

In the Senate of the United States,

December 19, 2010.

Resolved, That the bill from the House of Representatives (H.R. 2751) entitled “An Act to accelerate motor fuel savings nationwide and provide incentives to registered owners of high polluting automobiles to replace such automobiles with new fuel efficient and less polluting automobiles.”, do pass with the following

AMENDMENTS:

Strike all after the enacting clause and insert the following:

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*

1 *provision of the Federal Food, Drug, and Cosmetic Act (21*
 2 *U.S.C. 301 et seq.).*

3 (c) *TABLE OF CONTENTS.—The table of contents for*
 4 *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 oys-
 ters.*

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. 350c(a))

6 *is amended—*

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

9 *“RECORDS INSPECTION.—*

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

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

18 (3) *by striking the last sentence; and*

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

1 “(2) *USE OF OR EXPOSURE TO FOOD OF CON-*
2 *CERN.—If the Secretary believes that there is a rea-*
3 *sonable probability that the use of or exposure to an*
4 *article of food, and any other article of food that the*
5 *Secretary reasonably believes is likely to be affected in*
6 *a similar manner, will cause serious adverse health*
7 *consequences or death to humans or animals, each*
8 *person (excluding farms and restaurants) who manu-*
9 *factures, processes, packs, distributes, receives, holds,*
10 *or imports such article shall, at the request of an offi-*
11 *cer or employee duly designated by the Secretary, per-*
12 *mit such officer or employee, upon presentation of ap-*
13 *propriate credentials and a written notice to such*
14 *person, at reasonable times and within reasonable*
15 *limits and in a reasonable manner, to have access to*
16 *and copy all records relating to such article and to*
17 *any other article of food that the Secretary reasonably*
18 *believes is likely to be affected in a similar manner,*
19 *that are needed to assist the Secretary in determining*
20 *whether there is a reasonable probability that the use*
21 *of or exposure to the food will cause serious adverse*
22 *health consequences or death to humans or animals.*
23 “(3) *APPLICATION.—The requirement under*
24 *paragraphs (1) and (2) applies to all records relating*
25 *to the manufacture, processing, packing, distribution,*

1 *receipt, holding, or importation of such article main-*
2 *tained by or on behalf of such person in any format*
3 *(including paper and electronic formats) and at any*
4 *location.”.*

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

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

12 **(a) UPDATING OF FOOD CATEGORY REGULATIONS; BI-**
13 **ENNIAL REGISTRATION RENEWAL.**—*Section 415(a) (21*
14 *U.S.C. 350d(a)) is amended—*

15 *(1) in paragraph (2), by—*

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

21 *(B) inserting “, or any other food categories*
22 *as determined appropriate by the Secretary, in-*
23 *cluding by guidance” after “Code of Federal*
24 *Regulations”;*

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

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

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

16 (b) *SUSPENSION OF REGISTRATION.*—

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

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

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

3 (C) by inserting after subsection (a) the fol-
4 lowing:

5 “(b) *SUSPENSION OF REGISTRATION.*—

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

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

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

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

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

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

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

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

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

1 *cility subject to the order or modify the order, as*
2 *appropriate.*

3 “(4) *EFFECT OF SUSPENSION.*—*If the registra-*
4 *tion of a facility is suspended under this subsection,*
5 *no person shall import or export food into the United*
6 *States from such facility, offer to import or export*
7 *food into the United States from such facility, or oth-*
8 *erwise introduce food from such facility into inter-*
9 *state or intrastate commerce in the United States.*

10 “(5) *REGULATIONS.*—

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

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

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

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

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

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

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

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

22 (c) CLARIFICATION OF INTENT.—

23 (1) RETAIL FOOD ESTABLISHMENT.—The Sec-
24 retary shall amend the definition of the term “retail
25 food establishment” in section 1.227(b)(11) of title

1 21, Code of Federal Regulations to clarify that, in de-
2 termining the primary function of an establishment
3 or a retail food establishment under such section, the
4 sale of food products directly to consumers by such es-
5 tablishment and the sale of food directly to consumers
6 by such retail food establishment include—

7 (A) the sale of such food products or food di-
8 rectly to consumers by such establishment at a
9 roadside stand or farmers’ market where such
10 stand or market is located other than where the
11 food was manufactured or processed;

12 (B) the sale and distribution of such food
13 through a community supported agriculture pro-
14 gram; and

15 (C) the sale and distribution of such food at
16 any other such direct sales platform as deter-
17 mined by the Secretary.

18 (2) *DEFINITIONS.*—For purposes of paragraph
19 (1)—

20 (A) the term “community supported agri-
21 culture program” has the same meaning given
22 the term “community supported agriculture
23 (CSA) program” in section 249.2 of title 7, Code
24 of Federal Regulations (or any successor regula-
25 tion); and

1 (B) the term “consumer” does not include a
2 business.

3 (d) *CONFORMING AMENDMENTS.*—

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

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

11 **SEC. 103. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE**
12 **CONTROLS.**

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

15 **“SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVEN-**
16 **TIVE CONTROLS.**

17 “(a) *IN GENERAL.*—The owner, operator, or agent in
18 charge of a facility shall, in accordance with this section,
19 evaluate the hazards that could affect food manufactured,
20 processed, packed, or held by such facility, identify and im-
21 plement preventive controls to significantly minimize or
22 prevent the occurrence of such hazards and provide assur-
23 ances that such food is not adulterated under section 402
24 or misbranded under section 403(w), monitor the perform-

1 *ance of those controls, and maintain records of this moni-*
2 *toring as a matter of routine practice.*

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

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

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

13 “(B) *hazards that occur naturally, or may*
14 *be unintentionally introduced; and*

15 “(2) *identify and evaluate hazards that may be*
16 *intentionally introduced, including by acts of ter-*
17 *rorism; and*

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

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

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

1 “(2) any hazards identified in the hazard anal-
2 *ysis conducted under subsection (b)(2) will be signifi-*
3 *cantly minimized or prevented and addressed, con-*
4 *sistent with section 420, as applicable; and*

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

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

13 “(e) *CORRECTIVE ACTIONS.—The owner, operator, or*
14 *agent in charge of a facility shall establish procedures to*
15 *ensure that, if the preventive controls implemented under*
16 *subsection (c) are not properly implemented or are found*
17 *to be ineffective—*

18 “(1) *appropriate action is taken to reduce the*
19 *likelihood of recurrence of the implementation failure;*

20 “(2) *all affected food is evaluated for safety; and*

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

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

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

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

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

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

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

22 “(g) *RECORDKEEPING.*—*The owner, operator, or agent*
23 *in charge of a facility shall maintain, for not less than 2*
24 *years, records documenting the monitoring of the preventive*
25 *controls implemented under subsection (c), instances of non-*

1 *conformance material to food safety, the results of testing*
2 *and other appropriate means of verification under sub-*
3 *section (f)(4), instances when corrective actions were imple-*
4 *mented, and the efficacy of preventive controls and correc-*
5 *tive actions.*

6 “(h) *WRITTEN PLAN AND DOCUMENTATION.*—*The*
7 *owner, operator, or agent in charge of a facility shall pre-*
8 *pare a written plan that documents and describes the proce-*
9 *dures used by the facility to comply with the requirements*
10 *of this section, including analyzing the hazards under sub-*
11 *section (b) and identifying the preventive controls adopted*
12 *under subsection (c) to address those hazards. Such written*
13 *plan, together with the documentation described in sub-*
14 *section (g), shall be made promptly available to a duly au-*
15 *thorized representative of the Secretary upon oral or written*
16 *request.*

17 “(i) *REQUIREMENT TO REANALYZE.*—*The owner, op-*
18 *erator, or agent in charge of a facility shall conduct a rea-*
19 *nalysis under subsection (b) whenever a significant change*
20 *is made in the activities conducted at a facility operated*
21 *by such owner, operator, or agent if the change creates a*
22 *reasonable potential for a new hazard or a significant in-*
23 *crease in a previously identified hazard or not less fre-*
24 *quently than once every 3 years, whichever is earlier. Such*
25 *reanalysis shall be completed and additional preventive*

1 *controls needed to address the hazard identified, if any,*
2 *shall be implemented before the change in activities at the*
3 *facility is operative. Such owner, operator, or agent shall*
4 *revise the written plan required under subsection (h) if such*
5 *a significant change is made or document the basis for the*
6 *conclusion that no additional or revised preventive controls*
7 *are needed. The Secretary may require a reanalysis under*
8 *this section to respond to new hazards and developments*
9 *in scientific understanding, including, as appropriate, re-*
10 *sults from the Department of Homeland Security biological,*
11 *chemical, radiological, or other terrorism risk assessment.*

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

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

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

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

1 “(C) *The Thermally Processed Low-Acid*
 2 *Foods Packaged in Hermetically Sealed Con-*
 3 *tainers standards of the Food and Drug Admin-*
 4 *istration (or any successor standards).*

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

12 “(k) *EXCEPTION FOR ACTIVITIES OF FACILITIES SUB-*
 13 *JECT TO SECTION 419.—This section shall not apply to ac-*
 14 *tivities of a facility that are subject to section 419.*

15 “(l) *MODIFIED REQUIREMENTS FOR QUALIFIED FA-*
 16 *CILITIES.—*

17 “(1) *QUALIFIED FACILITIES.—*

18 “(A) *IN GENERAL.—A facility is a qualified*
 19 *facility for purposes of this subsection if the fa-*
 20 *cility meets the conditions under subparagraph*
 21 *(B) or (C).*

22 “(B) *VERY SMALL BUSINESS.—A facility is*
 23 *a qualified facility under this subparagraph—*

24 “(i) *if the facility, including any sub-*
 25 *sidary or affiliate of the facility, is, collec-*

1 *tively, a very small business (as defined in*
 2 *the regulations promulgated under sub-*
 3 *section (n)); and*

4 *“(ii) in the case where the facility is a*
 5 *subsidiary or affiliate of an entity, if such*
 6 *subsidiaries or affiliates, are, collectively, a*
 7 *very small business (as so defined).*

8 *“(C) LIMITED ANNUAL MONETARY VALUE OF*
 9 *SALES.—*

10 *“(i) IN GENERAL.—A facility is a*
 11 *qualified facility under this subparagraph*
 12 *if clause (ii) applies—*

13 *“(I) to the facility, including any*
 14 *subsidiary or affiliate of the facility,*
 15 *collectively; and*

16 *“(II) to the subsidiaries or affili-*
 17 *ates, collectively, of any entity of which*
 18 *the facility is a subsidiary or affiliate.*

19 *“(ii) AVERAGE ANNUAL MONETARY*
 20 *VALUE.—This clause applies if—*

21 *“(I) during the 3-year period pre-*
 22 *ceding the applicable calendar year,*
 23 *the average annual monetary value of*
 24 *the food manufactured, processed,*
 25 *packed, or held at such facility (or the*

1 *collective average annual monetary*
2 *value of such food at any subsidiary or*
3 *affiliate, as described in clause (i))*
4 *that is sold directly to qualified end-*
5 *users during such period exceeded the*
6 *average annual monetary value of the*
7 *food manufactured, processed, packed,*
8 *or held at such facility (or the collec-*
9 *tive average annual monetary value of*
10 *such food at any subsidiary or affil-*
11 *iate, as so described) sold by such facil-*
12 *ity (or collectively by any such sub-*
13 *subsidiary or affiliate) to all other pur-*
14 *chasers during such period; and*

15 “(II) *the average annual mone-*
16 *tary value of all food sold by such fa-*
17 *cility (or the collective average annual*
18 *monetary value of such food sold by*
19 *any subsidiary or affiliate, as de-*
20 *scribed in clause (i)) during such pe-*
21 *riod was less than \$500,000, adjusted*
22 *for inflation.*

23 “(2) *EXEMPTION.—A qualified facility—*

1 “(A) shall not be subject to the requirements
2 under subsections (a) through (i) and subsection
3 (n) in an applicable calendar year; and

4 “(B) shall submit to the Secretary—

5 “(i)(I) documentation that dem-
6 onstrates that the owner, operator, or agent
7 in charge of the facility has identified po-
8 tential hazards associated with the food
9 being produced, is implementing preventive
10 controls to address the hazards, and is mon-
11 itoring the preventive controls to ensure
12 that such controls are effective; or

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

22 “(ii) documentation, as specified by the
23 Secretary in a guidance document issued
24 not later than 1 year after the date of enact-
25 ment of this section, that the facility is a

1 *qualified facility under paragraph (1)(B) or*
2 *(1)(C).*

3 “(3) *WITHDRAWAL; RULE OF CONSTRUCTION.*—

4 “(A) *IN GENERAL.*—*In the event of an ac-*
5 *tive investigation of a foodborne illness outbreak*
6 *that is directly linked to a qualified facility sub-*
7 *ject to an exemption under this subsection, or if*
8 *the Secretary determines that it is necessary to*
9 *protect the public health and prevent or mitigate*
10 *a foodborne illness outbreak based on conduct or*
11 *conditions associated with a qualified facility*
12 *that are material to the safety of the food manu-*
13 *factured, processed, packed, or held at such facil-*
14 *ity, the Secretary may withdraw the exemption*
15 *provided to such facility under this subsection.*

16 “(B) *RULE OF CONSTRUCTION.*—*Nothing in*
17 *this subsection shall be construed to expand or*
18 *limit the inspection authority of the Secretary.*

19 “(4) *DEFINITIONS.*—*In this subsection:*

20 “(A) *AFFILIATE.*—*The term ‘affiliate’*
21 *means any facility that controls, is controlled by,*
22 *or is under common control with another facil-*
23 *ity.*

1 “(B) *QUALIFIED END-USER.*—*The term*
2 *‘qualified end-user’, with respect to a food,*
3 *means—*

4 “(i) *the consumer of the food; or*

5 “(ii) *a restaurant or retail food estab-*
6 *lishment (as those terms are defined by the*
7 *Secretary for purposes of section 415)*
8 *that—*

9 “(I) *is located—*

10 “(aa) *in the same State as*
11 *the qualified facility that sold the*
12 *food to such restaurant or estab-*
13 *lishment; or*

14 “(bb) *not more than 275*
15 *miles from such facility; and*

16 “(II) *is purchasing the food for*
17 *sale directly to consumers at such res-*
18 *taurant or retail food establishment.*

19 “(C) *CONSUMER.*—*For purposes of subpara-*
20 *graph (B), the term ‘consumer’ does not include*
21 *a business.*

22 “(D) *SUBSIDIARY.*—*The term ‘subsidiary’*
23 *means any company which is owned or con-*
24 *trolled directly or indirectly by another com-*
25 *pany.*

1 “(5) *STUDY.*—

2 “(A) *IN GENERAL.*—*The Secretary, in con-*
3 *sultation with the Secretary of Agriculture, shall*
4 *conduct a study of the food processing sector reg-*
5 *ulated by the Secretary to determine—*

6 “(i) *the distribution of food production*
7 *by type and size of operation, including*
8 *monetary value of food sold;*

9 “(ii) *the proportion of food produced*
10 *by each type and size of operation;*

11 “(iii) *the number and types of food fa-*
12 *cilities co-located on farms, including the*
13 *number and proportion by commodity and*
14 *by manufacturing or processing activity;*

15 “(iv) *the incidence of foodborne illness*
16 *originating from each size and type of oper-*
17 *ation and the type of food facilities for*
18 *which no reported or known hazard exists;*
19 *and*

20 “(v) *the effect on foodborne illness risk*
21 *associated with commingling, processing,*
22 *transporting, and storing food and raw ag-*
23 *ricultural commodities, including dif-*
24 *ferences in risk based on the scale and dura-*
25 *tion of such activities.*

1 “(B) *SIZE.*—*The results of the study con-*
2 *ducted under subparagraph (A) shall include the*
3 *information necessary to enable the Secretary to*
4 *define the terms ‘small business’ and ‘very small*
5 *business’, for purposes of promulgating the regu-*
6 *lation under subsection (n). In defining such*
7 *terms, the Secretary shall include consideration*
8 *of harvestable acres, income, the number of em-*
9 *ployees, and the volume of food harvested.*

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

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

22 “(7) *NOTIFICATION TO CONSUMERS.*—

23 “(A) *IN GENERAL.*—*A qualified facility that*
24 *is exempt from the requirements under sub-*
25 *sections (a) through (i) and subsection (n) and*

1 *does not prepare documentation under para-*
2 *graph (2)(B)(i)(I) shall—*

3 *“(i) with respect to a food for which a*
4 *food packaging label is required by the Sec-*
5 *retary under any other provision of this*
6 *Act, include prominently and conspicuously*
7 *on such label the name and business address*
8 *of the facility where the food was manufac-*
9 *tured or processed; or*

10 *“(ii) with respect to a food for which*
11 *a food packaging label is not required by*
12 *the Secretary under any other provisions of*
13 *this Act, prominently and conspicuously*
14 *display, at the point of purchase, the name*
15 *and business address of the facility where*
16 *the food was manufactured or processed, on*
17 *a label, poster, sign, placard, or documents*
18 *delivered contemporaneously with the food*
19 *in the normal course of business, or, in the*
20 *case of Internet sales, in an electronic no-*
21 *tice.*

22 *“(B) NO ADDITIONAL LABEL.—Subpara-*
23 *graph (A) does not provide authority to the Sec-*
24 *retary to require a label that is in addition to*

1 *any label required under any other provision of*
2 *this Act.*

3 “(m) *AUTHORITY WITH RESPECT TO CERTAIN FACILI-*
4 *TIES.—The Secretary may, by regulation, exempt or modify*
5 *the requirements for compliance under this section with re-*
6 *spect to facilities that are solely engaged in the production*
7 *of food for animals other than man, the storage of raw agri-*
8 *cultural commodities (other than fruits and vegetables) in-*
9 *tended for further distribution or processing, or the storage*
10 *of packaged foods that are not exposed to the environment.*

11 “(n) *REGULATIONS.—*

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

16 “(A) *to establish science-based minimum*
17 *standards for conducting a hazard analysis, doc-*
18 *umenting hazards, implementing preventive con-*
19 *trols, and documenting the implementation of*
20 *the preventive controls under this section; 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 regu-*
2 *lations 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 prac-*
10 *ticable for all sizes and types of facilities, includ-*
11 *ing small businesses such as a small food proc-*
12 *essing 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 sec-*
17 *tion 3502(2) of such Act) on the facility, and col-*
18 *lection of information (as defined in section*
19 *3502(3) of such Act), associated with such regu-*
20 *lations;*

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

24 “(D) *not require a facility to hire a consult-*
25 *ant or other third party to identify, implement,*

1 *certify, or audit preventative controls, except in*
2 *the case of negotiated enforcement resolutions*
3 *that may require such a consultant or third*
4 *party.*

5 “(4) *RULE OF CONSTRUCTION.*—*Nothing in this*
6 *subsection shall be construed to provide the Secretary*
7 *with the authority to prescribe specific technologies,*
8 *practices, or critical controls for an individual facil-*
9 *ity.*

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

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

20 “(1) *CRITICAL CONTROL POINT.*—*The term ‘crit-*
21 *ical control point’ means a point, step, or procedure*
22 *in a food process at which control can be applied and*
23 *is essential to prevent or eliminate a food safety haz-*
24 *ard or reduce such hazard to an acceptable level.*

1 “(2) *FACILITY*.—The term ‘facility’ means a do-
2 mestic facility or a foreign facility that is required to
3 register under section 415.

4 “(3) *PREVENTIVE CONTROLS*.—The term ‘preven-
5 tive controls’ means those risk-based, reasonably ap-
6 propriate procedures, practices, and processes that a
7 person knowledgeable about the safe manufacturing,
8 processing, packing, or holding of food would employ
9 to significantly minimize or prevent the hazards iden-
10 tified under the hazard analysis conducted under sub-
11 section (b) and that are consistent with the current
12 scientific understanding of safe food manufacturing,
13 processing, packing, or holding at the time of the
14 analysis. Those procedures, practices, and processes
15 may include the following:

16 “(A) Sanitation procedures for food contact
17 surfaces and utensils and food-contact surfaces of
18 equipment.

19 “(B) Supervisor, manager, and employee
20 hygiene training.

21 “(C) An environmental monitoring pro-
22 gram to verify the effectiveness of pathogen con-
23 trols in processes where a food is exposed to a po-
24 tential contaminant in the environment.

25 “(D) A food allergen control program.

1 “(E) A recall plan.

2 “(F) Current Good Manufacturing Practices
3 (cGMPs) under part 110 of title 21, Code of Fed-
4 eral Regulations (or any successor regulations).

5 “(G) Supplier verification activities that re-
6 late to the safety of food.”.

7 (b) *GUIDANCE DOCUMENT.*—The Secretary shall issue
8 a guidance document related to the regulations promulgated
9 under subsection (b)(1) with respect to the hazard analysis
10 and preventive controls under section 418 of the Federal
11 Food, Drug, and Cosmetic Act (as added by subsection (a)).

12 (c) *RULEMAKING.*—

13 (1) *PROPOSED RULEMAKING.*—

14 (A) *IN GENERAL.*—Not later than 9 months
15 after the date of enactment of this Act, the Sec-
16 retary of Health and Human Services (referred
17 to in this subsection as the “Secretary”) shall
18 publish a notice of proposed rulemaking in the
19 Federal Register to promulgate regulations with
20 respect to—

21 (i) activities that constitute on-farm
22 packing or holding of food that is not
23 grown, raised, or consumed on such farm or
24 another farm under the same ownership for
25 purposes of section 415 of the Federal Food,

1 *Drug, and Cosmetic Act (21 U.S.C. 350d),*
2 *as amended by this Act; and*

3 *(ii) activities that constitute on-farm*
4 *manufacturing or processing of food that is*
5 *not consumed on that farm or on another*
6 *farm under common ownership for purposes*
7 *of such section 415.*

8 *(B) CLARIFICATION.—The rulemaking de-*
9 *scribed under subparagraph (A) shall enhance*
10 *the implementation of such section 415 and clar-*
11 *ify the activities that are included as part of the*
12 *definition of the term “facility” under such sec-*
13 *tion 415. Nothing in this Act authorizes the Sec-*
14 *retary to modify the definition of the term “facil-*
15 *ity” under such section.*

16 *(C) SCIENCE-BASED RISK ANALYSIS.—In*
17 *promulgating regulations under subparagraph*
18 *(A), the Secretary shall conduct a science-based*
19 *risk analysis of—*

20 *(i) specific types of on-farm packing or*
21 *holding of food that is not grown, raised, or*
22 *consumed on such farm or another farm*
23 *under the same ownership, as such packing*
24 *and holding relates to specific foods; and*

1 (ii) *specific on-farm manufacturing*
2 *and processing activities as such activities*
3 *relate to specific foods that are not con-*
4 *sumed on that farm or on another farm*
5 *under common ownership.*

6 (D) *AUTHORITY WITH RESPECT TO CERTAIN*
7 *FACILITIES.—*

8 (i) *IN GENERAL.—In promulgating the*
9 *regulations under subparagraph (A), the*
10 *Secretary shall consider the results of the*
11 *science-based risk analysis conducted under*
12 *subparagraph (C), and shall exempt certain*
13 *facilities from the requirements in section*
14 *418 of the Federal Food, Drug, and Cos-*
15 *metic Act (as added by this section), includ-*
16 *ing hazard analysis and preventive controls,*
17 *and the mandatory inspection frequency in*
18 *section 421 of such Act (as added by section*
19 *201), or modify the requirements in such*
20 *sections 418 or 421, as the Secretary deter-*
21 *mines appropriate, if such facilities are en-*
22 *gaged only in specific types of on-farm*
23 *manufacturing, processing, packing, or*
24 *holding activities that the Secretary deter-*

1 *mines to be low risk involving specific foods*
2 *the Secretary determines to be low risk.*

3 *(ii) LIMITATION.—The exemptions or*
4 *modifications under clause (i) shall not in-*
5 *clude an exemption from the requirement to*
6 *register under section 415 of the Federal*
7 *Food, Drug, and Cosmetic Act (21 U.S.C.*
8 *350d), as amended by this Act, if applica-*
9 *ble, and shall apply only to small businesses*
10 *and very small businesses, as defined in the*
11 *regulation promulgated under section*
12 *418(n) of the Federal Food, Drug, and Cos-*
13 *metic Act (as added under subsection (a)).*

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

18 *(A) activities that constitute on-farm pack-*
19 *ing or holding of food that is not grown, raised,*
20 *or consumed on such farm or another farm*
21 *under the same ownership for purposes of section*
22 *415 of the Federal Food, Drug, and Cosmetic Act*
23 *(21 U.S.C. 350d), as amended by this Act;*

24 *(B) activities that constitute on-farm manu-*
25 *facturing or processing of food that is not con-*

1 *sumed on that farm or on another farm under*
2 *common ownership for purposes of such section*
3 *415; and*

4 *(C) the requirements under sections 418 and*
5 *421 of the Federal Food, Drug, and Cosmetic*
6 *Act, as added by this Act, from which the Sec-*
7 *retary may issue exemptions or modifications of*
8 *the requirements for certain types of facilities.*

9 *(d) SMALL ENTITY COMPLIANCE POLICY GUIDE.—Not*
10 *later than 180 days after the issuance of the regulations*
11 *promulgated under subsection (n) of section 418 of the Fed-*
12 *eral Food, Drug, and Cosmetic Act (as added by subsection*
13 *(a)), the Secretary shall issue a small entity compliance*
14 *policy guide setting forth in plain language the require-*
15 *ments of such section 418 and this section to assist small*
16 *entities in complying with the hazard analysis and other*
17 *activities required under such section 418 and this section.*

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

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

24 *(f) NO EFFECT ON HACCP AUTHORITIES.—Nothing*
25 *in the amendments made by this section limits the author-*

1 *ity of the Secretary under the Federal Food, Drug, and Cos-*
2 *metic Act (21 U.S.C. 301 et seq.) or the Public Health Serv-*
3 *ice Act (42 U.S.C. 201 et seq.) to revise, issue, or enforce*
4 *Hazard Analysis Critical Control programs and the Ther-*
5 *mally Processed Low-Acid Foods Packaged in Hermetically*
6 *Sealed Containers standards.*

7 *(g) DIETARY SUPPLEMENTS.—Nothing in the amend-*
8 *ments made by this section shall apply to any facility with*
9 *regard to the manufacturing, processing, packing, or hold-*
10 *ing of a dietary supplement that is in compliance with the*
11 *requirements of sections 402(g)(2) and 761 of the Federal*
12 *Food, Drug, and Cosmetic Act (21 U.S.C. 342(g)(2), 379aa-*
13 *1).*

14 *(h) UPDATING GUIDANCE RELATING TO FISH AND*
15 *FISHERIES PRODUCTS HAZARDS AND CONTROLS.—The*
16 *Secretary shall, not later than 180 days after the date of*
17 *enactment of this Act, update the Fish and Fisheries Prod-*
18 *ucts Hazards and Control Guidance to take into account*
19 *advances in technology that have occurred since the pre-*
20 *vious publication of such Guidance by the Secretary.*

21 *(i) EFFECTIVE DATES.—*

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

1 (2) *FLEXIBILITY FOR SMALL BUSINESSES.*—Not-
2 withstanding paragraph (1)—

3 (A) *the amendments made by this section*
4 *shall apply to a small business (as defined in the*
5 *regulations promulgated under section 418(n) of*
6 *the Federal Food, Drug, and Cosmetic Act (as*
7 *added by this section)) beginning on the date*
8 *that is 6 months after the effective date of such*
9 *regulations; and*

10 (B) *the amendments made by this section*
11 *shall apply to a very small business (as defined*
12 *in such regulations) beginning on the date that*
13 *is 18 months after the effective date of such regu-*
14 *lations.*

15 **SEC. 104. PERFORMANCE STANDARDS.**

16 (a) *IN GENERAL.*—*The Secretary shall, in coordina-*
17 *tion with the Secretary of Agriculture, not less frequently*
18 *than every 2 years, review and evaluate relevant health data*
19 *and other relevant information, including from toxi-*
20 *cological and epidemiological studies and analyses, current*
21 *Good Manufacturing Practices issued by the Secretary re-*
22 *lating to food, and relevant recommendations of relevant*
23 *advisory committees, including the Food Advisory Com-*
24 *mittee, to determine the most significant foodborne contami-*
25 *nants.*

1 (b) *GUIDANCE DOCUMENTS AND REGULATIONS.*—
2 *Based on the review and evaluation conducted under sub-*
3 *section (a), and when appropriate to reduce the risk of seri-*
4 *ous illness or death to humans or animals or to prevent*
5 *adulteration of the food under section 402 of the Federal*
6 *Food, Drug, or Cosmetic Act (21 U.S.C. 342) or to prevent*
7 *the spread by food of communicable disease under section*
8 *361 of the Public Health Service Act (42 U.S.C. 264), the*
9 *Secretary shall issue contaminant-specific and science-*
10 *based guidance documents, including guidance documents*
11 *regarding action levels, or regulations. Such guidance, in-*
12 *cluding guidance regarding action levels, or regulations—*
13 (1) *shall apply to products or product classes;*
14 (2) *shall, where appropriate, differentiate be-*
15 *tween food for human consumption and food intended*
16 *for consumption by animals other than humans; and*
17 (3) *shall not be written to be facility-specific.*
18 (c) *NO DUPLICATION OF EFFORTS.*—*The Secretary*
19 *shall coordinate with the Secretary of Agriculture to avoid*
20 *issuing duplicative guidance on the same contaminants.*
21 (d) *REVIEW.*—*The Secretary shall periodically review*
22 *and revise, as appropriate, the guidance documents, includ-*
23 *ing guidance documents regarding action levels, or regula-*
24 *tions promulgated under this section.*

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

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

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

6 “(a) *PROPOSED RULEMAKING.*—

7 “(1) *IN GENERAL.*—

8 “(A) *RULEMAKING.*—Not later than 1 year
9 after the date of enactment of the FDA Food
10 Safety Modernization Act, the Secretary, in co-
11 ordination with the Secretary of Agriculture and
12 representatives of State departments of agri-
13 culture (including with regard to the national
14 organic program established under the Organic
15 Foods Production Act of 1990), and in consulta-
16 tion with the Secretary of Homeland Security,
17 shall publish a notice of proposed rulemaking to
18 establish science-based minimum standards for
19 the safe production and harvesting of those types
20 of fruits and vegetables, including specific mixes
21 or categories of fruits and vegetables, that are
22 raw agricultural commodities for which the Sec-
23 retary has determined that such standards mini-
24 mize the risk of serious adverse health con-
25 sequences or death.

1 “(B) *DETERMINATION BY SECRETARY.*—
2 *With respect to small businesses and very small*
3 *businesses (as such terms are defined in the regu-*
4 *lation promulgated under subparagraph (A))*
5 *that produce and harvest those types of fruits*
6 *and vegetables that are raw agricultural com-*
7 *modities that the Secretary has determined are*
8 *low risk and do not present a risk of serious ad-*
9 *verse health consequences or death, the Secretary*
10 *may determine not to include production and*
11 *harvesting of such fruits and vegetables in such*
12 *rulemaking, or may modify the applicable re-*
13 *quirements of regulations promulgated pursuant*
14 *to this section.*

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

21 “(3) *CONTENT.*—*The proposed rulemaking under*
22 *paragraph (1) shall—*

23 “(A) *provide sufficient flexibility to be ap-*
24 *plicable to various types of entities engaged in*
25 *the production and harvesting of fruits and vege-*

1 *tables that are raw agricultural commodities, in-*
2 *cluding small businesses and entities that sell di-*
3 *rectly to consumers, and be appropriate to the*
4 *scale and diversity of the production and har-*
5 *vesting of such commodities;*

6 “(B) include, with respect to growing, har-

7 *vesting, sorting, packing, and storage operations,*
8 *science-based minimum standards related to soil*
9 *amendments, hygiene, packaging, temperature*
10 *controls, animals in the growing area, and*
11 *water;*

12 “(C) consider hazards that occur naturally,

13 *may be unintentionally introduced, or may be*
14 *intentionally introduced, including by acts of*
15 *terrorism;*

16 “(D) take into consideration, consistent

17 *with ensuring enforceable public health protec-*
18 *tion, conservation and environmental practice*
19 *standards and policies established by Federal*
20 *natural resource conservation, wildlife conserva-*
21 *tion, and environmental agencies;*

22 “(E) in the case of production that is cer-

23 *tified organic, not include any requirements that*
24 *conflict with or duplicate the requirements of the*
25 *national organic program established under the*

1 *Organic Foods Production Act of 1990, while*
2 *providing the same level of public health protec-*
3 *tion as the requirements under guidance docu-*
4 *ments, including guidance documents regarding*
5 *action levels, and regulations under the FDA*
6 *Food Safety Modernization Act; and*

7 *“(F) define, for purposes of this section, the*
8 *terms ‘small business’ and ‘very small business’*

9 *“(4) PRIORITIZATION.—The Secretary shall*
10 *prioritize the implementation of the regulations under*
11 *this section for specific fruits and vegetables that are*
12 *raw agricultural commodities based on known risks*
13 *which may include a history and severity of*
14 *foodborne illness outbreaks.*

15 *“(b) FINAL REGULATION.—*

16 *“(1) IN GENERAL.—Not later than 1 year after*
17 *the close of the comment period for the proposed rule-*
18 *making under subsection (a), the Secretary shall*
19 *adopt a final regulation to provide for minimum*
20 *science-based standards for those types of fruits and*
21 *vegetables, including specific mixes or categories of*
22 *fruits or vegetables, that are raw agricultural com-*
23 *modities, based on known safety risks, which may in-*
24 *clude a history of foodborne illness outbreaks.*

1 “(2) *FINAL REGULATION.*—*The final regulation*
2 *shall—*

3 “(A) *provide for coordination of education*
4 *and enforcement activities by State and local of-*
5 *ficials, as designated by the Governors of the re-*
6 *spective States or the appropriate elected State*
7 *official as recognized by State statute; and*

8 “(B) *include a description of the variance*
9 *process under subsection (c) and the types of per-*
10 *missible variances the Secretary may grant.*

11 “(3) *FLEXIBILITY FOR SMALL BUSINESSES.*—
12 *Notwithstanding paragraph (1)—*

13 “(A) *the regulations promulgated under this*
14 *section shall apply to a small business (as de-*
15 *fined in the regulation promulgated under sub-*
16 *section (a)(1)) after the date that is 1 year after*
17 *the effective date of the final regulation under*
18 *paragraph (1); and*

19 “(B) *the regulations promulgated under this*
20 *section shall apply to a very small business (as*
21 *defined in the regulation promulgated under sub-*
22 *section (a)(1)) after the date that is 2 years after*
23 *the effective date of the final regulation under*
24 *paragraph (1).*

25 “(c) *CRITERIA.*—

1 “(1) *IN GENERAL.*—*The regulations adopted*
2 *under subsection (b) shall—*

3 “(A) *set forth those procedures, processes,*
4 *and practices that the Secretary determines to*
5 *minimize the risk of serious adverse health con-*
6 *sequences or death, including procedures, proc-*
7 *esses, and practices that the Secretary determines*
8 *to be reasonably necessary to prevent the intro-*
9 *duction of known or reasonably foreseeable bio-*
10 *logical, chemical, and physical hazards, includ-*
11 *ing hazards that occur naturally, may be unin-*
12 *tentionally introduced, or may be intentionally*
13 *introduced, including by acts of terrorism, into*
14 *fruits and vegetables, including specific mixes or*
15 *categories of fruits and vegetables, that are raw*
16 *agricultural commodities and to provide reason-*
17 *able assurances that the produce is not adulter-*
18 *ated under section 402;*

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

23 “(C) *comply with chapter 35 of title 44,*
24 *United States Code (commonly known as the*
25 *‘Paperwork Reduction Act’), with special atten-*

1 *tion to minimizing the burden (as defined in sec-*
2 *tion 3502(2) of such Act) on the business, and*
3 *collection of information (as defined in section*
4 *3502(3) of such Act), associated with such regu-*
5 *lations;*

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

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

15 *“(F) permit States and foreign countries*
16 *from which food is imported into the United*
17 *States to request from the Secretary variances*
18 *from the requirements of the regulations, subject*
19 *to paragraph (2), where the State or foreign*
20 *country determines that the variance is necessary*
21 *in light of local growing conditions and that the*
22 *procedures, processes, and practices to be fol-*
23 *lowed under the variance are reasonably likely to*
24 *ensure that the produce is not adulterated under*
25 *section 402 and to provide the same level of pub-*

1 *lic health protection as the requirements of the*
2 *regulations adopted under subsection (b).*

3 “(2) *VARIANCES.*—

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

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

22 “(C) *DENIAL OF VARIANCES.*—*The Sec-*
23 *retary may deny a variance request if the Sec-*
24 *retary determines that such variance is not rea-*
25 *sonably likely to ensure that the food is not adul-*

1 *terated under section 402 and is not reasonably*
2 *likely to provide the same level of public health*
3 *protection as the requirements of the regulation*
4 *adopted under subsection (b). The Secretary shall*
5 *notify the person requesting such variance of the*
6 *reasons for the denial.*

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

16 *“(d) ENFORCEMENT.—The Secretary may coordinate*
17 *with the Secretary of Agriculture and, as appropriate, shall*
18 *contract and coordinate with the agency or department des-*
19 *ignated by the Governor of each State to perform activities*
20 *to ensure compliance with this section.*

21 *“(e) GUIDANCE.—*

22 *“(1) IN GENERAL.—Not later than 1 year after*
23 *the date of enactment of the FDA Food Safety Mod-*
24 *ernization Act, the Secretary shall publish, after con-*
25 *sultation with the Secretary of Agriculture, represent-*

1 *atives of State departments of agriculture, farmer*
2 *representatives, and various types of entities engaged*
3 *in the production and harvesting or importing of*
4 *fruits and vegetables that are raw agricultural com-*
5 *modities, including small businesses, updated good*
6 *agricultural practices and guidance for the safe pro-*
7 *duction and harvesting of specific types of fresh*
8 *produce under this section.*

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

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

23 “(A) *provide sufficient flexibility to be prac-*
24 *ticable for all sizes and types of facilities, includ-*

1 *ing small businesses such as a small food proc-*
2 *essing facility co-located on a farm; and*

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

6 “(f) *EXEMPTION FOR DIRECT FARM MARKETING.*—

7 “(1) *IN GENERAL.*—*A farm shall be exempt from*
8 *the requirements under this section in a calendar*
9 *year if—*

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

16 *“(B) the average annual monetary value of*
17 *all food sold during such period was less than*
18 *\$500,000, adjusted for inflation.*

19 “(2) *NOTIFICATION TO CONSUMERS.*—

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

22 *“(i) with respect to a food for which a*
23 *food packaging label is required by the Sec-*
24 *retary under any other provision of this*
25 *Act, include prominently and conspicuously*

1 *on such label the name and business address*
2 *of the farm where the produce was grown;*
3 *or*

4 “(i) *with respect to a food for which*
5 *a food packaging label is not required by*
6 *the Secretary under any other provision of*
7 *this Act, prominently and conspicuously*
8 *display, at the point of purchase, the name*
9 *and business address of the farm where the*
10 *produce was grown, on a label, poster, sign,*
11 *placard, or documents delivered contem-*
12 *poraneously with the food in the normal*
13 *course of business, or, in the case of Internet*
14 *sales, in an electronic notice.*

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

20 “(3) *WITHDRAWAL; RULE OF CONSTRUCTION.—*

21 “(A) *IN GENERAL.—In the event of an ac-*
22 *tive investigation of a foodborne illness outbreak*
23 *that is directly linked to a farm subject to an ex-*
24 *emption under this subsection, or if the Sec-*
25 *retary determines that it is necessary to protect*

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

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

11 “(4) *DEFINITIONS.*—

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

15 “(i) *the consumer of the food; or*

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

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

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

1 “(B) *CONSUMER*.—For purposes of subpara-
2 graph (A), the term ‘consumer’ does not include
3 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, harvesting,
7 holding, transportation, and sale of fresh fruits and
8 vegetables. Compliance with this subsection shall not
9 relieve any person from liability at common law or
10 under State statutory law.

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

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

18 “(h) *EXCEPTION FOR ACTIVITIES OF FACILITIES SUB-*
19 *JECT TO SECTION 418*.—This section shall not apply to ac-
20 tivities of a facility that are subject to section 418.”.

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

1 *icy guide setting forth in plain language the requirements*
 2 *of such section 419 and to assist small entities in complying*
 3 *with standards for safe production and harvesting and*
 4 *other activities required under such section.*

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

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

10 *(d) 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 Cos-*
 13 *metic Act (21 U.S.C. 301 et seq.) or the Public Health Serv-*
 14 *ice Act (42 U.S.C. 201 et seq.) to revise, issue, or enforce*
 15 *product and category-specific regulations, such as the Sea-*
 16 *food Hazard Analysis Critical Controls Points Program,*
 17 *the Juice Hazard Analysis Critical Control Program, and*
 18 *the Thermally Processed Low-Acid Foods Packaged in Her-*
 19 *metically Sealed Containers standards.*

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

22 *(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.),*
 23 *as amended by section 105, is amended by adding at the*
 24 *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 risk as-*
9 *sessments;*

10 “(B) *consider the best available under-*
11 *standing of uncertainties, risks, costs, and bene-*
12 *fits associated with guarding against intentional*
13 *adulteration of food at vulnerable points; and*

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

18 “(2) *LIMITED DISTRIBUTION.*—*In the interest of*
19 *national security, the Secretary, in consultation with*
20 *the Secretary of Homeland Security, may determine*
21 *the time, manner, and form in which determinations*
22 *made under paragraph (1) are made publicly avail-*
23 *able.*

24 “(b) *REGULATIONS.*—*Not later than 18 months after*
25 *the date of enactment of the FDA Food Safety Moderniza-*
26 *tion Act, the Secretary, in coordination with the Secretary*

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

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

9 “(2) *specify appropriate science-based mitigation*
10 *strategies or measures to prepare and protect the food*
11 *supply chain at specific vulnerable points, as appro-*
12 *priate.*

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

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

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

1 “(d) *EXCEPTION.*—*This section shall not apply to*
2 *farms, except for those that produce milk.*”

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

7 (b) *GUIDANCE DOCUMENTS.*—

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

18 (2) *CONTENT.*—*The guidance documents issued*
19 *under paragraph (1) shall—*

20 (A) *include a model assessment for a person*
21 *to use under subsection (b)(1) of section 420 of*
22 *the Federal Food, Drug, and Cosmetic Act, as*
23 *added by subsection (a);*

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

4 (C) specify situations in which the examples
5 of mitigation strategies or measures described in
6 subsection (b)(2) of such section are appropriate.

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

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

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

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

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

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

5 **“PART 6—FEES RELATED TO FOOD**

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

7 “(a) *IN GENERAL.*—

8 “(1) *PURPOSE AND AUTHORITY.*—For fiscal year
9 2010 and each subsequent fiscal year, the Secretary
10 shall, in accordance with this section, assess and col-
11 lect fees from—

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

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

1 “(C) each importer participating in the vol-
2 untary qualified importer program under section
3 806 in such year, to cover the administrative
4 costs of such program for such year; and

5 “(D) each importer subject to a reinspection
6 in such fiscal year, to cover reinspection-related
7 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 in-
13 spections conducted under section 704 subse-
14 quent to an inspection conducted under
15 such provision which identified noncompli-
16 ance materially related to a food safety re-
17 quirement of this Act, specifically to deter-
18 mine whether compliance has been achieved
19 to the Secretary’s satisfaction; and

20 “(ii) with respect to importers, 1 or
21 more examinations conducted under section
22 801 subsequent to an examination con-
23 ducted under such provision which identi-
24 fied noncompliance materially related to a
25 food safety requirement of this Act, specifi-

1 cally to determine whether compliance has
2 been achieved to the Secretary's satisfaction;

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

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

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

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

12 “(b) *ESTABLISHMENT OF FEES.*—

13 “(1) *IN GENERAL.*—Subject to subsections (c)
14 and (d), the Secretary shall establish the fees to be col-
15 lected under this section for each fiscal year specified
16 in subsection (a)(1), based on the methodology de-
17 scribed under paragraph (2), and shall publish such
18 fees in a *Federal Register* notice not later than 60
19 days before the start of each such year.

20 “(2) *FEE METHODOLOGY.*—

21 “(A) *FEES.*—Fees amounts established for
22 collection—

23 “(i) under subparagraph (A) of sub-
24 section (a)(1) for a fiscal year shall be based
25 on the Secretary's estimate of 100 percent of

1 *the costs of the reinspection-related activi-*
2 *ties (including by type or level of reinspec-*
3 *tion activity, as the Secretary determines*
4 *applicable) described in such subparagraph*
5 *(A) for such year;*

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

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

16 “(iv) under subparagraph (D) of sub-
17 section (a)(1) for a fiscal year shall be based
18 on the Secretary’s estimate of 100 percent of
19 the costs of the activities described in such
20 subparagraph (D) for such year.

21 “(B) *OTHER CONSIDERATIONS.*—

22 “(i) *VOLUNTARY QUALIFIED IMPORTER*
23 *PROGRAM.*—*In establishing the fee amounts*
24 *under subparagraph (A)(iii) for a fiscal*
25 *year, the Secretary shall provide for the*

1 *number of importers who have submitted to*
2 *the Secretary a notice under section 806(c)*
3 *informing the Secretary of the intent of*
4 *such importer to participate in the program*
5 *under section 806 in such fiscal year.*

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

16 “(i) *CREDITING OF FEES.*—*In estab-*
17 *lishing the fee amounts under subparagraph*
18 *(A) for a fiscal year, the Secretary shall*
19 *provide for the crediting of fees from the*
20 *previous year to the next year if the Sec-*
21 *retary overestimated the amount of fees*
22 *needed to carry out such activities, and con-*
23 *sider the need to account for any adjust-*
24 *ment of fees and such other factors as the*
25 *Secretary determines appropriate.*

1 “(iii) *PUBLISHED GUIDELINES.*—Not
2 *later than 180 days after the date of enact-*
3 *ment of the FDA Food Safety Moderniza-*
4 *tion Act, the Secretary shall publish in the*
5 *Federal Register a proposed set of guidelines*
6 *in consideration of the burden of fee*
7 *amounts on small business. Such consider-*
8 *ation may include reduced fee amounts for*
9 *small businesses. The Secretary shall pro-*
10 *vide for a period of public comment on such*
11 *guidelines. The Secretary shall adjust the fee*
12 *schedule for small businesses subject to such*
13 *fees only through notice and comment rule-*
14 *making.*

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

20 “(c) *LIMITATIONS.*—

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

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

8 “(2) *AUTHORITY.—If—*

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

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

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

18 “(3) *ADJUSTMENT FACTOR.—*

19 “(A) *IN GENERAL.—The adjustment factor*
20 *described in paragraph (1) shall be the total per-*
21 *centage change that occurred in the Consumer*
22 *Price Index for all urban consumers (all items;*
23 *United States city average) for the 12-month pe-*
24 *riod ending June 30 preceding the fiscal year,*

1 *but in no case shall such adjustment factor be*
2 *negative.*

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

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

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

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

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

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

1 retary may collect a fee from such facility or im-
2 porter.

3 “(d) *CREDITING AND AVAILABILITY OF FEES.*—Fees
4 authorized under subsection (a) shall be collected and avail-
5 able for obligation only to the extent and in the amount
6 provided in appropriations Acts. Such fees are authorized
7 to remain available until expended. Such sums as may be
8 necessary may be transferred from the Food and Drug Ad-
9 ministration salaries and expenses account without fiscal
10 year limitation to such appropriation account for salaries
11 and expenses with such fiscal year limitation. The sums
12 transferred shall be available solely for the purpose of pay-
13 ing the operating expenses of the Food and Drug Adminis-
14 tration employees and contractors performing activities as-
15 sociated with these food safety fees.

16 “(e) *COLLECTION OF FEES.*—

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

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

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

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

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

18 (b) *EXPORT CERTIFICATION FEES FOR FOODS AND*
19 *ANIMAL FEED.*—

20 (1) *AUTHORITY FOR EXPORT CERTIFICATIONS*
21 *FOR FOOD, INCLUDING ANIMAL FEED.*—Section
22 *801(e)(4)(A) (21 U.S.C. 381(e)(4)(A)) is amended—*

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

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

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

6 (2) *CLARIFICATION OF CERTIFICATION.*—Section
7 801(e)(4) (21 U.S.C. 381(e)(4)) is amended by insert-
8 ing after subparagraph (B) the following new sub-
9 paragraph:

10 “(C) For purposes of this paragraph, a cer-
11 tification by the Secretary shall be made on such
12 basis, and in such form (including a publicly
13 available listing) as the Secretary determines ap-
14 propriate.”.

15 (3) *LIMITATIONS ON THE USE AND AMOUNT OF*
16 *FEES.*—Paragraph (4) of section 801(e) (21 U.S.C.
17 381(e)) is amended by adding at the end the fol-
18 lowing:

19 “(D) With regard to fees pursuant to sub-
20 paragraph (B) in connection with written export
21 certifications for food:

22 “(i) Such fees shall be collected and
23 available solely for the costs of the Food and
24 Drug Administration associated with
25 issuing such certifications.

1 “(ii) Such fees may not be retained in
2 an amount that exceeds such costs for the
3 respective fiscal year.”

4 **SEC. 108. NATIONAL AGRICULTURE AND FOOD DEFENSE**
5 **STRATEGY.**

6 (a) *DEVELOPMENT AND SUBMISSION OF STRATEGY.*—

7 (1) *IN GENERAL.*—Not later than 1 year after
8 the date of enactment of this Act, the Secretary of
9 Health and Human Services and the Secretary of Ag-
10 riculture, in coordination with the Secretary of
11 Homeland Security, shall prepare and transmit to the
12 relevant committees of Congress, and make publicly
13 available on the Internet Web sites of the Department
14 of Health and Human Services and the Department
15 of Agriculture, the National Agriculture and Food De-
16 fense Strategy.

17 (2) *IMPLEMENTATION PLAN.*—The strategy shall
18 include an implementation plan for use by the Secre-
19 taries described under paragraph (1) in carrying out
20 the strategy.

21 (3) *RESEARCH.*—The strategy shall include a co-
22 ordinated research agenda for use by the Secretaries
23 described under paragraph (1) in conducting research
24 to support the goals and activities described in para-
25 graphs (1) and (2) of subsection (b).

1 (4) *REVISIONS.*—Not later than 4 years after the
2 date on which the strategy is submitted to the relevant
3 committees of Congress under paragraph (1), and not
4 less frequently than every 4 years thereafter, the Sec-
5 retary of Health and Human Services and the Sec-
6 retary of Agriculture, in coordination with the Sec-
7 retary of Homeland Security, shall revise and submit
8 to the relevant committees of Congress the strategy.

9 (5) *CONSISTENCY WITH EXISTING PLANS.*—The
10 strategy described in paragraph (1) shall be consistent
11 with—

12 (A) the National Incident Management Sys-

13 tem;

14 (B) the National Response Framework;

15 (C) the National Infrastructure Protection

16 Plan;

17 (D) the National Preparedness Goals; and

18 (E) other relevant national strategies.

19 (b) *COMPONENTS.*—

20 (1) *IN GENERAL.*—The strategy shall include a
21 description of the process to be used by the Depart-
22 ment of Health and Human Services, the Department
23 of Agriculture, and the Department of Homeland Se-
24 curity—

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

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

7 (2) GOALS.—The strategy shall include a de-
8 scription of the process to be used by the Department
9 of Health and Human Services, the Department of
10 Agriculture, and the Department of Homeland Secu-
11 rity to achieve the following goals:

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

15 (i) conducting vulnerability assess-
16 ments of the agriculture and food system;

17 (ii) mitigating vulnerabilities of the
18 system;

19 (iii) improving communication and
20 training relating to the system;

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

1 (v) developing modeling tools to im-
2 prove event consequence assessment and de-
3 cision support; and

4 (vi) preparing risk communication
5 tools and enhancing public awareness
6 through outreach.

7 (B) *DETECTION GOAL.*—Improve agri-
8 culture and food system detection capabilities
9 by—

10 (i) identifying contamination in food
11 products at the earliest possible time; and

12 (ii) conducting surveillance to prevent
13 the spread of diseases.

14 (C) *EMERGENCY RESPONSE GOAL.*—Ensure
15 an efficient response to agriculture and food
16 emergencies by—

17 (i) immediately investigating animal
18 disease outbreaks and suspected food con-
19 tamination;

20 (ii) preventing additional human ill-
21 nesses;

22 (iii) organizing, training, and equip-
23 ping animal, plant, and food emergency re-
24 sponse teams of—

25 (I) the Federal Government; and

1 (ii) State, local, and tribal gov-
2 ernments;

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

7 (v) ensuring consistent and organized
8 risk communication to the public by—

9 (I) the Federal Government;

10 (ii) State, local, and tribal gov-
11 ernments; and

12 (III) the private sector.

13 (D) *RECOVERY GOAL.*—Secure agriculture
14 and food production after an agriculture or food
15 emergency by—

16 (i) working with the private sector to
17 develop business recovery plans to rapidly
18 resume agriculture, food production, and
19 international trade;

20 (ii) conducting exercises of the plans
21 described in subparagraph (C) with the goal
22 of long-term recovery results;

23 (iii) rapidly removing, and effectively
24 disposing of—

1 (I) contaminated agriculture and
2 food products; and

3 (II) infected plants and animals;
4 and

5 (iv) decontaminating and restoring
6 areas affected by an agriculture or food
7 emergency.

8 (3) *EVALUATION.*—The Secretary, in coordina-
9 tion with the Secretary of Agriculture and the Sec-
10 retary of Homeland Security, shall—

11 (A) develop metrics to measure progress for
12 the evaluation process described in paragraph
13 (1)(B); and

14 (B) report on the progress measured in sub-
15 paragraph (A) as part of the National Agri-
16 culture and Food Defense strategy described in
17 subsection (a)(1).

18 (c) *LIMITED DISTRIBUTION.*—In the interest of na-
19 tional security, the Secretary of Health and Human Serv-
20 ices and the Secretary of Agriculture, in coordination with
21 the Secretary of Homeland Security, may determine the
22 manner and format in which the National Agriculture and
23 Food Defense strategy established under this section is made
24 publicly available on the Internet Web sites of the Depart-
25 ment of Health and Human Services, the Department of

1 *Homeland Security, and the Department of Agriculture, as*
2 *described in subsection (a)(1).*

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

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

15 *(1) facilitating partnerships between public and*
16 *private entities to help coordinate and enhance the*
17 *protection of the agriculture and food system of the*
18 *United States;*

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

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

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

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

6 *(A) animal or plant disease outbreaks;*

7 *(B) food contamination; and*

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

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

11 *(a) IN GENERAL.—*

12 *(1) INITIAL REPORT.—The Secretary, in coordi-*
13 *nation with the Secretary of Agriculture and the Sec-*
14 *retary of Homeland Security, shall, not later than 2*
15 *years after the date of enactment of this Act, submit*
16 *to Congress a comprehensive report that identifies*
17 *programs and practices that are intended to promote*
18 *the safety and supply chain security of food and to*
19 *prevent outbreaks of foodborne illness and other food-*
20 *related hazards that can be addressed through preven-*
21 *tive activities. Such report shall include a description*
22 *of the following:*

23 *(A) Analysis of the need for further regula-*
24 *tions or guidance to industry.*

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

7 (C) Systems to ensure the prompt distribu-
8 tion to the food industry of information and
9 technical assistance concerning preventive strate-
10 gies.

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

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

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

1 (G) *The estimated resources needed to effec-*
2 *tively implement the programs and practices*
3 *identified in the report developed in this section*
4 *over a 5-year period.*

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

9 (I) *Specific efforts taken pursuant to the*
10 *agreements authorized under section 421(c) of*
11 *the Federal Food, Drug, and Cosmetic Act (as*
12 *added by section 201), together with, as nec-*
13 *essary, a description of any additional authori-*
14 *ties necessary to improve seafood safety.*

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

19 (A) *reviews previous food safety programs*
20 *and practices;*

21 (B) *outlines the success of those programs*
22 *and practices;*

23 (C) *identifies future programs and prac-*
24 *tices; and*

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

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

14 (c) *CAPABILITY FOR LABORATORY ANALYSES; RE-*
15 *SEARCH*.—The report developed under subsection (a)(1)
16 shall provide a description of methods to increase capacity
17 to undertake analyses of food samples promptly after collec-
18 tion, to identify new and rapid analytical techniques, in-
19 cluding commercially-available techniques that can be em-
20 ployed at ports of entry and by Food Emergency Response
21 Network laboratories, and to provide for well-equipped and
22 staffed laboratory facilities and progress toward laboratory
23 accreditation under section 422 of the Federal Food, Drug,
24 and Cosmetic Act (as added by section 202).

1 (d) *INFORMATION TECHNOLOGY.*—The report devel-
2 oped under subsection (a)(1) shall include a description of
3 such information technology systems as may be needed to
4 identify risks and receive data from multiple sources, in-
5 cluding foreign governments, State, local, and tribal govern-
6 ments, other Federal agencies, the food industry, labora-
7 tories, laboratory networks, and consumers. The informa-
8 tion technology systems that the Secretary describes shall
9 also provide for the integration of the facility registration
10 system under section 415 of the Federal Food, Drug, and
11 Cosmetic Act (21 U.S.C. 350d), and the prior notice system
12 under section 801(m) of such Act (21 U.S.C. 381(m)) with
13 other information technology systems that are used by the
14 Federal Government for the processing of food offered for
15 import into the United States.

16 (e) *AUTOMATED RISK ASSESSMENT.*—The report de-
17 veloped under subsection (a)(1) shall include a description
18 of progress toward developing and improving an automated
19 risk assessment system for food safety surveillance and allo-
20 cation of resources.

21 (f) *TRACEBACK AND SURVEILLANCE REPORT.*—The
22 Secretary shall include in the report developed under sub-
23 section (a)(1) an analysis of the Food and Drug Adminis-
24 tration’s performance in foodborne illness outbreaks during
25 the 5-year period preceding the date of enactment of this

1 *Act involving fruits and vegetables that are raw agricul-*
2 *tural commodities (as defined in section 201(r) (21 U.S.C.*
3 *321(r)) and recommendations for enhanced surveillance,*
4 *outbreak response, and traceability. Such findings and rec-*
5 *ommendations shall address communication and coordina-*
6 *tion with the public, industry, and State and local govern-*
7 *ments, as such communication and coordination relates to*
8 *outbreak identification and traceback.*

9 *(g) BIENNIAL FOOD SAFETY AND FOOD DEFENSE RE-*
10 *SEARCH PLAN.—The Secretary, the Secretary of Agri-*
11 *culture, and the Secretary of Homeland Security shall, on*
12 *a biennial basis, submit to Congress a joint food safety and*
13 *food defense research plan which may include studying the*
14 *long-term health effects of foodborne illness. Such biennial*
15 *plan shall include a list and description of projects con-*
16 *ducted during the previous 2-year period and the plan for*
17 *projects to be conducted during the subsequent 2-year pe-*
18 *riod.*

19 *(h) EFFECTIVENESS OF PROGRAMS ADMINISTERED BY*
20 *THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.—*

21 *(1) IN GENERAL.—To determine whether existing*
22 *Federal programs administered by the Department of*
23 *Health and Human Services are effective in achieving*
24 *the stated goals of such programs, the Secretary shall,*

1 *beginning not later than 1 year after the date of en-*
2 *actment of this Act—*

3 *(A) conduct an annual evaluation of each*
4 *program of such Department to determine the ef-*
5 *fectiveness of each such program in achieving*
6 *legislated intent, purposes, and objectives; and*

7 *(B) submit to Congress a report concerning*
8 *such evaluation.*

9 *(2) CONTENT.—The report described under para-*
10 *graph (1)(B) shall—*

11 *(A) include conclusions concerning the rea-*
12 *sons that such existing programs have proven*
13 *successful or not successful and what factors con-*
14 *tributed to such conclusions;*

15 *(B) include recommendations for consolida-*
16 *tion and elimination to reduce duplication and*
17 *inefficiencies in such programs at such Depart-*
18 *ment as identified during the evaluation conduct*
19 *under this subsection; and*

20 *(C) be made publicly available in a publi-*
21 *cation entitled “Guide to the U.S. Department of*
22 *Health and Human Services Programs”.*

23 *(i) UNIQUE IDENTIFICATION NUMBERS.—*

24 *(1) IN GENERAL.—Not later than 1 year after*
25 *the date of enactment of this Act, the Secretary, act-*

1 *ing through the Commissioner of Food and Drugs,*
2 *shall conduct a study regarding the need for, and*
3 *challenges associated with, development and imple-*
4 *mentation of a program that requires a unique iden-*
5 *tification number for each food facility registered*
6 *with the Secretary and, as appropriate, each broker*
7 *that imports food into the United States. Such study*
8 *shall include an evaluation of the costs associated*
9 *with development and implementation of such a sys-*
10 *tem, and make recommendations about what new au-*
11 *thorities, if any, would be necessary to develop and*
12 *implement such a system.*

13 (2) *REPORT.*—*Not later than 15 months after the*
14 *date of enactment of this Act, the Secretary shall sub-*
15 *mit to Congress a report that describes the findings*
16 *of the study conducted under paragraph (1) and that*
17 *includes any recommendations determined appro-*
18 *priate by the Secretary.*

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

20 (a) *IN GENERAL.*—*Not later than 18 months after the*
21 *date of enactment of this Act, the Secretary shall promul-*
22 *gate regulations described in section 416(b) of the Federal*
23 *Food, Drug, and Cosmetic Act (21 U.S.C. 350e(b)).*

24 (b) *FOOD TRANSPORTATION STUDY.*—*The Secretary,*
25 *acting through the Commissioner of Food and Drugs, shall*

1 *conduct a study of the transportation of food for consump-*
 2 *tion in the United States, including transportation by air,*
 3 *that includes an examination of the unique needs of rural*
 4 *and frontier areas with regard to the delivery of safe food.*

5 **SEC. 112. FOOD ALLERGY AND ANAPHYLAXIS MANAGE-**
 6 **MENT.**

7 (a) *DEFINITIONS.—In this section:*

8 (1) *EARLY CHILDHOOD EDUCATION PROGRAM.—*
 9 *The term “early childhood education program”*
 10 *means—*

11 (A) *a Head Start program or an Early*
 12 *Head Start program carried out under the Head*
 13 *Start Act (42 U.S.C. 9831 et seq.);*

14 (B) *a State licensed or regulated child care*
 15 *program or school; or*

16 (C) *a State prekindergarten program that*
 17 *serves children from birth through kindergarten.*

18 (2) *ESEA DEFINITIONS.—The terms “local edu-*
 19 *cational agency”, “secondary school”, “elementary*
 20 *school”, and “parent” have the meanings given the*
 21 *terms in section 9101 of the Elementary and Sec-*
 22 *ondary Education Act of 1965 (20 U.S.C. 7801).*

23 (3) *SCHOOL.—The term “school” includes pub-*
 24 *lic—*

25 (A) *kindergartens;*

1 (B) elementary schools; and

2 (C) secondary schools.

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

5 (b) ESTABLISHMENT OF VOLUNTARY FOOD ALLERGY
6 AND ANAPHYLAXIS MANAGEMENT GUIDELINES.—

7 (1) ESTABLISHMENT.—

8 (A) IN GENERAL.—Not later than 1 year
9 after the date of enactment of this Act, the Sec-
10 retary, in consultation with the Secretary of
11 Education, shall—

12 (i) develop guidelines to be used on a
13 voluntary basis to develop plans for indi-
14 viduals to manage the risk of food allergy
15 and anaphylaxis in schools and early child-
16 hood education programs; and

17 (ii) make such guidelines available to
18 local educational agencies, schools, early
19 childhood education programs, and other
20 interested entities and individuals to be im-
21 plemented on a voluntary basis only.

22 (B) APPLICABILITY OF FERPA.—Each plan
23 described in subparagraph (A) that is developed
24 for an individual shall be considered an edu-
25 cation record for the purpose of section 444 of the

1 *General Education Provisions Act (commonly re-*
2 *ferred to as the “Family Educational Rights and*
3 *Privacy Act of 1974”)* (20 U.S.C. 1232g).

4 (2) *CONTENTS.—The voluntary guidelines devel-*
5 *oped by the Secretary under paragraph (1) shall ad-*
6 *dress each of the following and may be updated as the*
7 *Secretary determines necessary:*

8 (A) *Parental obligation to provide the*
9 *school or early childhood education program,*
10 *prior to the start of every school year, with—*

11 (i) *documentation from their child’s*
12 *physician or nurse—*

13 (I) *supporting a diagnosis of food*
14 *allergy, and any risk of anaphylaxis, if*
15 *applicable;*

16 (II) *identifying any food to which*
17 *the child is allergic;*

18 (III) *describing, if appropriate,*
19 *any prior history of anaphylaxis;*

20 (IV) *listing any medication pre-*
21 *scribed for the child for the treatment*
22 *of anaphylaxis;*

23 (V) *detailing emergency treatment*
24 *procedures in the event of a reaction;*

1 (VI) listing the signs and symp-
2 toms of a reaction; and

3 (VII) assessing the child's readi-
4 ness for self-administration of prescrip-
5 tion medication; and

6 (ii) a list of substitute meals that may
7 be offered to the child by school or early
8 childhood education program food service
9 personnel.

10 (B) The creation and maintenance of an in-
11 dividual plan for food allergy management, in
12 consultation with the parent, tailored to the
13 needs of each child with a documented risk for
14 anaphylaxis, including any procedures for the
15 self-administration of medication by such chil-
16 dren in instances where—

17 (i) the children are capable of self-ad-
18 ministering medication; and

19 (ii) such administration is not prohib-
20 ited by State law.

21 (C) Communication strategies between indi-
22 vidual schools or early childhood education pro-
23 grams and providers of emergency medical serv-
24 ices, including appropriate instructions for
25 emergency medical response.

1 (D) *Strategies to reduce the risk of exposure*
2 *to anaphylactic causative agents in classrooms*
3 *and common school or early childhood education*
4 *program areas such as cafeterias.*

5 (E) *The dissemination of general informa-*
6 *tion on life-threatening food allergies to school or*
7 *early childhood education program staff, parents,*
8 *and children.*

9 (F) *Food allergy management training of*
10 *school or early childhood education program per-*
11 *sonnel who regularly come into contact with chil-*
12 *dren with life-threatening food allergies.*

13 (G) *The authorization and training of*
14 *school or early childhood education program per-*
15 *sonnel to administer epinephrine when the nurse*
16 *is not immediately available.*

17 (H) *The timely accessibility of epinephrine*
18 *by school or early childhood education program*
19 *personnel when the nurse is not immediately*
20 *available.*

21 (I) *The creation of a plan contained in each*
22 *individual plan for food allergy management*
23 *that addresses the appropriate response to an in-*
24 *cident of anaphylaxis of a child while such child*
25 *is engaged in extracurricular programs of a*

1 *school or early childhood education program,*
2 *such as non-academic outings and field trips,*
3 *before- and after-school programs or before- and*
4 *after-early child education program programs,*
5 *and school-sponsored or early childhood edu-*
6 *cation program-sponsored programs held on*
7 *weekends.*

8 *(J) Maintenance of information for each*
9 *administration of epinephrine to a child at risk*
10 *for anaphylaxis and prompt notification to par-*
11 *ents.*

12 *(K) Other elements the Secretary determines*
13 *necessary for the management of food allergies*
14 *and anaphylaxis in schools and early childhood*
15 *education programs.*

16 *(3) RELATION TO STATE LAW.—Nothing in this*
17 *section or the guidelines developed by the Secretary*
18 *under paragraph (1) shall be construed to preempt*
19 *State law, including any State law regarding whether*
20 *students at risk for anaphylaxis may self-administer*
21 *medication.*

22 *(c) SCHOOL-BASED FOOD ALLERGY MANAGEMENT*
23 *GRANTS.—*

24 *(1) IN GENERAL.—The Secretary may award*
25 *grants to local educational agencies to assist such*

1 *agencies with implementing voluntary food allergy*
2 *and anaphylaxis management guidelines described in*
3 *subsection (b).*

4 (2) *APPLICATION.—*

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

11 (B) *CONTENTS.—Each application sub-*
12 *mitted under subparagraph (A) shall include—*

13 (i) *an assurance that the local edu-*
14 *cational agency has developed plans in ac-*
15 *cordance with the food allergy and anaphy-*
16 *laxis management guidelines described in*
17 *subsection (b);*

18 (ii) *a description of the activities to be*
19 *funded by the grant in carrying out the*
20 *food allergy and anaphylaxis management*
21 *guidelines, including—*

22 (I) *how the guidelines will be car-*
23 *ried out at individual schools served by*
24 *the local educational agency;*

1 (II) *how the local educational*
2 *agency will inform parents and stu-*
3 *dents of the guidelines in place;*

4 (III) *how school nurses, teachers,*
5 *administrators, and other school-based*
6 *staff will be made aware of, and given*
7 *training on, when applicable, the*
8 *guidelines in place; and*

9 (IV) *any other activities that the*
10 *Secretary determines appropriate;*

11 (iii) *an itemization of how grant funds*
12 *received under this subsection will be ex-*
13 *pende;d;*

14 (iv) *a description of how adoption of*
15 *the guidelines and implementation of grant*
16 *activities will be monitored; and*

17 (v) *an agreement by the local edu-*
18 *cational agency to report information re-*
19 *quired by the Secretary to conduct evalua-*
20 *tions under this subsection.*

21 (3) *USE OF FUNDS.—Each local educational*
22 *agency that receives a grant under this subsection*
23 *may use the grant funds for the following:*

24 (A) *Purchase of materials and supplies, in-*
25 *cluding limited medical supplies such as epi-*

1 *nephrene and disposable wet wipes, to support*
2 *carrying out the food allergy and anaphylaxis*
3 *management guidelines described in subsection*
4 *(b).*

5 *(B) In partnership with local health depart-*
6 *ments, school nurse, teacher, and personnel*
7 *training for food allergy management.*

8 *(C) Programs that educate students as to*
9 *the presence of, and policies and procedures in*
10 *place related to, food allergies and anaphylactic*
11 *shock.*

12 *(D) Outreach to parents.*

13 *(E) Any other activities consistent with the*
14 *guidelines described in subsection (b).*

15 *(4) DURATION OF AWARDS.—The Secretary may*
16 *award grants under this subsection for a period of not*
17 *more than 2 years. In the event the Secretary con-*
18 *ducts a program evaluation under this subsection,*
19 *funding in the second year of the grant, where appli-*
20 *cable, shall be contingent on a successful program*
21 *evaluation by the Secretary after the first year.*

22 *(5) LIMITATION ON GRANT FUNDING.—The Sec-*
23 *retary may not provide grant funding to a local edu-*
24 *cational agency under this subsection after such local*

1 *educational agency has received 2 years of grant*
2 *funding under this subsection.*

3 (6) *MAXIMUM AMOUNT OF ANNUAL AWARDS.—A*
4 *grant awarded under this subsection may not be*
5 *made in an amount that is more than \$50,000 annu-*
6 *ally.*

7 (7) *PRIORITY.—In awarding grants under this*
8 *subsection, the Secretary shall give priority to local*
9 *educational agencies with the highest percentages of*
10 *children who are counted under section 1124(c) of the*
11 *Elementary and Secondary Education Act of 1965*
12 *(20 U.S.C. 6333(c)).*

13 (8) *MATCHING FUNDS.—*

14 (A) *IN GENERAL.—The Secretary may not*
15 *award a grant under this subsection unless the*
16 *local educational agency agrees that, with respect*
17 *to the costs to be incurred by such local edu-*
18 *cational agency in carrying out the grant activi-*
19 *ties, the local educational agency shall make*
20 *available (directly or through donations from*
21 *public or private entities) non-Federal funds to-*
22 *ward such costs in an amount equal to not less*
23 *than 25 percent of the amount of the grant.*

24 (B) *DETERMINATION OF AMOUNT OF NON-*
25 *FEDERAL CONTRIBUTION.—Non-Federal funds*

1 *required under subparagraph (A) may be cash or*
2 *in kind, including plant, equipment, or services.*
3 *Amounts provided by the Federal Government,*
4 *and any portion of any service subsidized by the*
5 *Federal Government, may not be included in de-*
6 *termining the amount of such non-Federal funds.*

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

12 (10) *PROGRESS AND EVALUATIONS.—At the com-*
13 *pletion of the grant period referred to in paragraph*
14 *(4), a local educational agency shall provide the Sec-*
15 *retary with information on how grant funds were*
16 *spent and the status of implementation of the food al-*
17 *lergy and anaphylaxis management guidelines de-*
18 *scribed in subsection (b).*

19 (11) *SUPPLEMENT, NOT SUPPLANT.—Grant*
20 *funds received under this subsection shall be used to*
21 *supplement, and not supplant, non-Federal funds and*
22 *any other Federal funds available to carry out the ac-*
23 *tivities described in this subsection.*

24 (12) *AUTHORIZATION OF APPROPRIATIONS.—*
25 *There is authorized to be appropriated to carry out*

1 *this subsection \$30,000,000 for fiscal year 2011 and*
2 *such sums as may be necessary for each of the 4 suc-*
3 *ceeding fiscal years.*

4 *(d) VOLUNTARY NATURE OF GUIDELINES.—*

5 *(1) IN GENERAL.—The food allergy and anaphy-*
6 *laxis management guidelines developed by the Sec-*
7 *retary under subsection (b) are voluntary. Nothing in*
8 *this section or the guidelines developed by the Sec-*
9 *retary under subsection (b) shall be construed to re-*
10 *quire a local educational agency to implement such*
11 *guidelines.*

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

17 **SEC. 113. NEW DIETARY INGREDIENTS.**

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

20 *(1) by redesignating subsection (c) as subsection*
21 *(d); and*

22 *(2) by inserting after subsection (b) the fol-*
23 *lowing:*

24 *“(c) NOTIFICATION.—*

1 “(1) *IN GENERAL.*—*If the Secretary determines*
2 *that the information in a new dietary ingredient no-*
3 *tification submitted under this section for an article*
4 *purported to be a new dietary ingredient is inad-*
5 *equately to establish that a dietary supplement con-*
6 *taining such article will reasonably be expected to be*
7 *safe because the article may be, or may contain, an*
8 *anabolic steroid or an analogue of an anabolic ster-*
9 *oid, the Secretary shall notify the Drug Enforcement*
10 *Administration of such determination. Such notifica-*
11 *tion by the Secretary shall include, at a minimum,*
12 *the name of the dietary supplement or article, the*
13 *name of the person or persons who marketed the prod-*
14 *uct or made the submission of information regarding*
15 *the article to the Secretary under this section, and*
16 *any contact information for such person or persons*
17 *that the Secretary has.*

18 “(2) *DEFINITIONS.*—*For purposes of this sub-*
19 *section—*

20 “(A) *the term ‘anabolic steroid’ has the*
21 *meaning given such term in section 102(41) of*
22 *the Controlled Substances Act; and*

23 “(B) *the term ‘analogue of an anabolic ster-*
24 *oid’ means a substance whose chemical structure*

1 *is substantially similar to the chemical structure*
2 *of an anabolic steroid.”.*

3 (b) *GUIDANCE.—Not later than 180 days after the date*
4 *of enactment of this Act, the Secretary shall publish guid-*
5 *ance that clarifies when a dietary supplement ingredient*
6 *is a new dietary ingredient, when the manufacturer or dis-*
7 *tributor of a dietary ingredient or dietary supplement*
8 *should provide the Secretary with information as described*
9 *in section 413(a)(2) of the Federal Food, Drug, and Cos-*
10 *metic Act, the evidence needed to document the safety of new*
11 *dietary ingredients, and appropriate methods for estab-*
12 *lishing the identify of a new dietary ingredient.*

13 **SEC. 114. REQUIREMENT FOR GUIDANCE RELATING TO**
14 **POST HARVEST PROCESSING OF RAW OYS-**
15 **TERS.**

16 (a) *IN GENERAL.—Not later than 90 days prior to the*
17 *issuance of any guidance, regulation, or suggested amend-*
18 *ment by the Food and Drug Administration to the National*
19 *Shellfish Sanitation Program’s Model Ordinance, or the*
20 *issuance of any guidance or regulation by the Food and*
21 *Drug Administration relating to the Seafood Hazard Anal-*
22 *ysis Critical Control Points Program of the Food and Drug*
23 *Administration (parts 123 and 1240 of title 21, Code of*
24 *Federal Regulations (or any successor regulations), where*
25 *such guidance, regulation or suggested amendment relates*

1 *to post harvest processing for raw oysters, the Secretary*
2 *shall prepare and submit to the Committee on Health, Edu-*
3 *cation, Labor, and Pensions of the Senate and the Com-*
4 *mittee on Energy and Commerce of the House of Represent-*
5 *atives a report which shall include—*

6 (1) *an assessment of how post harvest processing*
7 *or other equivalent controls feasibly may be imple-*
8 *mented in the fastest, safest, and most economical*
9 *manner;*

10 (2) *the projected public health benefits of any*
11 *proposed post harvest processing;*

12 (3) *the projected costs of compliance with such*
13 *post harvest processing measures;*

14 (4) *the impact post harvest processing is expected*
15 *to have on the sales, cost, and availability of raw oys-*
16 *ters;*

17 (5) *criteria for ensuring post harvest processing*
18 *standards will be applied equally to shellfish imported*
19 *from all nations of origin;*

20 (6) *an evaluation of alternative measures to pre-*
21 *vent, eliminate, or reduce to an acceptable level the*
22 *occurrence of foodborne illness; and*

23 (7) *the extent to which the Food and Drug Ad-*
24 *ministration has consulted with the States and other*

1 *regulatory agencies, as appropriate, with regard to*
2 *post harvest processing measures.*

3 *(b) LIMITATION.—Subsection (a) shall not apply to the*
4 *guidance described in section 103(h).*

5 *(c) REVIEW AND EVALUATION.—Not later than 30*
6 *days after the Secretary issues a proposed regulation or*
7 *guidance described in subsection (a), the Comptroller Gen-*
8 *eral of the United States shall—*

9 *(1) review and evaluate the report described in*
10 *(a) and report to Congress on the findings of the esti-*
11 *mates and analysis in the report;*

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

18 *(3) evaluate the impact of post harvest proc-*
19 *essing on the competitiveness of the domestic oyster*
20 *industry in the United States and in international*
21 *markets.*

22 *(d) WAIVER.—The requirement of preparing a report*
23 *under subsection (a) shall be waived if the Secretary issues*
24 *a guidance that is adopted as a consensus agreement be-*
25 *tween Federal and State regulators and the oyster industry,*

1 *acting through the Interstate Shellfish Sanitation Con-*
2 *ference.*

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

5 **SEC. 115. PORT SHOPPING.**

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

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

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

1 (1) *under the Federal Alcohol Administration*
2 *Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle*
3 *E of the Internal Revenue Code of 1986 (26 U.S.C.*
4 *5001 et seq.) is required to obtain a permit or to reg-*
5 *ister with the Secretary of the Treasury as a condi-*
6 *tion of doing business in the United States; and*

7 (2) *under section 415 of the Federal Food, Drug,*
8 *and Cosmetic Act (21 U.S.C. 350d) is required to reg-*
9 *ister as a facility because such facility is engaged in*
10 *manufacturing, processing, packing, or holding 1 or*
11 *more alcoholic beverages, with respect to the activities*
12 *of such facility that relate to the manufacturing,*
13 *processing, packing, or holding of alcoholic beverages.*

14 **(b) LIMITED RECEIPT AND DISTRIBUTION OF NON-AL-**
15 *COHOL FOOD.—Subsection (a) shall not apply to a facility*
16 *engaged in the receipt and distribution of any non-alcohol*
17 *food, except that such paragraph shall apply to a facility*
18 *described in such paragraph that receives and distributes*
19 *non-alcohol food, provided such food is received and distrib-*
20 *uted—*

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

23 (2) *in amounts that constitute not more than 5*
24 *percent of the overall sales of such facility, as deter-*
25 *mined by the Secretary of the Treasury.*

1 (c) *RULE OF CONSTRUCTION.*—*Except as provided in*
 2 *subsections (a) and (b), this section shall not be construed*
 3 *to exempt any food, other than alcoholic beverages, as de-*
 4 *fin ed in section 214 of the Federal Alcohol Administration*
 5 *Act (27 U.S.C. 214), from the requirements of this Act (in-*
 6 *cluding the amendments made by this Act).*

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

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

13 (a) *TARGETING OF INSPECTION RESOURCES FOR DO-*
 14 *MESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF*
 15 *ENTRY.*—*Chapter IV (21 U.S.C. 341 et seq.), as amended*
 16 *by section 106, is amended by adding at the end the fol-*
 17 *lowing:*

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

21 ***“(a) IDENTIFICATION AND INSPECTION OF FACILI-***
 22 ***TIES.—***

23 ***“(1) IDENTIFICATION.***—*The Secretary shall iden-*
 24 *tify high-risk facilities and shall allocate resources to*
 25 *inspect facilities according to the known safety risks*

1 *of the facilities, which shall be based on the following*
2 *factors:*

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

6 “(B) *The compliance history of a facility,*
7 *including with regard to food recalls, outbreaks*
8 *of foodborne illness, and violations of food safety*
9 *standards.*

10 “(C) *The rigor and effectiveness of the fa-*
11 *ility’s hazard analysis and risk-based preven-*
12 *tive controls.*

13 “(D) *Whether the food manufactured, proc-*
14 *essed, packed, or held at the facility meets the*
15 *criteria for priority under section 801(h)(1).*

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

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

23 “(2) *INSPECTIONS.—*

24 “(A) *IN GENERAL.—Beginning on the date*
25 *of enactment of the FDA Food Safety Moderniza-*

1 *tion Act, the Secretary shall increase the fre-*
2 *quency of inspection of all facilities.*

3 “(B) *DOMESTIC HIGH-RISK FACILITIES.—*
4 *The Secretary shall increase the frequency of in-*
5 *spection of domestic facilities identified under*
6 *paragraph (1) as high-risk facilities such that*
7 *each such facility is inspected—*

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

12 “(ii) *not less often than once every 3*
13 *years thereafter.*

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

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

22 “(ii) *not less often than once every 5*
23 *years thereafter.*

24 “(D) *FOREIGN FACILITIES.—*

1 “(i) *YEAR 1.*—*In the 1-year period fol-*
2 *lowing the date of enactment of the FDA*
3 *Food Safety Modernization Act, the Sec-*
4 *retary shall inspect not fewer than 600 for-*
5 *foreign facilities.*

6 “(ii) *SUBSEQUENT YEARS.*—*In each of*
7 *the 5 years following the 1-year period de-*
8 *scribed in clause (i), the Secretary shall in-*
9 *spect not fewer than twice the number of*
10 *foreign facilities inspected by the Secretary*
11 *during the previous year.*

12 “(E) *RELIANCE ON FEDERAL, STATE, OR*
13 *LOCAL INSPECTIONS.*—*In meeting the inspection*
14 *requirements under this subsection for domestic*
15 *facilities, the Secretary may rely on inspections*
16 *conducted by other Federal, State, or local agen-*
17 *cies under interagency agreement, contract,*
18 *memoranda of understanding, or other obliga-*
19 *tion.*

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

1 “(1) *The known safety risks of the food imported.*

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

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

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

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

16 “(6) *Whether the food meets the criteria for pri-*
17 *ority under section 801(h)(1).*

18 “(7) *Whether the food or the facility that manu-*
19 *factured, processed, packed, or held such food received*
20 *a certification as described in section 801(q) 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 and*
2 *Human Services, the Secretary of Commerce, the Sec-*
3 *retary of Homeland Security, the Chairman of the*
4 *Federal Trade Commission, and the heads of other*
5 *appropriate agencies may enter into such agreements*
6 *as may be necessary or appropriate to improve sea-*
7 *food 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 testing*
19 *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 ex-*
2 *aminations and investigations under section 801*
3 *of this Act or section 203 of the Food Allergen*
4 *Labeling and Consumer Protection Act of 2004;*

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

11 “(G) *conducting joint training on subjects*
12 *that affect and strengthen seafood inspection ef-*
13 *fectiveness by Federal authorities; and*

14 “(H) *outreach on Federal efforts to enhance*
15 *seafood safety and compliance with Federal food*
16 *safety requirements.*

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

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

24 “(b) *ANNUAL REPORT.—Section 1003 (21 U.S.C. 393)*
25 *is amended by adding at the end the following:*

1 “(h) *ANNUAL REPORT REGARDING FOOD.*—Not later
2 *than February 1 of each year, the Secretary shall submit*
3 *to Congress a report, including efforts to coordinate and*
4 *cooperate with other Federal agencies with responsibilities*
5 *for food inspections, regarding—*

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

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

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

15 “(C) *the number of domestic facilities and*
16 *the number of foreign facilities registered pursu-*
17 *ant to section 415 that the Secretary inspected in*
18 *the previous fiscal year;*

19 “(D) *the number of domestic facilities and*
20 *the number of foreign facilities registered pursu-*
21 *ant to section 415 that were scheduled for inspec-*
22 *tion in the previous fiscal year and which the*
23 *Secretary did not inspect in such year;*

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

4 “(F) the number of high-risk facilities iden-
5 tified pursuant to section 421 that were sched-
6 uled for inspection in the previous fiscal year
7 and which the Secretary did not inspect in such
8 year.

9 “(2) information about food imports including—

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

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

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

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

24 “(A) the number of foreign offices estab-
25 lished; and

1 “(B) the number of personnel permanently
2 stationed in each foreign office.

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

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

13 **SEC. 202. LABORATORY ACCREDITATION FOR ANALYSES OF**
14 **FOODS.**

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

18 **“SEC. 422. LABORATORY ACCREDITATION FOR ANALYSES**
19 **OF FOODS.**

20 “(a) *RECOGNITION OF LABORATORY ACCREDITA-*
21 *TION.*—

22 “(1) *IN GENERAL.*—Not later than 2 years after
23 the date of enactment of the FDA Food Safety Mod-
24 ernization Act, the Secretary shall—

1 “(A) establish a program for the testing of
2 *food by accredited laboratories;*

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

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

16 “(2) *PROGRAM REQUIREMENTS.—The program*
17 *established under paragraph (1)(A) shall provide for*
18 *the recognition of laboratory accreditation bodies that*
19 *meet criteria established by the Secretary for accredi-*
20 *tation of laboratories, including independent private*
21 *laboratories and laboratories run and operated by a*
22 *Federal agency (including the Department of Com-*
23 *merce), State, or locality with a demonstrated capa-*
24 *bility to conduct 1 or more sampling and analytical*
25 *testing methodologies for food.*

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

9 “(4) *LIMITED DISTRIBUTION.*—*In the interest of*
10 *national security, the Secretary, in coordination with*
11 *the Secretary of Homeland Security, may determine*
12 *the time, manner, and form in which the registry es-*
13 *tablished under paragraph (1)(B) is made publicly*
14 *available.*

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

21 “(6) *MODEL LABORATORY STANDARDS.*—*The*
22 *Secretary shall develop model standards that a lab-*
23 *oratory shall meet to be accredited by a recognized ac-*
24 *creditation body for a specified sampling or analyt-*
25 *ical testing methodology and included in the registry*

1 provided for under paragraph (1). In developing the
2 model standards, the Secretary shall consult existing
3 standards for guidance. The model standards shall in-
4 clude—

5 “(A) methods to ensure that—

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

11 “(ii) internal quality systems are es-
12 tablished and maintained;

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

17 “(iv) individuals who conduct the sam-
18 pling and analyses are qualified by train-
19 ing and experience to do so; and

20 “(B) any other criteria determined appro-
21 priate by the Secretary.

22 “(7) REVIEW OF RECOGNITION.—To ensure com-
23 pliance with the requirements of this section, the Sec-
24 retary—

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

7 “(B) shall promptly revoke the recognition
8 of any accreditation body found not to be in
9 compliance with the requirements of this section,
10 specifying, as appropriate, any terms and condi-
11 tions necessary for laboratories accredited by
12 such body to continue to perform testing as de-
13 scribed in this section.

14 “(b) TESTING PROCEDURES.—

15 “(1) IN GENERAL.—Not later than 30 months
16 after the date of enactment of the FDA Food Safety
17 Modernization Act, food testing shall be conducted by
18 Federal laboratories or non-Federal laboratories that
19 have been accredited for the appropriate sampling or
20 analytical testing methodology or methodologies by a
21 recognized accreditation body on the registry estab-
22 lished by the Secretary under subsection (a)(1)(B)
23 whenever such testing is conducted—

24 “(A) by or on behalf of an owner or con-
25 signee—

1 “(i) in response to a specific testing re-
2 quirement under this Act or implementing
3 regulations, when applied to address an
4 identified or suspected food safety problem;
5 and

6 “(ii) as required by the Secretary, as
7 the Secretary deems appropriate, to address
8 an identified or suspected food safety prob-
9 lem; or

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

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

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

15 “(2) RESULTS OF TESTING.—The results of any
16 such testing shall be sent directly to the Food and
17 Drug Administration, except the Secretary may by
18 regulation exempt test results from such submission
19 requirement if the Secretary determines that such re-
20 sults do not contribute to the protection of public
21 health. Test results required to be submitted may be
22 submitted to the Food and Drug Administration
23 through electronic means.

24 “(3) EXCEPTION.—The Secretary may waive re-
25 quirements under this subsection if—

1 “(A) a new methodology or methodologies
2 have been developed and validated but a labora-
3 tory has not yet been accredited to perform such
4 methodology or methodologies; and

5 “(B) the use of such methodology or meth-
6 odologies are necessary to prevent, control, or
7 mitigate a food emergency or foodborne illness
8 outbreak.

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

17 “(d) *NO LIMIT ON SECRETARIAL AUTHORITY.*—Noth-
18 ing in this section shall be construed to limit the ability
19 of the Secretary to review and act upon information from
20 food testing, including determining the sufficiency of such
21 information and testing.”.

22 “(b) *FOOD EMERGENCY RESPONSE NETWORK.*—The
23 Secretary, in coordination with the Secretary of Agri-
24 culture, the Secretary of Homeland Security, and State,
25 local, and tribal governments shall, not later than 180 days

1 *after the date of enactment of this Act, and biennially there-*
2 *after, submit to the relevant committees of Congress, and*
3 *make publicly available on the Internet Web site of the De-*
4 *partment of Health and Human Services, a report on the*
5 *progress in implementing a national food emergency re-*
6 *sponse laboratory network that—*

7 (1) *provides ongoing surveillance, rapid detec-*
8 *tion, and surge capacity for large-scale food-related*
9 *emergencies, including intentional adulteration of the*
10 *food supply;*

11 (2) *coordinates the food laboratory capacities of*
12 *State, local, and tribal food laboratories, including*
13 *the adoption of novel surveillance and identification*
14 *technologies and the sharing of data between Federal*
15 *agencies and State laboratories to develop national*
16 *situational awareness;*

17 (3) *provides accessible, timely, accurate, and*
18 *consistent food laboratory services throughout the*
19 *United States;*

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

22 (5) *responds to food-related emergencies; and*

23 (6) *is integrated with relevant laboratory net-*
24 *works administered by other Federal agencies.*

1 **SEC. 203. INTEGRATED CONSORTIUM OF LABORATORY NET-**
2 **WORKS.**

3 (a) *IN GENERAL.*—*The Secretary of Homeland Secu-*
4 *rity, in coordination with the Secretary of Health and*
5 *Human Services, the Secretary of Agriculture, the Secretary*
6 *of Commerce, and the Administrator of the Environmental*
7 *Protection Agency, shall maintain an agreement through*
8 *which relevant laboratory network members, as determined*
9 *by the Secretary of Homeland Security, shall—*

10 (1) *agree on common laboratory methods in*
11 *order to reduce the time required to detect and re-*
12 *spond to foodborne illness outbreaks and facilitate the*
13 *sharing of knowledge and information relating to ani-*
14 *mal health, agriculture, and human health;*

15 (2) *identify means by which laboratory network*
16 *members could work cooperatively—*

17 (A) *to optimize national laboratory pre-*
18 *paredness; and*

19 (B) *to provide surge capacity during emer-*
20 *gencies; and*

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

24 (b) *REPORTING REQUIREMENT.*—*The Secretary of*
25 *Homeland Security shall, on a biennial basis, submit to*
26 *the relevant committees of Congress, and make publicly*

1 *available on the Internet Web site of the Department of*
2 *Homeland Security, a report on the progress of the inte-*
3 *grated consortium of laboratory networks, as established*
4 *under subsection (a), in carrying out this section.*

5 **SEC. 204. ENHANCING TRACKING AND TRACING OF FOOD**
6 **AND RECORDKEEPING.**

7 *(a) PILOT PROJECTS.—*

8 *(1) IN GENERAL.—Not later than 270 days after*
9 *the date of enactment of this Act, the Secretary of*
10 *Health and Human Services (referred to in this sec-*
11 *tion as the “Secretary”), taking into account rec-*
12 *ommendations from the Secretary of Agriculture and*
13 *representatives of State departments of health and ag-*
14 *riculture, shall establish pilot projects in coordination*
15 *with the food industry to explore and evaluate meth-*
16 *ods to rapidly and effectively identify recipients of*
17 *food to prevent or mitigate a foodborne illness out-*
18 *break and to address credible threats of serious ad-*
19 *verse health consequences or death to humans or ani-*
20 *mals as a result of such food being adulterated under*
21 *section 402 of the Federal Food, Drug, and Cosmetic*
22 *Act (21 U.S.C. 342) or misbranded under section*
23 *403(w) of such Act (21 U.S.C. 343(w)).*

24 *(2) CONTENT.—The Secretary shall conduct 1 or*
25 *more pilot projects under paragraph (1) in coordina-*

1 *tion with the processed food sector and 1 or more such*
2 *pilot projects in coordination with processors or dis-*
3 *tributors of fruits and vegetables that are raw agricul-*
4 *tural commodities. The Secretary shall ensure that the*
5 *pilot projects under paragraph (1) reflect the diver-*
6 *sity of the food supply and include at least 3 different*
7 *types of foods that have been the subject of significant*
8 *outbreaks during the 5-year period preceding the date*
9 *of enactment of this Act, and are selected in order*
10 *to—*

11 *(A) develop and demonstrate methods for*
12 *rapid and effective tracking and tracing of foods*
13 *in a manner that is practicable for facilities of*
14 *varying sizes, including small businesses;*

15 *(B) develop and demonstrate appropriate*
16 *technologies, including technologies existing on*
17 *the date of enactment of this Act, that enhance*
18 *the tracking and tracing of food; and*

19 *(C) inform the promulgation of regulations*
20 *under subsection (d).*

21 *(3) REPORT.—Not later than 18 months after the*
22 *date of enactment of this Act, the Secretary shall re-*
23 *port to Congress on the findings of the pilot projects*
24 *under this subsection together with recommendations*
25 *for improving the tracking and tracing of food.*

1 **(b) ADDITIONAL DATA GATHERING.**—

2 **(1) IN GENERAL.**—*The Secretary, in coordina-*
3 *tion with the Secretary of Agriculture and multiple*
4 *representatives of State departments of health and ag-*
5 *riculture, shall assess—*

6 **(A)** *the costs and benefits associated with*
7 *the adoption and use of several product tracing*
8 *technologies, including technologies used in the*
9 *pilot projects under subsection (a);*

10 **(B)** *the feasibility of such technologies for*
11 *different sectors of the food industry, including*
12 *small businesses; and*

13 **(C)** *whether such technologies are compat-*
14 *ible with the requirements of this subsection.*

15 **(2) REQUIREMENTS.**—*To the extent practicable,*
16 *in carrying out paragraph (1), the Secretary shall—*

17 **(A)** *evaluate domestic and international*
18 *product tracing practices in commercial use;*

19 **(B)** *consider international efforts, including*
20 *an assessment of whether product tracing re-*
21 *quirements developed under this section are com-*
22 *patible with global tracing systems, as appro-*
23 *priate; and*

24 **(C)** *consult with a diverse and broad range*
25 *of experts and stakeholders, including representa-*

1 *tives of the food industry, agricultural producers,*
2 *and nongovernmental organizations that rep-*
3 *resent the interests of consumers.*

4 *(c) PRODUCT TRACING SYSTEM.—The Secretary, in*
5 *consultation with the Secretary of Agriculture, shall, as ap-*
6 *propriate, establish within the Food and Drug Administra-*
7 *tion a product tracing system to receive information that*
8 *improves the capacity of the Secretary to effectively and*
9 *rapidly track and trace food that is in the United States*
10 *or offered for import into the United States. Prior to the*
11 *establishment of such product tracing system, the Secretary*
12 *shall examine the results of applicable pilot projects and*
13 *shall ensure that the activities of such system are adequately*
14 *supported by the results of such pilot projects.*

15 *(d) ADDITIONAL RECORDKEEPING REQUIREMENTS*
16 *FOR HIGH RISK FOODS.—*

17 *(1) IN GENERAL.—In order to rapidly and effec-*
18 *tively identify recipients of a food to prevent or miti-*
19 *gate a foodborne illness outbreak and to address cred-*
20 *ible threats of serious adverse health consequences or*
21 *death to humans or animals as a result of such food*
22 *being adulterated under section 402 of the Federal*
23 *Food, Drug, and Cosmetic Act or misbranded under*
24 *section 403(w) of such Act, not later than 2 years*
25 *after the date of enactment of this Act, the Secretary*

1 *shall publish a notice of proposed rulemaking to es-*
2 *tablish recordkeeping requirements, in addition to the*
3 *requirements under section 414 of the Federal Food,*
4 *Drug, and Cosmetic Act (21 U.S.C. 350c) and sub-*
5 *part J of part 1 of title 21, Code of Federal Regula-*
6 *tions (or any successor regulations), for facilities that*
7 *manufacture, process, pack, or hold foods that the Sec-*
8 *retary designates under paragraph (2) as high-risk*
9 *foods. The Secretary shall set an appropriate effective*
10 *date of such additional requirements for foods des-*
11 *ignated as high risk that takes into account the length*
12 *of time necessary to comply with such requirements.*
13 *Such requirements shall—*

14 *(A) relate only to information that is rea-*
15 *sonably available and appropriate;*

16 *(B) be science-based;*

17 *(C) not prescribe specific technologies for the*
18 *maintenance of records;*

19 *(D) ensure that the public health benefits of*
20 *imposing additional recordkeeping requirements*
21 *outweigh the cost of compliance with such re-*
22 *quirements;*

23 *(E) be scale-appropriate and practicable for*
24 *facilities of varying sizes and capabilities with*
25 *respect to costs and recordkeeping burdens, and*

1 *not require the creation and maintenance of du-*
2 *PLICATE records where the information is con-*
3 *tained in other company records kept in the nor-*
4 *mal course of business;*

5 *(F) minimize the number of different rec-*
6 *ordkeeping requirements for facilities that handle*
7 *more than 1 type of food;*

8 *(G) to the extent practicable, not require a*
9 *facility to change business systems to comply*
10 *with such requirements;*

11 *(H) allow any person subject to this sub-*
12 *section to maintain records required under this*
13 *subsection at a central or reasonably accessible*
14 *location provided that such records can be made*
15 *available to the Secretary not later than 24*
16 *hours after the Secretary requests such records;*
17 *and*

18 *(I) include a process by which the Secretary*
19 *may issue a waiver of the requirements under*
20 *this subsection if the Secretary determines that*
21 *such requirements would result in an economic*
22 *hardship for an individual facility or a type of*
23 *facility;*

24 *(J) be commensurate with the known safety*
25 *risks of the designated food;*

1 (K) take into account international trade
2 obligations;

3 (L) not require—

4 (i) a full pedigree, or a record of the
5 complete previous distribution history of the
6 food from the point of origin of such food;

7 (ii) records of recipients of a food be-
8 yond the immediate subsequent recipient of
9 such food; or

10 (iii) product tracking to the case level
11 by persons subject to such requirements; and

12 (M) include a process by which the Sec-
13 retary may remove a high-risk food designation
14 developed under paragraph (2) for a food or type
15 of food.

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

17 (A) IN GENERAL.—Not later than 1 year
18 after the date of enactment of this Act, and there-
19 after as the Secretary determines necessary, the
20 Secretary shall designate high-risk foods for
21 which the additional recordkeeping requirements
22 described in paragraph (1) are appropriate and
23 necessary to protect the public health. Each such
24 designation shall be based on—

1 (i) *the known safety risks of a par-*
2 *ticular food, including the history and se-*
3 *verity of foodborne illness outbreaks attrib-*
4 *uted to such food, taking into consideration*
5 *foodborne illness data collected by the Cen-*
6 *ters for Disease Control and Prevention;*

7 (ii) *the likelihood that a particular*
8 *food has a high potential risk for micro-*
9 *biological or chemical contamination or*
10 *would support the growth of pathogenic*
11 *microorganisms due to the nature of the*
12 *food or the processes used to produce such*
13 *food;*

14 (iii) *the point in the manufacturing*
15 *process of the food where contamination is*
16 *most likely to occur;*

17 (iv) *the likelihood of contamination*
18 *and steps taken during the manufacturing*
19 *process to reduce the possibility of contami-*
20 *nation;*

21 (v) *the likelihood that consuming a*
22 *particular food will result in a foodborne*
23 *illness due to contamination of the food;*
24 *and*

1 (vi) the likely or known severity, in-
2 cluding health and economic impacts, of a
3 foodborne illness attributed to a particular
4 food.

5 (B) LIST OF HIGH-RISK FOODS.—At the
6 time the Secretary promulgates the final rules
7 under paragraph (1), the Secretary shall publish
8 the list of the foods designated under subpara-
9 graph (A) as high-risk foods on the Internet
10 website of the Food and Drug Administration.
11 The Secretary may update the list to designate
12 new high-risk foods and to remove foods that are
13 no longer deemed to be high-risk foods, provided
14 that each such update to the list is consistent
15 with the requirements of this subsection and no-
16 tice of such update is published in the Federal
17 Register.

18 (3) PROTECTION OF SENSITIVE INFORMATION.—
19 In promulgating regulations under this subsection,
20 the Secretary shall take appropriate measures to en-
21 sure that there are effective procedures to prevent the
22 unauthorized disclosure of any trade secret or con-
23 fidential information that is obtained by the Sec-
24 retary pursuant to this section, including periodic

1 *risk assessment and planning to prevent unauthorized*
2 *release and controls to—*

3 *(A) prevent unauthorized reproduction of*
4 *trade secret or confidential information;*

5 *(B) prevent unauthorized access to trade se-*
6 *cret or confidential information; and*

7 *(C) maintain records with respect to access*
8 *by any person to trade secret or confidential in-*
9 *formation maintained by the agency.*

10 *(4) PUBLIC INPUT.—During the comment period*
11 *in the notice of proposed rulemaking under para-*
12 *graph (1), the Secretary shall conduct not less than*
13 *3 public meetings in diverse geographical areas of the*
14 *United States to provide persons in different regions*
15 *an opportunity to comment.*

16 *(5) RETENTION OF RECORDS.—Except as other-*
17 *wise provided in this subsection, the Secretary may*
18 *require that a facility retain records under this sub-*
19 *section for not more than 2 years, taking into consid-*
20 *eration the risk of spoilage, loss of value, or loss of*
21 *palatability of the applicable food when determining*
22 *the appropriate timeframes.*

23 *(6) LIMITATIONS.—*

24 *(A) FARM TO SCHOOL PROGRAMS.—In es-*
25 *tablishing requirements under this subsection,*

1 *the Secretary shall, in consultation with the Sec-*
2 *retary of Agriculture, consider the impact of re-*
3 *quirements on farm to school or farm to institu-*
4 *tion programs of the Department of Agriculture*
5 *and other farm to school and farm to institution*
6 *programs outside such agency, and shall modify*
7 *the requirements under this subsection, as appro-*
8 *priate, with respect to such programs so that the*
9 *requirements do not place undue burdens on*
10 *farm to school or farm to institution programs.*

11 *(B) IDENTITY-PRESERVED LABELS WITH*
12 *RESPECT TO FARM SALES OF FOOD THAT IS PRO-*
13 *DUCED AND PACKAGED ON A FARM.—The re-*
14 *quirements under this subsection shall not apply*
15 *to a food that is produced and packaged on a*
16 *farm if—*

17 *(i) the packaging of the food maintains*
18 *the integrity of the product and prevents*
19 *subsequent contamination or alteration of*
20 *the product; and*

21 *(ii) the labeling of the food includes the*
22 *name, complete address (street address,*
23 *town, State, country, and zip or other post-*
24 *al code), and business phone number of the*
25 *farm, unless the Secretary waives the re-*

1 *quirement to include a business phone num-*
2 *ber of the farm, as appropriate, in order to*
3 *accommodate a religious belief of the indi-*
4 *vidual in charge of such farm.*

5 (C) *FISHING VESSELS.*—*The requirements*
6 *under this subsection with respect to a food that*
7 *is produced through the use of a fishing vessel (as*
8 *defined in section 3(18) of the Magnuson-Stevens*
9 *Fishery Conservation and Management Act (16*
10 *U.S.C. 1802(18))) shall be limited to the require-*
11 *ments under subparagraph (F) until such time*
12 *as the food is sold by the owner, operator, or*
13 *agent in charge of such fishing vessel.*

14 (D) *COMMINGLED RAW AGRICULTURAL COM-*
15 *MODITIES.*—

16 (i) *LIMITATION ON EXTENT OF TRAC-*
17 *ING.*—*Recordkeeping requirements under*
18 *this subsection with regard to any commin-*
19 *gled raw agricultural commodity shall be*
20 *limited to the requirements under subpara-*
21 *graph (F).*

22 (ii) *DEFINITIONS.*—*For the purposes of*
23 *this subparagraph—*

24 (I) *the term “commingled raw ag-*
25 *ricultural commodity” means any*

1 *commodity that is combined or mixed*
2 *after harvesting, but before processing;*

3 (II) *the term “commingled raw*
4 *agricultural commodity” shall not in-*
5 *clude types of fruits and vegetables that*
6 *are raw agricultural commodities for*
7 *which the Secretary has determined*
8 *that standards promulgated under sec-*
9 *tion 419 of the Federal Food, Drug,*
10 *and Cosmetic Act (as added by section*
11 *105) would minimize the risk of seri-*
12 *ous adverse health consequences or*
13 *death; and*

14 (III) *the term “processing” means*
15 *operations that alter the general state*
16 *of the commodity, such as canning,*
17 *cooking, freezing, dehydration, milling,*
18 *grinding, pasteurization, or homogeni-*
19 *zation.*

20 (E) *EXEMPTION OF OTHER FOODS.—The*
21 *Secretary may, by notice in the Federal Register,*
22 *modify the requirements under this subsection*
23 *with respect to, or exempt a food or a type of fa-*
24 *cility from, the requirements of this subsection*
25 *(other than the requirements under subpara-*

1 *graph (F), if applicable) if the Secretary deter-*
2 *mines that product tracing requirements for such*
3 *food (such as bulk or commingled ingredients*
4 *that are intended to be processed to destroy*
5 *pathogens) or type of facility is not necessary to*
6 *protect the public health.*

7 *(F) RECORDKEEPING REGARDING PREVIOUS*
8 *SOURCES AND SUBSEQUENT RECIPIENTS.—In the*
9 *case of a person or food to which a limitation or*
10 *exemption under subparagraph (C), (D), or (E)*
11 *applies, if such person, or a person who manu-*
12 *factures, processes, packs, or holds such food, is*
13 *required to register with the Secretary under sec-*
14 *tion 415 of the Federal Food, Drug, and Cos-*
15 *metic Act (21 U.S.C. 350d) with respect to the*
16 *manufacturing, processing, packing, or holding*
17 *of the applicable food, the Secretary shall require*
18 *such person to maintain records that identify the*
19 *immediate previous source of such food and the*
20 *immediate subsequent recipient of such food.*

21 *(G) GROCERY STORES.—With respect to a*
22 *sale of a food described in subparagraph (H) to*
23 *a grocery store, the Secretary shall not require*
24 *such grocery store to maintain records under this*
25 *subsection other than records documenting the*

1 *farm that was the source of such food. The Sec-*
2 *retary shall not require that such records be kept*
3 *for more than 180 days.*

4 (H) *FARM SALES TO CONSUMERS.*—*The*
5 *Secretary shall not require a farm to maintain*
6 *any distribution records under this subsection*
7 *with respect to a sale of a food described in sub-*
8 *paragraph (I) (including a sale of a food that is*
9 *produced and packaged on such farm), if such*
10 *sale is made by the farm directly to a consumer.*

11 (I) *SALE OF A FOOD.*—*A sale of a food de-*
12 *scribed in this subparagraph is a sale of a food*
13 *in which—*

14 (i) *the food is produced on a farm; and*
15 (ii) *the sale is made by the owner, op-*
16 *erator, or agent in charge of such farm di-*
17 *rectly to a consumer or grocery store.*

18 (7) *NO IMPACT ON NON-HIGH-RISK FOODS.*—*The*
19 *recordkeeping requirements established under para-*
20 *graph (1) shall have no effect on foods that are not*
21 *designated by the Secretary under paragraph (2) as*
22 *high-risk foods. Foods described in the preceding sen-*
23 *tence shall be subject solely to the recordkeeping re-*
24 *quirements under section 414 of the Federal Food,*
25 *Drug, and Cosmetic Act (21 U.S.C. 350c) and sub-*

1 *part J of part 1 of title 21, Code of Federal Regula-*
2 *tions (or any successor regulations).*

3 *(e) EVALUATION AND RECOMMENDATIONS.—*

4 *(1) REPORT.—Not later than 1 year after the ef-*
5 *fective date of the final rule promulgated under sub-*
6 *section (d)(1), the Comptroller General of the United*
7 *States shall submit to Congress a report, taking into*
8 *consideration the costs of compliance and other regu-*
9 *latory burdens on small businesses and Federal,*
10 *State, and local food safety practices and require-*
11 *ments, that evaluates the public health benefits and*
12 *risks, if any, of limiting—*

13 *(A) the product tracing requirements under*
14 *subsection (d) to foods identified under para-*
15 *graph (2) of such subsection, including whether*
16 *such requirements provide adequate assurance of*
17 *traceability in the event of intentional adultera-*
18 *tion, including by acts of terrorism; and*

19 *(B) the participation of restaurants in the*
20 *recordkeeping requirements.*

21 *(2) DETERMINATION AND RECOMMENDATIONS.—*

22 *In conducting the evaluation and report under para-*
23 *graph (1), if the Comptroller General of the United*
24 *States determines that the limitations described in*
25 *such paragraph do not adequately protect the public*

1 *health, the Comptroller General shall submit to Con-*
2 *gress recommendations, if appropriate, regarding rec-*
3 *ordkeeping requirements for restaurants and addi-*
4 *tional foods, in order to protect the public health.*

5 *(f) FARMS.—*

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

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

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

24 *(C) was adulterated as described in sub-*
25 *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 request
4 under paragraph (1), the Secretary, in consultation
5 and coordination with State and local agencies re-
6 sponsible for food safety, as appropriate, shall issue a
7 written notice to the owner, operator, or agent of the
8 farm to which the article of food has been traced. The
9 individual providing such notice shall present to such
10 owner, operator, or agent appropriate credentials and
11 shall deliver such notice at reasonable times and with-
12 in reasonable limits and in a reasonable manner.

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

20 (4) *LIMITATION.*—A request made under para-
21 graph (1) shall not include a request for information
22 relating to the finances, pricing of commodities pro-
23 duced, personnel, research, sales (other than informa-
24 tion relating to shipping), or other disclosures that
25 may reveal trade secrets or confidential information

1 *from the farm to which the article of food has been*
2 *traced, other than information necessary to identify*
3 *potential immediate recipients of such food. Section*
4 *301(j) of the Federal Food, Drug, and Cosmetic Act*
5 *and the Freedom of Information Act shall apply with*
6 *respect to any confidential commercial information*
7 *that is disclosed to the Food and Drug Administra-*
8 *tion in the course of responding to a request under*
9 *paragraph (1).*

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

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

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

1 *complying with the recordkeeping requirements under such*
2 *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 the*
8 *date of enactment of this Act) beginning on the date*
9 *that is 1 year after the effective date of the final regu-*
10 *lations promulgated under subsection (d); and*

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

16 (j) *ENFORCEMENT.*—

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

23 (2) *IMPORTS.*—*Section 801(a) (21 U.S.C.*
24 *381(a)) is amended by inserting “or (4) the record-*
25 *keeping requirements under section 204 of the FDA*

1 *Food Safety Modernization Act (other than the re-*
2 *quirements under subsection (f) of such section) have*
3 *not been complied with regarding such article,” in the*
4 *third sentence before “then such article shall be re-*
5 *fused admission”.*

6 **SEC. 205. SURVEILLANCE.**

7 (a) *DEFINITION OF FOODBORNE ILLNESS OUT-*
8 *BREAK.—In this Act, the term “foodborne illness outbreak”*
9 *means the occurrence of 2 or more cases of a similar illness*
10 *resulting from the ingestion of a certain food.*

11 (b) *FOODBORNE ILLNESS SURVEILLANCE SYSTEMS.—*

12 (1) *IN GENERAL.—The Secretary, acting through*
13 *the Director of the Centers for Disease Control and*
14 *Prevention, shall enhance foodborne illness surveil-*
15 *lance systems to improve the collection, analysis, re-*
16 *porting, and usefulness of data on foodborne illnesses*
17 *by—*

18 (A) *coordinating Federal, State and local*
19 *foodborne illness surveillance systems, including*
20 *complaint systems, and increasing participation*
21 *in national networks of public health and food*
22 *regulatory agencies and laboratories;*

23 (B) *facilitating sharing of surveillance in-*
24 *formation on a more timely basis among govern-*
25 *mental agencies, including the Food and Drug*

1 *Administration, the Department of Agriculture,*
2 *the Department of Homeland Security, and*
3 *State and local agencies, and with the public;*

4 (C) *developing improved epidemiological*
5 *tools for obtaining quality exposure data and*
6 *microbiological methods for classifying cases;*

7 (D) *augmenting such systems to improve at-*
8 *tribution of a foodborne illness outbreak to a spe-*
9 *cific food;*

10 (E) *expanding capacity of such systems, in-*
11 *cluding working toward automatic electronic*
12 *searches, for implementation of identification*
13 *practices, including fingerprinting strategies, for*
14 *foodborne infectious agents, in order to identify*
15 *new or rarely documented causes of foodborne ill-*
16 *ness and submit standardized information to a*
17 *centralized database;*

18 (F) *allowing timely public access to aggre-*
19 *gated, de-identified surveillance data;*

20 (G) *at least annually, publishing current*
21 *reports on findings from such systems;*

22 (H) *establishing a flexible mechanism for*
23 *rapidly initiating scientific research by aca-*
24 *demically institutions;*

1 (I) *integrating foodborne illness surveillance*
2 *systems and data with other biosurveillance and*
3 *public health situational awareness capabilities*
4 *at the Federal, State, and local levels, including*
5 *by sharing foodborne illness surveillance data*
6 *with the National Biosurveillance Integration*
7 *Center; and*

8 (J) *other activities as determined appro-*
9 *priate by the Secretary.*

10 (2) *WORKING GROUP.—The Secretary shall sup-*
11 *port and maintain a diverse working group of experts*
12 *and stakeholders from Federal, State, and local food*
13 *safety and health agencies, the food and food testing*
14 *industries, consumer organizations, and academia.*
15 *Such working group shall provide the Secretary,*
16 *through at least annual meetings of the working*
17 *group and an annual public report, advice and rec-*
18 *ommendations on an ongoing and regular basis re-*
19 *garding the improvement of foodborne illness surveil-*
20 *lance and implementation of this section, including*
21 *advice and recommendations on—*

22 (A) *the priority needs of regulatory agen-*
23 *cies, the food industry, and consumers for infor-*
24 *mation and analysis on foodborne illness and its*
25 *causes;*

1 (B) opportunities to improve the effective-
2 ness of initiatives at the Federal, State, and
3 local levels, including coordination and integra-
4 tion of activities among Federal agencies, and
5 between the Federal, State, and local levels of
6 government;

7 (C) improvement in the timeliness and
8 depth of access by regulatory and health agen-
9 cies, the food industry, academic researchers, and
10 consumers to foodborne illness aggregated, de-
11 identified surveillance data collected by govern-
12 ment agencies at all levels, including data com-
13 piled by the Centers for Disease Control and Pre-
14 vention;

15 (D) key barriers at Federal, State, and local
16 levels to improving foodborne illness surveillance
17 and the utility of such surveillance for pre-
18 venting foodborne illness;

19 (E) the capabilities needed for establishing
20 automatic electronic searches of surveillance
21 data; and

22 (F) specific actions to reduce barriers to im-
23 provement, implement the working group's rec-
24 ommendations, and achieve the purposes of this

1 *section, with measurable objectives and timelines,*
2 *and identification of resource and staffing needs.*

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

7 (c) *IMPROVING FOOD SAFETY AND DEFENSE CAPACITY*
8 *AT THE STATE AND LOCAL LEVEL.—*

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

13 (A) *Improve foodborne illness outbreak re-*
14 *sponse and containment.*

15 (B) *Accelerate foodborne illness surveillance*
16 *and outbreak investigation, including rapid*
17 *shipment of clinical isolates from clinical labora-*
18 *tories to appropriate State laboratories, and con-*
19 *ducting more standardized illness outbreak inter-*
20 *views.*

21 (C) *Strengthen the capacity of State and*
22 *local agencies to carry out inspections and en-*
23 *force safety standards.*

24 (D) *Improve the effectiveness of Federal,*
25 *State, and local partnerships to coordinate food*

1 *safety and defense resources and reduce the inci-*
2 *dence of foodborne illness.*

3 *(E) Share information on a timely basis*
4 *among public health and food regulatory agen-*
5 *cies, with the food industry, with health care*
6 *providers, and with the public.*

7 *(F) Strengthen the capacity of State and*
8 *local agencies to achieve the goals described in*
9 *section 108.*

10 (2) *REVIEW.*—*In developing of the strategies re-*
11 *quired by paragraph (1), the Secretary shall, not*
12 *later than 1 year after the date of enactment of the*
13 *FDA Food Safety Modernization Act, complete a re-*
14 *view of State and local capacities, and needs for en-*
15 *hancement, which may include a survey with respect*
16 *to—*

17 *(A) staffing levels and expertise available to*
18 *perform food safety and defense functions;*

19 *(B) laboratory capacity to support surveil-*
20 *lance, outbreak response, inspection, and enforce-*
21 *ment activities;*

22 *(C) information systems to support data*
23 *management and sharing of food safety and de-*
24 *fense information among State and local agen-*

1 cies and with counterparts at the Federal level;
2 and

3 (D) other State and local activities and
4 needs as determined appropriate by the Sec-
5 retary.

6 (d) **FOOD SAFETY CAPACITY BUILDING GRANTS.**—Sec-
7 tion 317R(b) of the Public Health Service Act (42 U.S.C.
8 247b–20(b)) is amended—

9 (1) by striking “2002” and inserting “2010”;
10 and

11 (2) by striking “2003 through 2006” and insert-
12 ing “2011 through 2015”.

13 **SEC. 206. MANDATORY RECALL AUTHORITY.**

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

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

18 “(a) **VOLUNTARY PROCEDURES.**—If the Secretary de-
19 termines, based on information gathered through the report-
20 able food registry under section 417 or through any other
21 means, that there is a reasonable probability that an article
22 of food (other than infant formula) is adulterated under sec-
23 tion 402 or misbranded under section 403(w) and the use
24 of or exposure to such article will cause serious adverse
25 health consequences or death to humans or animals, the Sec-

1 *retary shall provide the responsible party (as defined in sec-*
2 *tion 417) with an opportunity to cease distribution and re-*
3 *call such article.*

4 “(b) *PREHEARING ORDER TO CEASE DISTRIBUTION*
5 *AND GIVE NOTICE.*—

6 “(1) *IN GENERAL.*—*If the responsible party re-*
7 *fuses to or does not voluntarily cease distribution or*
8 *recall such article within the time and in the manner*
9 *prescribed by the Secretary (if so prescribed), the Sec-*
10 *retary may, by order require, as the Secretary deems*
11 *necessary, such person to—*

12 “(A) *immediately cease distribution of such*
13 *article; and*

14 “(B) *as applicable, immediately notify all*
15 *persons—*

16 “(i) *manufacturing, processing, pack-*
17 *ing, transporting, distributing, receiving,*
18 *holding, or importing and selling such arti-*
19 *cle; and*

20 “(ii) *to which such article has been*
21 *distributed, transported, or sold, to imme-*
22 *diately cease distribution of such article.*

23 “(2) *REQUIRED ADDITIONAL INFORMATION.*—

24 “(A) *IN GENERAL.*—*If an article of food*
25 *covered by a recall order issued under paragraph*

1 (1)(B) has been distributed to a warehouse-based
2 third party logistics provider without providing
3 such provider sufficient information to know or
4 reasonably determine the precise identity of the
5 article of food covered by a recall order that is
6 in its possession, the notice provided by the re-
7 sponsible party subject to the order issued under
8 paragraph (1)(B) shall include such information
9 as is necessary for the warehouse-based third
10 party logistics provider to identify the food.

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

13 “(i) to exempt a warehouse-based third
14 party logistics provider from the require-
15 ments of this Act, including the require-
16 ments in this section and section 414; or

17 “(ii) to exempt a warehouse-based
18 third party logistics provider from being the
19 subject of a mandatory recall order.

20 “(3) DETERMINATION TO LIMIT AREAS AF-
21 FECTED.—If the Secretary requires a responsible
22 party to cease distribution under paragraph (1)(A) of
23 an article of food identified in subsection (a), the Sec-
24 retary may limit the size of the geographic area and

1 *the markets affected by such cessation if such limita-*
2 *tion would not compromise the public health.*

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

10 “(d) *POST-HEARING RECALL ORDER AND MODIFICA-*
11 *TION OF ORDER.—*

12 “(1) *AMENDMENT OF ORDER.—If, after pro-*
13 *viding opportunity for an informal hearing under*
14 *subsection (c), the Secretary determines that removal*
15 *of the article from commerce is necessary, the Sec-*
16 *retary shall, as appropriate—*

17 “(A) *amend the order to require recall of*
18 *such article or other appropriate action;*

19 “(B) *specify a timetable in which the recall*
20 *shall occur;*

21 “(C) *require periodic reports to the Sec-*
22 *retary describing the progress of the recall; and*

23 “(D) *provide notice to consumers to whom*
24 *such article was, or may have been, distributed.*

1 “(2) *VACATING OF ORDER.*—*If, after such hear-*
2 *ing, the Secretary determines that adequate grounds*
3 *do not exist to continue the actions required by the*
4 *order, or that such actions should be modified, the*
5 *Secretary shall vacate the order or modify the order.*

6 “(e) *RULE REGARDING ALCOHOLIC BEVERAGES.*—*The*
7 *Secretary shall not initiate a mandatory recall or take any*
8 *other action under this section with respect to any alcohol*
9 *beverage until the Secretary has provided the Alcohol and*
10 *Tobacco Tax and Trade Bureau with a reasonable oppor-*
11 *tunity to cease distribution and recall such article under*
12 *the Alcohol and Tobacco Tax and Trade Bureau authority.*

13 “(f) *COOPERATION AND CONSULTATION.*—*The Sec-*
14 *retary shall work with State and local public health officials*
15 *in carrying out this section, as appropriate.*

16 “(g) *PUBLIC NOTIFICATION.*—*In conducting a recall*
17 *under this section, the Secretary shall—*

18 “(1) *ensure that a press release is published re-*
19 *garding the recall, as well as alerts and public no-*
20 *tices, as appropriate, in order to provide notifica-*
21 *tion—*

22 “(A) *of the recall to consumers and retailers*
23 *to whom such article was, or may have been, dis-*
24 *tributed; and*

25 “(B) *that includes, at a minimum—*

1 “(i) the name of the article of food sub-
2 ject to the recall;

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

5 “(iii) to the extent practicable, infor-
6 mation for consumers about similar articles
7 of food that are not affected by the recall;

8 “(2) consult the policies of the Department of Ag-
9 riculture regarding providing to the public a list of
10 retail consignees receiving products involved in a
11 Class I recall and shall consider providing such a list
12 to the public, as determined appropriate by the Sec-
13 retary; and

14 “(3) if available, publish on the Internet Web
15 site of the Food and Drug Administration an image
16 of the article that is the subject of the press release de-
17 scribed in (1).

18 “(h) *NO DELEGATION.*—The authority conferred by
19 this section to order a recall or vacate a recall order shall
20 not be delegated to any officer or employee other than the
21 Commissioner.

22 “(i) *EFFECT.*—Nothing in this section shall affect the
23 authority of the Secretary to request or participate in a
24 voluntary recall, or to issue an order to cease distribution

1 *or to recall under any other provision of this Act or under*
2 *the Public Health Service Act.*

3 “(j) *COORDINATED COMMUNICATION.*—

4 “(1) *IN GENERAL.*—*To assist in carrying out the*
5 *requirements of this subsection, the Secretary shall es-*
6 *tablish an incident command operation or a similar*
7 *operation within the Department of Health and*
8 *Human Services that will operate not later than 24*
9 *hours after the initiation of a mandatory recall or the*
10 *recall of an article of food for which the use of, or ex-*
11 *posure to, such article will cause serious adverse*
12 *health consequences or death to humans or animals.*

13 “(2) *REQUIREMENTS.*—*To reduce the potential*
14 *for miscommunication during recalls or regarding in-*
15 *vestigations of a food borne illness outbreak associated*
16 *with a food that is subject to a recall, each incident*
17 *command operation or similar operation under para-*
18 *graph (1) shall use regular staff and resources of the*
19 *Department of Health and Human Services to—*

20 “(A) *ensure timely and coordinated commu-*
21 *nication within the Department, including en-*
22 *hanced communication and coordination between*
23 *different agencies and organizations within the*
24 *Department;*

1 “(B) ensure timely and coordinated commu-
2 nication from the Department, including public
3 statements, throughout the duration of the inves-
4 tigation and related foodborne illness outbreak;

5 “(C) identify a single point of contact with-
6 in the Department for public inquiries regarding
7 any actions by the Secretary related to a recall;

8 “(D) coordinate with Federal, State, local,
9 and tribal authorities, as appropriate, that have
10 responsibilities related to the recall of a food or
11 a foodborne illness outbreak associated with a
12 food that is subject to the recall, including notifi-
13 cation of the Secretary of Agriculture and the
14 Secretary of Education in the event such recalled
15 food is a commodity intended for use in a child
16 nutrition program (as identified in section 25(b)
17 of the Richard B. Russell National School Lunch
18 Act (42 U.S.C. 1769f(b)); and

19 “(E) conclude operations at such time as
20 the Secretary determines appropriate.

21 “(3) MULTIPLE RECALLS.—The Secretary may
22 establish multiple or concurrent incident command
23 operations or similar operations in the event of mul-
24 tiple recalls or foodborne illness outbreaks necessi-

1 *tating such action by the Department of Health and*
2 *Human Services.”.*

3 (b) *SEARCH ENGINE.*—*Not later than 90 days after*
4 *the date of enactment of this Act, the Secretary shall modify*
5 *the Internet Web site of the Food and Drug Administration*
6 *to include a search engine that—*

7 (1) *is consumer-friendly, as determined by the*
8 *Secretary; and*

9 (2) *provides a means by which an individual*
10 *may locate relevant information regarding each arti-*
11 *cle of food subject to a recall under section 423 of the*
12 *Federal Food, Drug, and Cosmetic Act and the status*
13 *of such recall (such as whether a recall is ongoing or*
14 *has been completed).*

15 (c) *CIVIL PENALTY.*—*Section 303(f)(2)(A) (21 U.S.C.*
16 *333(f)(2)(A)) is amended by inserting “or any person who*
17 *does not comply with a recall order under section 423” after*
18 *“section 402(a)(2)(B)”.*

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

22 *“(xx) The refusal or failure to follow an order under*
23 *section 423.”.*

24 (e) *GAO REVIEW.*—

1 (1) *IN GENERAL.*—Not later than 90 days after
2 the date of enactment of this Act, the Comptroller
3 General of the United States shall submit to Congress
4 a report that—

5 (A) *identifies State and local agencies with*
6 *the authority to require the mandatory recall of*
7 *food, and evaluates use of such authority with re-*
8 *gard to frequency, effectiveness, and appropriate-*
9 *ness, including consideration of any new or ex-*
10 *isting mechanisms available to compensate per-*
11 *sons for general and specific recall-related costs*
12 *when a recall is subsequently determined by the*
13 *relevant authority to have been an error;*

14 (B) *identifies Federal agencies, other than*
15 *the Department of Health and Human Services,*
16 *with mandatory recall authority and examines*
17 *use of that authority with regard to frequency,*
18 *effectiveness, and appropriateness, including any*
19 *new or existing mechanisms available to com-*
20 *pensate persons for general and specific recall-re-*
21 *lated costs when a recall is subsequently deter-*
22 *mined by the relevant agency to have been an*
23 *error;*

1 (C) considers models for farmer restitution
2 implemented in other nations in cases of erro-
3 neous recalls; and

4 (D) makes recommendations to the Sec-
5 retary regarding use of the authority under sec-
6 tion 423 of the Federal Food, Drug, and Cos-
7 metic Act (as added by this section) to protect
8 the public health while seeking to minimize un-
9 necessary economic costs.

10 (2) *EFFECT OF REVIEW.*—If the Comptroller
11 General of the United States finds, after the review
12 conducted under paragraph (1), that the mechanisms
13 described in such paragraph do not exist or are inad-
14 equate, then, not later than 90 days after the conclu-
15 sion of such review, the Secretary of Agriculture shall
16 conduct a study of the feasibility of implementing a
17 farmer indemnification program to provide restitu-
18 tion to agricultural producers for losses sustained as
19 a result of a mandatory recall of an agricultural com-
20 modity by a Federal or State regulatory agency that
21 is subsequently determined to be in error. The Sec-
22 retary of Agriculture shall submit to the Committee
23 on Agriculture of the House of Representatives and
24 the Committee on Agriculture, Nutrition, and For-

1 *estry of the Senate a report that describes the results*
2 *of the study, including any recommendations.*

3 *(f) ANNUAL REPORT TO CONGRESS.—*

4 *(1) IN GENERAL.—Not later than 2 years after*
5 *the date of enactment of this Act and annually there-*
6 *after, the Secretary of Health and Human Services*
7 *(referred to in this subsection as the “Secretary”)*
8 *shall submit a report to the Committee on Health,*
9 *Education, Labor, and Pensions of the Senate and the*
10 *Committee on Energy and Commerce of the House of*
11 *Representatives on the use of recall authority under*
12 *section 423 of the Federal Food, Drug, and Cosmetic*
13 *Act (as added by subsection (a)) and any public*
14 *health advisories issued by the Secretary that advise*
15 *against the consumption of an article of food on the*
16 *ground that the article of food is adulterated and*
17 *poses an imminent danger to health.*

18 *(2) CONTENT.—The report under paragraph (1)*
19 *shall include, with respect to the report year—*

20 *(A) the identity of each article of food that*
21 *was the subject of a public health advisory de-*
22 *scribed in paragraph (1), an opportunity to*
23 *cease distribution and recall under subsection (a)*
24 *of section 423 of the Federal Food, Drug, and*

1 *Cosmetic Act, or a mandatory recall order under*
2 *subsection (b) of such section;*

3 *(B) the number of responsible parties, as de-*
4 *finied in section 417 of the Federal Food, Drug,*
5 *and Cosmetic Act, formally given the oppor-*
6 *tunity to cease distribution of an article of food*
7 *and recall such article, as described in section*
8 *423(a) of such Act;*

9 *(C) the number of responsible parties de-*
10 *scribed in subparagraph (B) who did not cease*
11 *distribution of or recall an article of food after*
12 *given the opportunity to cease distribution or re-*
13 *call under section 423(a) of the Federal Food,*
14 *Drug, and Cosmetic Act;*

15 *(D) the number of recall orders issued under*
16 *section 423(b) of the Federal Food, Drug, and*
17 *Cosmetic Act; and*

18 *(E) a description of any instances in which*
19 *there was no testing that confirmed adulteration*
20 *of an article of food that was the subject of a re-*
21 *call under section 423(b) of the Federal Food,*
22 *Drug, and Cosmetic Act or a public health advi-*
23 *sory described in paragraph (1).*

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

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

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

6 (2) striking “presents a threat of serious adverse
7 health consequences or death to humans or animals”
8 and inserting “is adulterated or misbranded”.

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

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

17 **SEC. 208. DECONTAMINATION AND DISPOSAL STANDARDS**
18 **AND PLANS.**

19 (a) *IN GENERAL.*—The Administrator of the Environ-
20 mental Protection Agency (referred to in this section as the
21 “Administrator”), in coordination with the Secretary of
22 Health and Human Services, Secretary of Homeland Secu-
23 rity, and Secretary of Agriculture, shall provide support
24 for, and technical assistance to, State, local, and tribal gov-
25 ernments in preparing for, assessing, decontaminating, and
26 recovering from an agriculture or food emergency.

1 (b) *DEVELOPMENT OF STANDARDS.*—*In carrying out*
2 *subsection (a), the Administrator, in coordination with the*
3 *Secretary of Health and Human Services, Secretary of*
4 *Homeland Security, Secretary of Agriculture, and State,*
5 *local, and tribal governments, shall develop and disseminate*
6 *specific standards and protocols to undertake clean-up,*
7 *clearance, and recovery activities following the decon-*
8 *tamination and disposal of specific threat agents and for-*
9 *ign animal diseases.*

10 (c) *DEVELOPMENT OF MODEL PLANS.*—*In carrying*
11 *out subsection (a), the Administrator, the Secretary of*
12 *Health and Human Services, and the Secretary of Agri-*
13 *culture shall jointly develop and disseminate model plans*
14 *for—*

15 (1) *the decontamination of individuals, equip-*
16 *ment, and facilities following an intentional contami-*
17 *nation of agriculture or food; and*

18 (2) *the disposal of large quantities of animals,*
19 *plants, or food products that have been infected or*
20 *contaminated by specific threat agents and foreign*
21 *animal diseases.*

22 (d) *EXERCISES.*—*In carrying out subsection (a), the*
23 *Administrator, in coordination with the entities described*
24 *under subsection (b), shall conduct exercises at least annu-*
25 *ally to evaluate and identify weaknesses in the decon-*

1 *tamination and disposal model plans described in sub-*
2 *section (c). Such exercises shall be carried out, to the max-*
3 *imum extent practicable, as part of the national exercise*
4 *program under section 648(b)(1) of the Post-Katrina Emer-*
5 *gency Management Reform Act of 2006 (6 U.S.C.*
6 *748(b)(1)).*

7 *(e) MODIFICATIONS.—Based on the exercises described*
8 *in subsection (d), the Administrator, in coordination with*
9 *the entities described in subsection (b), shall review and*
10 *modify as necessary the plans described in subsection (c)*
11 *not less frequently than biennially.*

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

16 *(1) highest-risk biological, chemical, and radio-*
17 *logical threat agents;*

18 *(2) agents that could cause the greatest economic*
19 *devastation to the agriculture and food system; and*

20 *(3) agents that are most difficult to clean or re-*
21 *mediate.*

1 **SEC. 209. IMPROVING THE TRAINING OF STATE, LOCAL,**
2 **TERRITORIAL, AND TRIBAL FOOD SAFETY OF-**
3 **FICIALS.**

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

6 **“SEC. 1011. IMPROVING THE TRAINING OF STATE, LOCAL,**
7 **TERRITORIAL, AND TRIBAL FOOD SAFETY OF-**
8 **FICIALS.**

9 *“(a) TRAINING.—The Secretary shall set standards*
10 *and administer training and education programs for the*
11 *employees of State, local, territorial, and tribal food safety*
12 *officials relating to the regulatory responsibilities and poli-*
13 *cies established by this Act, including programs for—*

14 *“(1) scientific training;*

15 *“(2) training to improve the skill of officers and*
16 *employees authorized to conduct inspections under*
17 *sections 702 and 704;*

18 *“(3) training to achieve advanced product or*
19 *process specialization in such inspections;*

20 *“(4) training that addresses best practices;*

21 *“(5) training in administrative process and pro-*
22 *cedure and integrity issues;*

23 *“(6) training in appropriate sampling and lab-*
24 *oratory analysis methodology; and*

1 “(7) *training in building enforcement actions*
2 *following inspections, examinations, testing, and in-*
3 *vestigations.*

4 “(b) *PARTNERSHIPS WITH STATE AND LOCAL OFFI-*
5 *CIALS.—*

6 “(1) *IN GENERAL.—The Secretary, pursuant to a*
7 *contract or memorandum of understanding between*
8 *the Secretary and the head of a State, local, terri-*
9 *torial, or tribal department or agency, is authorized*
10 *and encouraged to conduct examinations, testing, and*
11 *investigations for the purposes of determining compli-*
12 *ance with the food safety provisions of this Act*
13 *through the officers and employees of such State, local,*
14 *territorial, or tribal department or agency.*

15 “(2) *CONTENT.—A contract or memorandum de-*
16 *scribed under paragraph (1) shall include provisions*
17 *to ensure adequate training of such officers and em-*
18 *ployees to conduct such examinations, testing, and in-*
19 *vestigations. The contract or memorandum shall con-*
20 *tain provisions regarding reimbursement. Such provi-*
21 *sions may, at the sole discretion of the head of the*
22 *other department or agency, require reimbursement,*
23 *in whole or in part, from the Secretary for the exami-*
24 *nations, testing, or investigations performed pursuant*

1 to this section by the officers or employees of the
2 State, territorial, or tribal department or agency.

3 “(3) *EFFECT.*—Nothing in this subsection shall
4 be construed to limit the authority of the Secretary
5 under section 702.

6 “(c) *EXTENSION SERVICE.*—The Secretary shall ensure
7 coordination with the extension activities of the National
8 Institute of Food and Agriculture of the Department of Ag-
9 riculture in advising producers and small processors
10 transitioning into new practices required as a result of the
11 enactment of the *FDA Food Safety Modernization Act* and
12 assisting regulated industry with compliance with such Act.

13 “(d) *NATIONAL FOOD SAFETY TRAINING, EDUCATION,*
14 *EXTENSION, OUTREACH AND TECHNICAL ASSISTANCE PRO-*
15 *GRAM.*—

16 “(1) *IN GENERAL.*—In order to improve food
17 safety and reduce the incidence of foodborne illness,
18 the Secretary shall, not later than 180 days after the
19 date of enactment of the *FDA Food Safety Moderniza-*
20 *tion Act*, enter into one or more memoranda of under-
21 standing, or enter into other cooperative agreements,
22 with the Secretary of Agriculture to establish a com-
23 petitive grant program within the National Institute
24 for Food and Agriculture to provide food safety train-

1 *ing, education, extension, outreach, and technical as-*
 2 *sistance to—*

3 *“(A) owners and operators of farms;*

4 *“(B) small food processors; and*

5 *“(C) small fruit and vegetable merchant*
 6 *wholesalers.*

7 *“(2) IMPLEMENTATION.—The competitive grant*
 8 *program established under paragraph (1) shall be*
 9 *carried out in accordance with section 405 of the Ag-*
 10 *ricultural Research, Extension, and Education Re-*
 11 *form Act of 1998.*

12 *“(e) AUTHORIZATION OF APPROPRIATIONS.—There are*
 13 *authorized to be appropriated such sums as may be nec-*
 14 *essary to carry out this section for fiscal years 2011 through*
 15 *2015.”.*

16 *(b) NATIONAL FOOD SAFETY TRAINING, EDUCATION,*
 17 *EXTENSION, OUTREACH, AND TECHNICAL ASSISTANCE*
 18 *PROGRAM.—Title IV of the Agricultural Research, Exten-*
 19 *sion, and Education Reform Act of 1998 is amended by*
 20 *inserting after section 404 (7 U.S.C. 7624) the following:*

21 **“SEC. 405. NATIONAL FOOD SAFETY TRAINING, EDUCATION,**
 22 **EXTENSION, OUTREACH, AND TECHNICAL AS-**
 23 **SISTANCE PROGRAM.**

24 *“(a) IN GENERAL.—The Secretary shall award grants*
 25 *under this section to carry out the competitive grant pro-*

1 *gram established under section 1011(d) of the Federal Food,*
2 *Drug, and Cosmetic Act, pursuant to any memoranda of*
3 *understanding entered into under such section.*

4 “(b) *INTEGRATED APPROACH.*—*The grant program*
5 *described under subsection (a) shall be carried out under*
6 *this section in a manner that facilitates the integration of*
7 *food safety standards and guidance with the variety of agri-*
8 *cultural production systems, encompassing conventional,*
9 *sustainable, organic, and conservation and environmental*
10 *practices.*

11 “(c) *PRIORITY.*—*In awarding grants under this sec-*
12 *tion, the Secretary shall give priority to projects that target*
13 *small and medium-sized farms, beginning farmers, socially*
14 *disadvantaged farmers, small processors, or small fresh*
15 *fruit and vegetable merchant wholesalers.*

16 “(d) *PROGRAM COORDINATION.*—

17 “(1) *IN GENERAL.*—*The Secretary shall coordi-*
18 *nate implementation of the grant program under this*
19 *section with the National Integrated Food Safety Ini-*
20 *tiative.*

21 “(2) *INTERACTION.*—*The Secretary shall—*

22 “(A) *in carrying out the grant program*
23 *under this section, take into consideration ap-*
24 *plied research, education, and extension results*

1 *obtained from the National Integrated Food*
2 *Safety Initiative; and*

3 “(B) *in determining the applied research*
4 *agenda for the National Integrated Food Safety*
5 *Initiative, take into consideration the needs ar-*
6 *ticulated by participants in projects funded by*
7 *the program under this section.*

8 “(e) *GRANTS.—*

9 “(1) *IN GENERAL.—In carrying out this section,*
10 *the Secretary shall make competitive grants to sup-*
11 *port training, education, extension, outreach, and*
12 *technical assistance projects that will help improve*
13 *public health by increasing the understanding and*
14 *adoption of established food safety standards, guid-*
15 *ance, and protocols.*

16 “(2) *ENCOURAGED FEATURES.—The Secretary*
17 *shall encourage projects carried out using grant funds*
18 *under this section to include co-management of food*
19 *safety, conservation systems, and ecological health.*

20 “(3) *MAXIMUM TERM AND SIZE OF GRANT.—*

21 “(A) *IN GENERAL.—A grant under this sec-*
22 *tion shall have a term that is not more than 3*
23 *years.*

24 “(B) *LIMITATION ON GRANT FUNDING.—The*
25 *Secretary may not provide grant funding to an*

1 *entity under this section after such entity has re-*
2 *ceived 3 years of grant funding under this sec-*
3 *tion.*

4 “(f) *GRANT ELIGIBILITY.*—

5 “(1) *IN GENERAL.*—*To be eligible for a grant*
6 *under this section, an entity shall be—*

7 “(A) *a State cooperative extension service;*

8 “(B) *a Federal, State, local, or tribal agen-*
9 *cy, a nonprofit community-based or non-govern-*
10 *mental organization, or an organization rep-*
11 *resenting owners and operators of farms, small*
12 *food processors, or small fruit and vegetable mer-*
13 *chant wholesalers that has a commitment to pub-*
14 *lic health and expertise in administering pro-*
15 *grams that contribute to food safety;*

16 “(C) *an institution of higher education (as*
17 *defined in section 101(a) of the Higher Edu-*
18 *cation Act of 1965 (20 U.S.C. 1001(a)) or a*
19 *foundation maintained by an institution of*
20 *higher education;*

21 “(D) *a collaboration of 2 of more eligible*
22 *entities described in this subsection; or*

23 “(E) *such other appropriate entity, as de-*
24 *termined by the Secretary.*

1 “(2) *MULTISTATE PARTNERSHIPS.*—*Grants*
2 *under this section may be made for projects involving*
3 *more than 1 State.*

4 “(g) *REGIONAL BALANCE.*—*In making grants under*
5 *this section, the Secretary shall, to the maximum extent*
6 *practicable, ensure—*

7 “(1) *geographic diversity; and*

8 “(2) *diversity of types of agricultural produc-*
9 *tion.*

10 “(h) *TECHNICAL ASSISTANCE.*—*The Secretary may*
11 *use funds made available under this section to provide tech-*
12 *nical assistance to grant recipients to further the purposes*
13 *of this section.*

14 “(i) *BEST PRACTICES AND MODEL PROGRAMS.*—
15 *Based on evaluations of, and responses arising from,*
16 *projects funded under this section, the Secretary may issue*
17 *a set of recommended best practices and models for food*
18 *safety training programs for agricultural producers, small*
19 *food processors, and small fresh fruit and vegetable mer-*
20 *chant wholesalers.*

21 “(j) *AUTHORIZATION OF APPROPRIATIONS.*—*For the*
22 *purposes of making grants under this section, there are au-*
23 *thorized to be appropriated such sums as may be necessary*
24 *for fiscal years 2011 through 2015.”.*

1 **SEC. 210. ENHANCING FOOD SAFETY.**

2 (a) *GRANTS TO ENHANCE FOOD SAFETY.*—Section
3 *1009 of the Federal Food, Drug, and Cosmetic Act (21*
4 *U.S.C. 399) is amended to read as follows:*

5 **“SEC. 1009. GRANTS TO ENHANCE FOOD SAFETY.**

6 “(a) *IN GENERAL.*—*The Secretary is authorized to*
7 *make grants to eligible entities to—*

8 “(1) *undertake examinations, inspections, and*
9 *investigations, and related food safety activities under*
10 *section 702;*

11 “(2) *train to the standards of the Secretary for*
12 *the examination, inspection, and investigation of food*
13 *manufacturing, processing, packing, holding, dis-*
14 *tribution, and importation, including as such exam-*
15 *ination, inspection, and investigation relate to retail*
16 *food establishments;*

17 “(3) *build the food safety capacity of the labora-*
18 *tories of such eligible entity, including the detection*
19 *of zoonotic diseases;*

20 “(4) *build the infrastructure and capacity of the*
21 *food safety programs of such eligible entity to meet*
22 *the standards as outlined in the grant application;*
23 *and*

24 “(5) *take appropriate action to protect the public*
25 *health in response to—*

1 “(A) a notification under section 1008, in-
2 cluding planning and otherwise preparing to
3 take such action; or

4 “(B) a recall of food under this Act.

5 “(b) *ELIGIBLE ENTITIES; APPLICATION.*—

6 “(1) *IN GENERAL.*—*In this section, the term ‘eli-*
7 *gible entity’ means an entity—*

8 “(A) *that is—*

9 “(i) *a State;*

10 “(ii) *a locality;*

11 “(iii) *a territory;*

12 “(iv) *an Indian tribe (as defined in*
13 *section 4(e) of the Indian Self-Determina-*
14 *tion and Education Assistance Act); or*

15 “(v) *a nonprofit food safety training*
16 *entity that collaborates with 1 or more in-*
17 *stitutions of higher education; and*

18 “(B) *that submits an application to the*
19 *Secretary at such time, in such manner, and in-*
20 *cluding such information as the Secretary may*
21 *reasonably require.*

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

1 “(A) an assurance that the eligible entity
2 has developed plans to engage in the types of ac-
3 tivities described in subsection (a);

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

6 “(C) an itemization of how grant funds re-
7 ceived under this section will be expended;

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

10 “(E) an agreement by the eligible entity to
11 report information required by the Secretary to
12 conduct evaluations under this section.

13 “(c) *LIMITATIONS.*—The funds provided under sub-
14 section (a) shall be available to an eligible entity that re-
15 ceives a grant under this section only to the extent such
16 entity funds the food safety programs of such entity inde-
17 pendently of any grant under this section in each year of
18 the grant at a level equal to the level of such funding in
19 the previous year, increased by the Consumer Price Index.
20 Such non-Federal matching funds may be provided directly
21 or through donations from public or private entities and
22 may be in cash or in-kind, fairly evaluated, including
23 plant, equipment, or services.

24 “(d) *ADDITIONAL AUTHORITY.*—The Secretary may—

1 “(1) award a grant under this section in each
2 subsequent fiscal year without reapplication for a pe-
3 riod of not more than 3 years, provided the require-
4 ments of subsection (c) are met for the previous fiscal
5 year; and

6 “(2) award a grant under this section in a fiscal
7 year for which the requirement of subsection (c) has
8 not been met only if such requirement was not met
9 because such funding was diverted for response to 1
10 or more natural disasters or in other extenuating cir-
11 cumstances that the Secretary may determine appro-
12 priate.

13 “(e) *DURATION OF AWARDS.*—The Secretary may
14 award grants to an individual grant recipient under this
15 section for periods of not more than 3 years. In the event
16 the Secretary conducts a program evaluation, funding in
17 the second year or third year of the grant, where applicable,
18 shall be contingent on a successful program evaluation by
19 the Secretary after the first year.

20 “(f) *PROGRESS AND EVALUATION.*—

21 “(1) *IN GENERAL.*—The Secretary shall measure
22 the status and success of each grant program author-
23 ized under the FDA Food Safety Modernization Act
24 (and any amendment made by such Act), including
25 the grant program under this section. A recipient of

1 *a grant described in the preceding sentence shall, at*
2 *the end of each grant year, provide the Secretary with*
3 *information on how grant funds were spent and the*
4 *status of the efforts by such recipient to enhance food*
5 *safety. To the extent practicable, the Secretary shall*
6 *take the performance of such a grant recipient into*
7 *account when determining whether to continue fund-*
8 *ing for such recipient.*

9 *“(2) NO DUPLICATION.—In carrying out para-*
10 *graph (1), the Secretary shall not duplicate the efforts*
11 *of the Secretary under other provisions of this Act or*
12 *the FDA Food Safety Modernization Act that require*
13 *measurement and review of the activities of grant re-*
14 *cipients under either such Act.*

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

20 *“(h) AUTHORIZATION OF APPROPRIATIONS.—For the*
21 *purpose of making grants under this section, there are au-*
22 *thorized to be appropriated such sums as may be necessary*
23 *for fiscal years 2011 through 2015.”.*

1 *and distribution, as well as leadership in the*
2 *laboratory, epidemiological, and environmental*
3 *detection and investigation of foodborne illness;*
4 *and*

5 “(C) *provide to the Secretary such informa-*
6 *tion, at such time, and in such manner, as the*
7 *Secretary may require.*

8 “(2) *WORKING GROUP.—Not later than 180 days*
9 *after the date of enactment of the FDA Food Safety*
10 *Modernization Act, the Secretary shall establish a di-*
11 *verse working group of experts and stakeholders from*
12 *Federal, State, and local food safety and health agen-*
13 *cies, the food industry, including food retailers and*
14 *food manufacturers, consumer organizations, and aca-*
15 *demia to make recommendations to the Secretary re-*
16 *garding designations of the Centers of Excellence.*

17 “(3) *ADDITIONAL CENTERS OF EXCELLENCE.—*
18 *The Secretary may designate eligible entities to be re-*
19 *gional Food Safety Centers of Excellence, in addition*
20 *to the 5 Centers designated under subsection (a).*

21 “(c) *ACTIVITIES.—Under the leadership of the Director*
22 *of the Centers for Disease Control and Prevention, each Cen-*
23 *ter of Excellence shall be based out of a selected State health*
24 *department, which shall provide assistance to other re-*

1 gional, State, and local departments of health through ac-
2 tivities that include—

3 “(1) providing resources, including timely infor-
4 mation concerning symptoms and tests, for frontline
5 health professionals interviewing individuals as part
6 of routine surveillance and outbreak investigations;

7 “(2) providing analysis of the timeliness and ef-
8 fectiveness of foodborne disease surveillance and out-
9 break response activities;

10 “(3) providing training for epidemiological and
11 environmental investigation of foodborne illness, in-
12 cluding suggestions for streamlining and standard-
13 izing the investigation process;

14 “(4) establishing fellowships, stipends, and schol-
15 arships to train future epidemiological and food-safe-
16 ty leaders and to address critical workforce shortages;

17 “(5) training and coordinating State and local
18 personnel;

19 “(6) strengthening capacity to participate in ex-
20 isting or new foodborne illness surveillance and envi-
21 ronmental assessment information systems; and

22 “(7) conducting research and outreach activities
23 focused on increasing prevention, communication,
24 and education regarding food safety.

1 “(d) *REPORT TO CONGRESS.*—Not later than 2 years
2 after the date of enactment of the *FDA Food Safety Mod-*
3 *ernization Act*, the Secretary shall submit to Congress a re-
4 port that—

5 “(1) describes the effectiveness of the Centers of
6 Excellence; and

7 “(2) provides legislative recommendations or de-
8 scribes additional resources required by the Centers of
9 Excellence.

10 “(e) *AUTHORIZATION OF APPROPRIATIONS.*—There is
11 authorized to be appropriated such sums as may be nec-
12 essary to carry out this section.

13 “(f) *NO DUPLICATION OF EFFORT.*—In carrying out
14 activities of the Centers of Excellence or other programs
15 under this section, the Secretary shall not duplicate other
16 Federal foodborne illness response efforts.”.

17 **SEC. 211. IMPROVING THE REPORTABLE FOOD REGISTRY.**

18 (a) *IN GENERAL.*—Section 417 (21 U.S.C. 350f) is
19 amended—

20 (1) by redesignating subsections (f) through (k)
21 as subsections (i) through (n), respectively; and

22 (2) by inserting after subsection (e) the following:

23 “(f) *CRITICAL INFORMATION.*—Except with respect to
24 fruits and vegetables that are raw agricultural commodities,
25 not more than 18 months after the date of enactment of

1 *the FDA Food Safety Modernization Act, the Secretary may*
2 *require a responsible party to submit to the Secretary con-*
3 *sumer-oriented information regarding a reportable food,*
4 *which shall include—*

5 “(1) *a description of the article of food as pro-*
6 *vided in subsection (e)(3);*

7 “(2) *as provided in subsection (e)(7), affected*
8 *product identification codes, such as UPC, SKU, or*
9 *lot or batch numbers sufficient for the consumer to*
10 *identify the article of food;*

11 “(3) *contact information for the responsible*
12 *party as provided in subsection (e)(8); and*

13 “(4) *any other information the Secretary deter-*
14 *mines is necessary to enable a consumer to accurately*
15 *identify whether such consumer is in possession of the*
16 *reportable food.*

17 “(g) *GROCERY STORE NOTIFICATION.—*

18 “(1) *ACTION BY SECRETARY.—The Secretary*
19 *shall—*

20 “(A) *prepare the critical information de-*
21 *scribed under subsection (f) for a reportable food*
22 *as a standardized one-page summary;*

23 “(B) *publish such one-page summary on the*
24 *Internet website of the Food and Drug Adminis-*
25 *tration in a format that can be easily printed by*

1 *a grocery store for purposes of consumer notifica-*
2 *tion.*

3 “(2) *ACTION BY GROCERY STORE.*—*A notifica-*
4 *tion described under paragraph (1)(B) shall include*
5 *the date and time such summary was posted on the*
6 *Internet website of the Food and Drug Administra-*
7 *tion.*

8 “(h) *CONSUMER NOTIFICATION.*—

9 “(1) *IN GENERAL.*—*If a grocery store sold a re-*
10 *portable food that is the subject of the posting and*
11 *such establishment is part of chain of establishments*
12 *with 15 or more physical locations, then such estab-*
13 *lishment shall, not later than 24 hours after a one*
14 *page summary described in subsection (g) is pub-*
15 *lished, prominently display such summary or the in-*
16 *formation from such summary via at least one of the*
17 *methods identified under paragraph (2) and main-*
18 *tain the display for 14 days.*

19 “(2) *LIST OF CONSPICUOUS LOCATIONS.*—*Not*
20 *more than 1 year after the date of enactment of the*
21 *FDA Food Safety Modernization Act, the Secretary*
22 *shall develop and publish a list of acceptable con-*
23 *spicuous locations and manners, from which grocery*
24 *stores shall select at least one, for providing the notifi-*

1 *cation required in paragraph (1). Such list shall in-*
2 *clude—*

3 *“(A) posting the notification at or near the*
4 *register;*

5 *“(B) providing the location of the reportable*
6 *food;*

7 *“(C) providing targeted recall information*
8 *given to customers upon purchase of a food; and*

9 *“(D) other such prominent and conspicuous*
10 *locations and manners utilized by grocery stores*
11 *as of the date of the enactment of the FDA Food*
12 *Safety Modernization Act to provide notice of*
13 *such recalls to consumers as considered appro-*
14 *priate by the Secretary.”.*

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

18 *“(yy) The knowing and willful failure to comply with*
19 *the notification requirement under section 417(h).”.*

20 *(c) CONFORMING AMENDMENT.—Section 301(e) (21*
21 *U.S.C. 331(e)) is amended by striking “417(g)” and insert-*
22 *ing “417(j)”.*

1 **TITLE III—IMPROVING THE**
2 **SAFETY OF IMPORTED FOOD**

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

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

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

7 “(a) *IN GENERAL.*—

8 “(1) *VERIFICATION REQUIREMENT.*—*Except as*
9 *provided under subsections (e) and (f), each importer*
10 *shall perform risk-based foreign supplier verification*
11 *activities for the purpose of verifying that the food*
12 *imported by the importer or agent of an importer*
13 *is—*

14 “(A) *produced in compliance with the re-*
15 *quirements of section 418 or section 419, as ap-*
16 *propriate; and*

17 “(B) *is not adulterated under section 402 or*
18 *misbranded under section 403(w).*

19 “(2) *IMPORTER DEFINED.*—*For purposes of this*
20 *section, the term ‘importer’ means, with respect to an*
21 *article of food—*

22 “(A) *the United States owner or consignee*
23 *of the article of food at the time of entry of such*
24 *article into the United States; or*

1 “(B) in the case when there is no United
2 States owner or consignee as described in sub-
3 paragraph (A), the United States agent or rep-
4 resentative of a foreign owner or consignee of the
5 article of food at the time of entry of such article
6 into the United States.

7 “(b) GUIDANCE.—Not later than 1 year after the date
8 of enactment of the FDA Food Safety Modernization Act,
9 the Secretary shall issue guidance to assist importers in de-
10 veloping foreign supplier verification programs.

11 “(c) REGULATIONS.—

12 “(1) IN GENERAL.—Not later than 1 year after
13 the date of enactment of the FDA Food Safety Mod-
14 ernization Act, the Secretary shall promulgate regula-
15 tions to provide for the content of the foreign supplier
16 verification program established under subsection (a).

17 “(2) REQUIREMENTS.—The regulations promul-
18 gated under paragraph (1)—

19 “(A) shall require that the foreign supplier
20 verification program of each importer be ade-
21 quate to provide assurances that each foreign
22 supplier to the importer produces the imported
23 food in compliance with—

24 “(i) processes and procedures, includ-
25 ing reasonably appropriate risk-based pre-

1 *ventive controls, that provide the same level*
2 *of public health protection as those required*
3 *under section 418 or section 419 (taking*
4 *into consideration variances granted under*
5 *section 419), as appropriate; and*

6 *“(ii) section 402 and section 403(w).*

7 *“(B) shall include such other requirements*
8 *as the Secretary deems necessary and appro-*
9 *priate to verify that food imported into the*
10 *United States is as safe as food produced and*
11 *sold within the United States.*

12 *“(3) CONSIDERATIONS.—In promulgating regu-*
13 *lations under this subsection, the Secretary shall, as*
14 *appropriate, take into account differences among im-*
15 *porters and types of imported foods, including based*
16 *on the level of risk posed by the imported food.*

17 *“(4) ACTIVITIES.—Verification activities under a*
18 *foreign supplier verification program under this sec-*
19 *tion may include monitoring records for shipments,*
20 *lot-by-lot certification of compliance, annual on-site*
21 *inspections, checking the hazard analysis and risk-*
22 *based preventive control plan of the foreign supplier,*
23 *and periodically testing and sampling shipments.*

24 *“(d) RECORD MAINTENANCE AND ACCESS.—Records of*
25 *an importer related to a foreign supplier verification pro-*

1 *gram shall be maintained for a period of not less than 2*
2 *years and shall be made available promptly to a duly au-*
3 *thorized representative of the Secretary upon request.*

4 “(e) *EXEMPTION OF SEAFOOD, JUICE, AND LOW-ACID*
5 *CANNED FOOD FACILITIES IN COMPLIANCE WITH*
6 *HACCP.—This section shall not apply to a facility if the*
7 *owner, operator, or agent in charge of such facility is re-*
8 *quired to comply with, and is in compliance with, 1 of the*
9 *following standards and regulations with respect to such fa-*
10 *cility:*

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

14 “(2) *The Juice Hazard Analysis Critical Control*
15 *Points Program of the Food and Drug Administra-*
16 *tion.*

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

21 *The exemption under paragraph (3) shall apply only with*
22 *respect to microbiological hazards that are regulated under*
23 *the standards for Thermally Processed Low-Acid Foods*
24 *Packaged in Hermetically Sealed Containers under part*

1 113 of chapter 21, Code of Federal Regulations (or any suc-
2 cessor regulations).

3 “(f) *ADDITIONAL EXEMPTIONS.*—The Secretary, by no-
4 tice published in the Federal Register, shall establish an ex-
5 emption from the requirements of this section for articles
6 of food imported in small quantities for research and eval-
7 uation purposes or for personal consumption, provided that
8 such foods are not intended for retail sale and are not sold
9 or distributed to the public.

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

16 (b) *PROHIBITED ACT.*—Section 301 (21 U.S.C. 331),
17 as amended by section 211, is amended by adding at the
18 end the following:

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

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

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

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

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

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

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

10 “(a) *IN GENERAL.*—Beginning not later than 18
11 months after the date of enactment of the *FDA Food Safety*
12 *Modernization Act*, the Secretary shall—

13 “(1) establish a program, in consultation with
14 the Secretary of Homeland Security—

15 “(A) to provide for the expedited review and
16 importation of food offered for importation by
17 importers who have voluntarily agreed to par-
18 ticipate in such program; and

19 “(B) consistent with section 808, establish a
20 process for the issuance of a facility certification
21 to accompany food offered for importation by
22 importers who have voluntarily agreed to par-
23 ticipate in such program; and

1 “(2) issue a guidance document related to par-
2 ticipation in, revocation of such participation in, re-
3 instatement in, and compliance with, such program.

4 “(b) *VOLUNTARY PARTICIPATION*.—An importer may
5 request the Secretary to provide for the expedited review
6 and importation of designated foods in accordance with the
7 program established by the Secretary under subsection (a).

8 “(c) *NOTICE OF INTENT TO PARTICIPATE*.—An im-
9 porter that intends to participate in the program under this
10 section in a fiscal year shall submit a notice and applica-
11 tion to the Secretary of such intent at the time and in a
12 manner established by the Secretary.

13 “(d) *ELIGIBILITY*.—Eligibility shall be limited to an
14 importer offering food for importation from a facility that
15 has a certification described in subsection (a). In reviewing
16 the applications and making determinations on such appli-
17 cations, the Secretary shall consider the risk of the food to
18 be imported based on factors, such as the following:

19 “(1) The known safety risks of the food to be im-
20 ported.

21 “(2) The compliance history of foreign suppliers
22 used by the importer, as appropriate.

23 “(3) The capability of the regulatory system of
24 the country of export to ensure compliance with

1 *United States food safety standards for a designated*
2 *food.*

3 “(4) *The compliance of the importer with the re-*
4 *quirements of section 805.*

5 “(5) *The recordkeeping, testing, inspections and*
6 *audits of facilities, traceability of articles of food,*
7 *temperature controls, and sourcing practices of the*
8 *importer.*

9 “(6) *The potential risk for intentional adultera-*
10 *tion of the food.*

11 “(7) *Any other factor that the Secretary deter-*
12 *mines appropriate.*

13 “(e) *REVIEW AND REVOCATION.—Any importer quali-*
14 *fied by the Secretary in accordance with the eligibility cri-*
15 *teria set forth in this section shall be reevaluated not less*
16 *often than once every 3 years and the Secretary shall*
17 *promptly revoke the qualified importer status of any im-*
18 *porter found not to be in compliance with such criteria.*

19 “(f) *FALSE STATEMENTS.—Any statement or represen-*
20 *tation made by an importer to the Secretary shall be subject*
21 *to section 1001 of title 18, United States Code.*

22 “(g) *DEFINITION.—For purposes of this section, the*
23 *term ‘importer’ means the person that brings food, or causes*
24 *food to be brought, from a foreign country into the customs*
25 *territory of the United States.’’.*

1 **SEC. 303. AUTHORITY TO REQUIRE IMPORT CERTIFI-**
2 **CATIONS FOR FOOD.**

3 (a) *IN GENERAL.*—Section 801(a) (21 U.S.C. 381(a))
4 is amended by inserting after the third sentence the fol-
5 lowing: “With respect to an article of food, if importation
6 of such food is subject to, but not compliant with, the re-
7 quirement under subsection (q) that such food be accom-
8 panied by a certification or other assurance that the food
9 meets applicable requirements of this Act, then such article
10 shall be refused admission.”.

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

14 “(q) *CERTIFICATIONS CONCERNING IMPORTED*
15 *FOODS.*—

16 “(1) *IN GENERAL.*—The Secretary may require,
17 as a condition of granting admission to an article of
18 food imported or offered for import into the United
19 States, that an entity described in paragraph (3) pro-
20 vide a certification, or such other assurances as the
21 Secretary determines appropriate, that the article of
22 food complies with applicable requirements of this
23 Act. Such certification or assurances may be provided
24 in the form of shipment-specific certificates, a listing
25 of certified facilities that manufacture, process, pack,

1 or hold such food, or in such other form as the Sec-
2 retary may specify.

3 “(2) *FACTORS TO BE CONSIDERED IN REQUIRING*
4 *CERTIFICATION.*—The Secretary shall base the deter-
5 mination that an article of food is required to have
6 a certification described in paragraph (1) on the risk
7 of the food, including—

8 “(A) known safety risks associated with the
9 food;

10 “(B) known food safety risks associated
11 with the country, territory, or region of origin of
12 the food;

13 “(C) a finding by the Secretary, supported
14 by scientific, risk-based evidence, that—

15 “(i) the food safety programs, systems,
16 and standards in the country, territory, or
17 region of origin of the food are inadequate
18 to ensure that the article of food is as safe
19 as a similar article of food that is manufac-
20 tured, processed, packed, or held in the
21 United States in accordance with the re-
22 quirements of this Act; and

23 “(ii) the certification would assist the
24 Secretary in determining whether to refuse

1 or admit the article of food under subsection
2 (a); and

3 “(D) information submitted to the Secretary
4 in accordance with the process established in
5 paragraph (7).

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

10 “(A) an agency or a representative of the
11 government of the country from which the article
12 of food at issue originated, as designated by the
13 Secretary; or

14 “(B) such other persons or entities accred-
15 ited pursuant to section 808 to provide such cer-
16 tification or assurance.

17 “(4) *RENEWAL AND REFUSAL OF CERTIFI-*
18 *CATIONS.*—The Secretary may—

19 “(A) require that any certification or other
20 assurance provided by an entity specified in
21 paragraph (2) be renewed by such entity at such
22 times as the Secretary determines appropriate;
23 and

1 “(B) refuse to accept any certification or
2 assurance if the Secretary determines that such
3 certification or assurance is not valid or reliable.

4 “(5) *ELECTRONIC SUBMISSION.*—The Secretary
5 shall provide for the electronic submission of certifi-
6 cations under this subsection.

7 “(6) *FALSE STATEMENTS.*—Any statement or
8 representation made by an entity described in para-
9 graph (2) to the Secretary shall be subject to section
10 1001 of title 18, United States Code.

11 “(7) *ASSESSMENT OF FOOD SAFETY PROGRAMS,*
12 *SYSTEMS, AND STANDARDS.*—If the Secretary deter-
13 mines that the food safety programs, systems, and
14 standards in a foreign region, country, or territory
15 are inadequate to ensure that an article of food is as
16 safe as a similar article of food that is manufactured,
17 processed, packed, or held in the United States in ac-
18 cordance with the requirements of this Act, the Sec-
19 retary shall, to the extent practicable, identify such
20 inadequacies and establish a process by which the for-
21 eign region, country, or territory may inform the Sec-
22 retary of improvements made to such food safety pro-
23 gram, system, or standard and demonstrate that those
24 controls are adequate to ensure that an article of food
25 is as safe as a similar article of food that is manufac-

1 *tured, processed, packed, or held in the United States*
2 *in accordance with the requirements of this Act.”.*

3 (c) *CONFORMING TECHNICAL AMENDMENT.*—Section
4 *801(b) (21 U.S.C. 381(b)) is amended in the second sentence*
5 *by striking “with respect to an article included within the*
6 *provision of the fourth sentence of subsection (a)” and in-*
7 *serting “with respect to an article described in subsection*
8 *(a) relating to the requirements of sections 760 or 761,”.*

9 (d) *NO LIMIT ON AUTHORITY.*—Nothing in the amend-
10 *ments made by this section shall limit the authority of the*
11 *Secretary to conduct inspections of imported food or to take*
12 *such other steps as the Secretary deems appropriate to de-*
13 *termine the admissibility of imported food.*

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

15 (a) *IN GENERAL.*—Section 801(m)(1) (21 U.S.C.
16 *381(m)(1)) is amended by inserting “any country to which*
17 *the article has been refused entry;” after “the country from*
18 *which the article is shipped;”.*

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

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

4 **SEC. 305. BUILDING CAPACITY OF FOREIGN GOVERNMENTS**
5 **WITH RESPECT TO FOOD SAFETY.**

6 (a) *IN GENERAL.*—*The Secretary shall, not later than*
7 *2 years of the date of enactment of this Act, develop a com-*
8 *prehensive plan to expand the technical, scientific, and reg-*
9 *ulatory food safety capacity of foreign governments, and*
10 *their respective food industries, from which foods are ex-*
11 *ported to the United States.*

12 (b) *CONSULTATION.*—*In developing the plan under*
13 *subsection (a), the Secretary shall consult with the Sec-*
14 *retary of Agriculture, Secretary of State, Secretary of the*
15 *Treasury, the Secretary of Homeland Security, the United*
16 *States Trade Representative, and the Secretary of Com-*
17 *merce, representatives of the food industry, appropriate for-*
18 *eign government officials, nongovernmental organizations*
19 *that represent the interests of consumers, and other stake-*
20 *holders.*

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

23 (1) *Recommendations for bilateral and multilat-*
24 *eral arrangements and agreements, including provi-*

1 *sions to provide for responsibility of exporting coun-*
2 *tries to ensure the safety of food.*

3 (2) *Provisions for secure electronic data sharing.*

4 (3) *Provisions for mutual recognition of inspec-*
5 *tion reports.*

6 (4) *Training of foreign governments and food*
7 *producers on United States requirements for safe food.*

8 (5) *Recommendations on whether and how to*
9 *harmonize requirements under the Codex*
10 *Alimentarius.*

11 (6) *Provisions for the multilateral acceptance of*
12 *laboratory methods and testing and detection tech-*
13 *niques.*

14 (d) *RULE OF CONSTRUCTION.—Nothing in this section*
15 *shall be construed to affect the regulation of dietary supple-*
16 *ments under the Dietary Supplement Health and Edu-*
17 *cation Act of 1994 (Public Law 103–417).*

18 **SEC. 306. INSPECTION OF FOREIGN FOOD FACILITIES.**

19 (a) *IN GENERAL.—Chapter VIII (21 U.S.C. 381 et*
20 *seq.), as amended by section 302, is amended by inserting*
21 *at the end the following:*

22 **“SEC. 807. INSPECTION OF FOREIGN FOOD FACILITIES.**

23 *“(a) INSPECTION.—The Secretary—*

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

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

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

9 *“(b) EFFECT OF INABILITY TO INSPECT.—Notwith-*
10 *standing any other provision of law, food shall be refused*
11 *admission into the United States if it is from a foreign*
12 *factory, warehouse, or other establishment of which the*
13 *owner, operator, or agent in charge, or the government of*
14 *the foreign country, refuses to permit entry of United States*
15 *inspectors or other individuals duly designated by the Sec-*
16 *retary, upon request, to inspect such factory, warehouse, or*
17 *other establishment. For purposes of this subsection, such*
18 *an owner, operator, or agent in charge shall be considered*
19 *to have refused an inspection if such owner, operator, or*
20 *agent in charge does not permit an inspection of a factory,*
21 *warehouse, or other establishment during the 24-hour period*
22 *after such request is submitted, or after such other time pe-*
23 *riod, as agreed upon by the Secretary and the foreign fac-*
24 *tory, warehouse, or other establishment.”.*

25 *(b) INSPECTION BY THE SECRETARY OF COMMERCE.—*

1 (1) *IN GENERAL.*—*The Secretary of Commerce,*
2 *in coordination with the Secretary of Health and*
3 *Human Services, may send 1 or more inspectors to*
4 *a country or facility of an exporter from which sea-*
5 *food imported into the United States originates. The*
6 *inspectors shall assess practices and processes used in*
7 *connection with the farming, cultivation, harvesting,*
8 *preparation for market, or transportation of such sea-*
9 *food and may provide technical assistance related to*
10 *such activities.*

11 (2) *INSPECTION REPORT.*—

12 (A) *IN GENERAL.*—*The Secretary of Health*
13 *and Human Services, in coordination with the*
14 *Secretary of Commerce, shall—*

15 (i) *prepare an inspection report for*
16 *each inspection conducted under paragraph*
17 (1);

18 (ii) *provide the report to the country*
19 *or exporter that is the subject of the report;*
20 *and*

21 (iii) *provide a 30-day period during*
22 *which the country or exporter may provide*
23 *a rebuttal or other comments on the find-*
24 *ings of the report to the Secretary of Health*
25 *and Human Services.*

1 (B) *DISTRIBUTION AND USE OF REPORT.*—
2 *The Secretary of Health and Human Services*
3 *shall consider the inspection reports described in*
4 *subparagraph (A) in distributing inspection re-*
5 *sources under section 421 of the Federal Food,*
6 *Drug, and Cosmetic Act, as added by section*
7 *201.*

8 **SEC. 307. ACCREDITATION OF THIRD-PARTY AUDITORS.**

9 *Chapter VIII (21 U.S.C. 381 et seq.), as amended by*
10 *section 306, is amended by adding at the end the following:*

11 **“SEC. 808. ACCREDITATION OF THIRD-PARTY AUDITORS.**

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

13 “(1) *AUDIT AGENT.*—*The term ‘audit agent’*
14 *means an individual who is an employee or agent of*
15 *an accredited third-party auditor and, although not*
16 *individually accredited, is qualified to conduct food*
17 *safety audits on behalf of an accredited third-party*
18 *auditor.*

19 “(2) *ACCREDITATION BODY.*—*The term ‘accredi-*
20 *tation body’ means an authority that performs ac-*
21 *creditation of third-party auditors.*

22 “(3) *THIRD-PARTY AUDITOR.*—*The term ‘third-*
23 *party auditor’ means a foreign government, agency of*
24 *a foreign government, foreign cooperative, or any*
25 *other third party, as the Secretary determines appro-*

1 *appropriate in accordance with the model standards de-*
2 *scribed in subsection (b)(2), that is eligible to be con-*
3 *sidered for accreditation to conduct food safety audits*
4 *to certify that eligible entities meet the applicable re-*
5 *quirements of this section. A third-party auditor may*
6 *be a single individual. A third-party auditor may*
7 *employ or use audit agents to help conduct consult-*
8 *ative and regulatory audits.*

9 *“(4) ACCREDITED THIRD-PARTY AUDITOR.—The*
10 *term ‘accredited third-party auditor’ means a third-*
11 *party auditor accredited by an accreditation body to*
12 *conduct audits of eligible entities to certify that such*
13 *eligible entities meet the applicable requirements of*
14 *this section. An accredited third-party auditor may*
15 *be an individual who conducts food safety audits to*
16 *certify that eligible entities meet the applicable re-*
17 *quirements of this section.*

18 *“(5) CONSULTATIVE AUDIT.—The term ‘consult-*
19 *ative audit’ means an audit of an eligible entity—*

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

24 *“(B) the results of which are for internal*
25 *purposes only.*

1 “(6) *ELIGIBLE ENTITY.*—*The term ‘eligible enti-*
2 *ty’ means a foreign entity, including a foreign facil-*
3 *ity registered under section 415, in the food import*
4 *supply chain that chooses to be audited by an accred-*
5 *ited third-party auditor or the audit agent of such ac-*
6 *credited third-party auditor.*

7 “(7) *REGULATORY AUDIT.*—*The term ‘regulatory*
8 *audit’ means an audit of an eligible entity—*

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

11 “(B) *the results of which determine—*

12 “(i) *whether an article of food manu-*
13 *factured, processed, packed, or held by such*
14 *entity is eligible to receive a food certifi-*
15 *cation under section 801(q); or*

16 “(ii) *whether a facility is eligible to re-*
17 *ceive a facility certification under section*
18 *806(a) for purposes of participating in the*
19 *program under section 806.*

20 “(b) *ACCREDITATION SYSTEM.*—

21 “(1) *ACCREDITATION BODIES.*—

22 “(A) *RECOGNITION OF ACCREDITATION BOD-*
23 *IES.*—

24 “(i) *IN GENERAL.*—*Not later than 2*
25 *years after the date of enactment of the*

1 *FDA Food Safety Modernization Act, the*
2 *Secretary shall establish a system for the*
3 *recognition of accreditation bodies that ac-*
4 *credit third-party auditors to certify that*
5 *eligible entities meet the applicable require-*
6 *ments of this section.*

7 *“(i) DIRECT ACCREDITATION.—If, by*
8 *the date that is 2 years after the date of es-*
9 *tablishment of the system described in*
10 *clause (i), the Secretary has not identified*
11 *and recognized an accreditation body to*
12 *meet the requirements of this section, the*
13 *Secretary may directly accredit third-party*
14 *auditors.*

15 *“(B) NOTIFICATION.—Each accreditation*
16 *body recognized by the Secretary shall submit to*
17 *the Secretary a list of all accredited third-party*
18 *auditors accredited by such body and the audit*
19 *agents of such auditors.*

20 *“(C) REVOCATION OF RECOGNITION AS AN*
21 *ACCREDITATION BODY.—The Secretary shall*
22 *promptly revoke the recognition of any accredita-*
23 *tion body found not to be in compliance with the*
24 *requirements of this section.*

1 “(D) *REINSTATEMENT.*—*The Secretary*
2 *shall establish procedures to reinstate recognition*
3 *of an accreditation body if the Secretary deter-*
4 *mines, based on evidence presented by such ac-*
5 *creditation body, that revocation was inappro-*
6 *priate or that the body meets the requirements*
7 *for recognition under this section.*

8 “(2) *MODEL ACCREDITATION STANDARDS.*—*Not*
9 *later than 18 months after the date of enactment of*
10 *the FDA Food Safety Modernization Act, the Sec-*
11 *retary shall develop model standards, including re-*
12 *quirements for regulatory audit reports, and each rec-*
13 *ognized accreditation body shall ensure that third-*
14 *party auditors and audit agents of such auditors meet*
15 *such standards in order to qualify such third-party*
16 *auditors as accredited third-party auditors under this*
17 *section. In developing the model standards, the Sec-*
18 *retary shall look to standards in place on the date of*
19 *the enactment of this section for guidance, to avoid*
20 *unnecessary duplication of efforts and costs.*

21 “(c) *THIRD-PARTY AUDITORS.*—

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

24 “(A) *FOREIGN GOVERNMENTS.*—*Prior to ac-*
25 *crediting a foreign government or an agency of*

1 *a foreign government as an accredited third-*
2 *party auditor, the accreditation body (or, in the*
3 *case of direct accreditation under subsection*
4 *(b)(1)(A)(ii), the Secretary) shall perform such*
5 *reviews and audits of food safety programs, sys-*
6 *tems, and standards of the government or agency*
7 *of the government as the Secretary deems nec-*
8 *essary, including requirements under the model*
9 *standards developed under subsection (b)(2), to*
10 *determine that the foreign government or agency*
11 *of the foreign government is capable of ade-*
12 *quately ensuring that eligible entities or foods*
13 *certified by such government or agency meet the*
14 *requirements of this Act with respect to food*
15 *manufactured, processed, packed, or held for im-*
16 *port into the United States.*

17 “(B) *FOREIGN COOPERATIVES AND OTHER*
18 *THIRD PARTIES.—Prior to accrediting a foreign*
19 *cooperative that aggregates the products of grow-*
20 *ers or processors, or any other third party to be*
21 *an accredited third-party auditor, the accredita-*
22 *tion body (or, in the case of direct accreditation*
23 *under subsection (b)(1)(A)(ii), the Secretary)*
24 *shall perform such reviews and audits of the*
25 *training and qualifications of audit agents used*

1 by that cooperative or party and conduct such
2 reviews of internal systems and such other inves-
3 tigation of the cooperative or party as the Sec-
4 retary deems necessary, including requirements
5 under the model standards developed under sub-
6 section (b)(2), to determine that each eligible en-
7 tity certified by the cooperative or party has sys-
8 tems and standards in use to ensure that such
9 entity or food meets the requirements of this Act.

10 “(2) *REQUIREMENT TO ISSUE CERTIFICATION OF*
11 *ELIGIBLE ENTITIES OR FOODS.—*

12 “(A) *IN GENERAL.—*An accreditation body
13 (or, in the case of direct accreditation under sub-
14 section (b)(1)(A)(ii), the Secretary) may not ac-
15 credit 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 certification
19 under section 806(a), as appropriate, to accom-
20 pany each food shipment for import into the
21 United States from an eligible entity, subject to
22 requirements set forth by the Secretary. Such
23 written or electronic certification may be in-
24 cluded with other documentation regarding such
25 food shipment. The Secretary shall consider cer-

1 *tifications under section 801(q) and participa-*
2 *tion in the voluntary qualified importer pro-*
3 *gram described in section 806 when targeting in-*
4 *spection 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 CERTIFI-*
19 *CATION.*—

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 may,
7 at any time, require the accredited third-party
8 auditor to submit to the Secretary an onsite
9 audit report and such other reports or documents
10 required as part of the audit process, for any eli-
11 gible entity certified by the third-party auditor
12 or audit agent of such auditor. Such report may
13 include documentation that the eligible entity is
14 in compliance with any applicable registration
15 requirements.

16 “(C) LIMITATION.—The requirement under
17 subparagraph (B) shall not include any report
18 or other documents resulting from a consultative
19 audit by the accredited third-party auditor, ex-
20 cept that the Secretary may access the results of
21 a consultative audit in accordance with section
22 414.

23 “(4) REQUIREMENTS OF ACCREDITED THIRD-
24 PARTY AUDITORS AND AUDIT AGENTS OF SUCH AUDI-
25 TORS.—

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 dis-
4 covers a condition that could cause or contribute
5 to a serious risk to the public health, such audi-
6 tor shall immediately notify the Secretary of—

7 “(i) the identification of the eligible en-
8 tity subject to the audit; and

9 “(ii) such condition.

10 “(B) *TYPES OF AUDITS.*—An accredited
11 third-party auditor or audit agent of such audi-
12 tor may perform consultative and regulatory au-
13 dits of eligible entities.

14 “(C) *LIMITATIONS.*—

15 “(i) *IN GENERAL.*—An accredited third
16 party auditor may not perform a regu-
17 latory audit of an eligible entity if such
18 agent has performed a consultative audit or
19 a regulatory audit of such eligible entity
20 during the previous 13-month period.

21 “(ii) *WAIVER.*—The Secretary may
22 waive the application of clause (i) if the
23 Secretary determines that there is insuffi-
24 cient access to accredited third-party audi-
25 tors in a country or region.

1 “(5) *CONFLICTS OF INTEREST.*—

2 “(A) *THIRD-PARTY AUDITORS.*—*An accredited*
3 *third-party auditor shall—*

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

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

14 “(iii) *annually make available to the*
15 *Secretary disclosures of the extent to which*
16 *such auditor and the officers and employees*
17 *of such auditor have maintained compliance*
18 *with clauses (i) and (ii) relating to finan-*
19 *cial conflicts of interest.*

20 “(B) *AUDIT AGENTS.*—*An audit agent*
21 *shall—*

22 “(i) *not own or operate an eligible en-*
23 *tity to be audited by such agent;*

24 “(ii) *in carrying out audits of eligible*
25 *entities under this section, have procedures*

1 to ensure that such agent does not have a fi-
2 nancial conflict of interest regarding an eli-
3 gible entity to be audited by such agent;
4 and

5 “(iii) annually make available to the
6 Secretary disclosures of the extent to which
7 such agent has maintained compliance with
8 clauses (i) and (ii) relating to financial
9 conflicts of interest.

10 “(C) *REGULATIONS.*—The Secretary shall
11 promulgate regulations not later than 18 months
12 after the date of enactment of the *FDA Food*
13 *Safety Modernization Act* to implement this sec-
14 tion and to ensure that there are protections
15 against conflicts of interest between an accred-
16 ited third-party auditor and the eligible entity to
17 be certified by such auditor or audited by such
18 audit agent. Such regulations shall include—

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

21 “(ii) a structure to decrease the poten-
22 tial for conflicts of interest, including tim-
23 ing and public disclosure, for fees paid by
24 eligible entities to accredited third-party
25 auditors; and

1 “(iii) appropriate limits on financial
2 affiliations between an accredited third-
3 party auditor or audit agents of such audi-
4 tor and any person that owns or operates
5 an eligible entity to be certified by such
6 auditor, as described in subparagraphs (A)
7 and (B).

8 “(6) WITHDRAWAL OF ACCREDITATION.—

9 “(A) IN GENERAL.—The Secretary shall
10 withdraw accreditation from an accredited
11 third-party auditor—

12 “(i) if food certified under section
13 801(q) or from a facility certified under
14 paragraph (2)(B) by such third-party audi-
15 tor is linked to an outbreak of foodborne ill-
16 ness that has a reasonable probability of
17 causing serious adverse health consequences
18 or death in humans or animals;

19 “(ii) following an evaluation and find-
20 ing by the Secretary that the third-party
21 auditor no longer meets the requirements for
22 accreditation; or

23 “(iii) following a refusal to allow
24 United States officials to conduct such au-
25 dits and investigations as may be necessary

1 to ensure continued compliance with the re-
2 quirements set forth in this section.

3 “(B) *ADDITIONAL BASIS FOR WITHDRAWAL*
4 *OF ACCREDITATION.*—*The Secretary may with-*
5 *draw accreditation from an accredited third-*
6 *party auditor in the case that such third-party*
7 *auditor is accredited by an accreditation body*
8 *for which recognition as an accreditation body*
9 *under subsection (b)(1)(C) is revoked, if the Sec-*
10 *retary determines that there is good cause for the*
11 *withdrawal.*

12 “(C) *EXCEPTION.*—*The Secretary may*
13 *wave the application of subparagraph (A)(i) if*
14 *the Secretary—*

15 “(i) *conducts an investigation of the*
16 *material facts related to the outbreak of*
17 *human or animal illness; and*

18 “(ii) *reviews the steps or actions taken*
19 *by the third party auditor to justify the cer-*
20 *tification and determines that the accredited*
21 *third-party auditor satisfied the require-*
22 *ments under section 801(q) of certifying the*
23 *food, or the requirements under paragraph*
24 *(2)(B) of certifying the entity.*

1 “(7) *REACCREDITATION.*—*The Secretary shall es-*
2 *tablish procedures to reinstate the accreditation of a*
3 *third-party auditor for which accreditation has been*
4 *withdrawn under paragraph (6)—*

5 “(A) *if the Secretary determines, based on*
6 *evidence presented, that the third-party auditor*
7 *satisfies the requirements of this section and ade-*
8 *quate grounds for revocation no longer exist; and*

9 “(B) *in the case of a third-party auditor*
10 *accredited by an accreditation body for which*
11 *recognition as an accreditation body under sub-*
12 *section (b)(1)(C) is revoked—*

13 “(i) *if the third-party auditor becomes*
14 *accredited not later than 1 year after rev-*
15 *ocation of accreditation under paragraph*
16 *(6)(A), through direct accreditation under*
17 *subsection (b)(1)(A)(ii) or by an accredita-*
18 *tion body in good standing; or*

19 “(ii) *under such conditions as the Sec-*
20 *retary may require for a third-party audi-*
21 *tor under paragraph (6)(B).*

22 “(8) *NEUTRALIZING COSTS.*—*The Secretary shall*
23 *establish by regulation a reimbursement (user fee)*
24 *program, similar to the method described in section*
25 *203(h) of the Agriculture Marketing Act of 1946, by*

1 *which the Secretary assesses fees and requires accred-*
2 *ited third-party auditors and audit agents to reim-*
3 *burse the Food and Drug Administration for the work*
4 *performed to establish and administer the accredita-*
5 *tion system under this section. The Secretary shall*
6 *make operating this program revenue-neutral and*
7 *shall not generate surplus revenue from such a reim-*
8 *bursement mechanism. Fees authorized under this*
9 *paragraph shall be collected and available for obliga-*
10 *tion only to the extent and in the amount provided*
11 *in advance in appropriation Acts. Such fees are au-*
12 *thorized to remain available until expended.*

13 “(d) *RECERTIFICATION OF ELIGIBLE ENTITIES.—An*
14 *eligible entity shall apply for annual recertification by an*
15 *accredited third-party auditor if such entity—*

16 “(1) *intends to participate in voluntary quali-*
17 *fied importer program under section 806; or*

18 “(2) *is required to provide to the Secretary a*
19 *certification under section 801(q) for any food from*
20 *such entity.*

21 “(e) *FALSE STATEMENTS.—Any statement or rep-*
22 *resentation made—*

23 “(1) *by an employee or agent of an eligible enti-*
24 *ty to an accredited third-party auditor or audit*
25 *agent; or*

1 “(2) by an accredited third-party auditor to the
2 Secretary,
3 shall be subject to section 1001 of title 18, United States
4 Code.

5 “(f) MONITORING.—To ensure compliance with the re-
6 quirements of this section, the Secretary shall—

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

10 “(2) periodically, or at least once every 4 years,
11 evaluate the performance of each accredited third-
12 party auditor, through the review of regulatory audit
13 reports by such auditors, the compliance history as
14 available of eligible entities certified by such auditors,
15 and any other measures deemed necessary by the Sec-
16 retary;

17 “(3) at any time, conduct an onsite audit of any
18 eligible entity certified by an accredited third-party
19 auditor, with or without the auditor present; and

20 “(4) take any other measures deemed necessary
21 by the Secretary.

22 “(g) PUBLICLY AVAILABLE REGISTRY.—The Secretary
23 shall establish a publicly available registry of accreditation
24 bodies and of accredited third-party auditors, including the
25 name of, contact information for, and other information

1 *deemed necessary by the Secretary about such bodies and*
2 *auditors.*

3 “(h) *LIMITATIONS.*—

4 “(1) *NO EFFECT ON SECTION 704 INSPECTIONS.*—
5 *The audits performed under this section shall not be*
6 *considered inspections under section 704.*

7 “(2) *NO EFFECT ON INSPECTION AUTHORITY.*—
8 *Nothing in this section affects the authority of the*
9 *Secretary to inspect any eligible entity pursuant to*
10 *this Act.*”

11 **SEC. 308. FOREIGN OFFICES OF THE FOOD AND DRUG AD-**
12 **MINISTRATION.**

13 (a) *IN GENERAL.*—*The Secretary shall establish offices*
14 *of the Food and Drug Administration in foreign countries*
15 *selected by the Secretary, to provide assistance to the appro-*
16 *priate governmental entities of such countries with respect*
17 *to measures to provide for the safety of articles of food and*
18 *other products regulated by the Food and Drug Administra-*
19 *tion exported by such country to the United States, includ-*
20 *ing by directly conducting risk-based inspections of such ar-*
21 *ticles and supporting such inspections by such govern-*
22 *mental entity.*

23 (b) *CONSULTATION.*—*In establishing the foreign offices*
24 *described in subsection (a), the Secretary shall consult with*

1 *the Secretary of State, the Secretary of Homeland Security,*
2 *and the United States Trade Representative.*

3 (c) *REPORT.*—Not later than October 1, 2011, the Sec-
4 *retary shall submit to Congress a report on the basis for*
5 *the selection by the Secretary of the foreign countries in*
6 *which the Secretary established offices, the progress which*
7 *such offices have made with respect to assisting the govern-*
8 *ments of such countries in providing for the safety of arti-*
9 *cles of food and other products regulated by the Food and*
10 *Drug Administration exported to the United States, and*
11 *the plans of the Secretary for establishing additional foreign*
12 *offices of the Food and Drug Administration, as appro-*
13 *priate.*

14 **SEC. 309. SMUGGLED FOOD.**

15 (a) *IN GENERAL.*—Not later than 180 days after the
16 *enactment of this Act, the Secretary shall, in coordination*
17 *with the Secretary of Homeland Security, develop and im-*
18 *plement a strategy to better identify smuggled food and pre-*
19 *vent entry of such food into the United States.*

20 (b) *NOTIFICATION TO HOMELAND SECURITY.*—Not
21 *later than 10 days after the Secretary identifies a smuggled*
22 *food that the Secretary believes would cause serious adverse*
23 *health consequences or death to humans or animals, the Sec-*
24 *retary shall provide to the Secretary of Homeland Security*
25 *a notification under section 417(n) of the Federal Food,*

1 *Drug, and Cosmetic Act (21 U.S.C. 350f(k)) describing the*
2 *smuggled food and, if available, the names of the individ-*
3 *uals or entities that attempted to import such food into the*
4 *United States.*

5 *(c) PUBLIC NOTIFICATION.—If the Secretary—*

6 *(1) identifies a smuggled food;*

7 *(2) reasonably believes exposure to the food*
8 *would cause serious adverse health consequences or*
9 *death to humans or animals; and*

10 *(3) reasonably believes that the food has entered*
11 *domestic commerce and is likely to be consumed,*

12 *the Secretary shall promptly issue a press release describing*
13 *that food and shall use other emergency communication or*
14 *recall networks, as appropriate, to warn consumers and*
15 *vendors about the potential threat.*

16 *(d) EFFECT OF SECTION.—Nothing in this section*
17 *shall affect the authority of the Secretary to issue public*
18 *notifications under other circumstances.*

19 *(e) DEFINITION.—In this subsection, the term “smug-*
20 *gled food” means any food that a person introduces into*
21 *the United States through fraudulent means or with the in-*
22 *tent to defraud or mislead.*

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

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

4 (a) *IN GENERAL.*—*There are authorized to be appro-*
5 *priated to carry out the activities of the Center for Food*
6 *Safety and Applied Nutrition, the Center for Veterinary*
7 *Medicine, and related field activities in the Office of Regu-*
8 *latory Affairs of the Food and Drug Administration such*
9 *sums as may be necessary for fiscal years 2011 through*
10 *2015.*

11 (b) *INCREASED NUMBER OF FIELD STAFF.*—

12 (1) *IN GENERAL.*—*To carry out the activities of*
13 *the Center for Food Safety and Applied Nutrition, the*
14 *Center for Veterinary Medicine, and related field ac-*
15 *tivities of the Office of Regulatory Affairs of the Food*
16 *and Drug Administration, the Secretary of Health*
17 *and Human Services shall increase the field staff of*
18 *such Centers and Office with a goal of not fewer*
19 *than—*

20 (A) *4,000 staff members in fiscal year 2011;*

21 (B) *4,200 staff members in fiscal year 2012;*

22 (C) *4,600 staff members in fiscal year 2013;*

23 *and*

24 (D) *5,000 staff members in fiscal year 2014.*

1 (2) *FIELD STAFF FOR FOOD DEFENSE.*—*The goal*
2 *under paragraph (1) shall include an increase of 150*
3 *employees by fiscal year 2011 to—*

4 (A) *provide additional detection of and re-*
5 *sponse to food defense threats; and*

6 (B) *detect, track, and remove smuggled food*
7 *(as defined in section 309) from commerce.*

8 **SEC. 402. EMPLOYEE PROTECTIONS.**

9 *Chapter X of the Federal Food, Drug, and Cosmetic*
10 *Act (21 U.S.C. 391 et seq.), as amended by section 209,*
11 *is further amended by adding at the end the following:*

12 **“SEC. 1012. EMPLOYEE PROTECTIONS.**

13 “(a) *IN GENERAL.*—*No entity engaged in the manu-*
14 *facture, processing, packing, transporting, distribution, re-*
15 *ception, holding, or importation of food may discharge an*
16 *employee or otherwise discriminate against an employee*
17 *with respect to compensation, terms, conditions, or privi-*
18 *leges of employment because the employee, whether at the*
19 *employee’s initiative or in the ordinary course of the em-*
20 *ployee’s duties (or any person acting pursuant to a request*
21 *of the employee)—*

22 “(1) *provided, caused to be provided, or is about*
23 *to provide or cause to be provided to the employer, the*
24 *Federal Government, or the attorney general of a*
25 *State information relating to any violation of, or any*

1 *act or omission the employee reasonably believes to be*
2 *a violation of any provision of this Act or any order,*
3 *rule, regulation, standard, or ban under this Act, or*
4 *any order, rule, regulation, standard, or ban under*
5 *this Act;*

6 “(2) *testified or is about to testify in a pro-*
7 *ceeding concerning such violation;*

8 “(3) *assisted or participated or is about to assist*
9 *or participate in such a proceeding; or*

10 “(4) *objected to, or refused to participate in, any*
11 *activity, policy, practice, or assigned task that the*
12 *employee (or other such person) reasonably believed to*
13 *be in violation of any provision of this Act, or any*
14 *order, rule, regulation, standard, or ban under this*
15 *Act.*

16 “(b) *PROCESS.—*

17 “(1) *IN GENERAL.—A person who believes that*
18 *he or she has been discharged or otherwise discrimi-*
19 *nated against by any person in violation of sub-*
20 *section (a) may, not later than 180 days after the*
21 *date on which such violation occurs, file (or have any*
22 *person file on his or her behalf) a complaint with the*
23 *Secretary of Labor (referred to in this section as the*
24 *‘Secretary’) alleging such discharge or discrimination*
25 *and identifying the person responsible for such act.*

1 *Upon receipt of such a complaint, the Secretary shall*
2 *notify, in writing, the person named in the complaint*
3 *of the filing of the complaint, of the allegations con-*
4 *tained in the complaint, of the substance of evidence*
5 *supporting the complaint, and of the opportunities*
6 *that will be afforded to such person under paragraph*
7 *(2).*

8 “(2) *INVESTIGATION.*—

9 “(A) *IN GENERAL.*—*Not later than 60 days*
10 *after the date of receipt of a complaint filed*
11 *under paragraph (1) and after affording the*
12 *complainant and the person named in the com-*
13 *plaint an opportunity to submit to the Secretary*
14 *a written response to the complaint and an op-*
15 *portunity to meet with a representative of the*
16 *Secretary to present statements from witnesses,*
17 *the Secretary shall initiate an investigation and*
18 *determine whether there is reasonable cause to*
19 *believe that the complaint has merit and notify,*
20 *in writing, the complainant and the person al-*
21 *leged to have committed a violation of subsection*
22 *(a) of the Secretary’s findings.*

23 “(B) *REASONABLE CAUSE FOUND; PRELIMI-*
24 *NARY ORDER.*—*If the Secretary concludes that*
25 *there is reasonable cause to believe that a viola-*

1 tion of subsection (a) has occurred, the Secretary
2 shall accompany the Secretary's findings with a
3 preliminary order providing the relief prescribed
4 by paragraph (3)(B). Not later than 30 days
5 after the date of notification of findings under
6 this paragraph, the person alleged to have com-
7 mitted the violation or the complainant may file
8 objections to the findings or preliminary order,
9 or both, and request a hearing on the record. The
10 filing of such objections shall not operate to stay
11 any reinstatement remedy contained in the pre-
12 liminary order. Any such hearing shall be con-
13 ducted expeditiously. If a hearing is not re-
14 quested in such 30-day period, the preliminary
15 order shall be deemed a final order that is not
16 subject to judicial review.

17 “(C) DISMISSAL OF COMPLAINT.—

18 “(i) STANDARD FOR COMPLAINANT.—

19 The Secretary shall dismiss a complaint
20 filed under this subsection and shall not
21 conduct an investigation otherwise required
22 under subparagraph (A) unless the com-
23 plainant makes a prima facie showing that
24 any behavior described in paragraphs (1)
25 through (4) of subsection (a) was a contrib-

1 *uting factor in the unfavorable personnel*
2 *action alleged in the complaint.*

3 “(ii) *STANDARD FOR EMPLOYER.*—Not-
4 *withstanding a finding by the Secretary*
5 *that the complainant has made the showing*
6 *required under clause (i), no investigation*
7 *otherwise required under subparagraph (A)*
8 *shall be conducted if the employer dem-*
9 *onstrates, by clear and convincing evidence,*
10 *that the employer would have taken the*
11 *same unfavorable personnel action in the*
12 *absence of that behavior.*

13 “(iii) *VIOLATION STANDARD.*—*The Sec-*
14 *retary may determine that a violation of*
15 *subsection (a) has occurred only if the com-*
16 *plainant demonstrates that any behavior*
17 *described in paragraphs (1) through (4) of*
18 *subsection (a) was a contributing factor in*
19 *the unfavorable personnel action alleged in*
20 *the complaint.*

21 “(iv) *RELIEF STANDARD.*—*Relief may*
22 *not be ordered under subparagraph (A) if*
23 *the employer 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 “(3) *FINAL ORDER.*—

4 “(A) *IN GENERAL.*—*Not later than 120*
5 *days after the date of conclusion of any hearing*
6 *under paragraph (2), the Secretary shall issue a*
7 *final order providing the relief prescribed by this*
8 *paragraph or denying the complaint. At any*
9 *time before issuance of a final order, a pro-*
10 *ceeding under this subsection may be terminated*
11 *on the basis of a settlement agreement entered*
12 *into by the Secretary, the complainant, and the*
13 *person alleged to have committed the violation.*

14 “(B) *CONTENT OF ORDER.*—*If, in response*
15 *to a complaint filed under paragraph (1), the*
16 *Secretary determines that a violation of sub-*
17 *section (a) has occurred, the Secretary shall*
18 *order the person who committed such violation—*

19 “(i) *to take affirmative action to abate*
20 *the violation;*

21 “(ii) *to reinstate the complainant to*
22 *his or her former position together with*
23 *compensation (including back pay) and re-*
24 *store the terms, conditions, and privileges*
25 *associated with his or her employment; and*

1 “(iii) to provide compensatory dam-
2 ages to the complainant.

3 “(C) *PENALTY.*—If such an order is issued
4 under this paragraph, the Secretary, at the re-
5 quest of the complainant, shall assess against the
6 person against whom the order is issued a sum
7 equal to the aggregate amount of all costs and
8 expenses (including attorneys’ and expert witness
9 fees) reasonably incurred, as determined by the
10 Secretary, by the complainant for, or in connec-
11 tion with, the bringing of the complaint upon
12 which the order was issued.

13 “(D) *BAD FAITH CLAIM.*—If the Secretary
14 finds that a complaint under paragraph (1) is
15 frivolous or has been brought in bad faith, the
16 Secretary may award to the prevailing employer
17 a reasonable attorneys’ fee, not exceeding \$1,000,
18 to be paid by the complainant.

19 “(4) *ACTION IN COURT.*—

20 “(A) *IN GENERAL.*—If the Secretary has not
21 issued a final decision within 210 days after the
22 filing of the complaint, or within 90 days after
23 receiving a written determination, the complain-
24 ant may bring an action at law or equity for de
25 novo review in the appropriate district court of

1 *the United States with jurisdiction, which shall*
2 *have jurisdiction over such an action without re-*
3 *gard to the amount in controversy, and which*
4 *action shall, at the request of either party to such*
5 *action, be tried by the court with a jury. The*
6 *proceedings shall be governed by the same legal*
7 *burdens of proof specified in paragraph (2)(C).*

8 “(B) *RELIEF.*—*The court shall have juris-*
9 *isdiction to grant all relief necessary to make the*
10 *employee whole, including injunctive relief and*
11 *compensatory damages, including—*

12 “(i) *reinstatement with the same se-*
13 *niority status that the employee would have*
14 *had, but for the discharge or discrimina-*
15 *tion;*

16 “(ii) *the amount of back pay, with in-*
17 *terest; and*

18 “(iii) *compensation for any special*
19 *damages sustained as a result of the dis-*
20 *charge or discrimination, including litiga-*
21 *tion costs, expert witness fees, and reason-*
22 *able attorney’s fees.*

23 “(5) *REVIEW.*—

24 “(A) *IN GENERAL.*—*Unless the complainant*
25 *brings an action under paragraph (4), any per-*

1 *son adversely affected or aggrieved by a final*
2 *order issued under paragraph (3) may obtain re-*
3 *view of the order in the United States Court of*
4 *Appeals for the circuit in which the violation,*
5 *with respect to which the order was issued, alleg-*
6 *edly occurred or the circuit in which the com-*
7 *plainant resided on the date of such violation.*
8 *The petition for review must be filed not later*
9 *than 60 days after the date of the issuance of the*
10 *final order of the Secretary. Review shall con-*
11 *form to chapter 7 of title 5, United States Code.*
12 *The commencement of proceedings under this*
13 *subparagraph shall not, unless ordered by the*
14 *court, operate as a stay of the order.*

15 *“(B) NO JUDICIAL REVIEW.—An order of*
16 *the Secretary with respect to which review could*
17 *have been obtained under subparagraph (A) shall*
18 *not be subject to judicial review in any criminal*
19 *or other civil proceeding.*

20 *“(6) FAILURE TO COMPLY WITH ORDER.—When-*
21 *ever any person has failed to comply with an order*
22 *issued under paragraph (3), the Secretary may file a*
23 *civil action in the United States district court for the*
24 *district in which the violation was found to occur, or*
25 *in the United States district court for the District of*

1 *Columbia, to enforce such order. In actions brought*
2 *under this paragraph, the district courts shall have*
3 *jurisdiction to grant all appropriate relief including,*
4 *but not limited to, injunctive relief and compensatory*
5 *damages.*

6 “(7) *CIVIL ACTION TO REQUIRE COMPLIANCE.*—

7 “(A) *IN GENERAL.*—A person on whose be-
8 *half an order was issued under paragraph (3)*
9 *may commence a civil action against the person*
10 *to whom such order was issued to require com-*
11 *pliance with such order. The appropriate United*
12 *States district court shall have jurisdiction,*
13 *without regard to the amount in controversy or*
14 *the citizenship of the parties, to enforce such*
15 *order.*

16 “(B) *AWARD.*—The court, in issuing any
17 *final order under this paragraph, may award*
18 *costs of litigation (including reasonable attor-*
19 *neys’ and expert witness fees) to any party*
20 *whenever the court determines such award is ap-*
21 *propriate.*

22 “(c) *EFFECT OF SECTION.*—

23 “(1) *OTHER LAWS.*—Nothing in this section pre-
24 *empts or diminishes any other safeguards against dis-*
25 *crimination, demotion, discharge, suspension, threats,*

1 *harassment, reprimand, retaliation, or any other*
2 *manner of discrimination provided by Federal or*
3 *State law.*

4 “(2) *RIGHTS OF EMPLOYEES.*—*Nothing in this*
5 *section shall be construed to diminish the rights,*
6 *privileges, or remedies of any employee under any*
7 *Federal or State law or under any collective bar-*
8 *gaining agreement. The rights and remedies in this*
9 *section may not be waived by any agreement, policy,*
10 *form, or condition of employment.*

11 “(d) *ENFORCEMENT.*—*Any nondiscretionary duty im-*
12 *posed by this section shall be enforceable in a mandamus*
13 *proceeding brought under section 1361 of title 28, United*
14 *States Code.*

15 “(e) *LIMITATION.*—*Subsection (a) shall not apply with*
16 *respect to an employee of an entity engaged in the manufac-*
17 *ture, processing, packing, transporting, distribution, recep-*
18 *tion, holding, or importation of food who, acting without*
19 *direction from such entity (or such entity’s agent), delib-*
20 *erately causes a violation of any requirement relating to*
21 *any violation or alleged violation of any order, rule, regula-*
22 *tion, standard, or ban under this Act.”.*

23 **SEC. 403. JURISDICTION; AUTHORITIES.**

24 *Nothing in this Act, or an amendment made by this*
25 *Act, shall be construed to—*

1 (1) *alter the jurisdiction between the Secretary of*
2 *Agriculture and the Secretary of Health and Human*
3 *Services, under applicable statutes, regulations, or*
4 *agreements regarding voluntary inspection of non-*
5 *amenable species under the Agricultural Marketing*
6 *Act of 1946 (7 U.S.C. 1621 et seq.);*

7 (2) *alter the jurisdiction between the Alcohol and*
8 *Tobacco Tax and Trade Bureau and the Secretary of*
9 *Health and Human Services, under applicable stat-*
10 *utes and regulations;*

11 (3) *limit the authority of the Secretary of Health*
12 *and Human Services under—*

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

16 (B) *the Public Health Service Act (42*
17 *U.S.C. 301 et seq.) as in effect on the day before*
18 *the date of enactment of this Act;*

19 (4) *alter or limit the authority of the Secretary*
20 *of Agriculture under the laws administered by such*
21 *Secretary, including—*

22 (A) *the Federal Meat Inspection Act (21*
23 *U.S.C. 601 et seq.);*

24 (B) *the Poultry Products Inspection Act (21*
25 *U.S.C. 451 et seq.);*

1 *agreement establishing the World Trade Organization or*
2 *any other treaty or international agreement to which the*
3 *United States is a party.*

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

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

Amend the title so as to read: “An Act to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.”.

Attest:

Secretary.

H.R. 2751

AMENDMENTS