

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—111th Cong., 2d Sess.

S. 510

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT In the Nature of a Substitute intended to be proposed by _____

Viz:

1 Strike all after the enacting clause and insert the following:
2

3 **SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.**
4

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

7 (b) **REFERENCES.**—Except as otherwise specified,
8 whenever in this Act an amendment is expressed in terms
9 of an amendment to a section or other provision, the reference
10 shall be considered to be made to a section or other
11 provision of the Federal Food, Drug, and Cosmetic Act
12 (21 U.S.C. 301 et seq.).

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

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

TITLE I—IMPROVING CAPACITY TO PREVENT FOOD SAFETY
PROBLEMS

- Sec. 101. Inspections of records.
- Sec. 102. Registration of food facilities.
- Sec. 103. Hazard analysis and risk-based preventive controls.
- Sec. 104. Performance standards.
- Sec. 105. Standards for produce safety.
- Sec. 106. Protection against intentional adulteration.
- Sec. 107. Authority to collect fees.
- Sec. 108. National agriculture and food defense strategy.
- Sec. 109. Food and Agriculture Coordinating Councils.
- Sec. 110. Building domestic capacity.
- Sec. 111. Sanitary transportation of food.
- Sec. 112. Food allergy and anaphylaxis management.
- Sec. 113. New dietary ingredients.
- Sec. 114. Requirement for guidance relating to post harvest processing of raw oysters.
- Sec. 115. Port shopping.
- Sec. 116. Alcohol-related facilities.

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

- Sec. 201. Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report.
- Sec. 202. Laboratory accreditation for analyses of foods.
- Sec. 203. Integrated consortium of laboratory networks.
- Sec. 204. Enhancing tracking and tracing of food and recordkeeping.
- Sec. 205. Surveillance.
- Sec. 206. Mandatory recall authority.
- Sec. 207. Administrative detention of food.
- Sec. 208. Decontamination and disposal standards and plans.
- Sec. 209. Improving the training of State, local, territorial, and tribal food safety officials.
- Sec. 210. Enhancing food safety.
- Sec. 211. Improving the reportable food registry.

TITLE III—IMPROVING THE SAFETY OF IMPORTED FOOD

- Sec. 301. Foreign supplier verification program.
- Sec. 302. Voluntary qualified importer program.
- Sec. 303. Authority to require import certifications for food.
- Sec. 304. Prior notice of imported food shipments.
- Sec. 305. Building capacity of foreign governments with respect to food safety.
- Sec. 306. Inspection of foreign food facilities.
- Sec. 307. Accreditation of third-party auditors.
- Sec. 308. Foreign offices of the Food and Drug Administration.
- Sec. 309. Smuggled food.

TITLE IV—MISCELLANEOUS PROVISIONS

Sec. 401. Funding for food safety.

Sec. 402. Employee protections.

Sec. 403. Jurisdiction; authorities.

Sec. 404. Compliance with international agreements.

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

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

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

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

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

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

19 (3) by striking the last sentence; and

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

21 “(2) USE OF OR EXPOSURE TO FOOD OF CON-
22 CERN.—If the Secretary believes that there is a rea-

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

22 “(3) APPLICATION.—The requirement under
23 paragraphs (1) and (2) applies to all records relating
24 to the manufacture, processing, packing, distribu-
25 tion, receipt, holding, or importation of such article

1 maintained by or on behalf of such person in any
2 format (including paper and electronic formats) and
3 at any location.”.

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

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

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

14 (1) in paragraph (2), by—

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

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

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

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

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

15 (b) SUSPENSION OF REGISTRATION.—

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

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

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

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

3 “(b) SUSPENSION OF REGISTRATION.—

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

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

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

15 “(ii) packed, received, or held such food.

16 “(2) HEARING ON SUSPENSION.—The Secretary
17 shall provide the registrant subject to an order
18 under paragraph (1) with an opportunity for an in-
19 formal hearing, to be held as soon as possible but
20 not later than 2 business days after the issuance of
21 the order or such other time period, as agreed upon
22 by the Secretary and the registrant, on the actions
23 required for reinstatement of registration and why
24 the registration that is subject to suspension should
25 be reinstated. The Secretary shall reinstate a reg-

1 istration if the Secretary determines, based on evi-
2 dence presented, that adequate grounds do not exist
3 to continue the suspension of the registration.

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

6 “(A) CORRECTIVE ACTION PLAN.—If, after
7 providing opportunity for an informal hearing
8 under paragraph (2), the Secretary determines
9 that the suspension of registration remains nec-
10 essary, the Secretary shall require the reg-
11 istrant to submit a corrective action plan to
12 demonstrate how the registrant plans to correct
13 the conditions found by the Secretary. The Sec-
14 retary shall review such plan not later than 14
15 days after the submission of the corrective ac-
16 tion plan or such other time period as deter-
17 mined by the Secretary.

18 “(B) VACATING OF ORDER.—Upon a de-
19 termination by the Secretary that adequate
20 grounds do not exist to continue the suspension
21 actions required by the order, or that such ac-
22 tions should be modified, the Secretary shall
23 promptly vacate the order and reinstate the reg-
24 istration of the facility subject to the order or
25 modify the order, as appropriate.

1 “(4) EFFECT OF SUSPENSION.—If the registra-
2 tion of a facility is suspended under this subsection,
3 no person shall import or export food into the
4 United States from such facility, offer to import or
5 export food into the United States from such facil-
6 ity, or otherwise introduce food from such facility
7 into interstate or intrastate commerce in the United
8 States.

9 “(5) REGULATIONS.—

10 “(A) IN GENERAL.—The Secretary shall
11 promulgate regulations to implement this sub-
12 section. The Secretary may promulgate such
13 regulations on an interim final basis.

14 “(B) REGISTRATION REQUIREMENT.—The
15 Secretary may require that registration under
16 this subsection be submitted in an electronic
17 format. Such requirement may not take effect
18 before the date that is 5 years after the date of
19 enactment of the FDA Food Safety Moderniza-
20 tion Act.

21 “(6) APPLICATION DATE.—Facilities shall be
22 subject to the requirements of this subsection begin-
23 ning on the earlier of—

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

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

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

8 (2) SMALL ENTITY COMPLIANCE POLICY
9 GUIDE.—Not later than 180 days after the issuance
10 of the regulations promulgated under section
11 415(b)(5) of the Federal Food, Drug, and Cosmetic
12 Act (as added by this section), the Secretary shall
13 issue a small entity compliance policy guide setting
14 forth in plain language the requirements of such
15 regulations to assist small entities in complying with
16 registration requirements and other activities re-
17 quired under such section.

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

22 (c) CONFORMING AMENDMENTS.—

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

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

6 **SEC. 103. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE**
7 **CONTROLS.**

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

10 **“SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVEN-**
11 **TIVE CONTROLS.**

12 “(a) IN GENERAL.—The owner, operator, or agent
13 in charge of a facility shall, in accordance with this sec-
14 tion, evaluate the hazards that could affect food manufac-
15 tured, processed, packed, or held by such facility, identify
16 and implement preventive controls to significantly mini-
17 mize or prevent the occurrence of such hazards and pro-
18 vide assurances that such food is not adulterated under
19 section 402 or misbranded under section 403(w), monitor
20 the performance of those controls, and maintain records
21 of this monitoring as a matter of routine practice.

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

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

4 “(A) biological, chemical, physical, and ra-
5 diological hazards, natural toxins, pesticides,
6 drug residues, decomposition, parasites, aller-
7 gens, and unapproved food and color additives;
8 and

9 “(B) hazards that occur naturally, or may
10 be unintentionally introduced; and

11 “(2) identify and evaluate hazards that may be
12 intentionally introduced, including by acts of ter-
13 rorism; and

14 “(3) develop a written analysis of the hazards.

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

19 “(1) hazards identified in the hazard analysis
20 conducted under subsection (b)(1) will be signifi-
21 cantly minimized or prevented;

22 “(2) any hazards identified in the hazard anal-
23 ysis conducted under subsection (b)(2) will be sig-
24 nificantly minimized or prevented and addressed,
25 consistent with section 420, as applicable; and

1 “(3) 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 to ensure that, if the preventive controls implemented
12 under subsection (c) are not properly implemented or are
13 found to be ineffective—

14 “(1) appropriate action is taken to reduce the
15 likelihood of recurrence of the implementation fail-
16 ure;

17 “(2) all affected food is evaluated for safety;
18 and

19 “(3) all affected food is prevented from entering
20 into commerce if the owner, operator or agent in
21 charge of such facility cannot ensure that the af-
22 fected food is not adulterated under section 402 or
23 misbranded under section 403(w).

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

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

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

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

9 “(4) the preventive controls implemented under
10 subsection (c) are effectively and significantly mini-
11 mizing or preventing the occurrence of identified
12 hazards, including through the use of environmental
13 and product testing programs and other appropriate
14 means; and

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

20 “(g) RECORDKEEPING.—The owner, operator, or
21 agent in charge of a facility shall maintain, for not less
22 than 2 years, records documenting the monitoring of the
23 preventive controls implemented under subsection (c), in-
24 stances of nonconformance material to food safety, the re-
25 sults of testing and other appropriate means of verification

1 under subsection (f)(4), instances when corrective actions
2 were implemented, and the efficacy of preventive controls
3 and corrective actions.

4 “(h) WRITTEN PLAN AND DOCUMENTATION.—The
5 owner, operator, or agent in charge of a facility shall pre-
6 pare a written plan that documents and describes the pro-
7 cedures used by the facility to comply with the require-
8 ments of this section, including analyzing the hazards
9 under subsection (b) and identifying the preventive con-
10 trols adopted under subsection (c) to address those haz-
11 ards. Such written plan, together with the documentation
12 described in subsection (g), shall be made promptly avail-
13 able to a duly authorized representative of the Secretary
14 upon oral or written request.

15 “(i) REQUIREMENT TO REANALYZE.—The owner,
16 operator, or agent in charge of a facility shall conduct a
17 reanalysis under subsection (b) whenever a significant
18 change is made in the activities conducted at a facility
19 operated by such owner, operator, or agent if the change
20 creates a reasonable potential for a new hazard or a sig-
21 nificant increase in a previously identified hazard or not
22 less frequently than once every 3 years, whichever is ear-
23 lier. Such reanalysis shall be completed and additional pre-
24 ventive controls needed to address the hazard identified,
25 if any, shall be implemented before the change in activities

1 at the facility is operative. Such owner, operator, or agent
2 shall revise the written plan required under subsection (h)
3 if such a significant change is made or document the basis
4 for the conclusion that no additional or revised preventive
5 controls are needed. The Secretary may require a reanaly-
6 sis under this section to respond to new hazards and devel-
7 opments in scientific understanding, including, as appro-
8 priate, results from the Department of Homeland Security
9 biological, chemical, radiological, or other terrorism risk
10 assessment.

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

13 “(1) IN GENERAL.—This section shall not apply
14 to a facility if the owner, operator, or agent in
15 charge of such facility is required to comply with,
16 and is in compliance with, 1 of the following stand-
17 ards and regulations with respect to such facility:

18 “(A) The Seafood Hazard Analysis Critical
19 Control Points Program of the Food and Drug
20 Administration.

21 “(B) The Juice Hazard Analysis Critical
22 Control Points Program of the Food and Drug
23 Administration.

24 “(C) The Thermally Processed Low-Acid
25 Foods Packaged in Hermetically Sealed Con-

1 tainers standards of the Food and Drug Ad-
2 ministration (or any successor standards).

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

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

13 “(l) AUTHORITY WITH RESPECT TO CERTAIN FA-
14 CILITIES.—The Secretary may, by regulation, exempt or
15 modify the requirements for compliance under this section
16 with respect to facilities that are solely engaged in the pro-
17 duction of food for animals other than man, the storage
18 of raw agricultural commodities (other than fruits and
19 vegetables) intended for further distribution or processing,
20 or the storage of packaged foods that are not exposed to
21 the environment.

22 “(m) REGULATIONS.—

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

1 regulations to establish science-based minimum
2 standards for conducting a hazard analysis, docu-
3 menting hazards, implementing preventive controls,
4 and documenting the implementation of the preven-
5 tive controls under this section.

6 “(2) COORDINATION.—In promulgating the reg-
7 ulations under paragraph (1), with regard to haz-
8 ards that may be intentionally introduced, including
9 by acts of terrorism, the Secretary shall coordinate
10 with the Secretary of Homeland Security, as appro-
11 priate.

12 “(3) CONTENT.—The regulations promulgated
13 under paragraph (1) shall—

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

18 “(B) comply with chapter 35 of title 44,
19 United States Code (commonly known as the
20 ‘Paperwork Reduction Act’), with special atten-
21 tion to minimizing the burden (as defined in
22 section 3502(2) of such Act) on the facility, and
23 collection of information (as defined in section
24 3502(3) of such Act), associated with such reg-
25 ulations;

1 “(C) acknowledge differences in risk and
2 minimize, as appropriate, the number of sepa-
3 rate standards that apply to separate foods;
4 and

5 “(D) not require a facility to hire a con-
6 sultant or other third party to identify, imple-
7 ment, certify, or audit preventative controls, ex-
8 cept in the case of negotiated enforcement reso-
9 lutions that may require such a consultant or
10 third party.

11 “(4) RULE OF CONSTRUCTION.—Nothing in
12 this subsection shall be construed to provide the Sec-
13 retary with the authority to prescribe specific tech-
14 nologies, practices, or critical controls for an indi-
15 vidual facility.

16 “(5) REVIEW.—In promulgating the regulations
17 under paragraph (1), the Secretary shall review reg-
18 ulatory hazard analysis and preventive control pro-
19 grams in existence on the date of enactment of the
20 FDA Food Safety Modernization Act, including the
21 Grade ‘A’ Pasteurized Milk Ordinance to ensure
22 that such regulations are consistent, to the extent
23 practicable, with applicable domestic and inter-
24 nationally-recognized standards in existence on such
25 date.

1 “(n) DEFINITIONS.—For purposes of this section:

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

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

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

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

1 “(B) Supervisor, manager, and employee
2 hygiene training.

3 “(C) An environmental monitoring pro-
4 gram to verify the effectiveness of pathogen
5 controls in processes where a food is exposed to
6 a potential contaminant in the environment.

7 “(D) A food allergen control program.

8 “(E) A recall plan.

9 “(F) Current Good Manufacturing Prac-
10 tices (cGMPs) under part 110 of title 21, Code
11 of Federal Regulations (or any successor regu-
12 lations).

13 “(G) Supplier verification activities that
14 relate to the safety of food.”.

15 (b) GUIDANCE DOCUMENT.—The Secretary shall
16 issue a guidance document related to the regulations pro-
17 mulgated under subsection (b)(1) with respect to the haz-
18 ard analysis and preventive controls under section 418 of
19 the Federal Food, Drug, and Cosmetic Act (as added by
20 subsection (a)).

21 (c) RULEMAKING.—

22 (1) PROPOSED RULEMAKING.—

23 (A) IN GENERAL.—Not later than 9
24 months after the date of enactment of this Act,
25 the Secretary of Health and Human Services

1 (referred to in this subsection as the “Sec-
2 retary”) shall publish a notice of proposed rule-
3 making in the Federal Register to promulgate
4 regulations with respect to—

5 (i) activities that constitute on-farm
6 packing or holding of food that is not
7 grown, raised, or consumed on such farm
8 or another farm under the same ownership
9 for purposes of section 415 of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C.
11 350d), as amended by this Act; and

12 (ii) activities that constitute on-farm
13 manufacturing or processing of food that is
14 not consumed on that farm or on another
15 farm under common ownership for pur-
16 poses of such section 415.

17 (B) CLARIFICATION.—The rulemaking de-
18 scribed under subparagraph (A) shall enhance
19 the implementation of such section 415 and
20 clarify the activities that are included as part of
21 the definition of the term “facility” under such
22 section 415. Nothing in this Act authorizes the
23 Secretary to modify the definition of the term
24 “facility” under such section.

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

5 (i) specific types of on-farm packing
6 or holding of food that is not grown,
7 raised, or consumed on such farm or an-
8 other farm under the same ownership, as
9 such packing and holding relates to spe-
10 cific foods; and

11 (ii) specific on-farm manufacturing
12 and processing activities as such activities
13 relate to specific foods that are not con-
14 sumed on that farm or on another farm
15 under common ownership.

16 (D) AUTHORITY WITH RESPECT TO CER-
17 TAIN FACILITIES.—

18 (i) IN GENERAL.—In promulgating
19 the regulations under subparagraph (A),
20 the Secretary shall consider the results of
21 the science-based risk analysis conducted
22 under subparagraph (C), and shall exempt
23 certain facilities from the requirements in
24 section 418 of the Federal Food, Drug,
25 and Cosmetic Act (as added by this sec-

1 paragraph (A). In defining such term,
2 the Secretary shall consider income,
3 harvestable acres, the number of em-
4 ployees, and the volume of the food
5 manufactured, processed, packed, or
6 held by a facility.

7 (2) FINAL REGULATIONS.—Not later than 9
8 months after the close of the comment period for the
9 proposed rulemaking under paragraph (1), the Sec-
10 retary shall adopt final rules with respect to—

11 (A) activities that constitute on-farm pack-
12 ing or holding of food that is not grown, raised,
13 or consumed on such farm or another farm
14 under the same ownership for purposes of sec-
15 tion 415 of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 350d), as amended by
17 this Act;

18 (B) activities that constitute on-farm man-
19 ufacturing or processing of food that is not con-
20 sumed on that farm or on another farm under
21 common ownership for purposes of such section
22 415; and

23 (C) the requirements under sections 418
24 and 421 of the Federal Food, Drug, and Cos-
25 metic Act, as added by this Act, from which the

1 Secretary may issue exemptions or modifica-
2 tions of the requirements for certain types of
3 facilities.

4 (d) SMALL ENTITY COMPLIANCE POLICY GUIDE.—
5 Not later than 180 days after the issuance of the regula-
6 tions promulgated under subsection (m) of section 418 of
7 the Federal Food, Drug, and Cosmetic Act (as added by
8 subsection (a)), the Secretary shall issue a small entity
9 compliance policy guide setting forth in plain language the
10 requirements of such section 418 and this section to assist
11 small entities in complying with the hazard analysis and
12 other activities required under such section 418 and this
13 section.

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

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

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

1 the Thermally Processed Low-Acid Foods Packaged in
2 Hermetically Sealed Containers standards.

3 (g) DIETARY SUPPLEMENTS.—Nothing in the
4 amendments made by this section shall apply to any facil-
5 ity with regard to the manufacturing, processing, packing,
6 or holding of a dietary supplement that is in compliance
7 with the requirements of sections 402(g)(2) and 761 of
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 342(g)(2), 379aa-1).

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

17 (i) EFFECTIVE DATE.—

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

21 (2) FLEXIBILITY FOR SMALL BUSINESSES.—

22 Notwithstanding paragraph (1)—

23 (A) the amendments made by this section
24 shall apply to a small business (as defined by
25 the Secretary for purposes of this section, not

1 later than 90 days after the date of enactment
2 of this Act) after the date that is 2 years after
3 the date of enactment of this Act; and

4 (B) the amendments made by this section
5 shall apply to a very small business (as defined
6 by the Secretary for purposes of this section,
7 not later than 90 days after the date of enact-
8 ment of this Act) after the date that is 3 years
9 after the date of enactment of this Act.

10 **SEC. 104. PERFORMANCE STANDARDS.**

11 (a) IN GENERAL.—The Secretary shall, in coordina-
12 tion with the Secretary of Agriculture, not less frequently
13 than every 2 years, review and evaluate relevant health
14 data and other relevant information, including from toxico-
15 logical and epidemiological studies and analyses, current
16 Good Manufacturing Practices issued by the Secretary re-
17 lating to food, and relevant recommendations of relevant
18 advisory committees, including the Food Advisory Com-
19 mittee, to determine the most significant foodborne con-
20 taminants.

21 (b) GUIDANCE DOCUMENTS AND REGULATIONS.—
22 Based on the review and evaluation conducted under sub-
23 section (a), and when appropriate to reduce the risk of
24 serious illness or death to humans or animals or to prevent
25 adulteration of the food under section 402 of the Federal

1 Food, Drug, or Cosmetic Act (21 U.S.C. 342) or to pre-
2 vent the spread by food of communicable disease under
3 section 361 of the Public Health Service Act (42 U.S.C.
4 264), the Secretary shall issue contaminant-specific and
5 science-based guidance documents, including guidance
6 documents regarding action levels, or regulations. Such
7 guidance, including guidance regarding action levels, or
8 regulations—

9 (1) shall apply to products or product classes;

10 (2) may differentiate between food for human
11 consumption and food intended for consumption by
12 animals other than humans; and

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

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

17 (d) REVIEW.—The Secretary shall periodically review
18 and revise, as appropriate, the guidance documents, in-
19 cluding guidance documents regarding action levels, or
20 regulations promulgated under this section.

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

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

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

2 “(a) PROPOSED RULEMAKING.—

3 “(1) IN GENERAL.—

4 “(A) RULEMAKING.—Not later than 1 year
5 after the date of enactment of the FDA Food
6 Safety Modernization Act, the Secretary, in co-
7 ordination with the Secretary of Agriculture
8 and representatives of State departments of ag-
9 riculture (including with regard to the national
10 organic program established under the Organic
11 Foods Production Act of 1990), and in con-
12 sultation with the Secretary of Homeland Secu-
13 rity, shall publish a notice of proposed rule-
14 making to establish science-based minimum
15 standards for the safe production and har-
16 vesting of those types of fruits and vegetables,
17 including specific mixes or categories of fruits
18 and vegetables, that are raw agricultural com-
19 modities for which the Secretary has deter-
20 mined that such standards minimize the risk of
21 serious adverse health consequences or death.

22 “(B) DETERMINATION BY SECRETARY.—

23 With respect to small and very small businesses
24 that produce and harvest those types of fruits
25 and vegetables that are raw agricultural com-
26 modities that the Secretary has determined are

1 low risk and do not present a risk of serious ad-
2 verse health consequences or death, the Sec-
3 retary may determine not to include production
4 and harvesting of such fruits and vegetables in
5 such rulemaking, or may modify the applicable
6 requirements of regulations promulgated pursu-
7 ant to this section.

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

14 “(3) CONTENT.—The proposed rulemaking
15 under paragraph (1) shall—

16 “(A) provide sufficient flexibility to be ap-
17 plicable to various types of entities engaged in
18 the production and harvesting of fruits and
19 vegetables that are raw agricultural commod-
20 ities, including small businesses and entities
21 that sell directly to consumers, and be appro-
22 priate to the scale and diversity of the produc-
23 tion and harvesting of such commodities;

24 “(B) include, with respect to growing, har-
25 vesting, sorting, packing, and storage oper-

1 a tions, science-based minimum standards re-
2 lated to soil amendments, hygiene, packaging,
3 temperature controls, animals in the growing
4 area, and water;

5 “(C) consider hazards that occur naturally,
6 may be unintentionally introduced, or may be
7 intentionally introduced, including by acts of
8 terrorism;

9 “(D) take into consideration, consistent
10 with ensuring enforceable public health protec-
11 tion, conservation and environmental practice
12 standards and policies established by Federal
13 natural resource conservation, wildlife conserva-
14 tion, and environmental agencies; and

15 “(E) in the case of production that is cer-
16 tified organic, not include any requirements
17 that conflict with or duplicate the requirements
18 of the national organic program established
19 under the Organic Foods Production Act of
20 1990, while providing the same level of public
21 health protection as the requirements under
22 guidance documents, including guidance docu-
23 ments regarding action levels, and regulations
24 under the FDA Food Safety Modernization Act.

1 “(4) PRIORITIZATION.—The Secretary shall
2 prioritize the implementation of the regulations
3 under this section for specific fruits and vegetables
4 that are raw agricultural commodities based on
5 known risks which may include a history and sever-
6 ity of foodborne illness outbreaks.

7 “(b) FINAL REGULATION.—

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

17 “(2) FINAL REGULATION.—The final regulation
18 shall—

19 “(A) provide for coordination of education
20 and enforcement activities by State and local
21 officials, as designated by the Governors of the
22 respective States or the appropriate elected
23 State official as recognized by State statute;
24 and

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

4 “(3) FLEXIBILITY FOR SMALL BUSINESSES.—
5 Notwithstanding paragraph (1)—

6 “(A) the regulations promulgated under
7 this section shall apply to a small business (as
8 defined by the Secretary for purposes of this
9 section, not later than 90 days after the date of
10 enactment of the FDA Food Safety Moderniza-
11 tion Act) after the date that is 1 year after the
12 effective date of the final regulation under
13 paragraph (1); and

14 “(B) the regulations promulgated under
15 this section shall apply to a very small business
16 (as defined by the Secretary for purposes of
17 this section, not later than 90 days after the
18 date of enactment of the FDA Food Safety
19 Modernization Act) after the date that is 2
20 years after the effective date of the final regula-
21 tion under paragraph (1).

22 “(c) CRITERIA.—

23 “(1) IN GENERAL.—The regulations adopted
24 under subsection (b) shall—

1 “(A) set forth those procedures, processes,
2 and practices that the Secretary determines to
3 minimize the risk of serious adverse health con-
4 sequences or death, including procedures, proc-
5 esses, and practices that the Secretary deter-
6 mines to be reasonably necessary to prevent the
7 introduction of known or reasonably foreseeable
8 biological, chemical, and physical hazards, in-
9 cluding hazards that occur naturally, may be
10 unintentionally introduced, or may be inten-
11 tionally introduced, including by acts of ter-
12 rorism, into fruits and vegetables, including
13 specific mixes or categories of fruits and vegeta-
14 bles, that are raw agricultural commodities and
15 to provide reasonable assurances that the
16 produce is not adulterated under section 402;

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

21 “(C) comply with chapter 35 of title 44,
22 United States Code (commonly known as the
23 ‘Paperwork Reduction Act’), with special atten-
24 tion to minimizing the burden (as defined in
25 section 3502(2) of such Act) on the facility, and

1 collection of information (as defined in section
2 3502(3) of such Act), associated with such reg-
3 ulations;

4 “(D) acknowledge differences in risk and
5 minimize, as appropriate, the number of sepa-
6 rate standards that apply to separate foods;
7 and

8 “(E) not require a facility to hire a con-
9 sultant or other third party to identify, imple-
10 ment, certify, compliance with these procedures,
11 processes, and practices, except in the case of
12 negotiated enforcement resolutions that may re-
13 quire such a consultant or third party; and

14 “(F) permit States and foreign countries
15 from which food is imported into the United
16 States to request from the Secretary variances
17 from the requirements of the regulations, sub-
18 ject to paragraph (2), where the State or for-
19 eign country determines that the variance is
20 necessary in light of local growing conditions
21 and that the procedures, processes, and prac-
22 tices to be followed under the variance are rea-
23 sonably likely to ensure that the produce is not
24 adulterated under section 402 and to provide
25 the same level of public health protection as the

1 requirements of the regulations adopted under
2 subsection (b).

3 “(2) VARIANCES.—

4 “(A) REQUESTS FOR VARIANCES.—A State
5 or foreign country from which food is imported
6 into the United States may in writing request
7 a variance from the Secretary. Such request
8 shall describe the variance requested and
9 present information demonstrating that the
10 variance does not increase the likelihood that
11 the food for which the variance is requested will
12 be adulterated under section 402, and that the
13 variance provides the same level of public health
14 protection as the requirements of the regula-
15 tions adopted under subsection (b). The Sec-
16 retary shall review such requests in a reason-
17 able timeframe.

18 “(B) APPROVAL OF VARIANCES.—The Sec-
19 retary may approve a variance in whole or in
20 part, as appropriate, and may specify the scope
21 of applicability of a variance to other similarly
22 situated persons.

23 “(C) DENIAL OF VARIANCES.—The Sec-
24 retary may deny a variance request if the Sec-
25 retary determines that such variance is not rea-

1 sonably likely to ensure that the food is not
2 adulterated under section 402 and is not rea-
3 sonably likely to provide the same level of public
4 health protection as the requirements of the
5 regulation adopted under subsection (b). The
6 Secretary shall notify the person requesting
7 such variance of the reasons for the denial.

8 “(D) MODIFICATION OR REVOCATION OF A
9 VARIANCE.—The Secretary, after notice and an
10 opportunity for a hearing, may modify or re-
11 voke a variance if the Secretary determines that
12 such variance is not reasonably likely to ensure
13 that the food is not adulterated under section
14 402 and is not reasonably likely to provide the
15 same level of public health protection as the re-
16 quirements of the regulations adopted under
17 subsection (b).

18 “(d) ENFORCEMENT.—The Secretary may coordinate
19 with the Secretary of Agriculture and, as appropriate,
20 shall contract and coordinate with the agency or depart-
21 ment designated by the Governor of each State to perform
22 activities to ensure compliance with this section.

23 “(e) GUIDANCE.—

24 “(1) IN GENERAL.—Not later than 1 year after
25 the date of enactment of the FDA Food Safety Mod-

1 ernization Act, the Secretary shall publish, after
2 consultation with the Secretary of Agriculture, rep-
3 resentatives of State departments of agriculture,
4 farmer representatives, and various types of entities
5 engaged in the production and harvesting or import-
6 ing of fruits and vegetables that are raw agricultural
7 commodities, including small businesses, updated
8 good agricultural practices and guidance for the safe
9 production and harvesting of specific types of fresh
10 produce under this section.

11 “(2) PUBLIC MEETINGS.—The Secretary shall
12 conduct not fewer than 3 public meetings in diverse
13 geographical areas of the United States as part of
14 an effort to conduct education and outreach regard-
15 ing the guidance described in paragraph (1) for per-
16 sons in different regions who are involved in the pro-
17 duction and harvesting of fruits and vegetables that
18 are raw agricultural commodities, including persons
19 that sell directly to consumers and farmer represent-
20 atives.

21 “(3) PAPERWORK REDUCTION.—The Secretary
22 shall ensure that any updated guidance under this
23 section will—

24 “(A) provide sufficient flexibility to be
25 practicable for all sizes and types of facilities,

1 including small businesses such as a small food
2 processing facility co-located on a farm; and

3 “(B) acknowledge differences in risk and
4 minimize, as appropriate, the number of sepa-
5 rate standards that apply to separate foods.

6 “(f) EXCEPTION FOR ACTIVITIES OF FACILITIES
7 SUBJECT TO SECTION 418.—This section shall not apply
8 to activities of a facility that are subject to section 418.”.

9 (b) SMALL ENTITY COMPLIANCE POLICY GUIDE.—
10 Not later than 180 days after the issuance of regulations
11 under section 419 of the Federal Food, Drug, and Cos-
12 metic Act (as added by subsection (a)), the Secretary of
13 Health and Human Services shall issue a small entity
14 compliance policy guide setting forth in plain language the
15 requirements of such section 419 and to assist small enti-
16 ties in complying with standards for safe production and
17 harvesting and other activities required under such sec-
18 tion.

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

22 “(vv) The failure to comply with the requirements
23 under section 419.”.

24 (d) NO EFFECT ON HACCP AUTHORITIES.—Noth-
25 ing in the amendments made by this section limits the au-

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

9 **SEC. 106. PROTECTION AGAINST INTENTIONAL ADULTERA-**
10 **TION.**

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

14 **“SEC. 420. PROTECTION AGAINST INTENTIONAL ADULTERA-**
15 **TION.**

16 “(a) DETERMINATIONS.—

17 “(1) IN GENERAL.—The Secretary shall—

18 “(A) conduct a vulnerability assessment of
19 the food system, including by consideration of
20 the Department of Homeland Security biologi-
21 cal, chemical, radiological, or other terrorism
22 risk assessments;

23 “(B) consider the best available under-
24 standing of uncertainties, risks, costs, and ben-
25 efits associated with guarding against inten-

1 tional adulteration of food at vulnerable points;
2 and

3 “(C) determine the types of science-based
4 mitigation strategies or measures that are nec-
5 essary to protect against the intentional adul-
6 teration of food.

7 “(2) LIMITED DISTRIBUTION.—In the interest
8 of national security, the Secretary, in consultation
9 with the Secretary of Homeland Security, may deter-
10 mine the time, manner, and form in which deter-
11 minations made under paragraph (1) are made pub-
12 licly available.

13 “(b) REGULATIONS.—Not later than 18 months after
14 the date of enactment of the FDA Food Safety Moderniza-
15 tion Act, the Secretary, in coordination with the Secretary
16 of Homeland Security and in consultation with the Sec-
17 retary of Agriculture, shall promulgate regulations to pro-
18 tect against the intentional adulteration of food subject
19 to this Act. Such regulations shall—

20 “(1) specify how a person shall assess whether
21 the person is required to implement mitigation strat-
22 egies or measures intended to protect against the in-
23 tentional adulteration of food; and

24 “(2) specify appropriate science-based mitiga-
25 tion strategies or measures to prepare and protect

1 the food supply chain at specific vulnerable points,
2 as appropriate.

3 “(c) APPLICABILITY.—Regulations promulgated
4 under subsection (b) shall apply only to food for which
5 there is a high risk of intentional contamination, as deter-
6 mined by the Secretary, in consultation with the Secretary
7 of Homeland Security, under subsection (a), that could
8 cause serious adverse health consequences or death to hu-
9 mans or animals and shall include those foods—

10 “(1) for which the Secretary has identified clear
11 vulnerabilities (including short shelf-life or suscepti-
12 bility to intentional contamination at critical control
13 points); and

14 “(2) in bulk or batch form, prior to being pack-
15 aged for the final consumer.

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

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

22 (b) GUIDANCE DOCUMENTS.—

23 (1) IN GENERAL.—Not later than 1 year after
24 the date of enactment of this Act, the Secretary of
25 Health and Human Services, in consultation with

1 the Secretary of Homeland Security and the Sec-
2 retary of Agriculture, shall issue guidance docu-
3 ments related to protection against the intentional
4 adulteration of food, including mitigation strategies
5 or measures to guard against such adulteration as
6 required under section 420 of the Federal Food,
7 Drug, and Cosmetic Act, as added by subsection (a).

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

10 (A) include a model assessment for a per-
11 son to use under subsection (b)(1) of section
12 420 of the Federal Food, Drug, and Cosmetic
13 Act, as added by subsection (a);

14 (B) include examples of mitigation strate-
15 gies or measures described in subsection (b)(2)
16 of such section; and

17 (C) specify situations in which the exam-
18 ples of mitigation strategies or measures de-
19 scribed in subsection (b)(2) of such section are
20 appropriate.

21 (3) LIMITED DISTRIBUTION.—In the interest of
22 national security, the Secretary of Health and
23 Human Services, in consultation with the Secretary
24 of Homeland Security, may determine the time,
25 manner, and form in which the guidance documents

1 issued under paragraph (1) are made public, includ-
2 ing by releasing such documents to targeted audi-
3 ences.

4 (c) PERIODIC REVIEW.—The Secretary of Health and
5 Human Services shall periodically review and, as appro-
6 priate, update the regulations under section 420(b) of the
7 Federal Food, Drug, and Cosmetic Act, as added by sub-
8 section (a), and the guidance documents under subsection
9 (b).

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

13 “(ww) The failure to comply with section 420.”.

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

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

19 **“PART 6—FEES RELATED TO FOOD**

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

21 “(a) IN GENERAL.—

22 “(1) PURPOSE AND AUTHORITY.—For fiscal
23 year 2010 and each subsequent fiscal year, the Sec-
24 retary shall, in accordance with this section, assess
25 and collect fees from—

1 “(A) the responsible party for each domes-
2 tic facility (as defined in section 415(b)) and
3 the United States agent for each foreign facility
4 subject to a reinspection in such fiscal year, to
5 cover reinspection-related costs for such year;

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

15 “(C) each importer participating in the
16 voluntary qualified importer program under sec-
17 tion 806 in such year, to cover the administra-
18 tive costs of such program for such year; and

19 “(D) each importer subject to a reinspec-
20 tion in such fiscal year, to cover reinspection-re-
21 lated costs for such year.

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

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

1 “(ii) assessing and collecting reinspec-
2 tion fees under this section; and

3 “(C) the term ‘responsible party’ has the
4 meaning given such term in section 417(a)(1).

5 “(b) ESTABLISHMENT OF FEES.—

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

13 “(2) FEE METHODOLOGY.—

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

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

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

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

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

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

17 “(B) OTHER CONSIDERATIONS.—

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

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

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

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

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

1 “(iii) PUBLISHED GUIDELINES.—Not
2 later than 180 days after the date of en-
3 actment of the FDA Food Safety Mod-
4 ernization Act, the Secretary shall publish
5 in the Federal Register a proposed set of
6 guidelines in consideration of the burden of
7 fee amounts on small business. Such con-
8 sideration may include reduced fee
9 amounts for small businesses. The Sec-
10 retary shall provide for a period of public
11 comment on such guidelines. The Secretary
12 shall adjust the fee schedule for small busi-
13 nesses subject to such fees only through
14 notice and comment rulemaking.

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

20 “(c) LIMITATIONS.—

21 “(1) IN GENERAL.—Fees under subsection (a)
22 shall be refunded for a fiscal year beginning after
23 fiscal year 2010 unless the amount of the total ap-
24 propriations for food safety activities at the Food
25 and Drug Administration for such fiscal year (ex-

1 including the amount of fees appropriated for such fis-
2 cal year) is equal to or greater than the amount of
3 appropriations for food safety activities at the Food
4 and Drug Administration for fiscal year 2009 (ex-
5 cluding the amount of fees appropriated for such fis-
6 cal year), multiplied by the adjustment factor under
7 paragraph (3).

8 “(2) AUTHORITY.—If—

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

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

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

18 “(3) ADJUSTMENT FACTOR.—

19 “(A) IN GENERAL.—The adjustment factor
20 described in paragraph (1) shall be the total
21 percentage change that occurred in the Con-
22 sumer Price Index for all urban consumers (all
23 items; United States city average) for the 12-
24 month period ending June 30 preceding the fis-

1 cal year, but in no case shall such adjustment
2 factor be negative.

3 “(B) COMPOUNDED BASIS.—The adjust-
4 ment under subparagraph (A) made each fiscal
5 year shall be added on a compounded basis to
6 the sum of all adjustments made each fiscal
7 year after fiscal year 2009.

8 “(4) LIMITATION ON AMOUNT OF CERTAIN
9 FEES.—

10 “(A) IN GENERAL.—Notwithstanding any
11 other provision of this section and subject to
12 subparagraph (B), the Secretary may not col-
13 lect fees in a fiscal year such that the amount
14 collected—

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

17 “(ii) under subparagraphs (A) and
18 (D) of subsection (a)(1) exceeds
19 \$25,000,000 combined.

20 “(B) EXCEPTION.—If a domestic facility
21 (as defined in section 415(b)) or an importer
22 becomes subject to a fee described in subpara-
23 graph (A), (B), or (D) of subsection (a)(1)
24 after the maximum amount of fees has been
25 collected by the Secretary under subparagraph

1 (A), the Secretary may collect a fee from such
2 facility or importer.

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

16 “(e) COLLECTION OF FEES.—

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

21 “(2) COLLECTION OF UNPAID FEES.—In any
22 case where the Secretary does not receive payment
23 of a fee assessed under this section within 30 days
24 after it is due, such fee shall be treated as a claim
25 of the United States Government subject to provi-

1 sions of subchapter II of chapter 37 of title 31,
2 United States Code.

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

13 “(g) AUTHORIZATION OF APPROPRIATIONS.—For fis-
14 cal year 2010 and each fiscal year thereafter, there is au-
15 thorized to be appropriated for fees under this section an
16 amount equal to the total revenue amount determined
17 under subsection (b) for the fiscal year, as adjusted or
18 otherwise affected under the other provisions of this sec-
19 tion.”.

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

22 (1) AUTHORITY FOR EXPORT CERTIFICATIONS
23 FOR FOOD, INCLUDING ANIMAL FEED.—Section
24 801(e)(4)(A) (21 U.S.C. 381(e)(4)(A)) is amend-
25 ed—

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

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

5 (C) in clause (ii) by striking “the drug”
6 each place it appears and inserting “the food,
7 drug”.

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

12 “(C) For purposes of this paragraph, a
13 certification by the Secretary shall be made on
14 such basis, and in such form (including a pub-
15 licly available listing) as the Secretary deter-
16 mines appropriate.”.

17 **SEC. 108. NATIONAL AGRICULTURE AND FOOD DEFENSE**
18 **STRATEGY.**

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

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

1 the relevant committees of Congress, and make pub-
2 licly available on the Internet Web sites of the De-
3 partment of Health and Human Services and the
4 Department 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, food production, and
8 international trade;

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

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

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

16 (II) infected plants and animals;
17 and

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

21 (3) EVALUATION.—The Secretary, in coordina-
22 tion with the Secretary of Agriculture and the Sec-
23 retary of Homeland Security, shall—

1 (A) develop metrics to measure progress
 2 for the evaluation process described in para-
 3 graph (1)(B); and

4 (B) report on the progress measured in
 5 subparagraph (A) as part of the National Agri-
 6 culture and Food Defense strategy described in
 7 subsection (a)(1).

8 (c) LIMITED DISTRIBUTION.—In the interest of na-
 9 tional security, the Secretary of Health and Human Serv-
 10 ices and the Secretary of Agriculture, in coordination with
 11 the Secretary of Homeland Security, may determine the
 12 manner and format in which the National Agriculture and
 13 Food Defense strategy established under this section is
 14 made publicly available on the Internet Web sites of the
 15 Department of Health and Human Services, the Depart-
 16 ment of Homeland Security, and the Department of Agri-
 17 culture, as described in subsection (a)(1).

18 **SEC. 109. FOOD AND AGRICULTURE COORDINATING COUN-**

19 **CILS.**

20 The Secretary of Homeland Security, in coordination
 21 with the Secretary of Health and Human Services and the
 22 Secretary of Agriculture, shall within 180 days of enact-
 23 ment of this Act, and annually thereafter, submit to the
 24 relevant committees of Congress, and make publicly avail-
 25 able on the Internet Web site of the Department of Home-

1 land Security, a report on the activities of the Food and
2 Agriculture Government Coordinating Council and the
3 Food and Agriculture Sector Coordinating Council, includ-
4 ing the progress of such Councils on—

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

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

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

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

20 (A) animal or plant disease outbreaks;

21 (B) food contamination; and

22 (C) natural disasters affecting agriculture
23 and food.

24 **SEC. 110. BUILDING DOMESTIC CAPACITY.**

25 (a) IN GENERAL.—

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

12 (A) Analysis of the need for further regula-
13 tions or guidance to industry.

14 (B) Outreach to food industry sectors, in-
15 cluding through the Food and Agriculture Co-
16 ordinating Councils referred to in section 109,
17 to identify potential sources of emerging threats
18 to the safety and security of the food supply
19 and preventive strategies to address those
20 threats.

21 (C) Systems to ensure the prompt distribu-
22 tion to the food industry of information and
23 technical assistance concerning preventive strat-
24 egies.

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

5 (E) Surveillance systems and laboratory
6 networks to rapidly detect and respond to
7 foodborne illness outbreaks and other food-re-
8 lated hazards, including how such systems and
9 networks are integrated.

10 (F) Outreach, education, and training pro-
11 vided to States and local governments to build
12 State and local food safety and food defense ca-
13 pabilities, including progress implementing
14 strategies developed under sections 108 and
15 205.

16 (G) The estimated resources needed to ef-
17 fectively implement the programs and practices
18 identified in the report developed in this section
19 over a 5-year period.

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

24 (I) Specific efforts taken pursuant to the
25 agreements authorized under section 421(c) of

1 the Federal Food, Drug, and Cosmetic Act (as
2 added by section 201), together with, as nec-
3 essary, a description of any additional authori-
4 ties necessary to improve seafood safety.

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

9 (A) reviews previous food safety programs
10 and practices;

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

13 (C) identifies future programs and prac-
14 tices; and

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

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

1 report as likely to contribute to the safety and security
2 of the food supply.

3 (c) CAPABILITY FOR LABORATORY ANALYSES; RE-
4 SEARCH.—The report developed under subsection (a)(1)
5 shall provide a description of methods to increase capacity
6 to undertake analyses of food samples promptly after col-
7 lection, to identify new and rapid analytical techniques,
8 including commercially-available techniques that can be
9 employed at ports of entry and by Food Emergency Re-
10 sponse Network laboratories, and to provide for well-
11 equipped and staffed laboratory facilities and progress to-
12 ward laboratory accreditation under section 422 of the
13 Federal Food, Drug, and Cosmetic Act (as added by sec-
14 tion 202).

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

1 notice system under section 801(m) of such Act (21
2 U.S.C. 381(m)) with other information technology systems
3 that are used by the Federal Government for the proc-
4 essing of food offered for import into the United States.

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

10 (f) TRACEBACK AND SURVEILLANCE REPORT.—The
11 Secretary shall include in the report developed under sub-
12 section (a)(1) an analysis of the Food and Drug Adminis-
13 tration’s performance in foodborne illness outbreaks dur-
14 ing the 5-year period preceding the date of enactment of
15 this Act involving fruits and vegetables that are raw agri-
16 cultural commodities (as defined in section 201(r) (21
17 U.S.C. 321(r)) and recommendations for enhanced sur-
18 veillance, outbreak response, and traceability. Such find-
19 ings and recommendations shall address communication
20 and coordination with the public, industry, and State and
21 local governments, as such communication and coordina-
22 tion relates to outbreak identification and traceback.

23 (g) BIENNIAL FOOD SAFETY AND FOOD DEFENSE
24 RESEARCH PLAN.—The Secretary, the Secretary of Agri-
25 culture, and the Secretary of Homeland Security shall, on

1 a biennial basis, submit to Congress a joint food safety
2 and food defense research plan which may include study-
3 ing the long-term health effects of foodborne illness. Such
4 biennial plan shall include a list and description of projects
5 conducted during the previous 2-year period and the plan
6 for projects to be conducted during the subsequent 2-year
7 period.

8 (h) EFFECTIVENESS OF PROGRAMS ADMINISTERED
9 BY THE DEPARTMENT OF HEALTH AND HUMAN SERV-
10 ICES.—

11 (1) IN GENERAL.—To determine whether exist-
12 ing Federal programs administered by the Depart-
13 ment of Health and Human Services are effective in
14 achieving the stated goals of such programs, the
15 Secretary shall, beginning not later than 1 year after
16 the date of enactment of this Act—

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

21 (B) submit to Congress a report con-
22 cerning such evaluation.

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

1 (A) include conclusions concerning the rea-
2 sons that such existing programs have proven
3 successful or not successful and what factors
4 contributed to such conclusions;

5 (B) include recommendations for consoli-
6 dation and elimination to reduce duplication
7 and inefficiencies in such programs at such De-
8 partment as identified during the evaluation
9 conduct under this subsection; and

10 (C) be made publicly available in a publica-
11 tion entitled “Guide to the U.S. Department of
12 Health and Human Services Programs”.

13 (i) UNIQUE IDENTIFICATION NUMBERS.—

14 (1) IN GENERAL.—Not later than 1 year after
15 the date of enactment of this Act, the Secretary, act-
16 ing through the Commissioner of Food and Drugs,
17 shall conduct a study regarding the need for, and
18 challenges associated with, development and imple-
19 mentation of a program that requires a unique iden-
20 tification number for each food facility registered
21 with the Secretary and, as appropriate, each broker
22 that imports food into the United States. Such study
23 shall include an evaluation of the costs associated
24 with development and implementation of such a sys-
25 tem, and make recommendations about what new

1 authorities, if any, would be necessary to develop
2 and implement such a system.

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

9 **SEC. 111. SANITARY TRANSPORTATION OF FOOD.**

10 (a) IN GENERAL.—Not later than 18 months after
11 the date of enactment of this Act, the Secretary shall pro-
12 mulgate regulations described in section 416(b) of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 350e(b)).

15 (b) FOOD TRANSPORTATION STUDY.—The Secretary,
16 acting through the Commissioner of Food and Drugs,
17 shall conduct a study of the transportation of food for con-
18 sumption in the United States, including transportation
19 by air, that includes an examination of the unique needs
20 of rural and frontier areas with regard to the delivery of
21 safe food.

22 **SEC. 112. FOOD ALLERGY AND ANAPHYLAXIS MANAGE-**
23 **MENT.**

24 (a) DEFINITIONS.—In this section:

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

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

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

9 (C) a State prekindergarten program that
10 serves children from birth through kinder-
11 garten.

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

17 (3) SCHOOL.—The term “school” includes pub-
18 lic—

19 (A) kindergartens;

20 (B) elementary schools; and

21 (C) secondary schools.

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

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

1 (1) ESTABLISHMENT.—

2 (A) IN GENERAL.—Not later than 1 year
3 after the date of enactment of this Act, the Sec-
4 retary, in consultation with the Secretary of
5 Education, shall—

6 (i) develop guidelines to be used on a
7 voluntary basis to develop plans for indi-
8 viduals to manage the risk of food allergy
9 and anaphylaxis in schools and early child-
10 hood education programs; and

11 (ii) make such guidelines available to
12 local educational agencies, schools, early
13 childhood education programs, and other
14 interested entities and individuals to be im-
15 plemented on a voluntary basis only.

16 (B) APPLICABILITY OF FERPA.—Each plan
17 described in subparagraph (A) that is developed
18 for an individual shall be considered an edu-
19 cation record for the purpose of section 444 of
20 the General Education Provisions Act (com-
21 monly referred to as the “Family Educational
22 Rights and Privacy Act of 1974”) (20 U.S.C.
23 1232g).

24 (2) CONTENTS.—The voluntary guidelines de-
25 veloped by the Secretary under paragraph (1) shall

1 address each of the following and may be updated
2 as the Secretary determines necessary:

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

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

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

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

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

15 (IV) listing any medication pre-
16 scribed for the child for the treatment
17 of anaphylaxis;

18 (V) detailing emergency treat-
19 ment procedures in the event of a re-
20 action;

21 (VI) listing the signs and symp-
22 toms of a reaction; and

23 (VII) assessing the child's readi-
24 ness for self-administration of pre-
25 scription medication; and

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

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

12 (i) the children are capable of self-ad-
13 ministering medication; and

14 (ii) such administration is not prohib-
15 ited by State law.

16 (C) Communication strategies between in-
17 dividual schools or early childhood education
18 programs and providers of emergency medical
19 services, including appropriate instructions for
20 emergency medical response.

21 (D) Strategies to reduce the risk of expo-
22 sure to anaphylactic causative agents in class-
23 rooms and common school or early childhood
24 education program areas such as cafeterias.

1 (E) The dissemination of general informa-
2 tion on life-threatening food allergies to school
3 or early childhood education program staff, par-
4 ents, and children.

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

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

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

17 (I) The creation of a plan contained in
18 each individual plan for food allergy manage-
19 ment that addresses the appropriate response to
20 an incident of anaphylaxis of a child while such
21 child is engaged in extracurricular programs of
22 a school or early childhood education program,
23 such as non-academic outings and field trips,
24 before- and after-school programs or before-
25 and after-early child education program pro-

1 grams, and school-sponsored or early childhood
2 education program-sponsored programs held on
3 weekends.

4 (J) Maintenance of information for each
5 administration of epinephrine to a child at risk
6 for anaphylaxis and prompt notification to par-
7 ents.

8 (K) Other elements the Secretary deter-
9 mines necessary for the management of food al-
10 lergies and anaphylaxis in schools and early
11 childhood education programs.

12 (3) RELATION TO STATE LAW.—Nothing in this
13 section or the guidelines developed by the Secretary
14 under paragraph (1) shall be construed to preempt
15 State law, including any State law regarding wheth-
16 er students at risk for anaphylaxis may self-admin-
17 ister medication.

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

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

25 (2) APPLICATION.—

1 (A) IN GENERAL.—To be eligible to receive
2 a grant under this subsection, a local edu-
3 cational agency shall submit an application to
4 the Secretary at such time, in such manner,
5 and including such information as the Secretary
6 may reasonably require.

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

9 (i) an assurance that the local edu-
10 cational agency has developed plans in ac-
11 cordance with the food allergy and anaphy-
12 laxis management guidelines described in
13 subsection (b);

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

18 (I) how the guidelines will be car-
19 ried out at individual schools served
20 by the local educational agency;

21 (II) how the local educational
22 agency will inform parents and stu-
23 dents of the guidelines in place;

24 (III) how school nurses, teachers,
25 administrators, and other school-based

1 staff will be made aware of, and given
2 training on, when applicable, the
3 guidelines in place; and

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

6 (iii) an itemization of how grant funds
7 received under this subsection will be ex-
8 pended;

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

12 (v) an agreement by the local edu-
13 cational agency to report information re-
14 quired by the Secretary to conduct evalua-
15 tions under this subsection.

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

19 (A) Purchase of materials and supplies, in-
20 cluding limited medical supplies such as epi-
21 nephrine and disposable wet wipes, to support
22 carrying out the food allergy and anaphylaxis
23 management guidelines described in subsection
24 (b).

1 (B) In partnership with local health de-
2 partments, school nurse, teacher, and personnel
3 training for food allergy management.

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

8 (D) Outreach to parents.

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

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

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

24 (6) MAXIMUM AMOUNT OF ANNUAL AWARDS.—
25 A grant awarded under this subsection may not be

1 made in an amount that is more than \$50,000 an-
2 nually.

3 (7) PRIORITY.—In awarding grants under this
4 subsection, the Secretary shall give priority to local
5 educational agencies with the highest percentages of
6 children who are counted under section 1124(c) of
7 the Elementary and Secondary Education Act of
8 1965 (20 U.S.C. 6333(c)).

9 (8) MATCHING FUNDS.—

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

20 (B) DETERMINATION OF AMOUNT OF NON-
21 FEDERAL CONTRIBUTION.—Non-Federal funds
22 required under subparagraph (A) may be cash
23 or in kind, including plant, equipment, or serv-
24 ices. Amounts provided by the Federal Govern-
25 ment, and any portion of any service subsidized

1 by the Federal Government, may not be in-
2 cluded in determining the amount of such non-
3 Federal funds.

4 (9) ADMINISTRATIVE FUNDS.—A local edu-
5 cational agency that receives a grant under this sub-
6 section may use not more than 2 percent of the
7 grant amount for administrative costs related to car-
8 rying out this subsection.

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

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

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

1 (d) VOLUNTARY NATURE OF GUIDELINES.—

2 (1) IN GENERAL.—The food allergy and ana-
3 phylaxis management guidelines developed by the
4 Secretary under subsection (b) are voluntary. Noth-
5 ing in this section or the guidelines developed by the
6 Secretary under subsection (b) shall be construed to
7 require a local educational agency to implement such
8 guidelines.

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

14 **SEC. 113. NEW DIETARY INGREDIENTS.**

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

17 (1) by redesignating subsection (c) as sub-
18 section (d); and

19 (2) by inserting after subsection (b) the fol-
20 lowing:

21 “(c) NOTIFICATION.—

22 “(1) IN GENERAL.—If the Secretary determines
23 that the information in a new dietary ingredient no-
24 tification submitted under this section for an article
25 purported to be a new dietary ingredient is inad-

1 equate to establish that a dietary supplement con-
2 taining such article will reasonably be expected to be
3 safe because the article may be, or may contain, an
4 anabolic steroid or an analogue of an anabolic ster-
5 oid, the Secretary shall notify the Drug Enforcement
6 Administration of such determination. Such notifica-
7 tion by the Secretary shall include, at a minimum,
8 the name of the dietary supplement or article, the
9 name of the person or persons who marketed the
10 product or made the submission of information re-
11 garding the article to the Secretary under this sec-
12 tion, and any contact information for such person or
13 persons that the Secretary has.

14 “(2) DEFINITIONS.—For purposes of this sub-
15 section—

16 “(A) the term ‘anabolic steroid’ has the
17 meaning given such term in section 102(41) of
18 the Controlled Substances Act; and

19 “(B) the term ‘analogue of an anabolic
20 steroid’ means a substance whose chemical
21 structure is substantially similar to the chem-
22 ical structure of an anabolic steroid.”.

23 (b) GUIDANCE.—Not later than 180 days after the
24 date of enactment of this Act, the Secretary shall publish
25 guidance that clarifies when a dietary supplement ingre-

1 dient is a new dietary ingredient, when the manufacturer
2 or distributor of a dietary ingredient or dietary supple-
3 ment should provide the Secretary with information as de-
4 scribed in section 413(a)(2) of the Federal Food, Drug,
5 and Cosmetic Act, the evidence needed to document the
6 safety of new dietary ingredients, and appropriate meth-
7 ods for establishing the identify of a new dietary ingre-
8 dient.

9 **SEC. 114. REQUIREMENT FOR GUIDANCE RELATING TO**
10 **POST HARVEST PROCESSING OF RAW OYS-**
11 **TERS.**

12 (a) IN GENERAL.—Not later than 90 days prior to
13 the issuance of any guidance, regulation, or suggested
14 amendment by the Food and Drug Administration to the
15 National Shellfish Sanitation Program’s Model Ordinance,
16 or the issuance of any guidance or regulation by the Food
17 and Drug Administration relating to the Seafood Hazard
18 Analysis Critical Control Points Program of the Food and
19 Drug Administration (parts 123 and 1240 of title 21,
20 Code of Federal Regulations (or any successor regula-
21 tions), where such guidance, regulation or suggested
22 amendment relates to post harvest processing for raw oys-
23 ters, the Secretary shall prepare and submit to the Com-
24 mittee on Health, Education, Labor, and Pensions of the
25 Senate and the Committee on Energy and Commerce of

1 the House of Representatives a report which shall in-
2 clude—

3 (1) an assessment of how post harvest proc-
4 essing or other equivalent controls feasibly may be
5 implemented in the fastest, safest, and most eco-
6 nomical manner;

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

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

11 (4) the impact post harvest processing is ex-
12 pected to have on the sales, cost, and availability of
13 raw oysters;

14 (5) criteria for ensuring post harvest processing
15 standards will be applied equally to shellfish im-
16 ported from all nations of origin;

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

20 (7) the extent to which the Food and Drug Ad-
21 ministration has consulted with the States and other
22 regulatory agencies, as appropriate, with regard to
23 post harvest processing measures.

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

1 (c) REVIEW AND EVALUATION.—Not later than 30
2 days after the Secretary issues a proposed regulation or
3 guidance described in subsection (a), the Comptroller Gen-
4 eral of the United States shall—

5 (1) review and evaluate the report described in
6 (a) and report to Congress on the findings of the es-
7 timates and analysis in the report;

8 (2) compare such proposed regulation or guid-
9 ance to similar regulations or guidance with respect
10 to other regulated foods, including a comparison of
11 risks the Secretary may find associated with seafood
12 and the instances of those risks in such other regu-
13 lated foods; and

14 (3) evaluate the impact of post harvest proc-
15 essing on the competitiveness of the domestic oyster
16 industry in the United States and in international
17 markets.

18 (d) WAIVER.—The requirement of preparing a report
19 under subsection (a) shall be waived if the Secretary issues
20 a guidance that is adopted as a consensus agreement be-
21 tween Federal and State regulators and the oyster indus-
22 try, acting through the Interstate Shellfish Sanitation
23 Conference.

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

1 **SEC. 115. PORT SHOPPING.**

2 Until the date on which the Secretary promulgates
3 a final rule that implements the amendments made by sec-
4 tion 308 of the Public Health Security and Bioterrorism
5 Preparedness and Response Act of 2002, (Public Law
6 107–188), the Secretary shall notify the Secretary of
7 Homeland Security of all instances in which the Secretary
8 refuses to admit a food into the United States under sec-
9 tion 801(a) of the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 381(a)) so that the Secretary of Homeland Se-
11 curity, acting through the Commissioner of Customs and
12 Border Protection, may prevent food refused admittance
13 into the United States by a United States port of entry
14 from being admitted by another United States port of
15 entry, through the notification of other such United States
16 ports of entry.

17 **SEC. 116. ALCOHOL-RELATED FACILITIES.**

18 (a) IN GENERAL.—Except as provided by sections
19 102, 206, 207, 302, 304, 402, 403, and 404 of this Act,
20 and the amendments made by such sections, nothing in
21 this Act, or the amendments made by this Act, shall be
22 construed to apply to a facility that—

23 (1) under the Federal Alcohol Administration
24 Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle
25 E of the Internal Revenue Code of 1986 (26 U.S.C.
26 5001 et seq.) is required to obtain a permit or to

1 register with the Secretary of the Treasury as a con-
2 dition of doing business in the United States; and

3 (2) under section 415 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 350d) is re-
5 quired to register as a facility because such facility
6 is engaged in manufacturing, processing, packing, or
7 holding 1 or more alcoholic beverages, with respect
8 to the activities of such facility that relate to the
9 manufacturing, processing, packing, or holding of al-
10 coholic beverages.

11 (b) LIMITED RECEIPT AND DISTRIBUTION OF NON-
12 ALCOHOL FOOD.—Subsection (a) shall not apply to a fa-
13 cility engaged in the receipt and distribution of any non-
14 alcohol food, except that such paragraph shall apply to a
15 facility described in such paragraph that receives and dis-
16 tributes non-alcohol food, provided such food is received
17 and distributed—

18 (1) in a prepackaged form that prevents any di-
19 rect human contact with such food; and

20 (2) in amounts that constitute not more than 5
21 percent of the overall sales of such facility, as deter-
22 mined by the Secretary of the Treasury.

23 (c) RULE OF CONSTRUCTION.—Except as provided in
24 subsections (a) and (b), this section shall not be construed
25 to exempt any food, other than alcoholic beverages, as de-

1 fined in section 214 of the Federal Alcohol Administration
2 Act (27 U.S.C. 214), from the requirements of this Act
3 (including the amendments made by this Act).

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

7 **SEC. 201. TARGETING OF INSPECTION RESOURCES FOR DO-**
8 **ESTIC FACILITIES, FOREIGN FACILITIES,**
9 **AND PORTS OF ENTRY; ANNUAL REPORT.**

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

15 **“SEC. 421. TARGETING OF INSPECTION RESOURCES FOR**
16 **DOMESTIC FACILITIES, FOREIGN FACILITIES,**
17 **AND PORTS OF ENTRY; ANNUAL REPORT.**

18 “(a) IDENTIFICATION AND INSPECTION OF FACILI-
19 TIES.—

20 “(1) IDENTIFICATION.—The Secretary shall
21 identify high-risk facilities and shall allocate re-
22 sources to inspect facilities according to the known
23 safety risks of the facilities, which shall be based on
24 the following factors:

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

4 “(B) The compliance history of a facility,
5 including with regard to food recalls, outbreaks
6 of foodborne illness, and violations of food safe-
7 ty standards.

8 “(C) The rigor and effectiveness of the fa-
9 cility’s hazard analysis and risk-based preven-
10 tive controls.

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

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

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

21 “(2) INSPECTIONS.—

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

1 Secretary shall inspect not fewer than 600
2 foreign facilities.

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

9 “(E) RELIANCE ON FEDERAL, STATE, OR
10 LOCAL INSPECTIONS.—In meeting the inspec-
11 tion requirements under this subsection for do-
12 mestic facilities, the Secretary may rely on in-
13 spections conducted by other Federal, State, or
14 local agencies under interagency agreement,
15 contract, memoranda of understanding, or other
16 obligation.

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

23 “(1) The known safety risks of the food im-
24 ported.

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

4 “(3) The compliance history of the importer, in-
5 cluding with regard to food recalls, outbreaks of
6 foodborne illness, and violations of food safety stand-
7 ards.

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

12 “(5) Whether the food importer participates in
13 the voluntary qualified importer program under sec-
14 tion 806.

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

17 “(7) Whether the food or the facility that man-
18 ufactured, processed, packed, or held such food re-
19 ceived a certification as described in section 801(q)
20 or 806.

21 “(8) Any other criteria deemed necessary and
22 appropriate by the Secretary for purposes of allo-
23 cating inspection resources.

24 “(c) INTERAGENCY AGREEMENTS WITH RESPECT TO
25 SEAFOOD.—

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

8 “(2) SCOPE OF AGREEMENTS.—The agreements
9 under paragraph (1) may include—

10 “(A) cooperative arrangements for exam-
11 ining and testing seafood imports that leverage
12 the resources, capabilities, and authorities of
13 each party to the agreement;

14 “(B) coordination of inspections of foreign
15 facilities to increase the percentage of imported
16 seafood and seafood facilities inspected;

17 “(C) standardization of data on seafood
18 names, inspection records, and laboratory test-
19 ing to improve interagency coordination;

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

22 “(E) a process, including the use or modi-
23 fication of existing processes, by which officers
24 and employees of the National Oceanic and At-
25 mospheric Administration may be duly des-

1 ignated by the Secretary to carry out seafood
2 examinations and investigations under section
3 801 of this Act or section 203 of the Food Al-
4 lergen Labeling and Consumer Protection Act
5 of 2004;

6 “(F) the sharing of information concerning
7 observed non-compliance with United States
8 food requirements domestically and in foreign
9 nations and new regulatory decisions and poli-
10 cies that may affect the safety of food imported
11 into the United States;

12 “(G) conducting joint training on subjects
13 that affect and strengthen seafood inspection
14 effectiveness by Federal authorities; and

15 “(H) outreach on Federal efforts to en-
16 hance seafood safety and compliance with Fed-
17 eral food safety requirements.

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

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

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

3 “(h) ANNUAL REPORT REGARDING FOOD.—Not
4 later than February 1 of each year, the Secretary shall
5 submit to Congress a report, including efforts to coordi-
6 nate and cooperate with other Federal agencies with re-
7 sponsibilities for food inspections, regarding—

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

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

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

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

21 “(D) the number of domestic facilities and
22 the number of foreign facilities registered pur-
23 suant to section 415 that were scheduled for in-
24 spection in the previous fiscal year and which
25 the Secretary did not inspect in such 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 were
6 scheduled for inspection in the previous fiscal
7 year and which the Secretary did not inspect in
8 such year.

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

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

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

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

23 “(3) information on the foreign offices of the
24 Food and Drug Administration including—

1 “(A) the number of foreign offices estab-
2 lished; and

3 “(B) the number of personnel permanently
4 stationed in each foreign office.

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

9 (c) ADVISORY COMMITTEE CONSULTATION.—In allo-
10 cating inspection resources as described in section 421 of
11 the Federal Food, Drug, and Cosmetic Act (as added by
12 subsection (a)), the Secretary may, as appropriate, consult
13 with any relevant advisory committee within the Depart-
14 ment of Health and Human Services.

15 **SEC. 202. LABORATORY ACCREDITATION FOR ANALYSES OF**
16 **FOODS.**

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

20 **“SEC. 422. LABORATORY ACCREDITATION FOR ANALYSES**
21 **OF FOODS.**

22 “(a) RECOGNITION OF LABORATORY ACCREDITA-
23 TION.—

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

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

6 “(B) establish a publicly available registry
7 of accreditation bodies recognized by the Sec-
8 retary and laboratories accredited by a recog-
9 nized accreditation body, including the name of,
10 contact information for, and other information
11 deemed appropriate by the Secretary about
12 such bodies and laboratories; and

13 “(C) require, as a condition of recognition
14 or accreditation, as appropriate, that recognized
15 accreditation bodies and accredited laboratories
16 report to the Secretary any changes that would
17 affect the recognition of such accreditation body
18 or the accreditation of such laboratory.

19 “(2) PROGRAM REQUIREMENTS.—The program
20 established under paragraph (1)(A) shall provide for
21 the recognition of laboratory accreditation bodies
22 that meet criteria established by the Secretary for
23 accreditation of laboratories, including laboratories
24 run and operated by a Federal agency (including the
25 Department of Commerce), State, or locality with a

1 demonstrated capability to conduct 1 or more sam-
2 pling and analytical testing methodologies for food.

3 “(3) INCREASING THE NUMBER OF QUALIFIED
4 LABORATORIES.—The Secretary shall work with the
5 laboratory accreditation bodies recognized under
6 paragraph (1), as appropriate, to increase the num-
7 ber of qualified laboratories that are eligible to per-
8 form testing under subparagraph (b) beyond the
9 number so qualified on the date of enactment of the
10 FDA Food Safety Modernization Act.

11 “(4) LIMITED DISTRIBUTION.—In the interest
12 of national security, the Secretary, in coordination
13 with the Secretary of Homeland Security, may deter-
14 mine the time, manner, and form in which the reg-
15 istry established under paragraph (1)(B) is made
16 publicly available.

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

23 “(6) MODEL LABORATORY STANDARDS.—The
24 Secretary shall develop model standards that a lab-
25 oratory shall meet to be accredited by a recognized

1 accreditation body for a specified sampling or ana-
2 lytical testing methodology and included in the reg-
3 istry provided for under paragraph (1). In devel-
4 oping the model standards, the Secretary shall con-
5 sult existing standards for guidance. The model
6 standards shall include—

7 “(A) methods to ensure that—

8 “(i) appropriate sampling, analytical
9 procedures (including rapid analytical pro-
10 cedures), and commercially available tech-
11 niques are followed and reports of analyses
12 are certified as true and accurate;

13 “(ii) internal quality systems are es-
14 tablished and maintained;

15 “(iii) procedures exist to evaluate and
16 respond promptly to complaints regarding
17 analyses and other activities for which the
18 laboratory is accredited; and

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

22 “(B) any other criteria determined appro-
23 priate by the Secretary.

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

4 “(A) shall periodically, and in no case less
5 than once every 5 years, reevaluate accredita-
6 tion bodies recognized under paragraph (1) and
7 may accompany auditors from an accreditation
8 body to assess whether the accreditation body
9 meets the criteria for recognition; and

10 “(B) shall promptly revoke the recognition
11 of any accreditation body found not to be in
12 compliance with the requirements of this sec-
13 tion, specifying, as appropriate, any terms and
14 conditions necessary for laboratories accredited
15 by such body to continue to perform testing as
16 described in this section.

17 “(b) TESTING PROCEDURES.—

18 “(1) IN GENERAL.—Not later than 30 months
19 after the date of enactment of the FDA Food Safety
20 Modernization Act, food testing shall be conducted
21 by Federal laboratories or non-Federal laboratories
22 that have been accredited for the appropriate sam-
23 pling or analytical testing methodology or meth-
24 odologies by a recognized accreditation body on the
25 registry established by the Secretary under sub-

1 section (a)(1)(B) whenever such testing is con-
2 ducted—

3 “(A) by or on behalf of an owner or con-
4 signee—

5 “(i) in response to a specific testing
6 requirement under this Act or imple-
7 menting regulations, when applied to ad-
8 dress an identified or suspected food safety
9 problem; and

10 “(ii) as required by the Secretary, as
11 the Secretary deems appropriate, to ad-
12 dress an identified or suspected food safety
13 problem; or

14 “(B) on behalf of an owner or consignee—

15 “(i) in support of admission of an ar-
16 ticle of food under section 801(a); and

17 “(ii) under an Import Alert that re-
18 quires successful consecutive tests.

19 “(2) RESULTS OF TESTING.—The results of
20 any such testing shall be sent directly to the Food
21 and Drug Administration, except the Secretary may
22 by regulation exempt test results from such submis-
23 sion requirement if the Secretary determines that
24 such results do not contribute to the protection of
25 public health. Test results required to be submitted

1 may be submitted to the Food and Drug Adminis-
2 tration through electronic means.

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

5 “(A) a new methodology or methodologies
6 have been developed and validated but a labora-
7 tory has not yet been accredited to perform
8 such methodology or methodologies; and

9 “(B) the use of such methodology or meth-
10 odologies are necessary to prevent, control, or
11 mitigate a food emergency or foodborne illness
12 outbreak.

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

21 “(d) NO LIMIT ON SECRETARIAL AUTHORITY.—
22 Nothing in this section shall be construed to limit the abil-
23 ity of the Secretary to review and act upon information
24 from food testing, including determining the sufficiency of
25 such information and testing.”.

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

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

15 (2) coordinates the food laboratory capacities of
16 State, local, and tribal food laboratories, including
17 the adoption of novel surveillance and identification
18 technologies and the sharing of data between Fed-
19 eral agencies and State laboratories to develop na-
20 tional situational awareness;

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

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

- 1 (5) responds to food-related emergencies; and
2 (6) is integrated with relevant laboratory net-
3 works administered by other Federal agencies.

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

6 (a) IN GENERAL.—The Secretary of Homeland Secu-
7 rity, in coordination with the Secretary of Health and
8 Human Services, the Secretary of Agriculture, the Sec-
9 retary of Commerce, and the Administrator of the Envi-
10 ronmental Protection Agency, shall maintain an agree-
11 ment through which relevant laboratory network members,
12 as determined by the Secretary of Homeland Security,
13 shall—

14 (1) agree on common laboratory methods in
15 order to reduce the time required to detect and re-
16 spond to foodborne illness outbreaks and facilitate
17 the sharing of knowledge and information relating to
18 animal health, agriculture, and human health;

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

21 (A) to optimize national laboratory pre-
22 paredness; and

23 (B) to provide surge capacity during emer-
24 gencies; and

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

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

11 **SEC. 204. ENHANCING TRACKING AND TRACING OF FOOD**
12 **AND RECORDKEEPING.**

13 (a) PILOT PROJECTS.—

14 (1) IN GENERAL.—Not later than 270 days
15 after the date of enactment of this Act, the Sec-
16 retary of Health and Human Services (referred to in
17 this section as the “Secretary”), taking into account
18 recommendations from the Secretary of Agriculture
19 and representatives of State departments of health
20 and agriculture, shall establish pilot projects in co-
21 ordination with the food industry to explore and
22 evaluate methods to rapidly and effectively identify
23 recipients of food to prevent or mitigate a foodborne
24 illness outbreak and to address credible threats of
25 serious adverse health consequences or death to hu-

1 mans or animals as a result of such food being adul-
2 terated under section 402 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 342) or mis-
4 branded under section 403(w) of such Act (21
5 U.S.C. 343(w)).

6 (2) CONTENT.—The Secretary shall conduct 1
7 or more pilot projects under paragraph (1) in coordi-
8 nation with the processed food sector and 1 or more
9 such pilot projects in coordination with processors or
10 distributors of fruits and vegetables that are raw ag-
11 ricultural commodities. The Secretary shall ensure
12 that the pilot projects under paragraph (1) reflect
13 the diversity of the food supply and include at least
14 3 different types of foods that have been the subject
15 of significant outbreaks during the 5-year period
16 preceding the date of enactment of this Act, and are
17 selected in order to—

18 (A) develop and demonstrate methods for
19 rapid and effective tracking and tracing of
20 foods in a manner that is practicable for facili-
21 ties of varying sizes, including small businesses;

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

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

3 (3) REPORT.—Not later than 18 months after
4 the date of enactment of this Act, the Secretary
5 shall report to Congress on the findings of the pilot
6 projects under this subsection together with rec-
7 ommendations for improving the tracking and trac-
8 ing of food.

9 (b) ADDITIONAL DATA GATHERING.—

10 (1) IN GENERAL.—The Secretary, in coordina-
11 tion with the Secretary of Agriculture and multiple
12 representatives of State departments of health and
13 agriculture, shall assess—

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

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

21 (C) whether such technologies are compat-
22 ible with the requirements of this subsection.

23 (2) REQUIREMENTS.—To the extent prac-
24 ticable, in carrying out paragraph (1), the Secretary
25 shall—

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

3 (B) consider international efforts, includ-
4 ing an assessment of whether product tracing
5 requirements developed under this section are
6 compatible with global tracing systems, as ap-
7 propriate; and

8 (C) consult with a diverse and broad range
9 of experts and stakeholders, including rep-
10 resentatives of the food industry, agricultural
11 producers, and nongovernmental organizations
12 that represent the interests of consumers.

13 (c) **PRODUCT TRACING SYSTEM.**—The Secretary, in
14 consultation with the Secretary of Agriculture, shall, as
15 appropriate, establish within the Food and Drug Adminis-
16 tration a product tracing system to receive information
17 that improves the capacity of the Secretary to effectively
18 and rapidly track and trace food that is in the United
19 States or offered for import into the United States. Prior
20 to the establishment of such product tracing system, the
21 Secretary shall examine the results of applicable pilot
22 projects and shall ensure that the activities of such system
23 are adequately supported by the results of such pilot
24 projects.

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

3 (1) IN GENERAL.—In order to rapidly and ef-
4 fectively identify recipients of a food to prevent or
5 mitigate a foodborne illness outbreak and to address
6 credible threats of serious adverse health con-
7 sequences or death to humans or animals as a result
8 of such food being adulterated under section 402 of
9 the Federal Food, Drug, and Cosmetic Act or mis-
10 branded under section 403(w) of such Act, not later
11 than 2 years after the date of enactment of this Act,
12 the Secretary shall publish a notice of proposed rule-
13 making to establish recordkeeping requirements, in
14 addition to the requirements under section 414 of
15 the Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 350c) and subpart J of part 1 of title 21,
17 Code of Federal Regulations (or any successor regu-
18 lations), for facilities that manufacture, process,
19 pack, or hold foods that the Secretary designates
20 under paragraph (2) as high-risk foods. The Sec-
21 retary shall set an appropriate effective date of such
22 additional requirements for foods designated as high
23 risk that takes into account the length of time nec-
24 essary to comply with such requirements. Such re-
25 quirements shall—

1 (A) relate only to information that is rea-
2 sonably available and appropriate;

3 (B) be science-based;

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

6 (D) ensure that the public health benefits
7 of imposing additional recordkeeping require-
8 ments outweigh the cost of compliance with
9 such requirements;

10 (E) be scale-appropriate and practicable
11 for facilities of varying sizes and capabilities
12 with respect to costs and recordkeeping bur-
13 dens, and not require the creation and mainte-
14 nance of duplicate records where the informa-
15 tion is contained in other company records kept
16 in the normal course of business;

17 (F) minimize the number of different rec-
18 ordkeeping requirements for facilities that han-
19 dle more than 1 type of food;

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

23 (H) allow any person subject to this sub-
24 section to maintain records required under this
25 subsection at a central or reasonably accessible

1 location provided that such records can be made
2 available to the Secretary not later than 24
3 hours after the Secretary requests such records;
4 and

5 (I) include a process by which the Sec-
6 retary may issue a waiver of the requirements
7 under this subsection if the Secretary deter-
8 mines that such requirements would result in
9 an economic hardship for an individual facility
10 or a type of facility;

11 (J) be commensurate with the known safe-
12 ty risks of the designated food;

13 (K) take into account international trade
14 obligations;

15 (L) not require—

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

20 (ii) records of recipients of a food be-
21 yond the immediate subsequent recipient of
22 such food; or

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

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

5 (2) DESIGNATION OF HIGH-RISK FOODS.—

6 (A) IN GENERAL.—Not later than 1 year
7 after the date of enactment of this Act, and
8 thereafter as the Secretary determines nec-
9 essary, the Secretary shall designate high-risk
10 foods for which the additional recordkeeping re-
11 quirements described in paragraph (1) are ap-
12 propriate and necessary to protect the public
13 health. Each such designation shall be based
14 on—

15 (i) the known safety risks of a par-
16 ticular food, including the history and se-
17 verity of foodborne illness outbreaks attrib-
18 uted to such food, taking into consider-
19 ation foodborne illness data collected by
20 the Centers for Disease Control and Pre-
21 vention;

22 (ii) the likelihood that a particular
23 food has a high potential risk for micro-
24 biological or chemical contamination or
25 would support the growth of pathogenic

1 microorganisms due to the nature of the
2 food or the processes used to produce such
3 food;

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

7 (iv) the likelihood of contamination
8 and steps taken during the manufacturing
9 process to reduce the possibility of con-
10 tamination;

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

15 (vi) the likely or known severity, in-
16 cluding health and economic impacts, of a
17 foodborne illness attributed to a particular
18 food.

19 (B) LIST OF HIGH-RISK FOODS.—At the
20 time the Secretary promulgates the final rules
21 under paragraph (1), the Secretary shall pub-
22 lish the list of the foods designated under sub-
23 paragraph (A) as high-risk foods on the Inter-
24 net website of the Food and Drug Administra-
25 tion. The Secretary may update the list to des-

1 ignate new high-risk foods and to remove foods
2 that are no longer deemed to be high-risk foods,
3 provided that each such update to the list is
4 consistent with the requirements of this sub-
5 section and notice of such update is published
6 in the Federal Register.

7 (3) PROTECTION OF SENSITIVE INFORMA-
8 TION.—In promulgating regulations under this sub-
9 section, the Secretary shall take appropriate meas-
10 ures to ensure that there are effective procedures to
11 prevent the unauthorized disclosure of any trade se-
12 cret or confidential information that is obtained by
13 the Secretary pursuant to this section, including
14 periodic risk assessment and planning to prevent un-
15 authorized release and controls to—

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

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

20 (C) maintain records with respect to access
21 by any person to trade secret or confidential in-
22 formation maintained by the agency.

23 (4) PUBLIC INPUT.—During the comment pe-
24 riod in the notice of proposed rulemaking under
25 paragraph (1), the Secretary shall conduct not less

1 than 3 public meetings in diverse geographical areas
2 of the United States to provide persons in different
3 regions an opportunity to comment.

4 (5) RETENTION OF RECORDS.—Except as oth-
5 erwise provided in this subsection, the Secretary may
6 require that a facility retain records under this sub-
7 section for not more than 2 years, taking into con-
8 sideration the risk of spoilage, loss of value, or loss
9 of palatability of the applicable food when deter-
10 mining the appropriate timeframes.

11 (6) LIMITATIONS.—

12 (A) FARM TO SCHOOL PROGRAMS.—In es-
13 tablishing requirements under this subsection,
14 the Secretary shall, in consultation with the
15 Secretary of Agriculture, consider the impact of
16 requirements on farm to school or farm to insti-
17 tution programs of the Department of Agri-
18 culture and other farm to school and farm to
19 institution programs outside such agency, and
20 shall modify the requirements under this sub-
21 section, as appropriate, with respect to such
22 programs so that the requirements do not place
23 undue burdens on farm to school or farm to in-
24 stitution programs.

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

7 (i) the packaging of the food main-
8 tains the integrity of the product and pre-
9 vents subsequent contamination or alter-
10 ation of the product; and

11 (ii) the labeling of the food includes
12 the name, complete address (street ad-
13 dress, town, State, country, and zip or
14 other postal code), and business phone
15 number of the farm, unless the Secretary
16 waives the requirement to include a busi-
17 ness phone number of the farm, as appro-
18 priate, in order to accommodate a religious
19 belief of the individual in charge of such
20 farm.

21 (C) FISHING VESSELS.—The requirements
22 under this subsection with respect to a food
23 that is produced through the use of a fishing
24 vessel (as defined in section 3(18) of the Mag-
25 nuson-Stevens Fishery Conservation and Man-

1 agement Act (16 U.S.C. 1802(18))) shall be
2 limited to the requirements under subparagraph
3 (F) until such time as the food is sold by the
4 owner, operator, or agent in charge of such
5 fishing vessel.

6 (D) COMMINGLED RAW AGRICULTURAL
7 COMMODITIES.—

8 (i) LIMITATION ON EXTENT OF TRAC-
9 ING.—Recordkeeping requirements under
10 this subsection with regard to any commin-
11 gled raw agricultural commodity shall be
12 limited to the requirements under subpara-
13 graph (F).

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

16 (I) the term “commingled raw
17 agricultural commodity” means any
18 commodity that is combined or mixed
19 after harvesting, but before proc-
20 essing;

21 (II) the term “commingled raw
22 agricultural commodity” shall not in-
23 clude types of fruits and vegetables
24 that are raw agricultural commodities
25 for which the Secretary has deter-

1 mined that standards promulgated
2 under section 419 of the Federal
3 Food, Drug, and Cosmetic Act (as
4 added by section 105) would minimize
5 the risk of serious adverse health con-
6 sequences or death; and

7 (III) the term “processing”
8 means operations that alter the gen-
9 eral state of the commodity, such as
10 canning, cooking, freezing, dehydra-
11 tion, milling, grinding, pasteurization,
12 or homogenization.

13 (E) EXEMPTION OF OTHER FOODS.—The
14 Secretary may, by notice in the Federal Reg-
15 ister, modify the requirements under this sub-
16 section with respect to, or exempt a food or a
17 type of facility from, the requirements of this
18 subsection (other than the requirements under
19 subparagraph (F), if applicable) if the Sec-
20 retary determines that product tracing require-
21 ments for such food (such as bulk or commin-
22 gled ingredients that are intended to be proc-
23 essed to destroy pathogens) or type of facility
24 is not necessary to protect the public health.

1 (F) RECORDKEEPING REGARDING PRE-
2 VIOUS SOURCES AND SUBSEQUENT RECIPI-
3 ENTS.—In the case of a person or food to which
4 a limitation or exemption under subparagraph
5 (C), (D), or (E) applies, if such person, or a
6 person who manufactures, processes, packs, or
7 holds such food, is required to register with the
8 Secretary under section 415 of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C.
10 350d) with respect to the manufacturing, proc-
11 essing, packing, or holding of the applicable
12 food, the Secretary shall require such person to
13 maintain records that identify the immediate
14 previous source of such food and the immediate
15 subsequent recipient of such food.

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

24 (H) FARM SALES TO CONSUMERS.—The
25 Secretary shall not require a farm to maintain

1 any distribution records under this subsection
2 with respect to a sale of a food described in
3 subparagraph (I) (including a sale of a food
4 that is produced and packaged on such farm),
5 if such sale is made by the farm directly to a
6 consumer.

7 (I) SALE OF A FOOD.—A sale of a food de-
8 scribed in this subparagraph is a sale of a food
9 in which—

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

11 and

12 (ii) the sale is made by the owner, op-
13 erator, or agent in charge of such farm di-
14 rectly to a consumer or grocery store.

15 (7) NO IMPACT ON NON-HIGH-RISK FOODS.—

16 The recordkeeping requirements established under
17 paragraph (1) shall have no effect on foods that are
18 not designated by the Secretary under paragraph (2)
19 as high-risk foods. Foods described in the preceding
20 sentence shall be subject solely to the recordkeeping
21 requirements under section 414 of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 350c) and sub-
23 part J of part 1 of title 21, Code of Federal Regula-
24 tions (or any successor regulations).

25 (e) EVALUATION AND RECOMMENDATIONS.—

1 (1) REPORT.—Not later than 1 year after the
2 effective date of the final rule promulgated under
3 subsection (d)(1), the Comptroller General of the
4 United States shall submit to Congress a report,
5 taking into consideration the costs of compliance
6 and other regulatory burdens on small businesses
7 and Federal, State, and local food safety practices
8 and requirements, that evaluates the public health
9 benefits and risks, if any, of limiting—

10 (A) the product tracing requirements
11 under subsection (d) to foods identified under
12 paragraph (2) of such subsection, including
13 whether such requirements provide adequate as-
14 surance of traceability in the event of inten-
15 tional adulteration, including by acts of ter-
16 rorism; and

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

19 (2) DETERMINATION AND RECOMMENDA-
20 TIONS.—In conducting the evaluation and report
21 under paragraph (1), if the Comptroller General of
22 the United States determines that the limitations de-
23 scribed in such paragraph do not adequately protect
24 the public health, the Comptroller General shall sub-
25 mit to Congress recommendations, if appropriate, re-

1 garding recordkeeping requirements for restaurants
2 and additional foods, in order to protect the public
3 health.

4 (f) FARMS.—

5 (1) REQUEST FOR INFORMATION.—Notwith-
6 standing subsection (d), during an active investiga-
7 tion of a foodborne illness outbreak, or if the Sec-
8 retary determines it is necessary to protect the pub-
9 lic health and prevent or mitigate a foodborne illness
10 outbreak, the Secretary, in consultation and coordi-
11 nation with State and local agencies responsible for
12 food safety, as appropriate, may request that the
13 owner, operator, or agent of a farm identify poten-
14 tial immediate recipients, other than consumers, of
15 an article of the food that is the subject of such in-
16 vestigation if the Secretary reasonably believes such
17 article of food—

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

20 (B) presents a threat of serious adverse
21 health consequences or death to humans or ani-
22 mals; and

23 (C) was adulterated as described in sub-
24 paragraph (A)(i) on a particular farm (as de-
25 fined in section 1.227 of chapter 21, Code of

1 Federal Regulations (or any successor regula-
2 tion)).

3 (2) MANNER OF REQUEST.—In making a re-
4 quest under paragraph (1), the Secretary, in con-
5 sultation and coordination with State and local agen-
6 cies responsible for food safety, as appropriate, shall
7 issue a written notice to the owner, operator, or
8 agent of the farm to which the article of food has
9 been traced. The individual providing such notice
10 shall present to such owner, operator, or agent ap-
11 propriate credentials and shall deliver such notice at
12 reasonable times and within reasonable limits and in
13 a reasonable manner.

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

21 (4) LIMITATION.—A request made under para-
22 graph (1) shall not include a request for information
23 relating to the finances, pricing of commodities pro-
24 duced, personnel, research, sales (other than infor-
25 mation relating to shipping), or other disclosures

1 that may reveal trade secrets or confidential infor-
2 mation from the farm to which the article of food
3 has been traced, other than information necessary to
4 identify potential immediate recipients of such food.
5 Section 301(j) of the Federal Food, Drug, and Cos-
6 metic Act and the Freedom of Information Act shall
7 apply with respect to any confidential commercial in-
8 formation that is disclosed to the Food and Drug
9 Administration in the course of responding to a re-
10 quest under paragraph (1).

11 (5) RECORDS.—Except with respect to identi-
12 fying potential immediate recipients in response to a
13 request under this subsection, nothing in this sub-
14 section shall require the establishment or mainte-
15 nance by farms of new records.

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

20 (h) SMALL ENTITY COMPLIANCE GUIDE.—Not later
21 than 180 days after promulgation of a final rule under
22 subsection (d), the Secretary shall issue a small entity
23 compliance guide setting forth in plain language the re-
24 quirements of the regulations under such subsection in
25 order to assist small entities, including farms and small

1 businesses, in complying with the recordkeeping require-
2 ments under such subsection.

3 (i) FLEXIBILITY FOR SMALL BUSINESSES.—Notwith-
4 standing any other provision of law, the regulations pro-
5 mulgated under subsection (d) shall apply—

6 (1) to small businesses (as defined by the Sec-
7 retary in section 103, not later than 90 days after
8 the date of enactment of this Act) beginning on the
9 date that is 1 year after the effective date of the
10 final regulations promulgated under subsection (d);
11 and

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

18 (j) ENFORCEMENT.—

19 (1) PROHIBITED ACTS.—Section 301(e) (21
20 U.S.C. 331(e)) is amended by inserting “; or the vio-
21 lation of any recordkeeping requirement under sec-
22 tion 204 of the FDA Food Safety Modernization Act
23 (except when such violation is committed by a
24 farm)” before the period at the end.

1 (2) IMPORTS.—Section 801(a) (21 U.S.C.
2 381(a)) is amended by inserting “or (4) the record-
3 keeping requirements under section 204 of the FDA
4 Food Safety Modernization Act (other than the re-
5 quirements under subsection (f) of such section)
6 have not been complied with regarding such article,”
7 in the third sentence before “then such article shall
8 be refused admission”.

9 **SEC. 205. SURVEILLANCE.**

10 (a) DEFINITION OF FOODBORNE ILLNESS OUT-
11 BREAK.—In this Act, the term “foodborne illness out-
12 break” means the occurrence of 2 or more cases of a simi-
13 lar illness resulting from the ingestion of a certain food.

14 (b) FOODBORNE ILLNESS SURVEILLANCE SYS-
15 TEMS.—

16 (1) IN GENERAL.—The Secretary, acting
17 through the Director of the Centers for Disease
18 Control and Prevention, shall enhance foodborne ill-
19 ness surveillance systems to improve the collection,
20 analysis, reporting, and usefulness of data on
21 foodborne illnesses by—

22 (A) coordinating Federal, State and local
23 foodborne illness surveillance systems, including
24 complaint systems, and increasing participation

1 in national networks of public health and food
2 regulatory agencies and laboratories;

3 (B) facilitating sharing of surveillance in-
4 formation on a more timely basis among gov-
5 ernmental agencies, including the Food and
6 Drug Administration, the Department of Agri-
7 culture, the Department of Homeland Security,
8 and State and local agencies, and with the pub-
9 lic;

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

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

16 (E) expanding capacity of such systems,
17 including working toward automatic electronic
18 searches, for implementation of identification
19 practices, including fingerprinting strategies,
20 for foodborne infectious agents, in order to
21 identify new or rarely documented causes of
22 foodborne illness and submit standardized infor-
23 mation to a centralized database;

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

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

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

6 (I) integrating foodborne illness surveil-
7 lance systems and data with other biosurveil-
8 lance and public health situational awareness
9 capabilities at the Federal, State, and local lev-
10 els, including by sharing foodborne illness sur-
11 veillance data with the National Biosurveillance
12 Integration Center; and

13 (J) other activities as determined appro-
14 priate by the Secretary.

15 (2) WORKING GROUP.—The Secretary shall
16 support and maintain a diverse working group of ex-
17 perts and stakeholders from Federal, State, and
18 local food safety and health agencies, the food and
19 food testing industries, consumer organizations, and
20 academia. Such working group shall provide the Sec-
21 retary, through at least annual meetings of the
22 working group and an annual public report, advice
23 and recommendations on an ongoing and regular
24 basis regarding the improvement of foodborne illness

1 surveillance and implementation of this section, in-
2 cluding advice and recommendations on—

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

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

13 (C) improvement in the timeliness and
14 depth of access by regulatory and health agen-
15 cies, the food industry, academic researchers,
16 and consumers to foodborne illness aggregated,
17 de-identified surveillance data collected by gov-
18 ernment agencies at all levels, including data
19 compiled by the Centers for Disease Control
20 and Prevention;

21 (D) key barriers at Federal, State, and
22 local levels to improving foodborne illness sur-
23 veillance and the utility of such surveillance for
24 preventing foodborne illness;

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

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

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

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

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

20 (A) Improve foodborne illness outbreak re-
21 sponse and containment.

22 (B) Accelerate foodborne illness surveil-
23 lance and outbreak investigation, including
24 rapid shipment of clinical isolates from clinical
25 laboratories to appropriate State laboratories,

1 and conducting more standardized illness out-
2 break interviews.

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

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

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

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

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

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

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

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

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

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

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

17 (2) by striking “2003 through 2006” and in-
18 serting “2011 through 2015”.

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

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

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

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

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

10 “(b) PREHEARING ORDER TO CEASE DISTRIBUTION
11 AND GIVE NOTICE.—

12 “(1) IN GENERAL.—If the responsible party re-
13 fuses to or does not voluntarily cease distribution or
14 recall such article within the time and in the manner
15 prescribed by the Secretary (if so prescribed), the
16 Secretary may, by order require, as the Secretary
17 deems necessary, such person to—

18 “(A) immediately cease distribution of
19 such article; and

20 “(B) as applicable, immediately notify all
21 persons—

22 “(i) manufacturing, processing, pack-
23 ing, transporting, distributing, receiving,
24 holding, or importing and selling such arti-
25 cle; and

1 “(ii) to which such article has been
2 distributed, transported, or sold, to imme-
3 diately cease distribution of such article.

4 “(2) REQUIRED ADDITIONAL INFORMATION.—

5 “(A) IN GENERAL.—If an article of food
6 covered by a recall order issued under para-
7 graph (1)(B) has been distributed to a ware-
8 house-based third party logistics provider with-
9 out providing such provider sufficient informa-
10 tion to know or reasonably determine the pre-
11 cise identity of the article of food covered by a
12 recall order that is in its possession, the notice
13 provided by the responsible party subject to the
14 order issued under paragraph (1)(B) shall in-
15 clude such information as is necessary for the
16 warehouse-based third party logistics provider
17 to identify the food.

18 “(B) RULES OF CONSTRUCTION.—Nothing
19 in this paragraph shall be construed—

20 “(i) to exempt a warehouse-based
21 third party logistics provider from the re-
22 quirements of this Act, including the re-
23 quirements in this section and section 414;
24 or

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

4 “(3) DETERMINATION TO LIMIT AREAS AF-
5 FECTED.—If the Secretary requires a responsible
6 party to cease distribution under paragraph (1)(A)
7 of an article of food identified in subsection (a), the
8 Secretary may limit the size of the geographic area
9 and the markets affected by such cessation if such
10 limitation would not compromise the public health.

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

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

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

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

3 “(B) specify a timetable in which the recall
4 shall occur;

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

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

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

14 “(e) RULE REGARDING ALCOHOLIC BEVERAGES.—
15 The Secretary shall not initiate a mandatory recall or take
16 any other action under this section with respect to any
17 alcohol beverage until the Secretary has provided the Alco-
18 hol and Tobacco Tax and Trade Bureau with a reasonable
19 opportunity to cease distribution and recall such article
20 under the Alcohol and Tobacco Tax and Trade Bureau
21 authority.

22 “(f) COOPERATION AND CONSULTATION.—The Sec-
23 retary shall work with State and local public health offi-
24 cials in carrying out this section, as appropriate.

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

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

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

10 “(B) that includes, at a minimum—

11 “(i) the name of the article of food
12 subject to the recall;

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

15 “(iii) to the extent practicable, infor-
16 mation for consumers about similar arti-
17 cles of food that are not affected by the re-
18 call;

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

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

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

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

14 “(j) COORDINATED COMMUNICATION.—

15 “(1) IN GENERAL.—To assist in carrying out
16 the requirements of this subsection, the Secretary
17 shall establish an incident command operation or a
18 similar operation within the Department of Health
19 and Human Services that will operate not later than
20 24 hours after the initiation of a mandatory recall
21 or the recall of an article of food for which the use
22 of, or exposure to, such article will cause serious ad-
23 verse health consequences or death to humans or
24 animals.

1 “(2) REQUIREMENTS.—To reduce the potential
2 for miscommunication during recalls or regarding in-
3 vestigations of a food borne illness outbreak associ-
4 ated with a food that is subject to a recall, each inci-
5 dent command operation or similar operation under
6 paragraph (1) shall use regular staff and resources
7 of the Department of Health and Human Services
8 to—

9 “(A) ensure timely and coordinated com-
10 munication within the Department, including
11 enhanced communication and coordination be-
12 tween different agencies and organizations with-
13 in the Department;

14 “(B) ensure timely and coordinated com-
15 munication from the Department, including
16 public statements, throughout the duration of
17 the investigation and related foodborne illness
18 outbreak;

19 “(C) identify a single point of contact
20 within the Department for public inquiries re-
21 garding any actions by the Secretary related to
22 a recall;

23 “(D) coordinate with Federal, State, local,
24 and tribal authorities, as appropriate, that have
25 responsibilities related to the recall of a food or

1 a foodborne illness outbreak associated with a
2 food that is subject to the recall, including noti-
3 fication of the Secretary of Agriculture and the
4 Secretary of Education in the event such re-
5 called food is a commodity intended for use in
6 a child nutrition program (as identified in sec-
7 tion 25(b) of the Richard B. Russell National
8 School Lunch Act (42 U.S.C. 1769f(b)); and

9 “(E) conclude operations at such time as
10 the Secretary determines appropriate.

11 “(3) MULTIPLE RECALLS.—The Secretary may
12 establish multiple or concurrent incident command
13 operations or similar operations in the event of mul-
14 tiple recalls or foodborne illness outbreaks necessi-
15 tating such action by the Department of Health and
16 Human Services.”.

17 (b) SEARCH ENGINE.—Not later than 90 days after
18 the date of enactment of this Act, the Secretary shall mod-
19 ify the Internet Web site of the Food and Drug Adminis-
20 tration to include a search engine that—

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

23 (2) provides a means by which an individual
24 may locate relevant information regarding each arti-
25 cle of food subject to a recall under section 420 of

1 the Federal Food, Drug, and Cosmetic Act and the
2 status of such recall (such as whether a recall is on-
3 going or has been completed).

4 (c) CIVIL PENALTY.—Section 303(f)(2)(A) (21
5 U.S.C. 333(f)(2)(A)) is amended by inserting “or any per-
6 son who does not comply with a recall order under section
7 423” after “section 402(a)(2)(B)”.

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

11 “(xx) The refusal or failure to follow an order under
12 section 423.”.

13 (e) GAO REVIEW.—

14 (1) IN GENERAL.—Not later than 90 days after
15 the date of enactment of this Act, the Comptroller
16 General of the United States shall submit to Con-
17 gress a report that—

18 (A) identifies State and local agencies with
19 the authority to require the mandatory recall of
20 food, and evaluates use of such authority with
21 regard to frequency, effectiveness, and appro-
22 priateness, including consideration of any new
23 or existing mechanisms available to compensate
24 persons for general and specific recall-related

1 costs when a recall is subsequently determined
2 by the relevant authority to have been an error;

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

13 (C) considers models for farmer restitution
14 implemented in other nations in cases of erro-
15 neous recalls; and

16 (D) makes recommendations to the Sec-
17 retary regarding use of the authority under sec-
18 tion 423 of the Federal Food, Drug, and Cos-
19 metic Act (as added by this section) to protect
20 the public health while seeking to minimize un-
21 necessary economic costs.

22 (2) EFFECT OF REVIEW.—If the Comptroller
23 General of the United States finds, after the review
24 conducted under paragraph (1), that the mecha-
25 nisms described in such paragraph do not exist or

1 are inadequate, then, not later than 90 days after
2 the conclusion of such review, the Secretary of Agri-
3 culture shall conduct a study of the feasibility of im-
4 plementing a farmer indemnification program to
5 provide restitution to agricultural producers for
6 losses sustained as a result of a mandatory recall of
7 an agricultural commodity by a Federal or State
8 regulatory agency that is subsequently determined to
9 be in error. The Secretary of Agriculture shall sub-
10 mit to the Committee on Agriculture of the House
11 of Representatives and the Committee on Agri-
12 culture, Nutrition, and Forestry of the Senate a re-
13 port that describes the results of the study, includ-
14 ing any recommendations.

15 (f) ANNUAL REPORT TO CONGRESS.—

16 (1) IN GENERAL.—Not later than 2 years after
17 the date of enactment of this Act and annually
18 thereafter, the Secretary of Health and Human
19 Services (referred to in this subsection as the “Sec-
20 retary”) shall submit a report to the Committee on
21 Health, Education, Labor, and Pensions of the Sen-
22 ate and the Committee on Energy and Commerce of
23 the House of Representatives on the use of recall au-
24 thority under section 423 of the Federal Food,
25 Drug, and Cosmetic Act (as added by subsection

1 (a)) and any public health advisories issued by the
2 Secretary that advise against the consumption of an
3 article of food on the ground that the article of food
4 is adulterated and poses an imminent danger to
5 health.

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

8 (A) the identity of each article of food that
9 was the subject of a public health advisory de-
10 scribed in paragraph (1), an opportunity to
11 cease distribution and recall under subsection
12 (a) of section 423 of the Federal Food, Drug,
13 and Cosmetic Act, or a mandatory recall order
14 under subsection (b) of such section;

15 (B) the number of responsible parties, as
16 defined in section 417 of the Federal Food,
17 Drug, and Cosmetic Act, formally given the op-
18 portunity to cease distribution of an article of
19 food and recall such article, as described in sec-
20 tion 423(a) of such Act;

21 (C) the number of responsible parties de-
22 scribed in subparagraph (B) who did not cease
23 distribution of or recall an article of food after
24 given the opportunity to cease distribution or

1 recall under section 423(a) of the Federal
2 Food, Drug, and Cosmetic Act;

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

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

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

13 (a) IN GENERAL.—Section 304(h)(1)(A) (21 U.S.C.
14 334(h)(1)(A)) is amended by—

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

17 (2) striking “presents a threat of serious ad-
18 verse health consequences or death to humans or
19 animals” and inserting “is adulterated or mis-
20 branded”.

21 (b) REGULATIONS.—Not later than 120 days after
22 the date of enactment of this Act, the Secretary shall issue
23 an interim final rule amending subpart K of part 1 of title
24 21, Code of Federal Regulations, to implement the amend-
25 ment made by this section.

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

4 **SEC. 208. DECONTAMINATION AND DISPOSAL STANDARDS**
5 **AND PLANS.**

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

15 (b) DEVELOPMENT OF STANDARDS.—In carrying out
16 subsection (a), the Administrator, in coordination with the
17 Secretary of Health and Human Services, Secretary of
18 Homeland Security, Secretary of Agriculture, and State,
19 local, and tribal governments, shall develop and dissemi-
20 nate specific standards and protocols to undertake clean-
21 up, clearance, and recovery activities following the decon-
22 tamination and disposal of specific threat agents and for-
23 eign animal diseases.

24 (c) DEVELOPMENT OF MODEL PLANS.—In carrying
25 out subsection (a), the Administrator, the Secretary of

1 Health and Human Services, and the Secretary of Agri-
2 culture shall jointly develop and disseminate model plans
3 for—

4 (1) the decontamination of individuals, equip-
5 ment, and facilities following an intentional contami-
6 nation of agriculture or food; and

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

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

21 (e) MODIFICATIONS.—Based on the exercises de-
22 scribed in subsection (d), the Administrator, in coordina-
23 tion with the entities described in subsection (b), shall re-
24 view and modify as necessary the plans described in sub-
25 section (c) not less frequently than biennially.

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

5 (1) highest-risk biological, chemical, and radio-
6 logical threat agents;

7 (2) agents that could cause the greatest eco-
8 nomic devastation to the agriculture and food sys-
9 tem; and

10 (3) agents that are most difficult to clean or re-
11 mediate.

12 **SEC. 209. IMPROVING THE TRAINING OF STATE, LOCAL,**
13 **TERRITORIAL, AND TRIBAL FOOD SAFETY OF-**
14 **FICIALS.**

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

18 **“SEC. 1011. IMPROVING THE TRAINING OF STATE, LOCAL,**
19 **TERRITORIAL, AND TRIBAL FOOD SAFETY OF-**
20 **FICIALS.**

21 “(a) TRAINING.—The Secretary shall set standards
22 and administer training and education programs for the
23 employees of State, local, territorial, and tribal food safety
24 officials relating to the regulatory responsibilities and poli-
25 cies established by this Act, including programs for—

1 “(1) scientific training;

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

5 “(3) training to achieve advanced product or
6 process specialization in such inspections;

7 “(4) training that addresses best practices;

8 “(5) training in administrative process and pro-
9 cedure and integrity issues;

10 “(6) training in appropriate sampling and lab-
11 oratory analysis methodology; and

12 “(7) training in building enforcement actions
13 following inspections, examinations, testing, and in-
14 vestigations.

15 “(b) PARTNERSHIPS WITH STATE AND LOCAL OFFI-
16 CIALS.—

17 “(1) IN GENERAL.—The Secretary, pursuant to
18 a contract or memorandum of understanding be-
19 tween the Secretary and the head of a State, local,
20 territorial, or tribal department or agency, is author-
21 ized and encouraged to conduct examinations, test-
22 ing, and investigations for the purposes of deter-
23 mining compliance with the food safety provisions of
24 this Act through the officers and employees of such

1 State, local, territorial, or tribal department or agen-
2 cy.

3 “(2) CONTENT.—A contract or memorandum
4 described under paragraph (1) shall include provi-
5 sions to ensure adequate training of such officers
6 and employees to conduct such examinations, test-
7 ing, and investigations. The contract or memo-
8 randum shall contain provisions regarding reim-
9 bursement. Such provisions may, at the sole discre-
10 tion of the head of the other department or agency,
11 require reimbursement, in whole or in part, from the
12 Secretary for the examinations, testing, or investiga-
13 tions performed pursuant to this section by the offi-
14 cers or employees of the State, territorial, or tribal
15 department or agency.

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

19 “(c) EXTENSION SERVICE.—The Secretary shall en-
20 sure coordination with the extension activities of the Na-
21 tional Institute of Food and Agriculture of the Depart-
22 ment of Agriculture in advising producers and small proc-
23 essors transitioning into new practices required as a result
24 of the enactment of the FDA Food Safety Modernization

1 Act and assisting regulated industry with compliance with
2 such Act.

3 “(d) NATIONAL FOOD SAFETY TRAINING, EDU-
4 CATION, EXTENSION, OUTREACH AND TECHNICAL AS-
5 SISTANCE PROGRAM.—

6 “(1) IN GENERAL.—In order to improve food
7 safety and reduce the incidence of foodborne illness,
8 the Secretary shall, not later than 180 days after
9 the date of enactment of the FDA Food Safety Mod-
10 ernization Act, enter into one or more memoranda of
11 understanding, or enter into other cooperative agree-
12 ments, with the Secretary of Agriculture to establish
13 a competitive grant program within the National In-
14 stitute for Food and Agriculture to provide food
15 safety training, education, extension, outreach, and
16 technical assistance to—

17 “(A) owners and operators of farms;

18 “(B) small food processors; and

19 “(C) small fruit and vegetable merchant
20 wholesalers.

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

1 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated such sums as may be
3 necessary to carry out this section for fiscal years 2011
4 through 2015.”.

5 (b) NATIONAL FOOD SAFETY TRAINING, EDU-
6 CATION, EXTENSION, OUTREACH, AND TECHNICAL AS-
7 SISTANCE PROGRAM.—Title IV of the Agricultural Re-
8 search, Extension, and Education Reform Act of 1998 is
9 amended by inserting after section 404 (7 U.S.C. 7624)
10 the following:

11 **“SEC. 405. NATIONAL FOOD SAFETY TRAINING, EDUCATION,**
12 **EXTENSION, OUTREACH, AND TECHNICAL AS-**
13 **SISTANCE PROGRAM.**

14 “(a) IN GENERAL.—The Secretary shall award
15 grants under this section to carry out the competitive
16 grant program established under section 1011(d) of the
17 Federal Food, Drug, and Cosmetic Act, pursuant to any
18 memoranda of understanding entered into under such sec-
19 tion.

20 “(b) INTEGRATED APPROACH.—The grant program
21 described under subsection (a) shall be carried out under
22 this section in a manner that facilitates the integration
23 of food safety standards and guidance with the variety of
24 agricultural production systems, encompassing conven-

1 tional, sustainable, organic, and conservation and environ-
2 mental practices.

3 “(c) PRIORITY.—In awarding grants under this sec-
4 tion, the Secretary shall give priority to projects that tar-
5 get small and medium-sized farms, beginning farmers, so-
6 cially disadvantaged farmers, small processors, or small
7 fresh fruit and vegetable merchant wholesalers.

8 “(d) PROGRAM COORDINATION.—

9 “(1) IN GENERAL.—The Secretary shall coordi-
10 nate implementation of the grant program under
11 this section with the National Integrated Food Safe-
12 ty Initiative.

13 “(2) INTERACTION.—The Secretary shall—

14 “(A) in carrying out the grant program
15 under this section, take into consideration ap-
16 plied research, education, and extension results
17 obtained from the National Integrated Food
18 Safety Initiative; and

19 “(B) in determining the applied research
20 agenda for the National Integrated Food Safety
21 Initiative, take into consideration the needs ar-
22 ticulated by participants in projects funded by
23 the program under this section.

24 “(e) GRANTS.—

1 “(1) IN GENERAL.—In carrying out this sec-
2 tion, the Secretary shall make competitive grants to
3 support training, education, extension, outreach, and
4 technical assistance projects that will help improve
5 public health by increasing the understanding and
6 adoption of established food safety standards, guid-
7 ance, and protocols.

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

13 “(3) MAXIMUM TERM AND SIZE OF GRANT.—

14 “(A) IN GENERAL.—A grant under this
15 section shall have a term that is not more than
16 3 years.

17 “(B) LIMITATION ON GRANT FUNDING.—

18 The Secretary may not provide grant funding to
19 an entity under this section after such entity
20 has received 3 years of grant funding under
21 this section.

22 “(f) GRANT ELIGIBILITY.—

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

25 “(A) a State cooperative extension service;

1 “(B) a Federal, State, local, or tribal agen-
2 cy, a nonprofit community-based or non-govern-
3 mental organization, or an organization rep-
4 resenting owners and operators of farms, small
5 food processors, or small fruit and vegetable
6 merchant wholesalers that has a commitment to
7 public health and expertise in administering
8 programs that contribute to food safety;

9 “(C) an institution of higher education (as
10 defined in section 101(a) of the Higher Edu-
11 cation Act of 1965 (20 U.S.C. 1001(a))) or a
12 foundation maintained by an institution of
13 higher education;

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

16 “(E) such other appropriate entity, as de-
17 termined by the Secretary.

18 “(2) MULTISTATE PARTNERSHIPS.—Grants
19 under this section may be made for projects involv-
20 ing more than 1 State.

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

24 “(1) geographic diversity; and

1 “(2) diversity of types of agricultural produc-
2 tion.

3 “(h) TECHNICAL ASSISTANCE.—The Secretary may
4 use funds made available under this section to provide
5 technical assistance to grant recipients to further the pur-
6 poses of this section.

7 “(i) BEST PRACTICES AND MODEL PROGRAMS.—
8 Based on evaluations of, and responses arising from,
9 projects funded under this section, the Secretary may
10 issue a set of recommended best practices and models for
11 food safety training programs for agricultural producers,
12 small food processors, and small fresh fruit and vegetable
13 merchant wholesalers.

14 “(j) AUTHORIZATION OF APPROPRIATIONS.—For the
15 purposes of making grants under this section, there are
16 authorized to be appropriated such sums as may be nec-
17 essary for fiscal years 2011 through 2015.”.

18 **SEC. 210. ENHANCING FOOD SAFETY.**

19 (a) GRANTS TO ENHANCE FOOD SAFETY.—Section
20 1009 of the Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 399) is amended to read as follows:

22 **“SEC. 1009. GRANTS TO ENHANCE FOOD SAFETY.**

23 “(a) IN GENERAL.—The Secretary is authorized to
24 make grants to eligible entities to—

1 “(1) undertake examinations, inspections, and
2 investigations, and related food safety activities
3 under section 702;

4 “(2) train to the standards of the Secretary for
5 the examination, inspection, and investigation of
6 food manufacturing, processing, packing, holding,
7 distribution, and importation, including as such ex-
8 amination, inspection, and investigation relate to re-
9 tail food establishments;

10 “(3) build the food safety capacity of the lab-
11 oratories of such eligible entity, including the detec-
12 tion of zoonotic diseases;

13 “(4) build the infrastructure and capacity of
14 the food safety programs of such eligible entity to
15 meet the standards as outlined in the grant applica-
16 tion; and

17 “(5) take appropriate action to protect the pub-
18 lic health in response to—

19 “(A) a notification under section 1008, in-
20 cluding planning and otherwise preparing to
21 take such action; or

22 “(B) a recall of food under this Act.

23 “(b) ELIGIBLE ENTITIES; APPLICATION.—

24 “(1) IN GENERAL.—In this section, the term
25 ‘eligible entity’ means an entity—

1 “(A) that is—

2 “(i) a State;

3 “(ii) a locality;

4 “(iii) a territory;

5 “(iv) an Indian tribe (as defined in
6 section 4(e) of the Indian Self-Determina-
7 tion and Education Assistance Act); or

8 “(v) a nonprofit food safety training
9 entity that collaborates with 1 or more in-
10 stitutions of higher education; and

11 “(B) that submits an application to the
12 Secretary at such time, in such manner, and in-
13 cluding such information as the Secretary may
14 reasonably require.

15 “(2) CONTENTS.—Each application submitted
16 under paragraph (1) shall include—

17 “(A) an assurance that the eligible entity
18 has developed plans to engage in the types of
19 activities described in subsection (a);

20 “(B) a description of the types of activities
21 to be funded by the grant;

22 “(C) an itemization of how grant funds re-
23 ceived under this section will be expended;

24 “(D) a description of how grant activities
25 will be monitored; and

1 “(E) an agreement by the eligible entity to
2 report information required by the Secretary to
3 conduct evaluations under this section.

4 “(c) LIMITATIONS.—The funds provided under sub-
5 section (a) shall be available to an eligible entity that re-
6 ceives a grant under this section only to the extent such
7 entity funds the food safety programs of such entity inde-
8 pendently of any grant under this section in each year of
9 the grant at a level equal to the level of such funding in
10 the previous year, increased by the Consumer Price Index.
11 Such non-Federal matching funds may be provided di-
12 rectly or through donations from public or private entities
13 and may be in cash or in-kind, fairly evaluated, including
14 plant, equipment, or services.

15 “(d) ADDITIONAL AUTHORITY.—The Secretary
16 may—

17 “(1) award a grant under this section in each
18 subsequent fiscal year without reapplication for a pe-
19 riod of not more than 3 years, provided the require-
20 ments of subsection (c) are met for the previous fis-
21 cal year; and

22 “(2) award a grant under this section in a fis-
23 cal year for which the requirement of subsection (c)
24 has not been met only if such requirement was not
25 met because such funding was diverted for response

1 to 1 or more natural disasters or in other extenu-
2 ating circumstances that the Secretary may deter-
3 mine appropriate.

4 “(e) DURATION OF AWARDS.—The Secretary may
5 award grants to an individual grant recipient under this
6 section for periods of not more than 3 years. In the event
7 the Secretary conducts a program evaluation, funding in
8 the second year or third year of the grant, where applica-
9 ble, shall be contingent on a successful program evaluation
10 by the Secretary after the first year.

11 “(f) PROGRESS AND EVALUATION.—

12 “(1) IN GENERAL.—The Secretary shall meas-
13 ure the status and success of each grant program
14 authorized under the FDA Food Safety Moderniza-
15 tion Act (and any amendment made by such Act),
16 including the grant program under this section. A
17 recipient of a grant described in the preceding sen-
18 tence shall, at the end of each grant year, provide
19 the Secretary with information on how grant funds
20 were spent and the status of the efforts by such re-
21 cipient to enhance food safety. To the extent prac-
22 ticable, the Secretary shall take the performance of
23 such a grant recipient into account when deter-
24 mining whether to continue funding for such recipi-
25 ent.

1 shall designate 5 Integrated Food Safety Centers of Excel-
2 lence (referred to in this section as the ‘Centers of Excel-
3 lence’) to serve as resources for Federal, State, and local
4 public health professionals to respond to foodborne illness
5 outbreaks. The Centers of Excellence shall be
6 headquartered at selected State health departments.

7 “(b) SELECTION OF CENTERS OF EXCELLENCE.—

8 “(1) ELIGIBLE ENTITIES.—To be eligible to be
9 designated as a Center of Excellence under sub-
10 section (a), an entity shall—

11 “(A) be a State health department;

12 “(B) partner with 1 or more institutions of
13 higher education that have demonstrated knowl-
14 edge, expertise, and meaningful experience with
15 regional or national food production, processing,
16 and distribution, as well as leadership in the
17 laboratory, epidemiological, and environmental
18 detection and investigation of foodborne illness;
19 and

20 “(C) provide to the Secretary such infor-
21 mation, at such time, and in such manner, as
22 the Secretary may require.

23 “(2) WORKING GROUP.—Not later than 180
24 days after the date of enactment of the FDA Food
25 Safety Modernization Act, the Secretary shall estab-

1 lish a diverse working group of experts and stake-
2 holders from Federal, State, and local food safety
3 and health agencies, the food industry, including
4 food retailers and food manufacturers, consumer or-
5 ganizations, and academia to make recommendations
6 to the Secretary regarding designations of the Cen-
7 ters of Excellence.

8 “(3) ADDITIONAL CENTERS OF EXCELLENCE.—
9 The Secretary may designate eligible entities to be
10 regional Food Safety Centers of Excellence, in addi-
11 tion to the 5 Centers designated under subsection
12 (a).

13 “(c) ACTIVITIES.—Under the leadership of the Direc-
14 tor of the Centers for Disease Control and Prevention,
15 each Center of Excellence shall be based out of a selected
16 State health department, which shall provide assistance to
17 other regional, State, and local departments of health
18 through activities that include—

19 “(1) providing resources, including timely infor-
20 mation concerning symptoms and tests, for frontline
21 health professionals interviewing individuals as part
22 of routine surveillance and outbreak investigations;

23 “(2) providing analysis of the timeliness and ef-
24 fectiveness of foodborne disease surveillance and out-
25 break response activities;

1 “(3) providing training for epidemiological and
2 environmental investigation of foodborne illness, in-
3 cluding suggestions for streamlining and standard-
4 izing the investigation process;

5 “(4) establishing fellowships, stipends, and
6 scholarships to train future epidemiological and
7 food-safety leaders and to address critical workforce
8 shortages;

9 “(5) training and coordinating State and local
10 personnel;

11 “(6) strengthening capacity to participate in ex-
12 isting or new foodborne illness surveillance and envi-
13 ronmental assessment information systems; and

14 “(7) conducting research and outreach activities
15 focused on increasing prevention, communication,
16 and education regarding food safety.

17 “(d) REPORT TO CONGRESS.—Not later than 2 years
18 after the date of enactment of the FDA Food Safety Mod-
19 ernization Act, the Secretary shall submit to Congress a
20 report that—

21 “(1) describes the effectiveness of the Centers
22 of Excellence; and

23 “(2) provides legislative recommendations or
24 describes additional resources required by the Cen-
25 ters of Excellence.

1 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
2 is authorized to be appropriated such sums as may be nec-
3 essary to carry out this section.

4 “(f) NO DUPLICATION OF EFFORT.—In carrying out
5 activities of the Centers of Excellence or other programs
6 under this section, the Secretary shall not duplicate other
7 Federal foodborne illness response efforts.”.

8 **SEC. 211. IMPROVING THE REPORTABLE FOOD REGISTRY.**

9 (a) IN GENERAL.—Section 417 (21 U.S.C. 350f) is
10 amended—

11 (1) by redesignating subsections (f) through (k)
12 as subsections (i) through (n), respectively; and

13 (2) by inserting after subsection (e) the fol-
14 lowing:

15 “(f) CRITICAL INFORMATION.—Except with respect
16 to fruits and vegetables that are raw agricultural commod-
17 ities, not more than 18 months after the date of enactment
18 of the FDA Food Safety Modernization Act, the Secretary
19 may require a responsible party to submit to the Secretary
20 consumer-oriented information regarding a reportable
21 food, which shall include—

22 “(1) a description of the article of food as pro-
23 vided in subsection (e)(3);

24 “(2) as provided in subsection (e)(7), affected
25 product identification codes, such as UPC, SKU, or

1 lot or batch numbers sufficient for the consumer to
2 identify the article of food;

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

5 “(4) any other information the Secretary deter-
6 mines is necessary to enable a consumer to accu-
7 rately identify whether such consumer is in posses-
8 sion of the reportable food.

9 “(g) GROCERY STORE NOTIFICATION.—

10 “(1) ACTION BY SECRETARY.—The Secretary
11 shall—

12 “(A) prepare the critical information de-
13 scribed under subsection (f) for a reportable
14 food as a standardized one-page summary;

15 “(B) publish such one-page summary on
16 the Internet website of the Food and Drug Ad-
17 ministration in a format that can be easily
18 printed by a grocery store for purposes of con-
19 sumer notification.

20 “(2) ACTION BY GROCERY STORE.—A notifica-
21 tion described under paragraph (1)(B) shall include
22 the date and time such summary was posted on the
23 Internet website of the Food and Drug Administra-
24 tion.

25 “(h) CONSUMER NOTIFICATION.—

1 “(1) IN GENERAL.—If a grocery store sold a re-
2 portable food that is the subject of the posting and
3 such establishment is part of chain of establishments
4 with 15 or more physical locations, then such estab-
5 lishment shall, not later than 24 hours after a one
6 page summary described in subsection (g) is pub-
7 lished, prominently display such summary or the in-
8 formation from such summary via at least one of the
9 methods identified under paragraph (2) and main-
10 tain the display for 14 days.

11 “(2) LIST OF CONSPICUOUS LOCATIONS.—Not
12 more than 1 year after the date of enactment of the
13 FDA Food Safety Modernization Act, the Secretary
14 shall develop and publish a list of acceptable con-
15 spicuous locations and manners, from which grocery
16 stores shall select at least one, for providing the no-
17 tification required in paragraph (1). Such list shall
18 include—

19 “(A) posting the notification at or near the
20 register;

21 “(B) providing the location of the report-
22 able food;

23 “(C) providing targeted recall information
24 given to customers upon purchase of a food;
25 and

1 “(D) other such prominent and con-
2 spicuous locations and manners utilized by gro-
3 cery stores as of the date of the enactment of
4 the FDA Food Safety Modernization Act to
5 provide notice of such recalls to consumers as
6 considered appropriate by the Secretary.”.

7 (b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331),
8 as amended by section 206, is amended by adding at the
9 end the following:

10 “(yy) The knowing and willful failure to comply with
11 the notification requirement under section 417(h).”.

12 (c) CONFORMING AMENDMENT.—Section 301(e) (21
13 U.S.C. 331(e)) is amended by striking “417(g)” and in-
14 serting “417(j)”.

15 **TITLE III—IMPROVING THE**
16 **SAFETY OF IMPORTED FOOD**

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

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

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

21 “(a) IN GENERAL.—

22 “(1) VERIFICATION REQUIREMENT.—Except as
23 provided under subsections (e) and (f), each im-
24 porter shall perform risk-based foreign supplier
25 verification activities for the purpose of verifying

1 that the food imported by the importer or agent of
2 an importer is—

3 “(A) produced in compliance with the re-
4 quirements of section 418 or section 419, as ap-
5 propriate; and

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

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

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

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

20 “(b) GUIDANCE.—Not later than 1 year after the
21 date of enactment of the FDA Food Safety Modernization
22 Act, the Secretary shall issue guidance to assist importers
23 in developing foreign supplier verification programs.

24 “(c) REGULATIONS.—

1 “(1) IN GENERAL.—Not later than 1 year after
2 the date of enactment of the FDA Food Safety Mod-
3 ernization Act, the Secretary shall promulgate regu-
4 lations to provide for the content of the foreign sup-
5 plier verification program established under sub-
6 section (a).

7 “(2) REQUIREMENTS.—The regulations promul-
8 gated under paragraph (1)—

9 “(A) shall require that the foreign supplier
10 verification program of each importer be ade-
11 quate to provide assurances that each foreign
12 supplier to the importer produces the imported
13 food in compliance with—

14 “(i) processes and procedures, includ-
15 ing reasonably appropriate risk-based pre-
16 ventive controls, that provide the same
17 level of public health protection as those
18 required under section 418 or section 419
19 (taking into consideration variances grant-
20 ed under section 419), as appropriate; and

21 “(ii) section 402 and section 403(w).

22 “(B) shall include such other requirements
23 as the Secretary deems necessary and appro-
24 priate to verify that food imported into the

1 United States is as safe as food produced and
2 sold within the United States.

3 “(3) CONSIDERATIONS.—In promulgating regu-
4 lations under this subsection, the Secretary shall, as
5 appropriate, take into account differences among im-
6 porters and types of imported foods, including based
7 on the level of risk posed by the imported food.

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

16 “(d) RECORD MAINTENANCE AND ACCESS.—Records
17 of an importer related to a foreign supplier verification
18 program shall be maintained for a period of not less than
19 2 years and shall be made available promptly to a duly
20 authorized representative of the Secretary upon request.

21 “(e) EXEMPTION OF SEAFOOD, JUICE, AND LOW-
22 ACID CANNED FOOD FACILITIES IN COMPLIANCE WITH
23 HACCP.—This section shall not apply to a facility if the
24 owner, operator, or agent in charge of such facility is re-
25 quired to comply with, and is in compliance with, 1 of the

1 following standards and regulations with respect to such
2 facility:

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

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

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

13 The exemption under paragraph (3) shall apply only with
14 respect to microbiological hazards that are regulated
15 under the standards for Thermally Processed Low-Acid
16 Foods Packaged in Hermetically Sealed Containers under
17 part 113 of chapter 21, Code of Federal Regulations (or
18 any successor regulations).

19 “(f) ADDITIONAL EXEMPTIONS.—The Secretary, by
20 notice published in the Federal Register, shall establish
21 an exemption from the requirements of this section for ar-
22 ticles of food imported in small quantities for research and
23 evaluation purposes or for personal consumption, provided
24 that such foods are not intended for retail sale and are
25 not sold or distributed to the public.

1 “(g) PUBLICATION OF LIST OF PARTICIPANTS.—The
2 Secretary shall publish and maintain on the Internet Web
3 site of the Food and Drug Administration a current list
4 that includes the name of, location of, and other informa-
5 tion deemed necessary by the Secretary about, importers
6 participating under this section.”.

7 (b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331),
8 as amended by section 211, is amended by adding at the
9 end the following:

10 “(zz) The importation or offering for importation of
11 a food if the importer (as defined in section 805) does
12 not have in place a foreign supplier verification program
13 in compliance with such section 805.”.

14 (c) IMPORTS.—Section 801(a) (21 U.S.C. 381(a)) is
15 amended by adding “or the importer (as defined in section
16 805) is in violation of such section 805” after “or in viola-
17 tion of section 505”.

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

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

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

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

2 “(a) IN GENERAL.—Beginning not later than 18
3 months after the date of enactment of the FDA Food
4 Safety Modernization Act, the Secretary shall—

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

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

11 “(B) consistent with section 808, establish
12 a process for the issuance of a facility certifi-
13 cation to accompany food offered for importa-
14 tion by importers who have voluntarily agreed
15 to participate in such program; and

16 “(2) issue a guidance document related to par-
17 ticipation in, revocation of such participation in, re-
18 instatement in, and compliance with, such program.

19 “(b) VOLUNTARY PARTICIPATION.—An importer may
20 request the Secretary to provide for the expedited review
21 and importation of designated foods in accordance with
22 the program established by the Secretary under subsection
23 (a).

24 “(c) NOTICE OF INTENT TO PARTICIPATE.—An im-
25 porter that intends to participate in the program under
26 this section in a fiscal year shall submit a notice and appli-

1 cation to the Secretary of such intent at the time and in
2 a manner established by the Secretary.

3 “(d) ELIGIBILITY.—Eligibility shall be limited to an
4 importer offering food for importation from a facility that
5 has a certification described in subsection (a). In reviewing
6 the applications and making determinations on such appli-
7 cations, the Secretary shall consider the risk of the food
8 to be imported based on factors, such as the following:

9 “(1) The known safety risks of the food to be
10 imported.

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

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

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

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

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

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

4 “(q) CERTIFICATIONS CONCERNING IMPORTED
5 FOODS.—

6 “(1) IN GENERAL.—The Secretary may require,
7 as a condition of granting admission to an article of
8 food imported or offered for import into the United
9 States, that an entity described in paragraph (3)
10 provide a certification, or such other assurances as
11 the Secretary determines appropriate, that the arti-
12 cle of food complies with applicable requirements of
13 this Act. Such certification or assurances may be
14 provided in the form of shipment-specific certifi-
15 cates, a listing of certified facilities that manufac-
16 ture, process, pack, or hold such food, or in such
17 other form as the Secretary may specify.

18 “(2) FACTORS TO BE CONSIDERED IN REQUIR-
19 ING CERTIFICATION.—The Secretary shall base the
20 determination that an article of food is required to
21 have a certification described in paragraph (1) on
22 the risk of the food, including—

23 “(A) known safety risks associated with
24 the food;

1 “(B) known food safety risks associated
2 with the country, territory, or region of origin
3 of the food;

4 “(C) a finding by the Secretary, supported
5 by scientific, risk-based evidence, that—

6 “(i) the food safety programs, sys-
7 tems, and standards in the country, terri-
8 tory, or region of origin of the food are in-
9 adequate to ensure that the article of food
10 is as safe as a similar article of food that
11 is manufactured, processed, packed, or
12 held in the United States in accordance
13 with the requirements of this Act; and

14 “(ii) the certification would assist the
15 Secretary in determining whether to refuse
16 or admit the article of food under sub-
17 section (a); and

18 “(D) information submitted to the Sec-
19 retary in accordance with the process estab-
20 lished in paragraph (7).

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

1 “(A) an agency or a representative of the
2 government of the country from which the arti-
3 cle of food at issue originated, as designated by
4 the Secretary; or

5 “(B) such other persons or entities accred-
6 ited pursuant to section 808 to provide such
7 certification or assurance.

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

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

15 “(B) refuse to accept any certification or
16 assurance if the Secretary determines that such
17 certification or assurance is not valid or reli-
18 able.

19 “(5) ELECTRONIC SUBMISSION.—The Secretary
20 shall provide for the electronic submission of certifi-
21 cations under this subsection.

22 “(6) FALSE STATEMENTS.—Any statement or
23 representation made by an entity described in para-
24 graph (2) to the Secretary shall be subject to section
25 1001 of title 18, United States Code.

1 “(7) ASSESSMENT OF FOOD SAFETY PROGRAMS,
2 SYSTEMS, AND STANDARDS.—If the Secretary deter-
3 mines that the food safety programs, systems, and
4 standards in a foreign region, country, or territory
5 are inadequate to ensure that an article of food is
6 as safe as a similar article of food that is manufac-
7 tured, processed, packed, or held in the United
8 States in accordance with the requirements of this
9 Act, the Secretary shall, to the extent practicable,
10 identify such inadequacies and establish a process by
11 which the foreign region, country, or territory may
12 inform the Secretary of improvements made to such
13 food safety program, system, or standard and dem-
14 onstrate that those controls are adequate to ensure
15 that an article of food is as safe as a similar article
16 of food that is manufactured, processed, packed, or
17 held in the United States in accordance with the re-
18 quirements of this Act.”.

19 (c) CONFORMING TECHNICAL AMENDMENT.—Sec-
20 tion 801(b) (21 U.S.C. 381(b)) is amended in the second
21 sentence by striking “with respect to an article included
22 within the provision of the fourth sentence of subsection
23 (a)” and inserting “with respect to an article described
24 in subsection (a) relating to the requirements of sections
25 760 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 inspections of imported food
4 or to take such other steps as the Secretary deems appro-
5 priate to determine the admissibility of imported food.

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

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

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

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

19 **SEC. 305. BUILDING CAPACITY OF FOREIGN GOVERNMENTS**
20 **WITH RESPECT TO FOOD SAFETY.**

21 (a) IN GENERAL.—The Secretary shall, not later
22 than 2 years of the date of enactment of this Act, develop
23 a comprehensive plan to expand the technical, scientific,
24 and regulatory food safety capacity of foreign govern-

1 ments, and their respective food industries, from which
2 foods are exported to the United States.

3 (b) CONSULTATION.—In developing the plan under
4 subsection (a), the Secretary shall consult with the Sec-
5 retary of Agriculture, Secretary of State, Secretary of the
6 Treasury, the Secretary of Homeland Security, the United
7 States Trade Representative, and the Secretary of Com-
8 merce, representatives of the food industry, appropriate
9 foreign government officials, nongovernmental organiza-
10 tions that represent the interests of consumers, and other
11 stakeholders.

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

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

18 (2) Provisions for secure electronic data shar-
19 ing.

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

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

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

4 (6) Provisions for the multilateral acceptance of
5 laboratory methods and testing and detection tech-
6 niques.

7 (d) **RULE OF CONSTRUCTION.**—Nothing in this sec-
8 tion shall be construed to affect the regulation of dietary
9 supplements under the Dietary Supplement Health and
10 Education Act of 1994 (Public Law 103–417).

11 **SEC. 306. INSPECTION OF FOREIGN FOOD FACILITIES.**

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

15 **“SEC. 807. INSPECTION OF FOREIGN FOOD FACILITIES.**

16 “(a) **INSPECTION.**—The Secretary—

17 “(1) may enter into arrangements and agree-
18 ments with foreign governments to facilitate the in-
19 spection of foreign facilities registered under section
20 415; and

21 “(2) shall direct resources to inspections of for-
22 eign facilities, suppliers, and food types, especially
23 such facilities, suppliers, and food types that present
24 a high risk (as identified by the Secretary), to help

1 ensure the safety and security of the food supply of
2 the United States.

3 “(b) EFFECT OF INABILITY TO INSPECT.—Notwith-
4 standing any other provision of law, food shall be refused
5 admission into the United States if it is from a foreign
6 factory, warehouse, or other establishment of which the
7 owner, operator, or agent in charge, or the government
8 of the foreign country, refuses to permit entry of United
9 States inspectors or other individuals duly designated by
10 the Secretary, upon request, to inspect such factory, ware-
11 house, or other establishment. For purposes of this sub-
12 section, such an owner, operator, or agent in charge shall
13 be considered to have refused an inspection if such owner,
14 operator, or agent in charge does not permit an inspection
15 of a factory, warehouse, or other establishment during the
16 24-hour period after such request is submitted, or after
17 such other time period, as agreed upon by the Secretary
18 and the foreign factory, warehouse, or other establish-
19 ment.”.

20 (b) INSPECTION BY THE SECRETARY OF COM-
21 MERCE.—

22 (1) IN GENERAL.—The Secretary of Commerce,
23 in coordination with the Secretary of Health and
24 Human Services, may send 1 or more inspectors to
25 a country or facility of an exporter from which sea-

1 food imported into the United States originates. The
2 inspectors shall assess practices and processes used
3 in connection with the farming, cultivation, har-
4 vesting, preparation for market, or transportation of
5 such seafood and may provide technical assistance
6 related to such activities.

7 (2) INSPECTION REPORT.—

8 (A) IN GENERAL.—The Secretary of
9 Health and Human Services, in coordination
10 with the Secretary of Commerce, shall—

11 (i) prepare an inspection report for
12 each inspection conducted under paragraph
13 (1);

14 (ii) provide the report to the country
15 or exporter that is the subject of the re-
16 port; and

17 (iii) provide a 30-day period during
18 which the country or exporter may provide
19 a rebuttal or other comments on the find-
20 ings of the report to the Secretary of
21 Health and Human Services.

22 (B) DISTRIBUTION AND USE OF RE-
23 PORT.—The Secretary of Health and Human
24 Services shall consider the inspection reports
25 described in subparagraph (A) in distributing

1 inspection resources under section 421 of the
2 Federal Food, Drug, and Cosmetic Act, as
3 added by section 201.

4 **SEC. 307. ACCREDITATION OF THIRD-PARTY AUDITORS.**

5 Chapter VIII (21 U.S.C. 381 et seq.), as amended
6 by section 306, is amended by adding at the end the fol-
7 lowing:

8 **“SEC. 808. ACCREDITATION OF THIRD-PARTY AUDITORS.**

9 “(a) DEFINITIONS.—In this section:

10 “(1) AUDIT AGENT.—The term ‘audit agent’
11 means an individual who is an employee or agent of
12 an accredited third-party auditor and, although not
13 individually accredited, is qualified to conduct food
14 safety audits on behalf of an accredited third-party
15 auditor.

16 “(2) ACCREDITATION BODY.—The term ‘ac-
17 creditation body’ means an authority that performs
18 accreditation of third-party auditors.

19 “(3) THIRD-PARTY AUDITOR.—The term ‘third-
20 party auditor’ means a foreign government, agency
21 of a foreign government, foreign cooperative, or any
22 other third party, as the Secretary determines ap-
23 propriate in accordance with the model standards
24 described in subsection (b)(2), that is eligible to be
25 considered for accreditation to conduct food safety

1 audits to certify that eligible entities meet the appli-
2 cable requirements of this section. A third-party
3 auditor may be a single individual. A third-party
4 auditor may employ or use audit agents to help con-
5 duct consultative and regulatory audits.

6 “(4) ACCREDITED THIRD-PARTY AUDITOR.—
7 The term ‘accredited third-party auditor’ means a
8 third-party auditor accredited by an accreditation
9 body to conduct audits of eligible entities to certify
10 that such eligible entities meet the applicable re-
11 quirements of this section. An accredited third-party
12 auditor may be an individual who conducts food
13 safety audits to certify that eligible entities meet the
14 applicable requirements of this section.

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

18 “(A) to determine whether such entity is in
19 compliance with the provisions of this Act and
20 with applicable industry standards and prac-
21 tices; and

22 “(B) the results of which are for internal
23 purposes only.

24 “(6) ELIGIBLE ENTITY.—The term ‘eligible en-
25 tity’ means a foreign entity, including a foreign fa-

1 cility registered under section 415, in the food im-
2 port supply chain that chooses to be audited by an
3 accredited third-party auditor or the audit agent of
4 such accredited third-party auditor.

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

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

9 “(B) the results of which determine—

10 “(i) whether an article of food manu-
11 factured, processed, packed, or held by
12 such entity is eligible to receive a food cer-
13 tification under section 801(q); or

14 “(ii) whether a facility is eligible to
15 receive a facility certification under section
16 806(a) for purposes of participating in the
17 program under section 806.

18 “(b) ACCREDITATION SYSTEM.—

19 “(1) ACCREDITATION BODIES.—

20 “(A) RECOGNITION OF ACCREDITATION
21 BODIES.—

22 “(i) IN GENERAL.—Not later than 2
23 years after the date of enactment of the
24 FDA Food Safety Modernization Act, the
25 Secretary shall establish a system for the

1 recognition of accreditation bodies that ac-
2 credit third-party auditors to certify that
3 eligible entities meet the applicable require-
4 ments of this section.

5 “(ii) DIRECT ACCREDITATION.—If, by
6 the date that is 2 years after the date of
7 establishment of the system described in
8 clause (i), the Secretary has not identified
9 and recognized an accreditation body to
10 meet the requirements of this section, the
11 Secretary may directly accredit third-party
12 auditors.

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

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

23 “(D) REINSTATEMENT.—The Secretary
24 shall establish procedures to reinstate recogni-
25 tion of an accreditation body if the Secretary

1 determines, based on evidence presented by
2 such accreditation body, that revocation was in-
3 appropriate or that the body meets the require-
4 ments for recognition under this section.

5 “(2) MODEL ACCREDITATION STANDARDS.—

6 Not later than 18 months after the date of enact-
7 ment of the FDA Food Safety Modernization Act,
8 the Secretary shall develop model standards, includ-
9 ing requirements for regulatory audit reports, and
10 each recognized accreditation body shall ensure that
11 third-party auditors and audit agents of such audi-
12 tors meet such standards in order to qualify such
13 third-party auditors as accredited third-party audi-
14 tors under this section. In developing the model
15 standards, the Secretary shall look to standards in
16 place on the date of the enactment of this section for
17 guidance, to avoid unnecessary duplication of efforts
18 and costs.

19 “(c) THIRD-PARTY AUDITORS.—

20 “(1) REQUIREMENTS FOR ACCREDITATION AS A
21 THIRD-PARTY AUDITOR.—

22 “(A) FOREIGN GOVERNMENTS.—Prior to
23 accrediting a foreign government or an agency
24 of a foreign government as an accredited third-
25 party auditor, the accreditation body (or, in the

1 case of direct accreditation under subsection
2 (b)(1)(A)(ii), the Secretary) shall perform such
3 reviews and audits of food safety programs, sys-
4 tems, and standards of the government or agen-
5 cy of the government as the Secretary deems
6 necessary, including requirements under the
7 model standards developed under subsection
8 (b)(2), to determine that the foreign govern-
9 ment or agency of the foreign government is ca-
10 pable of adequately ensuring that eligible enti-
11 ties or foods certified by such government or
12 agency meet the requirements of this Act with
13 respect to food manufactured, processed,
14 packed, or held for import into the United
15 States.

16 “(B) FOREIGN COOPERATIVES AND OTHER
17 THIRD PARTIES.—Prior to accrediting a foreign
18 cooperative that aggregates the products of
19 growers or processors, or any other third party
20 to be an accredited third-party auditor, the ac-
21 creditation body (or, in the case of direct ac-
22 creditation under subsection (b)(1)(A)(ii), the
23 Secretary) shall perform such reviews and au-
24 dits of the training and qualifications of audit
25 agents used by that cooperative or party and

1 conduct such reviews of internal systems and
2 such other investigation of the cooperative or
3 party as the Secretary deems necessary, includ-
4 ing requirements under the model standards de-
5 veloped under subsection (b)(2), to determine
6 that each eligible entity certified by the cooper-
7 ative or party has systems and standards in use
8 to ensure that such entity or food meets the re-
9 quirements of this Act.

10 “(2) REQUIREMENT TO ISSUE CERTIFICATION
11 OF ELIGIBLE ENTITIES OR FOODS.—

12 “(A) IN GENERAL.—An accreditation body
13 (or, in the case of direct accreditation under
14 subsection (b)(1)(A)(ii), the Secretary) may not
15 accredit a third-party auditor unless such third-
16 party auditor agrees to issue a written and, as
17 appropriate, electronic food certification, de-
18 scribed in section 801(q), or facility certifi-
19 cation under section 806(a), as appropriate, to
20 accompany each food shipment for import into
21 the United States from an eligible entity, sub-
22 ject to requirements set forth by the Secretary.
23 Such written or electronic certification may be
24 included with other documentation regarding
25 such food shipment. The Secretary shall con-

1 sider certifications under section 801(q) and
2 participation in the voluntary qualified importer
3 program described in section 806 when tar-
4 geting inspection resources under section 421.

5 “(B) PURPOSE OF CERTIFICATION.—The
6 Secretary shall use certification provided by ac-
7 credited third-party auditors to—

8 “(i) determine, in conjunction with
9 any other assurances the Secretary may re-
10 quire under section 801(q), whether a food
11 satisfies the requirements of such section;
12 and

13 “(ii) determine whether a facility is el-
14 igible to be a facility from which food may
15 be offered for import under the voluntary
16 qualified importer program under section
17 806.

18 “(C) REQUIREMENTS FOR ISSUING CER-
19 TIFICATION.—

20 “(i) IN GENERAL.—An accredited
21 third-party auditor shall issue a food cer-
22 tification under section 801(q) or a facility
23 certification described under subparagraph
24 (B) only after conducting a regulatory
25 audit and such other activities that may be

1 necessary to establish compliance with the
2 requirements of such sections.

3 “(ii) PROVISION OF CERTIFICATION.—
4 Only an accredited third-party auditor or
5 the Secretary may provide a facility certifi-
6 cation under section 806(a). Only those
7 parties described in 801(q)(3) or the Sec-
8 retary may provide a food certification
9 under 301(g).

10 “(3) AUDIT REPORT SUBMISSION REQUIRE-
11 MENTS.—

12 “(A) REQUIREMENTS IN GENERAL.—As a
13 condition of accreditation, not later than 45
14 days after conducting an audit, an accredited
15 third-party auditor or audit agent of such audi-
16 tor shall prepare, and, in the case of a regu-
17 latory audit, submit, the audit report for each
18 audit conducted, in a form and manner des-
19 ignated by the Secretary, which shall include—

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

23 “(ii) the dates of the audit;

24 “(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) RECORDS.—Following any accredita-
6 tion of a third-party auditor, the Secretary
7 may, at any time, require the accredited third-
8 party auditor to submit to the Secretary an on-
9 site audit report and such other reports or doc-
10 uments required as part of the audit process,
11 for any eligible entity certified by the third-
12 party auditor or audit agent of such auditor.
13 Such report may include documentation that
14 the eligible entity is in compliance with any ap-
15 plicable registration requirements.

16 “(C) LIMITATION.—The requirement
17 under subparagraph (B) shall not include any
18 report or other documents resulting from a con-
19 sultative audit by the accredited third-party
20 auditor, except that the Secretary may access
21 the results of a consultative audit in accordance
22 with section 414.

23 “(4) REQUIREMENTS OF ACCREDITED THIRD-
24 PARTY AUDITORS AND AUDIT AGENTS OF SUCH
25 AUDITORS.—

1 “(A) RISKS TO PUBLIC HEALTH.—If, at
2 any time during an audit, an accredited third-
3 party auditor or audit agent of such auditor
4 discovers a condition that could cause or con-
5 tribute to a serious risk to the public health,
6 such auditor shall immediately notify the Sec-
7 retary of—

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

10 “(ii) such condition.

11 “(B) TYPES OF AUDITS.—An accredited
12 third-party auditor or audit agent of such audi-
13 tor may perform consultative and regulatory
14 audits of eligible entities.

15 “(C) LIMITATIONS.—

16 “(i) IN GENERAL.—An accredited
17 third party auditor may not perform a reg-
18 ulatory audit of an eligible entity if such
19 agent has performed a consultative audit
20 or a regulatory audit of such eligible entity
21 during the previous 13-month period.

22 “(ii) WAIVER.—The Secretary may
23 waive the application of clause (i) if the
24 Secretary determines that there is insuffi-

1 cient access to accredited third-party audi-
2 tors in a country or region.

3 “(5) CONFLICTS OF INTEREST.—

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

6 “(i) not be owned, managed, or con-
7 trolled by any person that owns or operates
8 an eligible entity to be certified by such
9 auditor;

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

17 “(iii) annually make available to the
18 Secretary disclosures of the extent to
19 which such auditor and the officers and
20 employees of such auditor have maintained
21 compliance with clauses (i) and (ii) relat-
22 ing to financial conflicts of interest.

23 “(B) AUDIT AGENTS.—An audit agent
24 shall—

1 “(i) not own or operate an eligible en-
2 tity to be audited by such agent;

3 “(ii) in carrying out audits of eligible
4 entities under this section, have procedures
5 to ensure that such agent does not have a
6 financial conflict of interest regarding an
7 eligible entity to be audited by such agent;
8 and

9 “(iii) annually make available to the
10 Secretary disclosures of the extent to
11 which such agent has maintained compli-
12 ance with clauses (i) and (ii) relating to fi-
13 nancial conflicts of interest.

14 “(C) REGULATIONS.—The Secretary shall
15 promulgate regulations not later than 18
16 months after the date of enactment of the FDA
17 Food Safety Modernization Act to implement
18 this section and to ensure that there are protec-
19 tions against conflicts of interest between an
20 accredited third-party auditor and the eligible
21 entity to be certified by such auditor or audited
22 by such audit agent. Such regulations shall in-
23 clude—

24 “(i) requiring that audits performed
25 under this section be unannounced;

1 “(ii) a structure to decrease the po-
2 tential for conflicts of interest, including
3 timing and public disclosure, for fees paid
4 by eligible entities to accredited third-party
5 auditors; and

6 “(iii) appropriate limits on financial
7 affiliations between an accredited third-
8 party auditor or audit agents of such audi-
9 tor and any person that owns or operates
10 an eligible entity to be certified by such
11 auditor, as described in subparagraphs (A)
12 and (B).

13 “(6) WITHDRAWAL OF ACCREDITATION.—

14 “(A) IN GENERAL.—The Secretary shall
15 withdraw accreditation from an accredited
16 third-party auditor—

17 “(i) if food certified under section
18 801(q) or from a facility certified under
19 paragraph (2)(B) by such third-party audi-
20 tor is linked to an outbreak of foodborne
21 illness that has a reasonable probability of
22 causing serious adverse health con-
23 sequences or death in humans or animals;

24 “(ii) following an evaluation and find-
25 ing by the Secretary that the third-party

1 auditor no longer meets the requirements
2 for accreditation; or

3 “(iii) following a refusal to allow
4 United States officials to conduct such au-
5 dits and investigations as may be necessary
6 to ensure continued compliance with the
7 requirements set forth in this section.

8 “(B) ADDITIONAL BASIS FOR WITH-
9 DRAWAL OF ACCREDITATION.—The Secretary
10 may withdraw accreditation from an accredited
11 third-party auditor in the case that such third-
12 party auditor is accredited by an accreditation
13 body for which recognition as an accreditation
14 body under subsection (b)(1)(C) is revoked, if
15 the Secretary determines that there is good
16 cause for the withdrawal.

17 “(C) EXCEPTION.—The Secretary may
18 waive the application of subparagraph (A)(i) if
19 the Secretary—

20 “(i) conducts an investigation of the
21 material facts related to the outbreak of
22 human or animal illness; and

23 “(ii) reviews the steps or actions
24 taken by the third party auditor to justify
25 the certification and determines that the

1 accredited third-party auditor satisfied the
2 requirements under section 801(q) of certi-
3 fying the food, or the requirements under
4 paragraph (2)(B) of certifying the entity.

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

9 “(A) if the Secretary determines, based on
10 evidence presented, that the third-party auditor
11 satisfies the requirements of this section and
12 adequate grounds for revocation no longer exist;
13 and

14 “(B) in the case of a third-party auditor
15 accredited by an accreditation body for which
16 recognition as an accreditation body under sub-
17 section (b)(1)(C) is revoked—

18 “(i) if the third-party auditor becomes
19 accredited not later than 1 year after rev-
20 ocation of accreditation under paragraph
21 (6)(A), through direct accreditation under
22 subsection (b)(1)(A)(ii) or by an accredita-
23 tion body in good standing; or

1 “(ii) under such conditions as the Sec-
2 retary may require for a third-party audi-
3 tor under paragraph (6)(B).

4 “(8) NEUTRALIZING COSTS.—The Secretary
5 shall establish by regulation a reimbursement (user
6 fee) program, similar to the method described in sec-
7 tion 203(h) of the Agriculture Marketing Act of
8 1946, by which the Secretary assesses fees and re-
9 quires accredited third-party auditors and audit
10 agents to reimburse the Food and Drug Administra-
11 tion for the work performed to establish and admin-
12 ister the accreditation system under this section.
13 The Secretary shall make operating this program
14 revenue-neutral and shall not generate surplus rev-
15 enue from such a reimbursement mechanism. Fees
16 authorized under this paragraph shall be collected
17 and available for obligation only to the extent and in
18 the amount provided in advance in appropriation
19 Acts. Such fees are authorized to remain available
20 until expended.

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

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

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

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

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

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

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

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

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

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

1 “(3) at any time, conduct an onsite audit of
2 any eligible entity certified by an accredited third-
3 party auditor, with or without the auditor present;
4 and

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

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

13 “(h) LIMITATIONS.—

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

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

22 **SEC. 308. FOREIGN OFFICES OF THE FOOD AND DRUG AD-**
23 **MINISTRATION.**

24 “(a) IN GENERAL.—The Secretary shall establish of-
25 fices of the Food and Drug Administration in foreign

1 countries selected by the Secretary, to provide assistance
2 to the appropriate governmental entities of such countries
3 with respect to measures to provide for the safety of arti-
4 cles of food and other products regulated by the Food and
5 Drug Administration exported by such country to the
6 United States, including by directly conducting risk-based
7 inspections of such articles and supporting such inspec-
8 tions by such governmental entity.

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

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

1 **SEC. 309. SMUGGLED FOOD.**

2 (a) **IN GENERAL.**—Not later than 180 days after the
3 enactment of this Act, the Secretary shall, in coordination
4 with the Secretary of Homeland Security, develop and im-
5 plement a strategy to better identify smuggled food and
6 prevent entry of such food into the United States.

7 (b) **NOTIFICATION TO HOMELAND SECURITY.**—Not
8 later than 10 days after the Secretary identifies a smug-
9 gled food that the Secretary believes would cause serious
10 adverse health consequences or death to humans or ani-
11 mals, the Secretary shall provide to the Secretary of
12 Homeland Security a notification under section 417(n) of
13 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 350f(k)) describing the smuggled food and, if available,
15 the names of the individuals or entities that attempted to
16 import such food into the United States.

17 (c) **PUBLIC NOTIFICATION.**—If the Secretary—

18 (1) identifies a smuggled food;

19 (2) reasonably believes exposure to the food
20 would cause serious adverse health consequences or
21 death to humans or animals; and

22 (3) reasonably believes that the food has en-
23 tered domestic commerce and is likely to be con-
24 sumed,

25 the Secretary shall promptly issue a press release describ-
26 ing that food and shall use other emergency communica-

1 tion or recall networks, as appropriate, to warn consumers
2 and vendors about the potential threat.

3 (d) EFFECT OF SECTION.—Nothing in this section
4 shall affect the authority of the Secretary to issue public
5 notifications under other circumstances.

6 (e) DEFINITION.—In this subsection, the term
7 “smuggled food” means any food that a person introduces
8 into the United States through fraudulent means or with
9 the intent to defraud or mislead.

10 **TITLE IV—MISCELLANEOUS** 11 **PROVISIONS**

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

13 (a) IN GENERAL.—There are authorized to be appro-
14 priated to carry out the activities of the Center for Food
15 Safety and Applied Nutrition, the Center for Veterinary
16 Medicine, and related field activities in the Office of Regu-
17 latory Affairs of the Food and Drug Administration such
18 sums as may be necessary for fiscal years 2011 through
19 2015.

20 (b) INCREASED NUMBER OF FIELD STAFF.—

21 (1) IN GENERAL.—To carry out the activities of
22 the Center for Food Safety and Applied Nutrition,
23 the Center for Veterinary Medicine, and related field
24 activities of the Office of Regulatory Affairs of the
25 Food and Drug Administration, the Secretary of

1 Health and Human Services shall increase the field
2 staff of such Centers and Office with a goal of not
3 fewer than—

4 (A) 4,000 staff members in fiscal year
5 2011;

6 (B) 4,200 staff members in fiscal year
7 2012;

8 (C) 4,600 staff members in fiscal year
9 2013; and

10 (D) 5,000 staff members in fiscal year
11 2014.

12 (2) FIELD STAFF FOR FOOD DEFENSE.—The
13 goal under paragraph (1) shall include an increase
14 of 150 employees by fiscal year 2011 to—

15 (A) provide additional detection of and re-
16 sponse to food defense threats; and

17 (B) detect, track, and remove smuggled
18 food (as defined in section 310) from com-
19 merce.

20 **SEC. 402. EMPLOYEE PROTECTIONS.**

21 Chapter X of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 391 et seq.), as amended by section 209,
23 is further amended by adding at the end the following:

1 **“SEC. 1012. EMPLOYEE PROTECTIONS.**

2 “(a) IN GENERAL.—No entity engaged in the manu-
3 facture, processing, packing, transporting, distribution, re-
4 ception, holding, or importation of food may discharge an
5 employee or otherwise discriminate against an employee
6 with respect to compensation, terms, conditions, or privi-
7 leges of employment because the employee, whether at the
8 employee’s initiative or in the ordinary course of the em-
9 ployee’s duties (or any person acting pursuant to a request
10 of the employee)—

11 “(1) provided, caused to be provided, or is
12 about to provide or cause to be provided to the em-
13 ployer, the Federal Government, or the attorney
14 general of a State information relating to any viola-
15 tion of, or any act or omission the employee reason-
16 ably believes to be a violation of any provision of this
17 Act or any order, rule, regulation, standard, or ban
18 under this Act, or any order, rule, regulation, stand-
19 ard, or ban under this Act;

20 “(2) testified or is about to testify in a pro-
21 ceeding concerning such violation;

22 “(3) assisted or participated or is about to as-
23 sist or participate in such a proceeding; or

24 “(4) objected to, or refused to participate in,
25 any activity, policy, practice, or assigned task that
26 the employee (or other such person) reasonably be-

1 lieved to be in violation of any provision of this Act,
2 or any order, rule, regulation, standard, or ban
3 under this Act.

4 “(b) PROCESS.—

5 “(1) IN GENERAL.—A person who believes that
6 he or she has been discharged or otherwise discrimi-
7 nated against by any person in violation of sub-
8 section (a) may, not later than 180 days after the
9 date on which such violation occurs, file (or have any
10 person file on his or her behalf) a complaint with the
11 Secretary of Labor (referred to in this section as the
12 ‘Secretary’) alleging such discharge or discrimina-
13 tion and identifying the person responsible for such
14 act. Upon receipt of such a complaint, the Secretary
15 shall notify, in writing, the person named in the
16 complaint of the filing of the complaint, of the alle-
17 gations contained in the complaint, of the substance
18 of evidence supporting the complaint, and of the op-
19 portunities that will be afforded to such person
20 under paragraph (2).

21 “(2) INVESTIGATION.—

22 “(A) IN GENERAL.—Not later than 60
23 days after the date of receipt of a complaint
24 filed under paragraph (1) and after affording
25 the complainant and the person named in the

1 complaint an opportunity to submit to the Sec-
2 retary a written response to the complaint and
3 an opportunity to meet with a representative of
4 the Secretary to present statements from wit-
5 nesses, the Secretary shall initiate an investiga-
6 tion and determine whether there is reasonable
7 cause to believe that the complaint has merit
8 and notify, in writing, the complainant and the
9 person alleged to have committed a violation of
10 subsection (a) of the Secretary's findings.

11 “(B) REASONABLE CAUSE FOUND; PRE-
12 LIMINARY ORDER.—If the Secretary concludes
13 that there is reasonable cause to believe that a
14 violation of subsection (a) has occurred, the
15 Secretary shall accompany the Secretary's find-
16 ings with a preliminary order providing the re-
17 lief prescribed by paragraph (3)(B). Not later
18 than 30 days after the date of notification of
19 findings under this paragraph, the person al-
20 leged to have committed the violation or the
21 complainant may file objections to the findings
22 or preliminary order, or both, and request a
23 hearing on the record. The filing of such objec-
24 tions shall not operate to stay any reinstatement
25 remedy contained in the preliminary

1 order. Any such hearing shall be conducted ex-
2 peditiously. If a hearing is not requested in
3 such 30-day period, the preliminary order shall
4 be deemed a final order that is not subject to
5 judicial review.

6 “(C) DISMISSAL OF COMPLAINT.—

7 “(i) STANDARD FOR COMPLAINANT.—

8 The Secretary shall dismiss a complaint
9 filed under this subsection and shall not
10 conduct an investigation otherwise required
11 under subparagraph (A) unless the com-
12 plainant makes a prima facie showing that
13 any behavior described in paragraphs (1)
14 through (4) of subsection (a) was a con-
15 tributing factor in the unfavorable per-
16 sonnel action alleged in the complaint.

17 “(ii) STANDARD FOR EMPLOYER.—

18 Notwithstanding a finding by the Secretary
19 that the complainant has made the show-
20 ing required under clause (i), no investiga-
21 tion otherwise required under subpara-
22 graph (A) shall be conducted if the em-
23 ployer demonstrates, by clear and con-
24 vincing evidence, that the employer would

1 have taken the same unfavorable personnel
2 action in the absence of that behavior.

3 “(iii) VIOLATION STANDARD.—The
4 Secretary may determine that a violation
5 of subsection (a) has occurred only if the
6 complainant demonstrates that any behav-
7 ior described in paragraphs (1) through
8 (4) of subsection (a) was a contributing
9 factor in the unfavorable personnel action
10 alleged in the complaint.

11 “(iv) RELIEF STANDARD.—Relief may
12 not be ordered under subparagraph (A) if
13 the employer demonstrates by clear and
14 convincing evidence that the employer
15 would have taken the same unfavorable
16 personnel action in the absence of that be-
17 havior.

18 “(3) FINAL ORDER.—

19 “(A) IN GENERAL.—Not later than 120
20 days after the date of conclusion of any hearing
21 under paragraph (2), the Secretary shall issue
22 a final order providing the relief prescribed by
23 this paragraph or denying the complaint. At
24 any time before issuance of a final order, a pro-
25 ceeding under this subsection may be termi-

1 nated on the basis of a settlement agreement
2 entered into by the Secretary, the complainant,
3 and the person alleged to have committed the
4 violation.

5 “(B) CONTENT OF ORDER.—If, in re-
6 sponse to a complaint filed under paragraph
7 (1), the Secretary determines that a violation of
8 subsection (a) has occurred, the Secretary shall
9 order the person who committed such viola-
10 tion—

11 “(i) to take affirmative action to
12 abate the violation;

13 “(ii) to reinstate the complainant to
14 his or her former position together with
15 compensation (including back pay) and re-
16 store the terms, conditions, and privileges
17 associated with his or her employment; and

18 “(iii) to provide compensatory dam-
19 ages to the complainant.

20 “(C) PENALTY.—If such an order is issued
21 under this paragraph, the Secretary, at the re-
22 quest of the complainant, shall assess against
23 the person against whom the order is issued a
24 sum equal to the aggregate amount of all costs
25 and expenses (including attorneys’ and expert

1 witness fees) reasonably incurred, as deter-
2 mined by the Secretary, by the complainant for,
3 or in connection with, the bringing of the com-
4 plaint upon which the order was issued.

5 “(D) BAD FAITH CLAIM.—If the Secretary
6 finds that a complaint under paragraph (1) is
7 frivolous or has been brought in bad faith, the
8 Secretary may award to the prevailing employer
9 a reasonable attorneys’ fee, not exceeding
10 \$1,000, to be paid by the complainant.

11 “(4) ACTION IN COURT.—

12 “(A) IN GENERAL.—If the Secretary has
13 not issued a final decision within 210 days after
14 the filing of the complaint, or within 90 days
15 after receiving a written determination, the
16 complainant may bring an action at law or eq-
17 uity for de novo review in the appropriate dis-
18 trict court of the United States with jurisdic-
19 tion, which shall have jurisdiction over such an
20 action without regard to the amount in con-
21 troversy, and which action shall, at the request
22 of either party to such action, be tried by the
23 court with a jury. The proceedings shall be gov-
24 erned by the same legal burdens of proof speci-
25 fied in paragraph (2)(C).

1 “(B) RELIEF.—The court shall have juris-
2 diction to grant all relief necessary to make the
3 employee whole, including injunctive relief and
4 compensatory damages, including—

5 “(i) reinstatement with the same se-
6 niority status that the employee would
7 have had, but for the discharge or dis-
8 crimination;

9 “(ii) the amount of back pay, with in-
10 terest; and

11 “(iii) compensation for any special
12 damages sustained as a result of the dis-
13 charge or discrimination, including litiga-
14 tion costs, expert witness fees, and reason-
15 able attorney’s fees.

16 “(5) REVIEW.—

17 “(A) IN GENERAL.—Unless the complain-
18 ant brings an action under paragraph (4), any
19 person adversely affected or aggrieved by a final
20 order issued under paragraph (3) may obtain
21 review of the order in the United States Court
22 of Appeals for the circuit in which the violation,
23 with respect to which the order was issued, al-
24 legedly occurred or the circuit in which the
25 complainant resided on the date of such viola-

1 tion. The petition for review must be filed not
2 later than 60 days after the date of the
3 issuance of the final order of the Secretary. Re-
4 view shall conform to chapter 7 of title 5,
5 United States Code. The commencement of pro-
6 ceedings under this subparagraph shall not, un-
7 less ordered by the court, operate as a stay of
8 the order.

9 “(B) NO JUDICIAL REVIEW.—An order of
10 the Secretary with respect to which review could
11 have been obtained under subparagraph (A)
12 shall not be subject to judicial review in any
13 criminal or other civil proceeding.

14 “(6) FAILURE TO COMPLY WITH ORDER.—
15 Whenever any person has failed to comply with an
16 order issued under paragraph (3), the Secretary may
17 file a civil action in the United States district court
18 for the district in which the violation was found to
19 occur, or in the United States district court for the
20 District of Columbia, to enforce such order. In ac-
21 tions brought under this paragraph, the district
22 courts shall have jurisdiction to grant all appropriate
23 relief including, but not limited to, injunctive relief
24 and compensatory damages.

1 “(7) CIVIL ACTION TO REQUIRE COMPLI-
2 ANCE.—

3 “(A) IN GENERAL.—A person on whose be-
4 half an order was issued under paragraph (3)
5 may commence a civil action against the person
6 to whom such order was issued to require com-
7 pliance with such order. The appropriate
8 United States district court shall have jurisdic-
9 tion, without regard to the amount in con-
10 troversy or the citizenship of the parties, to en-
11 force such order.

12 “(B) AWARD.—The court, in issuing any
13 final order under this paragraph, may award
14 costs of litigation (including reasonable attor-
15 neys’ and expert witness fees) to any party
16 whenever the court determines such award is
17 appropriate.

18 “(c) EFFECT OF SECTION.—

19 “(1) OTHER LAWS.—Nothing in this section
20 preempts or diminishes any other safeguards against
21 discrimination, demotion, discharge, suspension,
22 threats, harassment, reprimand, retaliation, or any
23 other manner of discrimination provided by Federal
24 or State law.

1 “(2) RIGHTS OF EMPLOYEES.—Nothing in this
2 section shall be construed to diminish the rights,
3 privileges, or remedies of any employee under any
4 Federal or State law or under any collective bar-
5 gaining agreement. The rights and remedies in this
6 section may not be waived by any agreement, policy,
7 form, or condition of employment.

8 “(d) ENFORCEMENT.—Any nondiscretionary duty
9 imposed by this section shall be enforceable in a man-
10 damus proceeding brought under section 1361 of title 28,
11 United States Code.

12 “(e) LIMITATION.—Subsection (a) shall not apply
13 with respect to an employee of an entity engaged in the
14 manufacture, processing, packing, transporting, distribu-
15 tion, reception, holding, or importation of food who, acting
16 without direction from such entity (or such entity’s agent),
17 deliberately causes a violation of any requirement relating
18 to any violation or alleged violation of any order, rule, reg-
19 ulation, standard, or ban under this Act.”.

20 **SEC. 403. JURISDICTION; AUTHORITIES.**

21 Nothing in this Act, or an amendment made by this
22 Act, shall be construed to—

23 (1) alter the jurisdiction between the Secretary
24 of Agriculture and the Secretary of Health and
25 Human Services, under applicable statutes, regula-

1 tions, or agreements regarding voluntary inspection
2 of non-amenable species under the Agricultural Mar-
3 keting Act of 1946 (7 U.S.C. 1621 et seq.);

4 (2) alter the jurisdiction between the Alcohol
5 and Tobacco Tax and Trade Bureau and the Sec-
6 retary of Health and Human Services, under appli-
7 cable statutes and regulations;

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

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

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

16 (4) alter or limit the authority of the Secretary
17 of Agriculture under the laws administered by such
18 Secretary, including—

19 (A) the Federal Meat Inspection Act (21
20 U.S.C. 601 et seq.);

21 (B) the Poultry Products Inspection Act
22 (21 U.S.C. 451 et seq.);

23 (C) the Egg Products Inspection Act (21
24 U.S.C. 1031 et seq.);

1 (D) the United States Grain Standards
2 Act (7 U.S.C. 71 et seq.);

3 (E) the Packers and Stockyards Act, 1921
4 (7 U.S.C. 181 et seq.);

5 (F) the United States Warehouse Act (7
6 U.S.C. 241 et seq.);

7 (G) the Agricultural Marketing Act of
8 1946 (7 U.S.C. 1621 et seq.); and

9 (H) the Agricultural Adjustment Act (7
10 U.S.C. 601 et seq.), reenacted with the amend-
11 ments made by the Agricultural Marketing
12 Agreement Act of 1937; or

13 (5) alter, impede, or affect the authority of the
14 Secretary of Homeland Security under the Home-
15 land Security Act of 2002 (6 U.S.C. 101 et seq.) or
16 any other statute, including any authority related to
17 securing the borders of the United States, managing
18 ports of entry, or agricultural import and entry in-
19 spection activities.

20 **SEC. 404. COMPLIANCE WITH INTERNATIONAL AGREE-**
21 **MENTS.**

22 Nothing in this Act (or an amendment made by this
23 Act) shall be construed in a manner inconsistent with the
24 agreement establishing the World Trade Organization or

- 1 any other treaty or international agreement to which the
- 2 United States is a party.