
14 plans;

15 (v) developing modeling tools to im-
16 prove event consequence assessment and
17 decision support; and

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

21 (B) DETECTION GOAL.—Improve agri-
22 culture and food system detection capabilities
23 by—

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

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

3 (C) EMERGENCY RESPONSE GOAL.—En-
4 sure an efficient response to agriculture and
5 food emergencies by—

6 (i) immediately investigating animal
7 disease outbreaks and suspected food con-
8 tamination;

9 (ii) preventing additional human ill-
10 nesses;

11 (iii) organizing, training, and equip-
12 ping animal, plant, and food emergency re-
13 sponse teams of—

14 (I) the Federal Government; and

15 (II) State, local, and tribal gov-
16 ernments;

17 (iv) designing, developing, and evalu-
18 ating training and exercises carried out
19 under agriculture and food defense plans;
20 and

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

23 (I) the Federal Government;

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

1 (III) the private sector.

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

5 (i) working with the private sector to
6 develop business recovery plans to rapidly
7 resume agriculture and food production;

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

11 (iii) rapidly removing, and effectively
12 disposing of—

13 (I) contaminated agriculture and
14 food products; and

15 (II) infected plants and animals;
16 and

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

20 **SEC. 110. FOOD AND AGRICULTURE COORDINATING COUN-**
21 **CILS.**

22 The Secretary of Homeland Security, in consultation
23 with the Secretary of Health and Human Services and the
24 Secretary of Agriculture, shall within 180 days of enact-
25 ment of this Act, and annually thereafter, submit to the

1 relevant committees of Congress, and make publicly avail-
2 able on the Internet Web site of the Department of Home-
3 land Security, a report on the activities of the Food and
4 Agriculture Government Coordinating Council and the
5 Food and Agriculture Sector Coordinating Council, includ-
6 ing the progress of such Councils on—

7 (1) facilitating partnerships between public and
8 private entities to help unify and enhance the protec-
9 tion of the agriculture and food system of the
10 United States;

11 (2) providing for the regular and timely inter-
12 change of information between each council relating
13 to the security of the agriculture and food system
14 (including intelligence information);

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

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

22 (A) animal or plant disease outbreaks;

23 (B) food contamination; and

24 (C) natural disasters affecting agriculture
25 and food.

1 **SEC. 111. AUTHORITY TO COLLECT FEES.**

2 (a) FEES FOR REINSPECTION, RECALL, AND IMPOR-
 3 TATION ACTIVITIES.—Subchapter C of chapter VII (21
 4 U.S.C. 379f et seq.) is amended by inserting after section
 5 742 the following:

6 **“PART 6—FEES RELATED TO FOOD**

7 **“SEC. 743. AUTHORITY TO COLLECT AND USE FEES.**

8 “(a) IN GENERAL.—

9 “(1) PURPOSE AND AUTHORITY.—For fiscal
 10 year 2010 and each subsequent fiscal year, the Sec-
 11 retary shall, in accordance with this section, assess
 12 and collect fees from—

13 “(A) each domestic facility (as defined in
 14 section 415(b)) subject to a reinspection in such
 15 fiscal year, to cover reinspection-related costs
 16 for such year;

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

23 “(C) each importer participating in the
 24 voluntary qualified importer program under sec-
 25 tion 806 in such year, to cover the administra-
 26 tive costs such program for such year; and

1 “(D) each importer subject to a reinspec-
2 tion in such fiscal year at a port of entry, to
3 cover reinspection-related costs at ports of entry
4 for such year.

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

7 “(A) the term ‘reinspection’ means—

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

18 “(ii) with respect to importers, 1 or
19 more examinations conducted under sec-
20 tion 801 subsequent to an examination
21 conducted under such provision which
22 identified noncompliance materially related
23 to a food safety requirement of this Act,
24 specifically to determine whether compli-

1 ance has been achieved to the Secretary's
2 satisfaction; and

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

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

8 “(ii) assessing and collecting reinspec-
9 tion fees under this section.

10 “(b) ESTABLISHMENT OF FEES.—

11 “(1) IN GENERAL.—Subject to subsections (c)
12 and (d), the Secretary shall establish the fees to be
13 collected under this section for each fiscal year speci-
14 fied in subsection (a)(1), based on the methodology
15 described under paragraph (2), and shall publish
16 such fees in a Federal Register notice not later than
17 60 days before the start of each such year.

18 “(2) FEE METHODOLOGY.—

19 “(A) FEES.—Fees amounts established for
20 collection—

21 “(i) under subparagraph (A) of sub-
22 section (a)(1) for a fiscal year shall be
23 based on the Secretary's estimate of 100
24 percent of the costs of the reinspection-re-
25 lated activities (including by type or level

1 of reinspection activity, as the Secretary
2 determines applicable) described in such
3 subparagraph (A) for such year;

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

10 “(iii) under subparagraph (C) of sub-
11 section (a)(1) for a fiscal year shall be
12 based on the Secretary’s estimate of 100
13 percent of the costs of the activities de-
14 scribed in such subparagraph (C) for such
15 year; and

16 “(iv) under subparagraph (D) 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 activities de-
20 scribed in such subparagraph (D) for such
21 year.

22 “(B) OTHER CONSIDERATIONS.—

23 “(i) VOLUNTARY QUALIFIED IM-
24 PORTER PROGRAM.—

1 “(I) PARTICIPATION.—In estab-
2 lishing the fee amounts under sub-
3 paragraph (A)(iii) for a fiscal year,
4 the Secretary shall provide for the
5 number of importers who have sub-
6 mitted to the Secretary a notice under
7 section 806 informing the Secretary of
8 the intent of such importer to partici-
9 pate in the program under section
10 806 in such fiscal year.

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

21 “(ii) CREDITING OF FEES.—In estab-
22 lishing the fee amounts under subpara-
23 graph (A) for a fiscal year, the Secretary
24 shall provide for the crediting of fees from
25 the previous year to the next year if the

1 Secretary overestimated the amount of fees
2 needed to carry out such activities, and
3 consider the need to account for any ad-
4 justment of fees and such other factors as
5 the Secretary determines appropriate.

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

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

18 “(c) LIMITATIONS.—

19 “(1) IN GENERAL.—Fees under subsection (a)
20 shall be refunded for a fiscal year beginning after
21 fiscal year 2010 unless appropriations for the Center
22 for Food Safety and Applied Nutrition and the Cen-
23 ter for Veterinary Medicine and related activities of
24 the Office of Regulatory Affairs at the Food and
25 Drug Administration for such fiscal year (excluding

1 the amount of fees appropriated for such fiscal year)
2 are equal to or greater than the amount of appro-
3 priations for the Center for Food Safety and Applied
4 Nutrition and the Center for Veterinary Medicine
5 and related activities of the Office of Regulatory Af-
6 fairs at the Food and Drug Administration for the
7 preceding fiscal year (excluding the amount of fees
8 appropriated for such fiscal year) multiplied by 1
9 plus 4.5 percent.

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

19 “(3) LIMITATION ON AMOUNT OF CERTAIN
20 FEES.—

21 “(A) IN GENERAL.—Notwithstanding any
22 other provision of this section and subject to
23 subparagraph (B), the Secretary may not col-
24 lect fees in a fiscal year such that the amount
25 collected—

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

3 “(ii) under subparagraphs (A) and
4 (D) of subsection (a)(1) exceeds
5 \$25,000,000 combined.

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

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

1 and Drug Administration employees and contractors per-
2 forming activities associated with these food safety fees.

3 “(e) COLLECTION OF FEES.—

4 “(1) IN GENERAL.—The Secretary shall specify
5 in the Federal Register notice described in sub-
6 section (b)(1) the time and manner in which fees as-
7 sessed under this section shall be collected.

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

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

1 “(g) AUTHORIZATION OF APPROPRIATIONS.—For fis-
 2 cal year 2010 and each fiscal year thereafter, there is au-
 3 thorized to be appropriated for fees under this section an
 4 amount equal to the total revenue amount determined
 5 under subsection (b) for the fiscal year, as adjusted or
 6 otherwise affected under the other provisions of this sec-
 7 tion.”.

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

10 (1) AUTHORITY FOR EXPORT CERTIFICATIONS
 11 FOR FOOD, INCLUDING ANIMAL FEED.—Section
 12 801(e)(4)(A) (21 U.S.C. 381(e)(4)(A)) is amend-
 13 ed—

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

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

18 (C) in clause (ii), by striking “the drug”
 19 each place it appears and inserting “the food,
 20 drug”.

21 (2) CLARIFICATION OF CERTIFICATION.—Sec-
 22 tion 801(e)(4) (21 U.S.C. 381(e)(4)) is amended by
 23 inserting after subparagraph (B) the following new
 24 subparagraph:

1 “(C) For purposes of this paragraph, a
 2 certification by the Secretary shall be made on
 3 such basis, and in such form (including a pub-
 4 licly available listing) as the Secretary deter-
 5 mines appropriate.”.

6 **TITLE II—DETECTION AND** 7 **SURVEILLANCE**

8 **SEC. 201. RECOGNITION OF LABORATORY ACCREDITATION** 9 **FOR ANALYSES OF FOODS.**

10 (a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et
 11 seq.), as amended by section 107, is amended by adding
 12 at the end the following:

13 **“SEC. 422. RECOGNITION OF LABORATORY ACCREDITATION** 14 **FOR ANALYSES OF FOODS.**

15 “(a) RECOGNITION OF LABORATORY ACCREDITA-
 16 TION.—

17 “(1) IN GENERAL.—Not later than 2 years
 18 after the date of enactment of this section, the Sec-
 19 retary shall—

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

1 “(B) establish a publicly available registry
2 of accreditation bodies, including the name of,
3 contact information for, and other information
4 deemed necessary by the Secretary about such
5 bodies.

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

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

17 “(B) internal quality systems are estab-
18 lished and maintained;

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

23 “(D) individuals who conduct the analyses
24 are qualified by training and experience to do
25 so; and

1 “(E) any other criteria determined appro-
2 priate by the Secretary.

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

6 “(A) periodically, or at least every 5 years,
7 reevaluate accreditation bodies recognized under
8 paragraph (1); and

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

12 “(b) TESTING PROCEDURES.—Food testing shall be
13 conducted by either Federal laboratories or non-Federal
14 laboratories that have been accredited by an accreditation
15 body on the registry established by the Secretary under
16 subsection (a) whenever such testing—

17 “(1) is either conducted by or on behalf of an
18 owner or consignee—

19 “(A) in support of admission of an article
20 of food under section 801(a); or

21 “(B) under an Import Alert that requires
22 successful consecutive tests; or

23 “(2) is required by the Secretary as the Sec-
24 retary deems appropriate to identify or address a

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

3 The results of any such testing shall be sent directly to
4 the Food and Drug Administration.

5 “(c) REVIEW BY SECRETARY.—If food testing per-
6 formed by a laboratory run and operated by a State or
7 locality that is accredited by an accreditation body on the
8 registry established by the Secretary under subsection (a)
9 result in a State recalling a food, the Secretary shall re-
10 view the testing results for the purpose of determining the
11 need for a national recall or other compliance and enforce-
12 ment activities.”.

13 (b) FOOD EMERGENCY RESPONSE NETWORK.—The
14 Secretary, in coordination with the Secretary of Agri-
15 culture, the Secretary of Homeland Security, and State,
16 local, and tribal governments shall, not later than 180
17 days after the date of enactment of this Act, and biennially
18 thereafter, submit to the relevant committees of Congress,
19 and make publicly available on the Internet Web site of
20 the Department of Health and Human Services, a report
21 on the progress in implementing a national food emer-
22 gency response laboratory network that—

23 (1) provides ongoing surveillance, rapid detec-
24 tion, and surge capacity for large-scale food-related

1 emergencies, including intentional adulteration of
2 the food supply;

3 (2) coordinates the food laboratory capacities of
4 State food laboratories, including the sharing of data
5 between State laboratories to develop national situa-
6 tional awareness;

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

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

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

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

15 **SEC. 202. INTEGRATED CONSORTIUM OF LABORATORY**
16 **NETWORKS.**

17 (a) IN GENERAL.—The Secretary of Homeland Secu-
18 rity, in consultation with the Secretary of Health and
19 Human Services, the Secretary of Agriculture, and the
20 Administrator of the Environmental Protection Agency,
21 shall maintain an agreement through which relevant lab-
22 oratory network members, as determined by the Secretary
23 of Homeland Security, shall—

24 (1) agree on common laboratory methods in
25 order to facilitate the sharing of knowledge and in-

1 formation relating to animal health, agriculture, and
2 human health;

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

5 (A) to optimize national laboratory pre-
6 paredness; and

7 (B) to provide surge capacity during emer-
8 gencies; and

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

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

19 **SEC. 203. BUILDING DOMESTIC CAPACITY.**

20 (a) IN GENERAL.—

21 (1) INITIAL REPORT.—The Secretary shall, not
22 later than 2 years after the date of enactment of
23 this Act, submit to Congress a comprehensive report
24 that identifies programs and practices that are in-
25 tended to promote the safety and security of food

1 and to prevent outbreaks of food-borne illness and
2 other food-related hazards that can be addressed
3 through preventive activities. Such report shall in-
4 clude a description of the following:

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

7 (B) Outreach to food industry sectors, in-
8 cluding through the Food and Agriculture Co-
9 ordinating Councils referred to in section 111,
10 to identify potential sources of emerging threats
11 to the safety and security of the food supply
12 and preventive strategies to address those
13 threats.

14 (C) Systems to ensure the prompt distribu-
15 tion to the food industry of information and
16 technical assistance concerning preventive strat-
17 egies.

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

22 (E) Surveillance systems and laboratory
23 networks to rapidly detect and respond to food-
24 borne illness outbreaks and other food-related

1 hazards, including how such systems and net-
2 works are integrated.

3 (F) Outreach, education, and training pro-
4 vided to States to build State food safety and
5 food defense capabilities, including progress im-
6 plementing strategies developed under sections
7 109 and 205.

8 (G) The estimated resources needed to ef-
9 fectively implement the programs and practices
10 identified in the report developed in this section
11 over a 5-year period.

12 (2) BIENNIAL REPORTS.—On a biennial basis
13 following the submission of the report under para-
14 graph (1), the Secretary shall submit to Congress a
15 report that—

16 (A) reviews previous food safety programs
17 and practices;

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

20 (C) identifies future programs and prac-
21 tices; and

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

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

11 (c) CAPABILITY FOR LABORATORY ANALYSES; RE-
12 SEARCH.—The report developed under subsection (a)(1)
13 shall provide a description of methods to increase capacity
14 to undertake analyses of food samples promptly after col-
15 lection, to identify new and rapid analytical techniques,
16 including techniques that can be employed at ports of
17 entry and through Food Emergency Response Network
18 laboratories, and to provide for well-equipped and staffed
19 laboratory facilities.

20 (d) INFORMATION TECHNOLOGY.—The report devel-
21 oped under subsection (a)(1) shall include a description
22 of such information technology systems as may be needed
23 to identify risks and receive data from multiple sources,
24 including foreign governments, State, local, and tribal gov-
25 ernments, other Federal agencies, the food industry, lab-

1 oratories, laboratory networks, and consumers. The infor-
2 mation technology systems that the Secretary describes
3 shall also provide for the integration of the facility reg-
4 istration system under section 415 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 350d), and the prior
6 notice system under section 801(m) of such Act (21
7 U.S.C. 381(m)) with other information technology systems
8 that are used by the Federal Government for the proc-
9 essing of food offered for import into the United States.

10 (e) AUTOMATED RISK ASSESSMENT.—The report de-
11 veloped under subsection (a)(1) shall include a description
12 of progress toward developing and improving an auto-
13 mated risk assessment system for food safety surveillance
14 and allocation of resources.

15 (f) TRACEBACK AND SURVEILLANCE REPORT.—The
16 Secretary shall include in the report developed under sub-
17 section (a)(1) an analysis of the Food and Drug Adminis-
18 tration’s performance in food-borne illness outbreaks dur-
19 ing the 5-year period preceding the date of enactment of
20 this Act involving fruits and vegetables that are raw agri-
21 cultural commodities (as defined in section 201(r) of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 321(r))) and recommendations for enhanced surveillance,
24 outbreak response, and traceability. Such findings and
25 recommendations shall address communication and coordi-

1 nation with the public and industry, outbreak identifica-
2 tion, and traceback.

3 (g) BIENNIAL FOOD SAFETY AND FOOD DEFENSE
4 RESEARCH PLAN.—The Secretary and the Secretary of
5 Agriculture shall, on a biennial basis, submit to Congress
6 a joint food safety and food defense research plan which
7 may include studying the long-term health effects of food-
8 borne illness. Such biennial plan shall include a list and
9 description of projects conducted during the previous 2-
10 year period and the plan for projects to be conducted dur-
11 ing the following 2-year period.

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

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

19 (b) PILOT PROJECT.—

20 (1) IN GENERAL.—Not later than 12 months
21 after the date of enactment of this Act, the Sec-
22 retary shall establish a pilot project in coordination
23 with the produce industry to explore and evaluate
24 new methods for rapidly and effectively tracking and
25 tracing fruits and vegetables that are raw agricul-

1 tural commodities so that, if an outbreak occurs in-
2 volving such a fruit or vegetable, the Secretary may
3 quickly identify the source of the outbreak and the
4 recipients of the contaminated food.

5 (2) CONTENT.—The Secretary shall select par-
6 ticipants from the produce industry to run projects
7 which overall shall include at least 3 different types
8 of fruits or vegetables that have been the subject of
9 outbreaks during the 10-year period preceding the
10 date of enactment of this Act, and shall be selected
11 in order to develop and demonstrate—

12 (A) methods that are applicable and appro-
13 priate for small businesses; and

14 (B) technologies, including existing tech-
15 nologies, that enhance traceback and trace for-
16 ward.

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

24 (d) TRACEBACK PERFORMANCE REQUIREMENTS.—
25 Not later than 24 months after the date of enactment of

1 this Act, the Secretary shall publish a notice of proposed
2 rulemaking to establish standards for the type of informa-
3 tion, format, and timeframe for persons to submit records
4 to aid the Secretary in effectively and rapidly tracking and
5 tracing, in the event of an outbreak, fruits and vegetables
6 that are raw agricultural commodities. Nothing in this sec-
7 tion shall be construed as giving the Secretary the author-
8 ity to prescribe specific technologies for the maintenance
9 of records.

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

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

20 **SEC. 205. SURVEILLANCE.**

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

1 (b) FOOD-BORNE ILLNESS SURVEILLANCE SYS-
2 TEMS.—

3 (1) IN GENERAL.—The Secretary, acting
4 through the Director of the Centers for Disease
5 Control and Prevention, shall enhance food-borne ill-
6 ness surveillance systems to improve the collection,
7 analysis, reporting, and usefulness of data on food-
8 borne illnesses by—

9 (A) coordinating Federal, State and local
10 food-borne illness surveillance systems, includ-
11 ing complaint systems, and increasing participa-
12 tion in national networks of public health and
13 food regulatory agencies and laboratories;

14 (B) facilitating sharing of findings on a
15 more timely basis among governmental agen-
16 cies, including the Food and Drug Administra-
17 tion, the Department of Agriculture, and State
18 and local agencies, and with the public;

19 (C) ensuring early notification to the af-
20 fected food industry when a particular food may
21 be suspected in the outbreak and sharing of all
22 relevant data with the affected food industry
23 during the course of the investigation;

1 (D) developing improved epidemiological
2 tools for obtaining quality exposure data, and
3 microbiological methods for classifying cases;

4 (E) augmenting such systems to improve
5 attribution of a food-borne illness outbreak to a
6 specific food;

7 (F) expanding capacity of such systems,
8 including working toward automatic electronic
9 searches, for implementation of fingerprinting
10 strategies for food-borne infectious agents, in
11 order to identify new or rarely documented
12 causes of food-borne illness and submit stand-
13 ardized information to a centralized database;

14 (G) allowing timely public access to aggre-
15 gated, de-identified surveillance data;

16 (H) at least annually, publishing current
17 reports on findings from such systems;

18 (I) establishing a flexible mechanism for
19 rapidly initiating scientific research by academic
20 institutions;

21 (J) integrating food-borne illness surveil-
22 lance systems and data with other biosurveil-
23 lance and public health situational awareness
24 capabilities at the state and federal levels; and

1 (K) other activities as determined appro-
2 priate by the Secretary.

3 (2) ADVISORY GROUP ON IMPROVING
4 FOODBORNE ILLNESS SURVEILLANCE AND OUT-
5 BREAK INVESTIGATIONS.—

6 (A) IN GENERAL.—The Secretary shall
7 support and maintain a diverse working group
8 of experts and stakeholders from Federal,
9 State, and local food safety and health agencies,
10 the food industry, consumer organizations, and
11 academia. Such working group shall provide the
12 Secretary, through at least annual meetings of
13 the working group and an annual public report,
14 advice and recommendations on an ongoing and
15 regular basis regarding the improvement of
16 food-borne illness surveillance, outbreak inves-
17 tigation, and implementation of this section, in-
18 cluding advice and recommendations on—

19 (i) the priority needs of regulatory
20 agencies, the food industry, and consumers
21 for information and analysis on food-borne
22 illness and its causes;

23 (ii) the priority needs of regulatory
24 agencies, the food industry, and consumers
25 for information and analysis on outbreak

1 investigations that can be used to improve
2 the line of authority and accountability;

3 (iii) opportunities to improve the ef-
4 fectiveness of initiatives at the Federal,
5 State, and local levels, including coordina-
6 tion and integration of activities among
7 Federal agencies, and between the Federal,
8 State, and local levels of government;

9 (iv) improvement in the timeliness and
10 depth of access by regulatory and health
11 agencies, the food industry, academic re-
12 searchers, and consumers to food-borne ill-
13 ness surveillance data and food recall sur-
14 vey data collected by government agencies
15 at all levels, including data compiled by the
16 Centers for Disease Control and Preven-
17 tion;

18 (v) key barriers to improvement in
19 food-borne illness surveillance and its util-
20 ity for preventing food-borne illness at
21 Federal, State, and local levels;

22 (vi) the capabilities needed for estab-
23 lishing automatic electronic searches of
24 surveillance data; and

1 (vii) specific actions to reduce barriers
2 to improvement, implement the working
3 group's recommendations, and achieve the
4 purposes of this section, with measurable
5 objectives and timelines, and identification
6 of resource and staffing needs.

7 (3) ADDITIONAL DUTIES.—The Secretary shall
8 also utilize the working group under paragraph (1)
9 to assist in outbreak investigations as deemed appro-
10 priate.

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

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

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

19 (B) Accelerate food-borne illness surveil-
20 lance and outbreak investigation, including
21 rapid shipment of clinical isolates from clinical
22 laboratories to appropriate State laboratories,
23 and conducting more standardized illness out-
24 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 partnerships to coordinate food safety
6 and defense resources and reduce the incidence
7 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 109.

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 this
18 Act, complete a review of State and local capacities,
19 and needs for enhancement, which may include a
20 survey with respect to—

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

23 (B) laboratory capacity to support surveil-
24 lance, outbreak response, inspection, and en-
25 forcement activities;

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

6 (D) other State and local activities and
 7 needs as determined appropriate by the Sec-
 8 retary.

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

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

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

16 **TITLE III—SPECIFIC PROVI-** 17 **SIONS FOR IMPORTED FOOD**

18 **SEC. 301. FOREIGN SUPPLIER VERIFICATION PROGRAM.**

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

21 **“SEC. 805. FOREIGN SUPPLIER VERIFICATION PROGRAM.**

22 **“(a) IN GENERAL.—**

23 **“(1) VERIFICATION REQUIREMENT.—**Each
 24 United States importer of record shall perform risk-
 25 based foreign supplier verification activities in ac-

1 cordance with regulations promulgated under sub-
2 section (c) for the purpose of verifying that the food
3 imported by the importer of record or its agent is—

4 “(A) produced in compliance with the re-
5 quirements of section 419 or 420, as appro-
6 priate; and

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

9 “(2) IMPORTER EXCLUSION.—For purposes of
10 this section, an ‘importer of record’ shall not include
11 a person holding a valid license under section 641 of
12 the Tariff Act of 1930 (19 U.S.C. 1641) (referred
13 to as a ‘customs broker’) if the customs broker has
14 executed a written agreement with another person
15 who has agreed to comply with the requirements of
16 this section with regard to food imported or offered
17 for import by the customs broker.

18 “(b) GUIDANCE.—Not later than 270 days after the
19 date of the enactment of this section, the Secretary shall
20 issue guidance to assist United States importers of record
21 in developing foreign supplier verification programs.

22 “(c) REGULATIONS.—

23 “(1) IN GENERAL.—Not later than 1 year after
24 issuing guidance under subsection (b), the Secretary
25 shall promulgate regulations to provide for the con-

1 tent of the foreign supplier verification program es-
2 tablished under subsection (a). Such regulations
3 shall, as appropriate, include a process for
4 verification by a United States importer of record,
5 with respect to each foreign supplier from which it
6 obtains food, that the imported food is produced in
7 compliance with the requirements of section 419 or
8 420, as appropriate, and is not adulterated under
9 section 402 or misbranded under section 403(w).

10 “(2) VERIFICATION.—The regulations under
11 paragraph (1) shall require that the foreign supplier
12 verification program of each importer of record be
13 adequate to provide assurances that each foreign
14 supplier to the importer of record produces the im-
15 ported food employing processes and procedures, in-
16 cluding risk-based reasonably appropriate preventive
17 controls, that are documented in a written plan
18 under subsection (d) and equivalent in preventing
19 adulteration and reducing hazards as those required
20 by section 419 or section 420, as appropriate.

21 “(3) ACTIVITIES.—Verification activities under
22 a foreign supplier verification program under this
23 section may include monitoring records for ship-
24 ments, lot-by-lot certification of compliance, annual
25 on-site inspections, checking the hazard analysis and

1 risk-based preventive control plan of the foreign sup-
2 plier, and periodically testing and sampling ship-
3 ments.

4 “(d) RECORD MAINTENANCE AND ACCESS.—Each
5 facility required to be registered under section 415 that
6 is, as determined by the Secretary, a high-risk facility
7 shall submit to the Secretary a written plan that docu-
8 ments and describes its hazard analysis and preventative
9 control procedures. The Secretary or a duly authorized
10 representative of the Secretary may review the plan and
11 may make recommendations to improve the effectiveness
12 of the plan in preventing or minimizing the threat of seri-
13 ous adverse health consequences or death to humans or
14 animals. Records of all United States importers related
15 to a foreign supplier verification program shall be main-
16 tained for a period of not less than 2 years and shall be
17 made available promptly to a duly authorized representa-
18 tive of the Secretary upon request.

19 “(e) DEEMED COMPLIANCE OF SEAFOOD, JUICE,
20 AND LOW-ACID CANNED FOOD FACILITIES IN COMPLI-
21 ANCE WITH HACCP.—An owner, operator, or agent in
22 charge of a facility required to comply with 1 of the fol-
23 lowing standards and regulations with respect to such fa-
24 cility shall be deemed to be in compliance with this section
25 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 106, is amended by adding at the
19 end the following:

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

1 (c) IMPORTS.—Section 801(a) (21 U.S.C. 381(a)) is
2 amended by adding “or the importer of record is in viola-
3 tion of section 805” after “or in violation of section 505”.

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

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

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

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

12 “(a) IN GENERAL.—Beginning not later than 1 year
13 after the date of enactment of this section, the Secretary
14 shall—

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

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

23 “(b) VOLUNTARY PARTICIPATION.—An importer may
24 request the Secretary to provide for the expedited review

1 and importation of designated foods in accordance with
2 the program procedures established by the Secretary.

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

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

11 “(2) The compliance history of the foreign sup-
12 plier.

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

16 “(4) The compliance of the importer with the
17 requirements of section 805.

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

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

24 “(7) Any other factor that the Secretary deter-
25 mines appropriate.

1 “(d) REVIEW AND REVOCATION.—Any importer
 2 qualified by the Secretary in accordance with the eligibility
 3 criteria set forth in this section shall be reevaluated not
 4 less often than once every 3 years and the Secretary shall
 5 promptly revoke the qualified importer status of any im-
 6 porter found not to be in compliance with such criteria.

7 “(e) DEFINITION.—For purposes of this section, the
 8 term ‘importer’ means the person that brings food, or
 9 causes food to be brought, from a foreign country into the
 10 customs territory of the United States.”.

11 **SEC. 303. AUTHORITY TO REQUIRE IMPORT CERTIFI-**
 12 **CATIONS FOR FOOD.**

13 (a) IN GENERAL.—Section 801(a) (21 U.S.C.
 14 381(a)) is amended by inserting after the third sentence
 15 the following: “With respect to an article of food, if impor-
 16 tation of such food is subject to, but not compliant with,
 17 the requirement under subsection (p) that such food be
 18 accompanied by a certification or other assurance that the
 19 food meets some or all applicable requirements of this Act,
 20 then such article shall be refused admission.”.

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

24 “(p) CERTIFICATIONS CONCERNING IMPORTED
 25 FOODS.—

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

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

22 “(A) an agency or a representative of the
23 government of the country from which the arti-
24 cle of food at issue originated, as designated by
25 such government or the Secretary; or

1 “(B) such other persons or entities accred-
2 ited pursuant to section 809 to provide such
3 certification or assurance.

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

6 “(A) require that any certification or other
7 assurance provided by an entity specified in
8 paragraph (2) be renewed by such entity at
9 such times as the Secretary determines appro-
10 priate; and

11 “(B) refuse to accept any certification or
12 assurance if the Secretary determines that such
13 certification or assurance is no longer valid or
14 reliable.

15 “(4) ELECTRONIC SUBMISSION.—The Secretary
16 shall provide for the electronic submission of certifi-
17 cations under this subsection.”.

18 (c) CONFORMING TECHNICAL AMENDMENT.—Sec-
19 tion 801(b) (21 U.S.C. 381(b)) is amended in the second
20 sentence by striking “with respect to an article included
21 within the provision of the fourth sentence of subsection
22 (a)” and inserting “with respect to an article described
23 in subsection (a) relating to the requirements of sections
24 760 or 761,”.

1 (d) NO LIMIT ON AUTHORITY.—Nothing in the
2 amendments made by this section shall limit the authority
3 of the Secretary to conduct random inspections of im-
4 ported food or to take such other steps as the Secretary
5 deems appropriate to determine the admissibility of im-
6 ported food.

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

8 (a) IN GENERAL.—Section 801(m)(1) (21 U.S.C.
9 381(m)(1)) is amended by inserting “any country to which
10 the article has been refused entry;” after “the country
11 from which the article is shipped;”.

12 (b) REGULATIONS.—Not later than 120 days after
13 the date of enactment of this Act, the Secretary shall issue
14 an interim final rule amending subpart I of part 1 of title
15 21, Code of Federal Regulations, to implement the amend-
16 ment made by this section.

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

20 **SEC. 305. REVIEW OF A REGULATORY AUTHORITY OF A**
21 **FOREIGN COUNTRY.**

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

1 **“SEC. 807. REVIEW OF A REGULATORY AUTHORITY OF A**
2 **FOREIGN COUNTRY.**

3 “The Secretary may review information from a coun-
4 try outlining the statutes, regulations, standards, and con-
5 trols of such country, and conduct on-site audits in such
6 country to verify the implementation of those statutes,
7 regulations, standards, and controls. Based on such re-
8 view, the Secretary shall determine whether such country
9 can provide reasonable assurances that the food supply of
10 the country is equivalent in safety to food manufactured,
11 processed, packed, or held in the United States.”.

12 **SEC. 306. BUILDING CAPACITY OF FOREIGN GOVERNMENTS**
13 **WITH RESPECT TO FOOD.**

14 (a) IN GENERAL.—The Secretary shall, not later
15 than 2 years of the date of enactment of this Act, develop
16 a comprehensive plan to expand the technical, scientific,
17 and regulatory capacity of foreign governments, and their
18 respective food industries, from which foods are exported
19 to the United States.

20 (b) CONSULTATION.—In developing the plan under
21 subsection (a), the Secretary shall consult with the Sec-
22 retary of Agriculture, Secretary of State, Secretary of the
23 Treasury, and the Secretary of Commerce, representatives
24 of the food industry, appropriate foreign government offi-
25 cials, and nongovernmental organizations that represent
26 the interests of consumers, and other stakeholders.

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

3 (1) Recommendations for bilateral and multilat-
4 eral arrangements and agreements, including provi-
5 sions to provide for responsibility of exporting coun-
6 tries to ensure the safety of food.

7 (2) Provisions for electronic data sharing.

8 (3) Provisions for mutual recognition of inspec-
9 tion reports.

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

13 (5) Recommendations to harmonize require-
14 ments under the Codex Alimentarius.

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

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

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

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

22 “(a) INSPECTION.—The Secretary—

23 “(1) may enter into arrangements and agree-
24 ments with foreign governments to facilitate the in-

1 spection of foreign facilities registered under section
2 415; and

3 “(2) shall direct resources to inspections of for-
4 eign facilities, suppliers, and food types, especially
5 such facilities, suppliers, and food types that present
6 a high risk (as identified by the Secretary), to help
7 ensure the safety and security of the food supply of
8 the United States.

9 “(b) EFFECT OF INABILITY TO INSPECT.—Notwith-
10 standing any other provision of law, food shall be refused
11 admission into the United States if it is from a foreign
12 facility registered under section 415 of which the owner,
13 operator, or agent in charge of the facility, or the govern-
14 ment of the foreign country, refuses to permit entry of
15 United States inspectors, upon request, to inspect such fa-
16 cility. For purposes of this subsection, such an owner, op-
17 erator, or agent in charge shall be considered to have re-
18 fused an inspection if such owner, operator, or agent in
19 charge refuses such a request to inspect a facility more
20 than 48 hours after such request is submitted.”.

21 **SEC. 308. THIRD-PARTY ACCREDITATION OF QUALIFIED**
22 **AUDITORS AND AUDIT AGENTS.**

23 Chapter VIII (21 U.S.C. 381 et seq.), as amended
24 by section 307, is further amended by adding at the end
25 the following:

1 **“SEC. 809. THIRD-PARTY AUDITORS AND AUDIT AGENTS AC-**
2 **CREDITATION.**

3 “(a) DEFINITIONS.—In this section:

4 “(1) ACCREDITATION BODY.—The term ‘ac-
5 creditation body’ means a recognized authority that
6 performs accreditation of third-party auditors and
7 audit agents.

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

12 “(3) ACCREDITED AUDIT AGENT.—The term
13 ‘accredited audit agent’ means an audit agent ac-
14 credited by an accreditation body under this section.

15 “(4) ACCREDITED THIRD-PARTY AUDITOR.—
16 The term ‘accredited third-party auditor’ means a
17 third-party auditor accredited by an accreditation
18 body under this section.

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

22 “(A) to determine whether such entity is in
23 compliance with the provisions of this Act and
24 with applicable industry standards and prac-
25 tices; and

1 “(B) the results of which are for internal
2 facility purposes only.

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

8 “(7) REGULATORY AUDIT.—The term ‘regu-
9 latory audit’ means an audit of an eligible entity—
10 “(A) to determine whether such entity is in
11 compliance with the provisions of this Act; and

12 “(B) the results of which determine—
13 “(i) whether an entity is eligible to re-
14 ceive a certification under section 801(p);
15 and

16 “(ii) whether the entity is eligible to
17 participate in the voluntary qualified im-
18 porter program under section 806.

19 “(8) THIRD-PARTY AUDITOR.—The term ‘third-
20 party auditor’ means a foreign government, foreign
21 cooperative, or any other qualified third party, as
22 the Secretary determines appropriate, that conducts
23 audits of eligible entities to certify that such eligible
24 entities meet the applicable requirements of this sec-
25 tion.

1 “(b) SYSTEM OF ACCREDITATION.—

2 “(1) ACCREDITATION BODIES.—

3 “(A) ACCREDITATION BODIES RECOGNITION.—No later than 2 years after the date of
4 enactment of the Safe Food Enforcement, Assessment, Standards and Targeting Act of
5 2009, the Secretary shall establish a system for
6 the recognition of accreditation bodies that ac-
7 credit third-party auditors and audit agents to
8 certify that eligible entities meet the applicable
9 requirements of this Act.
10

11
12 “(B) NOTIFICATION.—Each accreditation
13 body recognized by the Secretary under this
14 section shall submit to the Secretary a list of all
15 accredited third-party auditors and audit agents
16 accredited by such body.

17 “(C) REVOCATION OF ACCREDITATION
18 BODY RECOGNITION.—The Secretary shall
19 promptly revoke the recognition of any accredi-
20 tation body found not to be in compliance with
21 the requirements of this section.

22 “(2) MODEL ACCREDITATION STANDARDS.—
23 The Secretary shall develop model standards, includ-
24 ing audit report requirements, and each recognized
25 accreditation body shall ensure that third-party

1 auditors and audit agents meet such standards in
2 order to qualify as an accredited third-party auditor
3 or audit agent under this section. In developing the
4 model standards, the Secretary shall look to stand-
5 ards in place on the date of the enactment of this
6 section for guidance, to avoid unnecessary duplica-
7 tion of efforts and costs.

8 “(c) THIRD-PARTY AUDITORS AND AUDIT AGEN-
9 CIES.—

10 “(1) THIRD-PARTY AUDITOR OR AUDIT AGENT
11 ACCREDITATION REQUIREMENTS.—

12 “(A) FOREIGN GOVERNMENTS.—Prior to
13 accrediting a foreign government as an accred-
14 ited third-party auditor, the accreditation body
15 shall perform such reviews and audits of food
16 safety programs, systems, and standards of the
17 government as the Secretary deems necessary
18 to determine that the foreign government is ca-
19 pable of adequately ensuring that eligible enti-
20 ties certified by such government meet the re-
21 quirements of this Act with respect to food
22 manufactured, processed, packed, or held for
23 import to the United States.

24 “(B) FOREIGN COOPERATIVES AND OTHER
25 THIRD PARTIES.—Prior to accrediting a foreign

1 cooperative that aggregates the products of
2 growers or processors, or any other third party
3 that the Secretary determines appropriate to be
4 an accredited third-party auditor or audit
5 agent, the accreditation body shall perform such
6 reviews and audits of the training and qualifica-
7 tions of auditors used by that cooperative or
8 party and conduct such reviews of internal sys-
9 tems and such other investigation of the cooper-
10 ative or party as the Secretary deems necessary
11 to determine that each eligible entity certified
12 by the cooperative or party has systems and
13 standards in use to ensure that such entity
14 meets the requirements of this Act.

15 “(2) REQUIREMENT TO ISSUE CERTIFICATION
16 OF ELIGIBLE ENTITIES.—

17 “(A) IN GENERAL.—An accreditation body
18 may not accredit a third-party auditor or audit
19 agent unless such third-party auditor or audit
20 agent agrees to issue a written and electronic
21 certification to accompany each food shipment
22 for import into the United States from an eligi-
23 ble entity certified by the third-party auditor or
24 audit agent, subject to requirements set forth
25 by the Secretary. The Secretary shall consider

1 such certificates when targeting inspection re-
2 sources under section 421.

3 “(B) PURPOSE OF CERTIFICATION.—The
4 Secretary shall use evidence of certification pro-
5 vided by accredited third-party auditors and
6 audit agents—

7 “(i) to determine the eligibility of an
8 importer to receive a certification under
9 section 801(p); and

10 “(ii) to determine the eligibility of an
11 importer to participate in the voluntary
12 qualified importer program under section
13 806.

14 “(3) AUDIT REPORT REQUIREMENTS.—

15 “(A) REQUIREMENTS IN GENERAL.—As a
16 condition of accreditation, an accredited third-
17 party auditor or audit agent shall prepare the
18 audit report for an audit, in a form and manner
19 designated by the Secretary, which shall in-
20 clude—

21 “(i) the identity of the persons at the
22 audited eligible entity responsible for com-
23 pliance with food safety requirements;

24 “(ii) the dates of the audit;

25 “(iii) the scope of the audit; and

1 “(iv) any other information required
2 by the Secretary that relates to or may in-
3 fluence an assessment of compliance with
4 this Act.

5 “(B) SUBMISSION OF REPORTS TO THE
6 SECRETARY.—

7 “(i) IN GENERAL.—Following any ac-
8 creditation of a third-party auditor or
9 audit agent, the Secretary may, at any
10 time, require the accredited third-party
11 auditor or audit agent to submit to the
12 Secretary an onsite audit report and such
13 other reports or documents required as
14 part of the audit process, for any eligible
15 entity certified by the third-party auditor
16 or audit agent. Such report may include
17 documentation that the eligible entity is in
18 compliance with any applicable registration
19 requirements.

20 “(ii) LIMITATION.—The requirement
21 under clause (i) shall not include any re-
22 port or other documents resulting from a
23 consultative audit by the accredited third-
24 party auditor or audit agent, except that
25 the Secretary may access the results of a

1 consultative audit in accordance with sec-
2 tion 414.

3 “(4) AUDIT AGENT REQUIREMENTS.—

4 “(A) PUBLIC HEALTH RISKS.—If, at any
5 time during an audit, an accredited audit agent
6 discovers a condition that could cause or con-
7 tribute to a serious risk to the public health,
8 the audit agent shall immediately notify the
9 Secretary of—

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

12 “(ii) such condition.

13 “(B) AUDIT TYPES.—An accredited audit
14 agent may perform consultative and regulatory
15 audits of eligible entities.

16 “(C) LIMITATIONS.—An accredited audit
17 agent may not perform a regulatory audit of an
18 eligible entity if such agent has performed a
19 consultative audit or a regulatory audit of such
20 eligible entity during the previous 24-month pe-
21 riod.

22 “(5) CONFLICTS OF INTEREST.—

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

1 “(i) not be owned, managed, or con-
2 trolled by any person that owns or operates
3 an eligible entity to be certified by such
4 auditor;

5 “(ii) in carrying out audits of eligible
6 entities under this section, have procedures
7 to ensure against the use of any officer or
8 employee of such auditor that has a finan-
9 cial conflict of interest regarding an eligi-
10 ble entity to be certified by such auditor;
11 and

12 “(iii) annually make available to the
13 Secretary disclosures of the extent to
14 which such auditor and the officers and
15 employees of such auditor have maintained
16 compliance with clauses (i) and (ii) relat-
17 ing to financial conflicts of interest.

18 “(B) AUDIT AGENTS.—An accredited audit
19 agent shall—

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

22 “(ii) in carrying out audits of eligible
23 entities under this section, have procedures
24 to ensure that such agent does not have a
25 financial conflict of interest regarding an

1 eligible entity to be certified by such agent;

2 and

3 “(iii) annually make available to the
4 Secretary disclosures of the extent to
5 which such agent has maintained compli-
6 ance with clauses (i) and (ii) relating to fi-
7 nancial conflicts of interest.

8 “(C) REGULATIONS.—The Secretary shall
9 promulgate regulations not later than 18
10 months after the date of enactment of the Safe
11 Food Enforcement, Assessment, Standards, and
12 Targeting Act of 2009 to ensure that there are
13 protections against conflicts of interest between
14 an accredited third-party auditor or audit agent
15 and the eligible entity to be certified by such
16 auditor or audit agent. Such regulations shall
17 include—

18 “(i) requiring that audits performed
19 under this section be unannounced;

20 “(ii) a structure, including timing and
21 public disclosure, for fees paid by eligible
22 entities to accredited third-party auditors
23 or audit agents to decrease the potential
24 for conflicts of interest; and

1 “(iii) appropriate limits on financial
2 affiliations between an accredited third-
3 party auditor or audit agent and any per-
4 son that owns or operates an eligible entity
5 to be certified by such auditor or audit
6 agent.

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

10 “(A) if food from an eligible entity cer-
11 tified by such third-party auditor or audit agent
12 is linked to an outbreak of human or animal ill-
13 ness;

14 “(B) following a performance audit and
15 finding by the Secretary that the third-party
16 auditor or audit agent no longer meets the re-
17 quirements for accreditation; or

18 “(C) following a refusal to allow United
19 States officials to conduct such audits and in-
20 vestigations as may be necessary to ensure con-
21 tinued compliance with the requirements set
22 forth in this section.

23 “(7) NEUTRALIZING COSTS.—The Secretary
24 shall establish a method, similar to the method used
25 by the Department of Agriculture, by which accred-

1 ited third-party auditors and audit agents reimburse
2 the Food and Drug Administration for the work per-
3 formed to establish and administer the accreditation
4 system under this section. The Secretary shall make
5 operating this program revenue-neutral and shall not
6 generate surplus revenue from such a reimburse-
7 ment mechanism.

8 “(d) ELIGIBLE ENTITIES RECERTIFICATION.—An el-
9 igible entity shall apply for annual recertification by an
10 accredited third-party auditor or audit agent if such enti-
11 ty—

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

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

17 “(e) FALSE STATEMENTS.—Any statement or rep-
18 resentation made—

19 “(1) by an employee or agent of an eligible enti-
20 ty to an accredited third-party auditor or audit
21 agent; or

22 “(2) by an accredited third-party auditor or an
23 audit agent to the Secretary,
24 shall be subject to section 1001 of title 18, United States
25 Code.”.

1 **SEC. 309. 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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