

111<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# S. 510

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## AN ACT

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

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

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

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

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

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

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

**TITLE I—IMPROVING CAPACITY TO PREVENT FOOD SAFETY  
 PROBLEMS**

- Sec. 101. Inspections of records.
- Sec. 102. Registration of food facilities.
- Sec. 103. Hazard analysis and risk-based preventive controls.
- Sec. 104. Performance standards.
- Sec. 105. Standards for produce safety.
- Sec. 106. Protection against intentional adulteration.
- Sec. 107. Authority to collect fees.
- Sec. 108. National agriculture and food defense strategy.
- Sec. 109. Food and Agriculture Coordinating Councils.
- Sec. 110. Building domestic capacity.
- Sec. 111. 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 facili-  
ties, and ports of entry; annual report.
- Sec. 202. Laboratory accreditation for analyses of foods.
- Sec. 203. Integrated consortium of laboratory networks.

- Sec. 204. Enhancing tracking and tracing of food and recordkeeping.
- Sec. 205. Surveillance.
- Sec. 206. Mandatory recall authority.
- Sec. 207. Administrative detention of food.
- Sec. 208. Decontamination and disposal standards and plans.
- Sec. 209. Improving the training of State, local, territorial, and tribal food safety officials.
- Sec. 210. Enhancing food safety.
- Sec. 211. Improving the reportable food registry.

#### TITLE III—IMPROVING THE SAFETY OF IMPORTED FOOD

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

#### TITLE IV—MISCELLANEOUS PROVISIONS

- Sec. 401. Funding for food safety.
- Sec. 402. Employee protections.
- Sec. 403. Jurisdiction; authorities.
- Sec. 404. Compliance with international agreements.
- Sec. 405. Determination of budgetary effects.

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

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

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

7 (1) by striking the heading and all 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-

1 ably believes is likely to be affected in a similar man-  
2 ner, is”;

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

7 (3) by striking the last sentence; and

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

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

1 reasonably believes is likely to be affected in a simi-  
2 lar manner, that are needed to assist the Secretary  
3 in determining whether there is a reasonable prob-  
4 ability that the use of or exposure to the food will  
5 cause serious adverse health consequences or death  
6 to humans or animals.

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

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

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

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

24 (1) in paragraph (2), by—

1 (A) striking “conducts business and” and  
2 inserting “conducts business, the e-mail address  
3 for the contact person of the facility or, in the  
4 case of a foreign facility, the United States  
5 agent for the facility, and”; and

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

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

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

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

1 (b) SUSPENSION OF REGISTRATION.—

2 (1) IN GENERAL.—Section 415 (21 U.S.C.  
3 350d) is amended—

4 (A) in subsection (a)(2), by inserting after  
5 the first sentence the following: “The registra-  
6 tion shall contain an assurance that the Sec-  
7 retary will be permitted to inspect such facility  
8 at the times and in the manner permitted by  
9 this Act.”;

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

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

14 “(b) SUSPENSION OF REGISTRATION.—

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

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

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

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

2           “(2) HEARING ON SUSPENSION.—The Secretary  
3 shall provide the registrant subject to an order  
4 under paragraph (1) with an opportunity for an in-  
5 formal hearing, to be held as soon as possible but  
6 not later than 2 business days after the issuance of  
7 the order or such other time period, as agreed upon  
8 by the Secretary and the registrant, on the actions  
9 required for reinstatement of registration and why  
10 the registration that is subject to suspension should  
11 be reinstated. The Secretary shall reinstate a reg-  
12 istration if the Secretary determines, based on evi-  
13 dence presented, that adequate grounds do not exist  
14 to continue the suspension of the registration.

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

17           “(A) CORRECTIVE ACTION PLAN.—If, after  
18 providing opportunity for an informal hearing  
19 under paragraph (2), the Secretary determines  
20 that the suspension of registration remains nec-  
21 essary, the Secretary shall require the reg-  
22 istrant to submit a corrective action plan to  
23 demonstrate how the registrant plans to correct  
24 the conditions found by the Secretary. The Sec-  
25 retary shall review such plan not later than 14



1           days after the submission of the corrective ac-  
2           tion plan or such other time period as deter-  
3           mined by the Secretary.

4           “(B) VACATING OF ORDER.—Upon a de-  
5           termination by the Secretary that adequate  
6           grounds do not exist to continue the suspension  
7           actions required by the order, or that such ac-  
8           tions should be modified, the Secretary shall  
9           promptly vacate the order and reinstate the reg-  
10          istration of the facility subject to the order or  
11          modify the order, as appropriate.

12          “(4) EFFECT OF SUSPENSION.—If the registra-  
13          tion of a facility is suspended under this subsection,  
14          no person shall import or export food into the  
15          United States from such facility, offer to import or  
16          export food into the United States from such facil-  
17          ity, or otherwise introduce food from such facility  
18          into interstate or intrastate commerce in the United  
19          States.

20          “(5) REGULATIONS.—

21                 “(A) IN GENERAL.—The Secretary shall  
22                 promulgate regulations to implement this sub-  
23                 section. The Secretary may promulgate such  
24                 regulations on an interim final basis.

1           “(B) REGISTRATION REQUIREMENT.—The  
2           Secretary may require that registration under  
3           this section be submitted in an electronic for-  
4           mat. Such requirement may not take effect be-  
5           fore the date that is 5 years after the date of  
6           enactment of the FDA Food Safety Moderniza-  
7           tion Act.

8           “(6) APPLICATION DATE.—Facilities shall be  
9           subject to the requirements of this subsection begin-  
10          ning on the earlier of—

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

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

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

20           (2) SMALL ENTITY COMPLIANCE POLICY  
21           GUIDE.—Not later than 180 days after the issuance  
22           of the regulations promulgated under section  
23           415(b)(5) of the Federal Food, Drug, and Cosmetic  
24           Act (as added by this section), the Secretary shall  
25           issue a small entity compliance policy guide setting

1       forth in plain language the requirements of such  
2       regulations to assist small entities in complying with  
3       registration requirements and other activities re-  
4       quired under such section.

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

9       (c) CLARIFICATION OF INTENT.—

10               (1) RETAIL FOOD ESTABLISHMENT.—The Sec-  
11       retary shall amend the definition of the term “retail  
12       food establishment” in section in 1.227(b)(11) of  
13       title 21, Code of Federal Regulations to clarify that,  
14       in determining the primary function of an establish-  
15       ment or a retail food establishment under such sec-  
16       tion, the sale of food products directly to consumers  
17       by such establishment and the sale of food directly  
18       to consumers by such retail food establishment in-  
19       clude—

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

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

4 (C) the sale and distribution of such food  
5 at any other such direct sales platform as deter-  
6 mined by the Secretary.

7 (2) DEFINITIONS.—For purposes of paragraph  
8 (1)—

9 (A) the term “community supported agri-  
10 culture program” has the same meaning given  
11 the term “community supported agriculture  
12 (CSA) program” in section 249.2 of title 7,  
13 Code of Federal Regulations (or any successor  
14 regulation); and

15 (B) the term “consumer” does not include  
16 a business.

17 (d) CONFORMING AMENDMENTS.—

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

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

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

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

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

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

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

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

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

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

3           “(2) identify and evaluate hazards that may be  
4           intentionally introduced, including by acts of ter-  
5           rorism; and

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

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

11          “(1) hazards identified in the hazard analysis  
12          conducted under subsection (b)(1) will be signifi-  
13          cantly minimized or prevented;

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

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

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

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

6           “(1) appropriate action is taken to reduce the  
7 likelihood of recurrence of the implementation fail-  
8 ure;

9           “(2) all affected food is evaluated for safety;  
10 and

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

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

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

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

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

1           “(4) the preventive controls implemented under  
2           subsection (c) are effectively and significantly mini-  
3           mizing or preventing the occurrence of identified  
4           hazards, including through the use of environmental  
5           and product testing programs and other appropriate  
6           means; and

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

12          “(g) RECORDKEEPING.—The owner, operator, or  
13          agent in charge of a facility shall maintain, for not less  
14          than 2 years, records documenting the monitoring of the  
15          preventive controls implemented under subsection (c), in-  
16          stances of nonconformance material to food safety, the re-  
17          sults of testing and other appropriate means of verification  
18          under subsection (f)(4), instances when corrective actions  
19          were implemented, and the efficacy of preventive controls  
20          and corrective actions.

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



1 under subsection (b) and identifying the preventive con-  
2 trols adopted under subsection (c) to address those haz-  
3 ards. Such written plan, together with the documentation  
4 described in subsection (g), shall be made promptly avail-  
5 able to a duly authorized representative of the Secretary  
6 upon oral or written request.

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

1 biological, chemical, radiological, or other terrorism risk  
2 assessment.

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

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

10 “(A) The Seafood Hazard Analysis Critical  
11 Control Points Program of the Food and Drug  
12 Administration.

13 “(B) The Juice Hazard Analysis Critical  
14 Control Points Program of the Food and Drug  
15 Administration.

16 “(C) The Thermally Processed Low-Acid  
17 Foods Packaged in Hermetically Sealed Con-  
18 tainers standards of the Food and Drug Ad-  
19 ministration (or any successor standards).

20 “(2) APPLICABILITY.—The exemption under  
21 paragraph (1)(C) shall apply only with respect to  
22 microbiological hazards that are regulated under the  
23 standards for Thermally Processed Low-Acid Foods  
24 Packaged in Hermetically Sealed Containers under

1 part 113 of chapter 21, Code of Federal Regulations  
 2 (or any successor regulations).

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

6 “(l) MODIFIED REQUIREMENTS FOR QUALIFIED FA-  
 7 CILITIES.—

8 “(1) QUALIFIED FACILITIES.—

9 “(A) IN GENERAL.—A facility is a quali-  
 10 fied facility for purposes of this subsection if  
 11 the facility meets the conditions under subpara-  
 12 graph (B) or (C).

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

15 “(i) if the facility, including any sub-  
 16 sidiary or affiliate of the facility, is, collec-  
 17 tively, a very small business (as defined in  
 18 the regulations promulgated under sub-  
 19 section (n)); and

20 “(ii) in the case where the facility is  
 21 a subsidiary or affiliate of an entity, if  
 22 such subsidiaries or affiliates, are, collec-  
 23 tively, a very small business (as so de-  
 24 fined).

1                   “(C) LIMITED ANNUAL MONETARY VALUE  
2                   OF SALES.—

3                   “(i) IN GENERAL.—A facility is a  
4                   qualified facility under this subparagraph  
5                   if clause (ii) applies—

6                   “(I) to the facility, including any  
7                   subsidiary or affiliate of the facility,  
8                   collectively; and

9                   “(II) to the subsidiaries or affili-  
10                  ates, collectively, of any entity of  
11                  which the facility is a subsidiary or af-  
12                  filiate.

13                  “(ii) AVERAGE ANNUAL MONETARY  
14                  VALUE.—This clause applies if—

15                  “(I) during the 3-year period pre-  
16                  ceding the applicable calendar year,  
17                  the average annual monetary value of  
18                  the food manufactured, processed,  
19                  packed, or held at such facility (or the  
20                  collective average annual monetary  
21                  value of such food at any subsidiary  
22                  or affiliate, as described in clause (i))  
23                  that is sold directly to qualified end-  
24                  users during such period exceeded the  
25                  average annual monetary value of the

1 food manufactured, processed, packed,  
2 or held at such facility (or the collec-  
3 tive average annual monetary value of  
4 such food at any subsidiary or affil-  
5 iate, as so described) sold by such fa-  
6 cility (or collectively by any such sub-  
7 sidiary or affiliate) to all other pur-  
8 chasers during such period; and

9 “(II) the average annual mone-  
10 tary value of all food sold by such fa-  
11 cility (or the collective average annual  
12 monetary value of such food sold by  
13 any subsidiary or affiliate, as de-  
14 scribed in clause (i)) during such pe-  
15 riod was less than \$500,000, adjusted  
16 for inflation.

17 “(2) EXEMPTION.—A qualified facility—

18 “(A) shall not be subject to the require-  
19 ments under subsections (a) through (i) and  
20 subsection (n) in an applicable calendar year;  
21 and

22 “(B) shall submit to the Secretary—

23 “(i)(I) documentation that dem-  
24 onstrates that the owner, operator, or  
25 agent in charge of the facility has identi-

1           fied potential hazards associated with the  
2           food being produced, is implementing pre-  
3           ventive controls to address the hazards,  
4           and is monitoring the preventive controls  
5           to ensure that such controls are effective;  
6           or

7           “(II) documentation (which may in-  
8           clude licenses, inspection reports, certifi-  
9           cates, permits, credentials, certification by  
10          an appropriate agency (such as a State de-  
11          partment of agriculture), or other evidence  
12          of oversight), as specified by the Secretary,  
13          that the facility is in compliance with  
14          State, local, county, or other applicable  
15          non-Federal food safety law; and

16          “(ii) documentation, as specified by  
17          the Secretary in a guidance document  
18          issued not later than 1 year after the date  
19          of enactment of this section, that the facil-  
20          ity is a qualified facility under paragraph  
21          (1)(B) or (1)(C).

22          “(3) WITHDRAWAL; RULE OF CONSTRUC-  
23          TION.—

24          “(A) IN GENERAL.—In the event of an ac-  
25          tive investigation of a foodborne illness out-

1 break that is directly linked to a qualified facil-  
2 ity subject to an exemption under this sub-  
3 section, or if the Secretary determines that it is  
4 necessary to protect the public health and pre-  
5 vent or mitigate a foodborne illness outbreak  
6 based on conduct or conditions associated with  
7 a qualified facility that are material to the safe-  
8 ty of the food manufactured, processed, packed,  
9 or held at such facility, the Secretary may with-  
10 draw the exemption provided to such facility  
11 under this subsection.

12 “(B) RULE OF CONSTRUCTION.—Nothing  
13 in this subsection shall be construed to expand  
14 or limit the inspection authority of the Sec-  
15 retary.

16 “(4) DEFINITIONS.—In this subsection:

17 “(A) AFFILIATE.—The term ‘affiliate’  
18 means any facility that controls, is controlled  
19 by, or is under common control with another fa-  
20 cility.

21 “(B) QUALIFIED END-USER.—The term  
22 ‘qualified end-user’, with respect to a food,  
23 means—

24 “(i) the consumer of the food; or

1           “(ii) a restaurant or retail food estab-  
2           lishment (as those terms are defined by the  
3           Secretary for purposes of section 415)  
4           that—

5                   “(I) is located—

6                           “(aa) in the same State as  
7                           the qualified facility that sold the  
8                           food to such restaurant or estab-  
9                           lishment; or

10                           “(bb) not more than 275  
11                           miles from such facility; and

12                           “(II) is purchasing the food for  
13                           sale directly to consumers at such res-  
14                           taurant or retail food establishment.

15           “(C) CONSUMER.—For purposes of sub-  
16           paragraph (B), the term ‘consumer’ does not  
17           include a business.

18           “(D) SUBSIDIARY.—The term ‘subsidiary’  
19           means any company which is owned or con-  
20           trolled directly or indirectly by another com-  
21           pany.

22           “(5) STUDY.—

23                   “(A) IN GENERAL.—The Secretary, in con-  
24                   sultation with the Secretary of Agriculture,  
25                   shall conduct a study of the food processing



1 sector regulated by the Secretary to deter-  
2 mine—

3 “(i) the distribution of food produc-  
4 tion by type and size of operation, includ-  
5 ing monetary value of food sold;

6 “(ii) the proportion of food produced  
7 by each type and size of operation;

8 “(iii) the number and types of food  
9 facilities co-located on farms, including the  
10 number and proportion by commodity and  
11 by manufacturing or processing activity;

12 “(iv) the incidence of foodborne illness  
13 originating from each size and type of op-  
14 eration and the type of food facilities for  
15 which no reported or known hazard exists;  
16 and

17 “(v) the effect on foodborne illness  
18 risk associated with commingling, proc-  
19 essing, transporting, and storing food and  
20 raw agricultural commodities, including  
21 differences in risk based on the scale and  
22 duration of such activities.

23 “(B) SIZE.—The results of the study con-  
24 ducted under subparagraph (A) shall include  
25 the information necessary to enable the Sec-

1           retary to define the terms ‘small business’ and  
2           ‘very small business’, for purposes of promul-  
3           gating the regulation under subsection (n). In  
4           defining such terms, the Secretary shall include  
5           consideration of harvestable acres, income, the  
6           number of employees, and the volume of food  
7           harvested.

8           “(C) SUBMISSION OF REPORT.—Not later  
9           than 18 months after the date of enactment the  
10          FDA Food Safety Modernization Act, the Sec-  
11          retary shall submit to Congress a report that  
12          describes the results of the study conducted  
13          under subparagraph (A).

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

20          “(7) NOTIFICATION TO CONSUMERS.—

21                 “(A) IN GENERAL.—A qualified facility  
22                 that is exempt from the requirements under  
23                 subsections (a) through (i) and subsection (n)  
24                 and does not prepare documentation under  
25                 paragraph (2)(B)(i)(I) shall—

1           “(i) with respect to a food for which  
2           a food packaging label is required by the  
3           Secretary under any other provision of this  
4           Act, include prominently and conspicuously  
5           on such label the name and business ad-  
6           dress of the facility where the food was  
7           manufactured or processed; or

8           “(ii) with respect to a food for which  
9           a food packaging label is not required by  
10          the Secretary under any other provisions of  
11          this Act, prominently and conspicuously  
12          display, at the point of purchase, the name  
13          and business address of the facility where  
14          the food was manufactured or processed,  
15          on a label, poster, sign, placard, or docu-  
16          ments delivered contemporaneously with  
17          the food in the normal course of business,  
18          or, in the case of Internet sales, in an elec-  
19          tronic notice.

20          “(B) NO ADDITIONAL LABEL.—Subpara-  
21          graph (A) does not provide authority to the  
22          Secretary to require a label that is in addition  
23          to any label required under any other provision  
24          of this Act.

1       “(m) AUTHORITY WITH RESPECT TO CERTAIN FA-  
2 CILITIES.—The Secretary may, by regulation, exempt or  
3 modify the requirements for compliance under this section  
4 with respect to facilities that are solely engaged in the pro-  
5 duction of food for animals other than man, the storage  
6 of raw agricultural commodities (other than fruits and  
7 vegetables) intended for further distribution or processing,  
8 or the storage of packaged foods that are not exposed to  
9 the environment.

10       “(n) REGULATIONS.—

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

15           “(A) to establish science-based minimum  
16 standards for conducting a hazard analysis,  
17 documenting hazards, implementing preventive  
18 controls, and documenting the implementation  
19 of the preventive controls under this section;  
20 and

21           “(B) to define, for purposes of this section,  
22 the terms ‘small business’ and ‘very small busi-  
23 ness’, taking into consideration the study de-  
24 scribed in subsection (l)(5).

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

7           “(3) CONTENT.—The regulations promulgated  
8           under paragraph (1)(A) shall—

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

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

21                   “(C) acknowledge differences in risk and  
22                   minimize, as appropriate, the number of sepa-  
23                   rate standards that apply to separate foods;  
24                   and

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

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

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

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

23                 “(1) CRITICAL CONTROL POINT.—The term  
24                 ‘critical control point’ means a point, step, or proce-  
25                 dure in a food process at which control can be ap-

1       plied and is essential to prevent or eliminate a food  
2       safety hazard or reduce such hazard to an accept-  
3       able level.

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

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

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

22               “(B) Supervisor, manager, and employee  
23      hygiene training.

24               “(C) An environmental monitoring pro-  
25      gram to verify the effectiveness of pathogen

1 controls in processes where a food is exposed to  
2 a potential contaminant in the environment.

3 “(D) A food allergen control program.

4 “(E) A recall plan.

5 “(F) Current Good Manufacturing Prac-  
6 tices (cGMPs) under part 110 of title 21, Code  
7 of Federal Regulations (or any successor regu-  
8 lations).

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

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

17 (c) RULEMAKING.—

18 (1) PROPOSED RULEMAKING.—

19 (A) IN GENERAL.—Not later than 9  
20 months after the date of enactment of this Act,  
21 the Secretary of Health and Human Services  
22 (referred to in this subsection as the “Sec-  
23 retary”) shall publish a notice of proposed rule-  
24 making in the Federal Register to promulgate  
25 regulations with respect to—



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

8 (ii) activities that constitute on-farm  
9 manufacturing or processing of food that is  
10 not consumed on that farm or on another  
11 farm under common ownership for pur-  
12 poses of such section 415.

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

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

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

7 (ii) specific on-farm manufacturing  
8 and processing activities as such activities  
9 relate to specific foods that are not con-  
10 sumed on that farm or on another farm  
11 under common ownership.

12 (D) AUTHORITY WITH RESPECT TO CER-  
13 TAIN FACILITIES.—

14 (i) IN GENERAL.—In promulgating  
15 the regulations under subparagraph (A),  
16 the Secretary shall consider the results of  
17 the science-based risk analysis conducted  
18 under subparagraph (C), and shall exempt  
19 certain facilities from the requirements in  
20 section 418 of the Federal Food, Drug,  
21 and Cosmetic Act (as added by this sec-  
22 tion), including hazard analysis and pre-  
23 ventive controls, and the mandatory in-  
24 spection frequency in section 421 of such  
25 Act (as added by section 201), or modify

1 the requirements in such sections 418 or  
2 421, as the Secretary determines appro-  
3 priate, if such facilities are engaged only in  
4 specific types of on-farm manufacturing,  
5 processing, packing, or holding activities  
6 that the Secretary determines to be low  
7 risk involving specific foods the Secretary  
8 determines to be low risk.

9 (ii) LIMITATION.—The exemptions or  
10 modifications under clause (i) shall not in-  
11 clude an exemption from the requirement  
12 to register under section 415 of the Fed-  
13 eral Food, Drug, and Cosmetic Act (21  
14 U.S.C. 350d), as amended by this Act, if  
15 applicable, and shall apply only to small  
16 businesses and very small businesses, as  
17 defined in the regulation promulgated  
18 under section 418(n) of the Federal Food,  
19 Drug, and Cosmetic Act (as added under  
20 subsection (a)).

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

1 (A) activities that constitute on-farm pack-  
2 ing or holding of food that is not grown, raised,  
3 or consumed on such farm or another farm  
4 under the same ownership for purposes of sec-  
5 tion 415 of the Federal Food, Drug, and Cos-  
6 metic Act (21 U.S.C. 350d), as amended by  
7 this Act;

8 (B) activities that constitute on-farm man-  
9 ufacturing or processing of food that is not con-  
10 sumed on that farm or on another farm under  
11 common ownership for purposes of such section  
12 415; and

13 (C) the requirements under sections 418  
14 and 421 of the Federal Food, Drug, and Cos-  
15 metic Act, as added by this Act, from which the  
16 Secretary may issue exemptions or modifica-  
17 tions of the requirements for certain types of  
18 facilities.

19 (d) SMALL ENTITY COMPLIANCE POLICY GUIDE.—  
20 Not later than 180 days after the issuance of the regula-  
21 tions promulgated under subsection (n) of section 418 of  
22 the Federal Food, Drug, and Cosmetic Act (as added by  
23 subsection (a)), the Secretary shall issue a small entity  
24 compliance policy guide setting forth in plain language the  
25 requirements of such section 418 and this section to assist

1 small entities in complying with the hazard analysis and  
2 other activities required under such section 418 and this  
3 section.

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

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

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

18 (g) DIETARY SUPPLEMENTS.—Nothing in the  
19 amendments made by this section shall apply to any facil-  
20 ity with regard to the manufacturing, processing, packing,  
21 or holding of a dietary supplement that is in compliance  
22 with the requirements of sections 402(g)(2) and 761 of  
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
24 342(g)(2), 379aa–1).

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

8       (i) EFFECTIVE DATES.—

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

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

14           (A) the amendments made by this section  
15 shall apply to a small business (as defined in  
16 the regulations promulgated under section  
17 418(n) of the Federal Food, Drug, and Cos-  
18 metic Act (as added by this section)) beginning  
19 on the date that is 6 months after the effective  
20 date of such regulations; and

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

1 **SEC. 104. PERFORMANCE STANDARDS.**

2 (a) IN GENERAL.—The Secretary shall, in coordina-  
3 tion with the Secretary of Agriculture, not less frequently  
4 than every 2 years, review and evaluate relevant health  
5 data and other relevant information, including from toxic-  
6 ological and epidemiological studies and analyses, current  
7 Good Manufacturing Practices issued by the Secretary re-  
8 lating to food, and relevant recommendations of relevant  
9 advisory committees, including the Food Advisory Com-  
10 mittee, to determine the most significant foodborne con-  
11 taminants.

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

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

1           (2) shall, where appropriate, differentiate be-  
2           tween food for human consumption and food in-  
3           tended for consumption by animals other than hu-  
4           mans; and

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

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

9           (d) REVIEW.—The Secretary shall periodically review  
10          and revise, as appropriate, the guidance documents, in-  
11          cluding guidance documents regarding action levels, or  
12          regulations promulgated under this section.

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

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

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

18          “(a) PROPOSED RULEMAKING.—

19               “(1) IN GENERAL.—

20                       “(A) RULEMAKING.—Not later than 1 year  
21                       after the date of enactment of the FDA Food  
22                       Safety Modernization Act, the Secretary, in co-  
23                       ordination with the Secretary of Agriculture  
24                       and representatives of State departments of ag-  
25                       riculture (including with regard to the national



1 organic program established under the Organic  
2 Foods Production Act of 1990), and in con-  
3 sultation with the Secretary of Homeland Secu-  
4 rity, shall publish a notice of proposed rule-  
5 making to establish science-based minimum  
6 standards for the safe production and har-  
7 vesting of those types of fruits and vegetables,  
8 including specific mixes or categories of fruits  
9 and vegetables, that are raw agricultural com-  
10 modities for which the Secretary has deter-  
11 mined that such standards minimize the risk of  
12 serious adverse health consequences or death.

13 “(B) DETERMINATION BY SECRETARY.—

14 With respect to small businesses and very small  
15 businesses (as such terms are defined in the  
16 regulation promulgated under subparagraph  
17 (A)) that produce and harvest those types of  
18 fruits and vegetables that are raw agricultural  
19 commodities that the Secretary has determined  
20 are low risk and do not present a risk of serious  
21 adverse health consequences or death, the Sec-  
22 retary may determine not to include production  
23 and harvesting of such fruits and vegetables in  
24 such rulemaking, or may modify the applicable

1 requirements of regulations promulgated pursu-  
2 ant to this section.

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

9 “(3) CONTENT.—The proposed rulemaking  
10 under paragraph (1) shall—

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

19 “(B) include, with respect to growing, har-  
20 vesting, sorting, packing, and storage oper-  
21 ations, science-based minimum standards re-  
22 lated to soil amendments, hygiene, packaging,  
23 temperature controls, animals in the growing  
24 area, and water;

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

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

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

22          “(F) define, for purposes of this section,  
23          the terms ‘small business’ and ‘very small busi-  
24          ness’

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 in the regulation promulgated under  
9           subsection (a)(1)) after the date that is 1 year  
10          after the effective date of the final regulation  
11          under paragraph (1); and

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

18          “(c) CRITERIA.—

19          “(1) IN GENERAL.—The regulations adopted  
20          under subsection (b) shall—

21                 “(A) set forth those procedures, processes,  
22                 and practices that the Secretary determines to  
23                 minimize the risk of serious adverse health con-  
24                 sequences or death, including procedures, proc-  
25                 esses, and practices that the Secretary deter-

1 mines to be reasonably necessary to prevent the  
2 introduction of known or reasonably foreseeable  
3 biological, chemical, and physical hazards, in-  
4 cluding hazards that occur naturally, may be  
5 unintentionally introduced, or may be inten-  
6 tionally introduced, including by acts of ter-  
7 rorism, into fruits and vegetables, including  
8 specific mixes or categories of fruits and vegeta-  
9 bles, that are raw agricultural commodities and  
10 to provide reasonable assurances that the  
11 produce is not adulterated under section 402;

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

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

24 “(D) acknowledge differences in risk and  
25 minimize, as appropriate, the number of sepa-

1 rate standards that apply to separate foods;  
2 and

3 “(E) not require a business to hire a con-  
4 sultant or other third party to identify, imple-  
5 ment, certify, compliance with these procedures,  
6 processes, and practices, except in the case of  
7 negotiated enforcement resolutions that may re-  
8 quire such a consultant or third party; and

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

23 “(2) VARIANCES.—

24 “(A) REQUESTS FOR VARIANCES.—A State  
25 or foreign country from which food is imported

1 into the United States may in writing request  
2 a variance from the Secretary. Such request  
3 shall describe the variance requested and  
4 present information demonstrating that the  
5 variance does not increase the likelihood that  
6 the food for which the variance is requested will  
7 be adulterated under section 402, and that the  
8 variance provides the same level of public health  
9 protection as the requirements of the regula-  
10 tions adopted under subsection (b). The Sec-  
11 retary shall review such requests in a reason-  
12 able timeframe.

13 “(B) APPROVAL OF VARIANCES.—The Sec-  
14 retary may approve a variance in whole or in  
15 part, as appropriate, and may specify the scope  
16 of applicability of a variance to other similarly  
17 situated persons.

18 “(C) DENIAL OF VARIANCES.—The Sec-  
19 retary may deny a variance request if the Sec-  
20 retary determines that such variance is not rea-  
21 sonably likely to ensure that the food is not  
22 adulterated under section 402 and is not rea-  
23 sonably likely to provide the same level of public  
24 health protection as the requirements of the  
25 regulation adopted under subsection (b). The



1 Secretary shall notify the person requesting  
2 such variance of the reasons for the denial.

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

13 “(d) ENFORCEMENT.—The Secretary may coordinate  
14 with the Secretary of Agriculture and, as appropriate,  
15 shall contract and coordinate with the agency or depart-  
16 ment designated by the Governor of each State to perform  
17 activities to ensure compliance with this section.

18 “(e) GUIDANCE.—

19 “(1) IN GENERAL.—Not later than 1 year after  
20 the date of enactment of the FDA Food Safety Mod-  
21 ernization Act, the Secretary shall publish, after  
22 consultation with the Secretary of Agriculture, rep-  
23 resentatives of State departments of agriculture,  
24 farmer representatives, and various types of entities  
25 engaged in the production and harvesting or import-

1 ing of fruits and vegetables that are raw agricultural  
2 commodities, including small businesses, updated  
3 good agricultural practices and guidance for the safe  
4 production and harvesting of specific types of fresh  
5 produce under this section.

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

17 “(3) PAPERWORK REDUCTION.—The Secretary  
18 shall ensure that any updated guidance under this  
19 section will—

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

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

4           “(f) EXEMPTION FOR DIRECT FARM MARKETING.—

5           “(1) IN GENERAL.—A farm shall be exempt  
6           from the requirements under this section in a cal-  
7           endar year if—

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

14          “(B) the average annual monetary value of  
15          all food sold during such period was less than  
16          \$500,000, adjusted for inflation.

17          “(2) NOTIFICATION TO CONSUMERS.—

18          “(A) IN GENERAL.—A farm that is exempt  
19          from the requirements under this section  
20          shall—

21                 “(i) with respect to a food for which  
22                 a food packaging label is required by the  
23                 Secretary under any other provision of this  
24                 Act, include prominently and conspicuously  
25                 on such label the name and business ad-

1 dress of the farm where the produce was  
2 grown; or

3 “(ii) with respect to a food for which  
4 a food packaging label is not required by  
5 the Secretary under any other provision of  
6 this Act, prominently and conspicuously  
7 display, at the point of purchase, the name  
8 and business address of the farm where  
9 the produce was grown, on a label, poster,  
10 sign, placard, or documents delivered con-  
11 temporaneously with the food in the nor-  
12 mal course of business, or, in the case of  
13 Internet sales, in an electronic notice.

14 “(B) NO ADDITIONAL LABEL.—Subpara-  
15 graph (A) does not provide authority to the  
16 Secretary to require a label that is in addition  
17 to any label required under any other provision  
18 of this Act.

19 “(3) WITHDRAWAL; RULE OF CONSTRUC-  
20 TION.—

21 “(A) IN GENERAL.—In the event of an ac-  
22 tive investigation of a foodborne illness out-  
23 break that is directly linked to a farm subject  
24 to an exemption under this subsection, or if the  
25 Secretary determines that it is necessary to pro-

1 tect the public health and prevent or mitigate  
2 a foodborne illness outbreak based on conduct  
3 or conditions associated with a farm that are  
4 material to the safety of the food produced or  
5 harvested at such farm, the Secretary may  
6 withdraw the exemption provided to such farm  
7 under this subsection.

8 “(B) RULE OF CONSTRUCTION.—Nothing  
9 in this subsection shall be construed to expand  
10 or limit the inspection authority of the Sec-  
11 retary.

12 “(4) DEFINITIONS.—

13 “(A) QUALIFIED END-USER.—In this sub-  
14 section, the term ‘qualified end-user’, with re-  
15 spect to a food means—

16 “(i) the consumer of the food; or

17 “(ii) a restaurant or retail food estab-  
18 lishment (as those terms are defined by the  
19 Secretary for purposes of section 415) that  
20 is located—

21 “(I) in the same State as the  
22 farm that produced the food; or

23 “(II) not more than 275 miles  
24 from such farm.

1           “(B) CONSUMER.—For purposes of sub-  
2           paragraph (A), the term ‘consumer’ does not  
3           include a business.

4           “(5) NO PREEMPTION.—Nothing in this sub-  
5           section preempts State, local, county, or other non-  
6           Federal law regarding the safe production, har-  
7           vesting, holding, transportation, and sale of fresh  
8           fruits and vegetables. Compliance with this sub-  
9           section shall not relieve any person from liability at  
10          common law or under State statutory law.

11          “(6) LIMITATION OF EFFECT.—Nothing in this  
12          subsection shall prevent the Secretary from exer-  
13          cising any authority granted in the other sections of  
14          this Act.

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

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

21          (b) SMALL ENTITY COMPLIANCE POLICY GUIDE.—  
22          Not later than 180 days after the issuance of regulations  
23          under section 419 of the Federal Food, Drug, and Cos-  
24          metic Act (as added by subsection (a)), the Secretary of  
25          Health and Human Services shall issue a small entity

1 compliance policy guide setting forth in plain language the  
2 requirements of such section 419 and to assist small enti-  
3 ties in complying with standards for safe production and  
4 harvesting and other activities required under such sec-  
5 tion.

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

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

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

21 **SEC. 106. PROTECTION AGAINST INTENTIONAL ADULTERA-**  
22 **TION.**

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

1 **“SEC. 420. PROTECTION AGAINST INTENTIONAL ADULTERA-**  
2 **TION.**

3 “(a) DETERMINATIONS.—

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

5 “(A) conduct a vulnerability assessment of  
6 the food system, including by consideration of  
7 the Department of Homeland Security biological,  
8 chemical, radiological, or other terrorism  
9 risk assessments;

10 “(B) consider the best available under-  
11 standing of uncertainties, risks, costs, and ben-  
12 efits associated with guarding against inten-  
13 tional adulteration of food at vulnerable points;  
14 and

15 “(C) determine the types of science-based  
16 mitigation strategies or measures that are nec-  
17 essary to protect against the intentional adul-  
18 teration of food.

19 “(2) LIMITED DISTRIBUTION.—In the interest  
20 of national security, the Secretary, in consultation  
21 with the Secretary of Homeland Security, may deter-  
22 mine the time, manner, and form in which deter-  
23 minations made under paragraph (1) are made pub-  
24 licly available.

25 “(b) REGULATIONS.—Not later than 18 months after  
26 the date of enactment of the FDA Food Safety Moderniza-



1 tion Act, the Secretary, in coordination with the Secretary  
2 of Homeland Security and in consultation with the Sec-  
3 retary of Agriculture, shall promulgate regulations to pro-  
4 tect against the intentional adulteration of food subject  
5 to this Act. Such regulations shall—

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

10 “(2) specify appropriate science-based mitiga-  
11 tion strategies or measures to prepare and protect  
12 the food supply chain at specific vulnerable points,  
13 as appropriate.

14 “(c) **APPLICABILITY.**—Regulations promulgated  
15 under subsection (b) shall apply only to food for which  
16 there is a high risk of intentional contamination, as deter-  
17 mined by the Secretary, in consultation with the Secretary  
18 of Homeland Security, under subsection (a), that could  
19 cause serious adverse health consequences or death to hu-  
20 mans or animals and shall include those foods—

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

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

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

5           “(e) DEFINITION.—For purposes of this section, the  
6 term ‘farm’ has the meaning given that term in section  
7 1.227 of title 21, Code of Federal Regulations (or any suc-  
8 cessor regulation).”.

9           (b) GUIDANCE DOCUMENTS.—

10           (1) IN GENERAL.—Not later than 1 year after  
11 the date of enactment of this Act, the Secretary of  
12 Health and Human Services, in consultation with  
13 the Secretary of Homeland Security and the Sec-  
14 retary of Agriculture, shall issue guidance docu-  
15 ments related to protection against the intentional  
16 adulteration of food, including mitigation strategies  
17 or measures to guard against such adulteration as  
18 required under section 420 of the Federal Food,  
19 Drug, and Cosmetic Act, as added by subsection (a).

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

22           (A) include a model assessment for a per-  
23 son to use under subsection (b)(1) of section  
24 420 of the Federal Food, Drug, and Cosmetic  
25 Act, as added by subsection (a);

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

4 (C) specify situations in which the exam-  
5 ples of mitigation strategies or measures de-  
6 scribed in subsection (b)(2) of such section are  
7 appropriate.

8 (3) LIMITED DISTRIBUTION.—In the interest of  
9 national security, the Secretary of Health and  
10 Human Services, in consultation with the Secretary  
11 of Homeland Security, may determine the time,  
12 manner, and form in which the guidance documents  
13 issued under paragraph (1) are made public, includ-  
14 ing by releasing such documents to targeted audi-  
15 ences.

16 (c) PERIODIC REVIEW.—The Secretary of Health and  
17 Human Services shall periodically review and, as appro-  
18 priate, update the regulations under section 420(b) of the  
19 Federal Food, Drug, and Cosmetic Act, as added by sub-  
20 section (a), and the guidance documents under subsection  
21 (b).

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

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

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

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

6 **“PART 6—FEES RELATED TO FOOD**

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

8 “(a) IN GENERAL.—

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

13 “(A) the responsible party for each domes-  
14 tic facility (as defined in section 415(b)) and  
15 the United States agent for each foreign facility  
16 subject to a reinspection in such fiscal year, to  
17 cover reinspection-related costs for such year;

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

1           “(C) each importer participating in the  
2 voluntary qualified importer program under sec-  
3 tion 806 in such year, to cover the administra-  
4 tive costs of such program for such year; and

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

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

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

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

21           “(ii) with respect to importers, 1 or  
22 more examinations conducted under sec-  
23 tion 801 subsequent to an examination  
24 conducted under such provision which  
25 identified noncompliance materially related

1 to a food safety requirement of this Act,  
2 specifically to determine whether compli-  
3 ance has been achieved to the Secretary's  
4 satisfaction;

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

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

10 “(ii) assessing and collecting reinspec-  
11 tion fees under this section; and

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

14 “(b) ESTABLISHMENT OF FEES.—

15 “(1) IN GENERAL.—Subject to subsections (c)  
16 and (d), the Secretary shall establish the fees to be  
17 collected under this section for each fiscal year speci-  
18 fied in subsection (a)(1), based on the methodology  
19 described under paragraph (2), and shall publish  
20 such fees in a Federal Register notice not later than  
21 60 days before the start of each such year.

22 “(2) FEE METHODOLOGY.—

23 “(A) FEES.—Fees amounts established for  
24 collection—

1           “(i) under subparagraph (A) of sub-  
2           section (a)(1) for a fiscal year shall be  
3           based on the Secretary’s estimate of 100  
4           percent of the costs of the reinspection-re-  
5           lated activities (including by type or level  
6           of reinspection activity, as the Secretary  
7           determines applicable) described in such  
8           subparagraph (A) for such year;

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

15          “(iii) under subparagraph (C) of sub-  
16          section (a)(1) for a fiscal year shall be  
17          based on the Secretary’s estimate of 100  
18          percent of the costs of the activities de-  
19          scribed in such subparagraph (C) for such  
20          year; and

21          “(iv) under subparagraph (D) of sub-  
22          section (a)(1) for a fiscal year shall be  
23          based on the Secretary’s estimate of 100  
24          percent of the costs of the activities de-

1           scribed in such subparagraph (D) for such  
2           year.

3           “(B) OTHER CONSIDERATIONS.—

4                 “(i) VOLUNTARY QUALIFIED IM-  
5           PORTER PROGRAM.—

6                         “(I) PARTICIPATION.—In estab-  
7                         lishing the fee amounts under sub-  
8                         paragraph (A)(iii) for a fiscal year,  
9                         the Secretary shall provide for the  
10                        number of importers who have sub-  
11                        mitted to the Secretary a notice under  
12                        section 806(c) informing the Sec-  
13                        retary of the intent of such importer  
14                        to participate in the program under  
15                        section 806 in such fiscal year.

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



1           “(ii) CREDITING OF FEES.—In estab-  
2           lishing the fee amounts under subpara-  
3           graph (A) for a fiscal year, the Secretary  
4           shall provide for the crediting of fees from  
5           the previous year to the next year if the  
6           Secretary overestimated the amount of fees  
7           needed to carry out such activities, and  
8           consider the need to account for any ad-  
9           justment of fees and such other factors as  
10          the Secretary determines appropriate.

11          “(iii) PUBLISHED GUIDELINES.—Not  
12          later than 180 days after the date of en-  
13          actment of the FDA Food Safety Mod-  
14          ernization Act, the Secretary shall publish  
15          in the Federal Register a proposed set of  
16          guidelines in consideration of the burden of  
17          fee amounts on small business. Such con-  
18          sideration may include reduced fee  
19          amounts for small businesses. The Sec-  
20          retary shall provide for a period of public  
21          comment on such guidelines. The Secretary  
22          shall adjust the fee schedule for small busi-  
23          nesses subject to such fees only through  
24          notice and comment rulemaking.

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

6           “(c) LIMITATIONS.—

7           “(1) IN GENERAL.—Fees under subsection (a)  
8 shall be refunded for a fiscal year beginning after  
9 fiscal year 2010 unless the amount of the total ap-  
10 propriations for food safety activities at the Food  
11 and Drug Administration for such fiscal year (ex-  
12 cluding the amount of fees appropriated for such fis-  
13 cal year) is equal to or greater than the amount of  
14 appropriations for food safety activities at the Food  
15 and Drug Administration for fiscal year 2009 (ex-  
16 cluding the amount of fees appropriated for such fis-  
17 cal year), multiplied by the adjustment factor under  
18 paragraph (3).

19           “(2) AUTHORITY.—If—

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

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

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

5 “(3) ADJUSTMENT FACTOR.—

6 “(A) IN GENERAL.—The adjustment factor  
7 described in paragraph (1) shall be the total  
8 percentage change that occurred in the Con-  
9 sumer Price Index for all urban consumers (all  
10 items; United States city average) for the 12-  
11 month period ending June 30 preceding the fis-  
12 cal year, but in no case shall such adjustment  
13 factor be negative.

14 “(B) COMPOUNDED BASIS.—The adjust-  
15 ment under subparagraph (A) made each fiscal  
16 year shall be added on a compounded basis to  
17 the sum of all adjustments made each fiscal  
18 year after fiscal year 2009.

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

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

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

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

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

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

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

3 “(e) COLLECTION OF FEES.—

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

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

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

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

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

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

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

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

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

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

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

6 **SEC. 108. NATIONAL AGRICULTURE AND FOOD DEFENSE**  
7           **STRATEGY.**

8           (a) DEVELOPMENT AND SUBMISSION OF STRAT-  
9 EGY.—

10           (1) IN GENERAL.—Not later than 1 year after  
11           the date of enactment of this Act, the Secretary of  
12           Health and Human Services and the Secretary of  
13           Agriculture, in coordination with the Secretary of  
14           Homeland Security, shall prepare and transmit to  
15           the relevant committees of Congress, and make pub-  
16           licly available on the Internet Web sites of the De-  
17           partment of Health and Human Services and the  
18           Department of Agriculture, the National Agriculture  
19           and Food Defense Strategy.

20           (2) IMPLEMENTATION PLAN.—The strategy  
21           shall include an implementation plan for use by the  
22           Secretaries described under paragraph (1) in car-  
23           rying out the strategy.

24           (3) RESEARCH.—The strategy shall include a  
25           coordinated research agenda for use by the Secre-

1 taries described under paragraph (1) in conducting  
2 research to support the goals and activities described  
3 in paragraphs (1) and (2) of subsection (b).

4 (4) REVISIONS.—Not later than 4 years after  
5 the date on which the strategy is submitted to the  
6 relevant committees of Congress under paragraph  
7 (1), and not less frequently than every 4 years there-  
8 after, the Secretary of Health and Human Services  
9 and the Secretary of Agriculture, in coordination  
10 with the Secretary of Homeland Security, shall re-  
11 vise and submit to the relevant committees of Con-  
12 gress the strategy.

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

16 (A) the National Incident Management  
17 System;

18 (B) the National Response Framework;

19 (C) the National Infrastructure Protection  
20 Plan;

21 (D) the National Preparedness Goals; and

22 (E) other relevant national strategies.

23 (b) COMPONENTS.—

24 (1) IN GENERAL.—The strategy shall include a  
25 description of the process to be used by the Depart-



1       ment of Health and Human Services, the Depart-  
2       ment of Agriculture, and the Department of Home-  
3       land Security—

4               (A) to achieve each goal described in para-  
5               graph (2); and

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

10       (2) GOALS.—The strategy shall include a de-  
11       scription of the process to be used by the Depart-  
12       ment of Health and Human Services, the Depart-  
13       ment of Agriculture, and the Department of Home-  
14       land Security to achieve the following goals:

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

18                       (i) conducting vulnerability assess-  
19                       ments of the agriculture and food system;

20                       (ii) mitigating vulnerabilities of the  
21                       system;

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

1 (iv) developing and conducting exer-  
2 cises to test decontamination and disposal  
3 plans;

4 (v) developing modeling tools to im-  
5 prove event consequence assessment and  
6 decision support; and

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

10 (B) DETECTION GOAL.—Improve agri-  
11 culture and food system detection capabilities  
12 by—

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

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

17 (C) EMERGENCY RESPONSE GOAL.—En-  
18 sure an efficient response to agriculture and  
19 food emergencies by—

20 (i) immediately investigating animal  
21 disease outbreaks and suspected food con-  
22 tamination;

23 (ii) preventing additional human ill-  
24 nesses;

1 (iii) organizing, training, and equip-  
2 ping animal, plant, and food emergency re-  
3 sponse teams of—

4 (I) the Federal Government; and

5 (II) State, local, and tribal gov-  
6 ernments;

7 (iv) designing, developing, and evalu-  
8 ating training and exercises carried out  
9 under agriculture and food defense plans;  
10 and

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

13 (I) the Federal Government;

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

16 (III) the private sector.

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

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

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

4 (iii) rapidly removing, and effectively  
5 disposing of—

6 (I) contaminated agriculture and  
7 food products; and

8 (II) infected plants and animals;  
9 and

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

13 (3) EVALUATION.—The Secretary, in coordina-  
14 tion with the Secretary of Agriculture and the Sec-  
15 retary of Homeland Security, shall—

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

19 (B) report on the progress measured in  
20 subparagraph (A) as part of the National Agri-  
21 culture and Food Defense strategy described in  
22 subsection (a)(1).

23 (c) LIMITED DISTRIBUTION.—In the interest of na-  
24 tional security, the Secretary of Health and Human Serv-  
25 ices and the Secretary of Agriculture, in coordination with

1 the Secretary of Homeland Security, may determine the  
2 manner and format in which the National Agriculture and  
3 Food Defense strategy established under this section is  
4 made publicly available on the Internet Web sites of the  
5 Department of Health and Human Services, the Depart-  
6 ment of Homeland Security, and the Department of Agri-  
7 culture, as described in subsection (a)(1).

8 **SEC. 109. FOOD AND AGRICULTURE COORDINATING COUN-**  
9 **CILS.**

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

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

24 (2) providing for the regular and timely inter-  
25 change of information between each council relating

1 to the security of the agriculture and food system  
2 (including intelligence information);

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

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

10 (A) animal or plant disease outbreaks;

11 (B) food contamination; and

12 (C) natural disasters affecting agriculture  
13 and food.

14 **SEC. 110. BUILDING DOMESTIC CAPACITY.**

15 (a) IN GENERAL.—

16 (1) INITIAL REPORT.—The Secretary, in coordi-  
17 nation with the Secretary of Agriculture and the  
18 Secretary of Homeland Security, shall, not later  
19 than 2 years after the date of enactment of this Act,  
20 submit to Congress a comprehensive report that  
21 identifies programs and practices that are intended  
22 to promote the safety and supply chain security of  
23 food and to prevent outbreaks of foodborne illness  
24 and other food-related hazards that can be ad-

1 dressed through preventive activities. Such report  
2 shall include a description of the following:

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

5 (B) Outreach to food industry sectors, in-  
6 cluding through the Food and Agriculture Co-  
7 ordinating Councils referred to in section 109,  
8 to identify potential sources of emerging threats  
9 to the safety and security of the food supply  
10 and preventive strategies to address those  
11 threats.

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

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

20 (E) Surveillance systems and laboratory  
21 networks to rapidly detect and respond to  
22 foodborne illness outbreaks and other food-re-  
23 lated hazards, including how such systems and  
24 networks are integrated.

1           (F) Outreach, education, and training pro-  
2           vided to States and local governments to build  
3           State and local food safety and food defense ca-  
4           pabilities, including progress implementing  
5           strategies developed under sections 108 and  
6           205.

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

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

15          (I) Specific efforts taken pursuant to the  
16          agreements authorized under section 421(c) of  
17          the Federal Food, Drug, and Cosmetic Act (as  
18          added by section 201), together with, as nec-  
19          essary, a description of any additional authori-  
20          ties necessary to improve seafood safety.

21          (2) BIENNIAL REPORTS.—On a biennial basis  
22          following the submission of the report under para-  
23          graph (1), the Secretary shall submit to Congress a  
24          report that—



1 (A) reviews previous food safety programs  
2 and practices;

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

5 (C) identifies future programs and prac-  
6 tices; and

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

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

20 (c) CAPABILITY FOR LABORATORY ANALYSES; RE-  
21 SEARCH.—The report developed under subsection (a)(1)  
22 shall provide a description of methods to increase capacity  
23 to undertake analyses of food samples promptly after col-  
24 lection, to identify new and rapid analytical techniques,  
25 including commercially-available techniques that can be

1 employed at ports of entry and by Food Emergency Re-  
2 sponse Network laboratories, and to provide for well-  
3 equipped and staffed laboratory facilities and progress to-  
4 ward laboratory accreditation under section 422 of the  
5 Federal Food, Drug, and Cosmetic Act (as added by sec-  
6 tion 202).

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

22 (e) AUTOMATED RISK ASSESSMENT.—The report de-  
23 veloped under subsection (a)(1) shall include a description  
24 of progress toward developing and improving an auto-

1 mated risk assessment system for food safety surveillance  
2 and allocation of resources.

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

16 (g) BIENNIAL FOOD SAFETY AND FOOD DEFENSE  
17 RESEARCH PLAN.—The Secretary, the Secretary of Agri-  
18 culture, and the Secretary of Homeland Security shall, on  
19 a biennial basis, submit to Congress a joint food safety  
20 and food defense research plan which may include study-  
21 ing the long-term health effects of foodborne illness. Such  
22 biennial plan shall include a list and description of projects  
23 conducted during the previous 2-year period and the plan  
24 for projects to be conducted during the subsequent 2-year  
25 period.

1 (h) EFFECTIVENESS OF PROGRAMS ADMINISTERED  
2 BY THE DEPARTMENT OF HEALTH AND HUMAN SERV-  
3 ICES.—

4 (1) IN GENERAL.—To determine whether exist-  
5 ing Federal programs administered by the Depart-  
6 ment of Health and Human Services are effective in  
7 achieving the stated goals of such programs, the  
8 Secretary shall, beginning not later than 1 year after  
9 the date of enactment of this Act—

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

14 (B) submit to Congress a report con-  
15 cerning such evaluation.

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

18 (A) include conclusions concerning the rea-  
19 sons that such existing programs have proven  
20 successful or not successful and what factors  
21 contributed to such conclusions;

22 (B) include recommendations for consoli-  
23 dation and elimination to reduce duplication  
24 and inefficiencies in such programs at such De-

1           partment as identified during the evaluation  
2           conduct under this subsection; and

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

6           (i) UNIQUE IDENTIFICATION NUMBERS.—

7                   (1) IN GENERAL.—Not later than 1 year after  
8           the date of enactment of this Act, the Secretary, act-  
9           ing through the Commissioner of Food and Drugs,  
10          shall conduct a study regarding the need for, and  
11          challenges associated with, development and imple-  
12          mentation of a program that requires a unique iden-  
13          tification number for each food facility registered  
14          with the Secretary and, as appropriate, each broker  
15          that imports food into the United States. Such study  
16          shall include an evaluation of the costs associated  
17          with development and implementation of such a sys-  
18          tem, and make recommendations about what new  
19          authorities, if any, would be necessary to develop  
20          and implement such a system.

21                   (2) REPORT.—Not later than 15 months after  
22          the date of enactment of this Act, the Secretary  
23          shall submit to Congress a report that describes the  
24          findings of the study conducted under paragraph (1)

1 and that includes any recommendations determined  
2 appropriate by the Secretary.

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

4 (a) IN GENERAL.—Not later than 18 months after  
5 the date of enactment of this Act, the Secretary shall pro-  
6 mulgate regulations described in section 416(b) of the  
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
8 350e(b)).

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

16 **SEC. 112. FOOD ALLERGY AND ANAPHYLAXIS MANAGE-**  
17 **MENT.**

18 (a) DEFINITIONS.—In this section:

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

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

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

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

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

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

13 (A) kindergartens;

14 (B) elementary schools; and

15 (C) secondary schools.

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

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

20 (1) ESTABLISHMENT.—

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

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

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

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

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

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



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

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

8                   (i) the children are capable of self-ad-  
9 ministering medication; and

10                   (ii) such administration is not prohib-  
11 ited by State law.

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

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

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

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

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

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

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

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

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

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

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

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

22               (2) APPLICATION.—

23                   (A) IN GENERAL.—To be eligible to receive  
24                   a grant under this subsection, a local edu-  
25                   cational agency shall submit an application to

1 the Secretary at such time, in such manner,  
2 and including such information as the Secretary  
3 may reasonably require.

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

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

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

15 (I) how the guidelines will be car-  
16 ried out at individual schools served  
17 by the local educational agency;

18 (II) how the local educational  
19 agency will inform parents and stu-  
20 dents of the guidelines in place;

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

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

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

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

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

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

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

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

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

5           (D) Outreach to parents.

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

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

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

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

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

7           (8) MATCHING FUNDS.—

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

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



1           cluded in determining the amount of such non-  
2           Federal funds.

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

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

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

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

25          (d) VOLUNTARY NATURE OF GUIDELINES.—

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

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

13 **SEC. 113. NEW DIETARY INGREDIENTS.**

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

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

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

20                 “(c) NOTIFICATION.—

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

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

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

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

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

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

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

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

11 (a) IN GENERAL.—Not later than 90 days prior to  
12 the issuance of any guidance, regulation, or suggested  
13 amendment by the Food and Drug Administration to the  
14 National Shellfish Sanitation Program’s Model Ordinance,  
15 or the issuance of any guidance or regulation by the Food  
16 and Drug Administration relating to the Seafood Hazard  
17 Analysis Critical Control Points Program of the Food and  
18 Drug Administration (parts 123 and 1240 of title 21,  
19 Code of Federal Regulations (or any successor regula-  
20 tions), where such guidance, regulation or suggested  
21 amendment relates to post harvest processing for raw oys-  
22 ters, the Secretary shall prepare and submit to the Com-  
23 mittee on Health, Education, Labor, and Pensions of the  
24 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 **MESTIC 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           “(B) DOMESTIC HIGH-RISK FACILITIES.—  
2           The Secretary shall increase the frequency of  
3           inspection of domestic facilities identified under  
4           paragraph (1) as high-risk facilities such that  
5           each such facility is inspected—

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

10                   “(ii) not less often than once every 3  
11                   years thereafter.

12           “(C) DOMESTIC NON-HIGH-RISK FACILI-  
13           TIES.—The Secretary shall ensure that each do-  
14           mestic facility that is not identified under para-  
15           graph (1) as a high-risk facility is inspected—

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

20                   “(ii) not less often than once every 5  
21                   years thereafter.

22           “(D) FOREIGN FACILITIES.—

23                   “(i) YEAR 1.—In the 1-year period  
24                   following the date of enactment of the  
25                   FDA Food Safety Modernization Act, the

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           “(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 independent  
24 private laboratories and laboratories run and oper-  
25 ated by a Federal agency (including the Department

1 of Commerce), State, or locality with a demonstrated  
2 capability to conduct 1 or more sampling and analyt-  
3 ical testing methodologies for food.

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

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

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

24 “(6) MODEL LABORATORY STANDARDS.—The  
25 Secretary shall develop model standards that a lab-

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

8 “(A) methods to ensure that—

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

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

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

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

23 “(B) any other criteria determined appro-  
24 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           ignite 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) on a particular farm (as defined

1           in section 1.227 of chapter 21, Code of Federal  
2           Regulations (or any successor regulation)).

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 423 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 U.S.C.  
16 391 et seq.) is amended by adding at the end the fol-  
17 lowing:

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 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 or 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—

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“(A) that is—

“(i) a State;

“(ii) a locality;

“(iii) a territory;

“(iv) an Indian tribe (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act); or

“(v) a nonprofit food safety training entity that collaborates with 1 or more institutions of higher education; and

“(B) that submits an application to the Secretary at such time, in such manner, and including such information as the Secretary may reasonably require.

“(2) CONTENTS.—Each application submitted under paragraph (1) shall include—

“(A) an assurance that the eligible entity has developed plans to engage in the types of activities described in subsection (a);

“(B) a description of the types of activities to be funded by the grant;

“(C) an itemization of how grant funds received under this section will be expended;

“(D) a description of how grant activities will be monitored; and



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

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

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

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

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

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

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 309) 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.

3 **SEC. 405. DETERMINATION OF BUDGETARY EFFECTS.**

4 The budgetary effects of this Act, for the purpose of  
5 complying with the Statutory Pay-As-You-Go-Act of 2010,  
6 shall be determined by reference to the latest statement  
7 titled “Budgetary Effects of PAYGO Legislation” for this  
8 Act, submitted for printing in the Congressional Record  
9 by the Chairman of the Senate Budget Committee, pro-  
10 vided that such statement has been submitted prior to the  
11 vote on passage.

Passed the Senate November 30, 2010.

Attest:

*Secretary.*





117<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**S. 510**

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**AN ACT**

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