

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 2749, AS FORWARDED BY THE SUB-
COMMITTEE ON HEALTH ON JUNE 10, 2009
OFFERED BY MR. WAXMAN OF CALIFORNIA**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the “Food Safety Enhance-
3 ment Act of 2009”.

4 SEC. 2. TABLE OF CONTENTS.

5 The table of contents of this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.
- Sec. 3. References.
- Sec. 4. Rules of construction.
- Sec. 5. USDA exemptions.
- Sec. 6. Alcohol-related facilities.

TITLE I—FOOD SAFETY

Subtitle A—Prevention

- Sec. 101. Changes in registration of food facilities.
- Sec. 102. Hazard analysis, risk-based preventive controls, food safety plan, finished product test results from category 1 facilities.
- Sec. 103. Performance standards.
- Sec. 104. Safety standards for produce and certain other raw agricultural commodities.
- Sec. 105. Risk-based inspection schedule.
- Sec. 106. Access to records.
- Sec. 107. Traceability of food.
- Sec. 108. Reinspection and food recall fees applicable to facilities.
- Sec. 109. Certification and accreditation.
- Sec. 110. Testing by accredited laboratories.
- Sec. 111. Notification, nondistribution, and recall of adulterated or misbranded food.
- Sec. 112. Reportable food registry; exchange of information.

- Sec. 113. Safe and secure food importation program.
- Sec. 114. Infant formula.

Subtitle B—Intervention

- Sec. 121. Surveillance.
- Sec. 122. Public education and advisory system.
- Sec. 123. Research.

Subtitle C—Response

- Sec. 131. Procedures for seizure.
- Sec. 132. Administrative detention.
- Sec. 133. Quarantine authority for foods.
- Sec. 134. Criminal penalties.
- Sec. 135. Civil penalties for violations relating to food.
- Sec. 136. Improper import entry filings.

TITLE II—MISCELLANEOUS

- Sec. 201. Food substances generally recognized as safe.
- Sec. 202. Country of origin labeling; disclosure of source of ingredients.
- Sec. 203. Exportation certificate program.
- Sec. 204. Registration for commercial importers of food; fee.
- Sec. 205. Registration for customs brokers and filers; fee.
- Sec. 206. Unique identification number for food facilities, importers, custom brokers, and filers.
- Sec. 207. Prohibition against delaying, limiting, or refusing inspection.
- Sec. 208. Dedicated foreign inspectorate.
- Sec. 209. Plan and review of continued operation of field laboratories.
- Sec. 210. False or misleading reporting to FDA.
- Sec. 211. Subpoena authority.
- Sec. 212. Whistleblower protections.
- Sec. 213. Extraterritorial jurisdiction.
- Sec. 214. Support for training institutes.
- Sec. 215. Bisphenol A in food and beverage containers.

1 **SEC. 3. REFERENCES.**

2 Except as otherwise specified, whenever in this Act
3 an amendment is expressed in terms of an amendment to
4 a section or other provision, the reference shall be consid-
5 ered to be made to a section or other provision of the Fed-
6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
7 seq.).

1 **SEC. 4. RULES OF CONSTRUCTION.**

2 (a) Nothing in this Act or any amendment made by
3 this Act shall be construed to prohibit or limit—

4 (1) any cause of action under State law; or

5 (2) the introduction of evidence of compliance
6 or noncompliance with the requirements of the Fed-
7 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301
8 et seq.).

9 (b) Nothing in this Act or any amendment made by
10 this Act shall be construed to—

11 (1) alter the jurisdiction between the Secretary
12 of Agriculture and the Secretary of Health and
13 Human Services, under applicable statutes and regu-
14 lations;

15 (2) limit the authority of the Secretary of
16 Health and Human Services to issue regulations re-
17 lated to the safety of food under—

18 (A) the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 301 et seq.) as in effect on the
20 day before the date of the enactment of this
21 Act; or

22 (B) the Public Health Service Act (42
23 U.S.C. 301 et seq.) as in effect on the day be-
24 fore the date of the enactment of this Act; or

25 (3) impede, minimize, or affect the authority of
26 the Secretary of Agriculture to prevent, control, or

1 mitigate a plant or animal health emergency, or a
2 food emergency involving products regulated under
3 the Federal Meat Inspection Act (21 U.S.C. 601 et
4 seq.), the Poultry Products Inspection Act (21
5 U.S.C. 451 et seq.), or the Egg Products Inspection
6 Act (21 U.S.C. 1031 et seq.).

7 **SEC. 5. USDA EXEMPTIONS.**

8 (a) **USDA-REGULATED PRODUCTS.**—Food is exempt
9 from the requirements of this Act if such food is regulated
10 by the Secretary of Agriculture under the Federal Meat
11 Inspection Act, the Poultry Products Inspection Act, or
12 the Egg Products Inspection Act.

13 (b) **USDA-REGULATED FACILITIES.**—A facility is
14 exempt from the requirements of this Act if such facility
15 is regulated exclusively as an official establishment by the
16 Secretary of Agriculture under the Federal Meat Inspec-
17 tion Act, the Poultry Products Inspection Act, or the Egg
18 Products Inspection Act.

19 (c) **FARMS.**—A farm is exempt from the requirements
20 of this Act to the extent such farm raises animals from
21 which food is derived that is regulated under the Federal
22 Meat Inspection Act, the Poultry Products Inspection Act,
23 or the Egg Products Inspection Act.

1 **SEC. 6. ALCOHOL-RELATED FACILITIES.**

2 (a) IN GENERAL.—With the exception of the amend-
3 ments made by section 101(a) and (b) and section 113
4 of this Act, nothing in this Act, or the amendments made
5 by this Act, shall be construed to apply to a facility that—

6 (1) under the Federal Alcohol Administration
7 Act or chapter 51 of subtitle E of the Internal Rev-
8 enue Code, is required to obtain a permit or to reg-
9 ister with the Secretary of the Treasury as a condi-
10 tion of doing business in the United States; and

11 (2) under section 415 of the Federal Food,
12 Drug, and Cosmetic Act, as amended by this Act, is
13 required to register as a facility solely because such
14 facility is engaged in manufacturing, processing,
15 packing, or holding 1 or more alcoholic beverages.

16 (b) RULE OF CONSTRUCTION.—This section shall not
17 be construed to exempt any food, apart from distilled spir-
18 its, wine, and malt beverages, as defined in section 211
19 of the Federal Alcohol Administration Act, from the re-
20 quirements of this Act and the amendments made by this
21 Act.

1 **TITLE I—FOOD SAFETY**
2 **Subtitle A—Prevention**

3 **SEC. 101. CHANGES IN REGISTRATION OF FOOD FACILI-**
4 **TIES.**

5 (a) MISBRANDING.—Section 403 (21 U.S.C. 343) is
6 amended by adding at the end the following:

7 “(z) If it was manufactured, processed, packed, or
8 held in a facility that is not duly registered under section
9 415, including a facility whose registration is canceled or
10 suspended under such section.”.

11 (b) ANNUAL REGISTRATION.—

12 (1) IN GENERAL.—Section 415(a) (21 U.S.C.
13 350d(a)) is amended—

14 (A) in the first sentence of paragraph
15 (1)—

16 (i) by striking “require that” and in-
17 serting “require that, on or before Decem-
18 ber 31 of each year,”; and

19 (ii) by striking “food for consumption
20 in the United States” and inserting “food
21 for consumption in the United States or
22 for export from the United States”;

23 (B) in subparagraphs (A) and (B) of para-
24 graph (1), by inserting “and pay the registra-
25 tion fee required under section 743” after “sub-

1 mit a registration to the Secretary” each place
2 it appears;

3 (C) in the first sentence of paragraph (2),
4 by inserting “in electronic format” after “sub-
5 mit”; and

6 (D) in paragraph (4), by inserting after
7 the first sentence the following: “The Secretary
8 shall remove from such list the name of any fa-
9 cility that fails to reregister in accordance with
10 this section, that fails to pay the registration
11 fee required under section 743, or whose reg-
12 istration is canceled by the registrant, canceled
13 by the Secretary in accordance with this sec-
14 tion, or suspended by the Secretary in accord-
15 ance with this section.”.

16 (2) CONTENTS OF REGISTRATION.—Paragraph
17 (2) of section 415(a) (21 U.S.C. 350d(a)), as
18 amended by paragraph (1), is amended by striking
19 “containing information” and all that follows and in-
20 serting the following: “containing information that
21 identifies the following:

22 “(A) The name, address, and emergency
23 contact information of the facility being reg-
24 istered.

1 “(B) The primary purpose and business
2 activity of the facility, including the dates of op-
3 eration if the facility is seasonal.

4 “(C) The general food category (as defined
5 by the Secretary by guidance) of each food
6 manufactured, processed, packed, or held at the
7 facility.

8 “(D) All trade names under which the fa-
9 cility conducts business related to food.

10 “(E) The name, address, and 24-hour
11 emergency contact information of the United
12 States distribution agent for the facility, which
13 agent shall have access to the information re-
14 quired to be maintained under section 414(d)
15 for food that is manufactured, processed,
16 packed, or held at the facility.

17 “(F) If the facility is located outside of the
18 United States, the name, address, and emer-
19 gency contact information for a United States
20 agent.

21 “(G) The unique facility identifier of the
22 facility, as specified under section 911.

23 “(H) Such additional information per-
24 taining to the facility as the Secretary may re-
25 quire by regulation.

1 The registrant shall notify the Secretary of any
2 change in the submitted information not later than
3 30 days after the date of such change, unless other-
4 wise specified by the Secretary.”.

5 (3) SUSPENSION AND CANCELLATION AUTHOR-
6 ITY.—Section 415(a) (21 U.S.C. 350d(a)), as
7 amended by paragraphs (1) and (2), is further
8 amended by adding at the end the following:

9 “(5) SUSPENSION OF REGISTRATION.—

10 “(A) IN GENERAL.—The Secretary may
11 suspend the registration of any facility reg-
12 istered under this section for a violation of this
13 Act that could result in serious adverse health
14 consequences or death to humans or animals.

15 “(B) NOTICE OF SUSPENSION.—Susten-
16 sion of a registration shall be preceded by—

17 “(i) notice to the facility of the intent
18 to suspend the registration; and

19 “(ii) an opportunity for an informal
20 hearing, as defined in guidance or regula-
21 tions issued by the Secretary, concerning
22 the suspension of such registration for
23 such facility.

24 “(C) REQUEST.—The owner, operator, or
25 agent in charge of a facility whose registration

1 is suspended may request that the Secretary va-
2 cate the suspension of registration when such
3 owner, operator, or agent has corrected the vio-
4 lation that is the basis for such suspension.

5 “(D) VACATING OF SUSPENSION.—If,
6 based on an inspection of the facility or other
7 information, the Secretary determines that ade-
8 quate reasons do not exist to continue the sus-
9 pension of a registration, the Secretary shall va-
10 cate such suspension.

11 “(6) CANCELLATION OF REGISTRATION.—

12 “(A) IN GENERAL.—Not earlier than 10
13 days after providing the notice under subpara-
14 graph (B), the Secretary may cancel a registra-
15 tion if the Secretary determines that—

16 “(i) the registration was not updated
17 in accordance with this section or other-
18 wise contains false, incomplete, or inac-
19 curate information; or

20 “(ii) the required registration fee has
21 not been paid within 30 days after the date
22 due.

23 “(B) NOTICE OF CANCELLATION.—Can-
24 cellation shall be preceded by notice to the facil-

1 ity of the intent to cancel the registration and
2 the basis for such cancellation.

3 “(C) TIMELY UPDATE OR CORRECTION.—
4 If the registration for the facility is updated or
5 corrected no later than 7 days after notice is
6 provided under subparagraph (B), the Sec-
7 retary shall not cancel such registration.

8 “(7) REPORT TO CONGRESS.—Not later than
9 March 30th of each year, the Secretary shall submit
10 to the Congress a report, based on the registrations
11 on or before December 31 of the previous year, on
12 the following:

13 “(A) The number of facilities registered
14 under this section.

15 “(B) The number of such facilities that are
16 domestic.

17 “(C) The number of such facilities that are
18 foreign.

19 “(D) The number of such facilities that
20 are high-risk.

21 “(E) The number of such facilities that are
22 low-risk.

23 “(F) The number of such facilities that
24 hold food.

1 “(8) LIMITATION ON DELEGATION.—The au-
2 thority conferred by this subsection to issue an order
3 to suspend a registration or cancel a registration
4 shall not be delegated to any officer or employee
5 other than the Commissioner of Food and Drugs,
6 the Principal Deputy Commissioner, the Associate
7 Commissioner for Regulatory Affairs, or the Direc-
8 tor for the Center for Food Safety and Applied Nu-
9 trition, of the Food and Drug Administration.”.

10 (c) REGISTRATION FEE.—Chapter VII (21 U.S.C.
11 371 et seq.) is amended by adding at the end of sub-
12 chapter C the following:

13 **“PART 6—FEES RELATING TO FOOD**

14 **“SEC. 743. FACILITY REGISTRATION FEE.**

15 “(a) IN GENERAL.—

16 “(1) ASSESSMENT AND COLLECTION.—Begin-
17 ning in fiscal year 2010, the Secretary shall assess
18 and collect an annual fee for the registration of a fa-
19 cility under section 415.

20 “(2) PAYABLE DATE.—A fee under this section
21 shall be payable—

22 “(A) for a facility that was not registered
23 under section 415 for the preceding fiscal year,
24 on the date of registration; and

25 “(B) for any other facility—

1 “(i) for fiscal year 2010, not later
2 than the sooner of 90 days after the date
3 of the enactment of this part or December
4 31, 2009; and

5 “(ii) for a subsequent fiscal year, not
6 later than December 31 of such fiscal year.

7 “(b) FEE AMOUNTS.—

8 “(1) IN GENERAL.—The registration fee under
9 subsection (a) shall be—

10 “(A) for fiscal year 2010, \$500; and

11 “(B) for fiscal year 2011 and each subse-
12 quent fiscal year, the fee for fiscal year 2010 as
13 adjusted under subsection (c).

14 “(2) ANNUAL FEE SETTING.—The Secretary
15 shall, not later than 60 days before the start of fis-
16 cal year 2011 and each subsequent fiscal year, es-
17 tablish, for the next fiscal year, registration fees
18 under subsection (a), as described in paragraph (1).

19 “(3) MAXIMUM AMOUNT.—Notwithstanding
20 paragraph (1), a person who owns or operates mul-
21 tiple facilities for which a fee must be paid under
22 this section for a fiscal year shall be liable for not
23 more than \$175,000 in aggregate fees under this
24 section for such fiscal year.

1 “(c) INFLATION ADJUSTMENT.—For fiscal year 2011
2 and each subsequent fiscal year, the fee amount under
3 subsection (b)(1) shall be adjusted by the Secretary by no-
4 tice, published in the Federal Register, to reflect the
5 greater of—

6 “(1) the total percentage change that occurred
7 in the Consumer Price Index for all urban con-
8 sumers (all items; U.S. city average) for the 12-
9 month period ending June 30 preceding the fiscal
10 year for which fees are being established;

11 “(2) the total percentage change for the pre-
12 vious fiscal year in basic pay under the General
13 Schedule in accordance with section 5332 of title 5,
14 United States Code, as adjusted by any locality-
15 based comparability payment pursuant to section
16 5304 of such title for Federal employees stationed in
17 the District of Columbia; or

18 “(3) the average annual change in the cost, per
19 full-time equivalent position of the Food and Drug
20 Administration, of all personnel compensation and
21 benefits paid with respect to such positions for the
22 first 5 years of the preceding 6 fiscal years.

23 The adjustment made each fiscal year under this sub-
24 section shall be added on a compounded basis to the sum

1 of all adjustments made each fiscal year after fiscal year
2 2010 under this subsection.

3 “(d) LIMITATIONS.—

4 “(1) IN GENERAL.—Fees under subsection (a)
5 shall be refunded for a fiscal year beginning after
6 fiscal year 2010 unless appropriations for salaries
7 and expenses of the Food and Drug Administration
8 for such fiscal year (excluding the amount of fees
9 appropriated for such fiscal year) are equal to or
10 greater than the amount of appropriations for the
11 salaries and expenses of the Food and Drug Admin-
12 istration for fiscal year 2010 (excluding the amount
13 of fees appropriated for such fiscal year) multiplied
14 by the adjustment factor applicable to the fiscal year
15 involved.

16 “(2) AUTHORITY.—If the Secretary does not
17 assess fees under subsection (a) during any portion
18 of a fiscal year because of paragraph (1) and if at
19 a later date in such fiscal year the Secretary may as-
20 sess such fees, the Secretary may assess and collect
21 such fees, without any modification in the rate, for
22 registration under section 415 at any time in such
23 fiscal year.

24 “(3) ADJUSTMENT FACTOR.—In this sub-
25 section, the term ‘adjustment factor’ applicable to a

1 fiscal year is the Consumer Price Index for all urban
2 consumers (all items; United States city average) for
3 October of the preceding fiscal year divided by such
4 Index for October 2009.

5 “(e) CREDITING AND AVAILABILITY OF FEES.—

6 “(1) IN GENERAL.—Fees authorized under sub-
7 section (a) shall be collected and available for obliga-
8 tion only to the extent and in the amount provided
9 in advance in appropriations Acts. Such fees are au-
10 thorized to remain available until expended. Such
11 sums as may be necessary may be transferred from
12 the Food and Drug Administration salaries and ex-
13 penses appropriation account without fiscal year lim-
14 itation to such appropriation account for salaries
15 and expenses with such fiscal year limitation.

16 “(2) COLLECTIONS AND APPROPRIATIONS
17 ACTS.—The fees authorized by this section—

18 “(A) shall be retained in each fiscal year in
19 an amount not to exceed the amount specified
20 in appropriation Acts, or otherwise made avail-
21 able for obligation, for such fiscal year; and

22 “(B) shall only be collected and available
23 to defray the costs of food safety activities.

24 “(3) AUTHORIZATION OF APPROPRIATIONS.—

25 For each of fiscal years 2010 through 2014, there

1 are authorized to be appropriated for fees under this
2 section such sums as may be necessary.

3 “(4) PUBLIC MEETINGS.—For each fiscal year,
4 the Secretary shall hold a public meeting on how
5 fees collected under this section will be used to de-
6 fray the costs of food safety activities in order to so-
7 licit the views of the regulated industry, consumers,
8 and other interested stakeholders.

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

15 “(g) CONSTRUCTION.—This section may not be con-
16 strued to require that the number of full-time equivalent
17 positions in the Department of Health and Human Serv-
18 ices, for officers, employees, and advisory committees not
19 engaged in food safety activities, be reduced to offset the
20 number of officers, employees, and advisory committees so
21 engaged.

22 “(h) ANNUAL FISCAL REPORTS.—Beginning with
23 fiscal year 2011, not later than 120 days after the end
24 of each fiscal year for which fees are collected under this
25 section, the Secretary shall prepare and submit to the

1 Committee on Energy and Commerce of the House of
2 Representatives and the Committee on Health, Education,
3 Labor, and Pensions of the Senate a report on the imple-
4 mentation of the authority for such fees during such fiscal
5 year and the use, by the Food and Drug Administration,
6 of the fees collected for such fiscal year.

7 “(i) DEFINITIONS.—In this section:

8 “(1) The term ‘costs of food safety activities’
9 means the expenses incurred in connection with food
10 safety activities for—

11 “(A) officers and employees of the Food
12 and Drug Administration, contractors of the
13 Food and Drug Administration, advisory com-
14 mittees, and costs related to such officers, em-
15 ployees, and committees and to contracts with
16 such contractors;

17 “(B) laboratory capacity;

18 “(C) management of information, and the
19 acquisition, maintenance, and repair of tech-
20 nology resources;

21 “(D) leasing, maintenance, renovation, and
22 repair of facilities and acquisition, maintenance,
23 and repair of fixtures, furniture, scientific
24 equipment, and other necessary materials and
25 supplies; and

1 “(E) collecting fees under this section and
2 accounting for resources allocated for food safe-
3 ty activities.

4 “(2) The term ‘food safety activities’ means ac-
5 tivities related to compliance by facilities registered
6 under section 415 with the requirements of this Act
7 relating to food (including research related to and
8 the development of standards (such as performance
9 standards and preventive controls), risk assessments,
10 hazard analyses, inspection planning and inspec-
11 tions, third-party inspections, compliance review and
12 enforcement, import review, information technology
13 support, test development, product sampling, risk
14 communication, and administrative detention).”.

15 (d) TRANSITIONAL PROVISIONS.—

16 (1) FEES.—The Secretary of Health and
17 Human Services shall first impose the fee estab-
18 lished under section 743 of the Federal Food, Drug,
19 and Cosmetic Act, as added by subsection (c), for
20 fiscal years beginning with fiscal year 2010.

21 (2) MODIFICATION OF REGISTRATION FORM.—

22 Not later than 180 days after the date of the enact-
23 ment of this Act, the Secretary of Health and
24 Human Services shall modify the registration form
25 under section 415 of the Federal Food, Drug, and

1 Cosmetic Act (21 U.S.C. 350d) to comply with the
2 amendments made by this section.

3 (3) APPLICATION.—The amendments made by
4 this section, other than subsections (b)(2) and (c),
5 shall take effect on the date that is 30 days after
6 the date on which such modified registration form
7 takes effect, but not later than 210 days after the
8 date of the enactment of this Act.

9 (4) SUNSET DATE.—Section 743 of the Federal
10 Food, Drug, and Cosmetic Act, as added by sub-
11 section (c), does not authorize the assessment or col-
12 lection of a fee for registration under section 415 of
13 such Act (21 U.S.C. 360) occurring after fiscal year
14 2014.

15 **SEC. 102. HAZARD ANALYSIS, RISK-BASED PREVENTIVE**
16 **CONTROLS, FOOD SAFETY PLAN, FINISHED**
17 **PRODUCT TEST RESULTS FROM CATEGORY 1**
18 **FACILITIES.**

19 (a) HAZARD ANALYSIS, RISK-BASED PREVENTIVE
20 CONTROLS, FOOD SAFETY PLAN.—

21 (1) ADULTERATED FOOD.—Section 402 (21
22 U.S.C. 342) is amended by adding at the end the
23 following:

1 “(j) If it has been manufactured, processed, packed,
2 transported, or held under conditions that do not meet the
3 requirements of sections 418 and 418A.”.

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

7 **“SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVEN-**
8 **TIVE CONTROLS.**

9 “(a) IN GENERAL.—The owner, operator, or agent
10 of a facility shall, in accordance with this section—

11 “(1) conduct a hazard analysis (or more than
12 one if appropriate);

13 “(2) identify, implement, and validate effective
14 preventive controls;

15 “(3) monitor preventive controls;

16 “(4) institute corrective actions when—

17 “(A) monitoring shows that preventive con-
18 trols have not been properly implemented; or

19 “(B) monitoring and verification show that
20 such controls were ineffective;

21 “(5) conduct verification activities;

22 “(6) maintain records of monitoring, corrective
23 action, and verification; and

24 “(7) reanalyze for hazards.

25 “(b) IDENTIFICATION OF HAZARDS.—

1 “(1) IN GENERAL.—The owner, operator, or
2 agent of a facility shall evaluate whether there are
3 any hazards, including hazards due to the source of
4 the ingredients, that are reasonably likely to occur
5 in the absence of preventive controls that may affect
6 the safety, wholesomeness, or sanitation of the food
7 manufactured, processed, packed, transported, or
8 held by the facility, including—

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

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

18 “(2) IDENTIFIED BY THE SECRETARY.—The
19 Secretary may, by regulation or guidance, identify
20 hazards that are reasonably likely to occur in the ab-
21 sence of preventive controls.

22 “(3) HAZARD ANALYSIS.—The owner, operator,
23 or agent of a facility shall identify and describe the
24 hazards evaluated under paragraph (1) or identified

1 under paragraph (2), to the extent applicable to the
2 facility, in a hazard analysis.

3 “(c) PREVENTIVE CONTROLS.—

4 “(1) IN GENERAL.—The owner, operator, or
5 agent of a facility shall identify, implement, and vali-
6 date effective preventive controls to prevent, elimi-
7 nate, or reduce to acceptable levels the occurrence of
8 any hazards identified in the hazard analysis under
9 subsection (b)(3).

10 “(2) IDENTIFIED BY THE SECRETARY.—

11 “(A) ESTABLISHMENT.—The Secretary
12 may establish by regulation or guidance preven-
13 tive controls for specific product types to pre-
14 vent intentional or unintentional contamination
15 throughout the supply chain. The owner, oper-
16 ator, or agent of a facility shall implement any
17 preventive controls identified by the Secretary
18 under this paragraph.

19 “(B) ALTERNATIVE CONTROLS.—Such reg-
20 ulation or guidance shall allow the owner, oper-
21 ator, or agent of a facility to implement an al-
22 ternative preventive control to one established
23 by the Secretary, provided that, in response to
24 a request by the Secretary, the owner, operator,
25 or agent can present to the Secretary data or

1 other information sufficient to demonstrate that
2 the alternative control effectively addresses the
3 hazard, including meeting any applicable per-
4 formance standard.

5 “(C) LIMITATION.—Subparagraph (B)
6 shall not apply to any preventive control de-
7 scribed in subparagraph (A), (B), or (E) of
8 subsection (i)(2).

9 “(d) MONITORING.—The owner, operator, or agent of
10 a facility shall monitor the implementation of preventive
11 controls under subsection (c) to identify any circumstances
12 in which the preventive controls are not fully implemented
13 or verification shows that such controls were ineffective.

14 “(e) CORRECTIVE ACTIONS.—The owner, operator,
15 or agent of a facility shall establish and implement proce-
16 dures to ensure that, if the preventive controls under sub-
17 section (c) are not fully implemented or are not effective—

18 “(1) no product from such facility enters com-
19 merce; and

20 “(2) appropriate action is taken to reduce the
21 likelihood of recurrence of the implementation fail-
22 ure.

23 “(f) VERIFICATION.—The owner, operator, or agent
24 of a facility shall ensure that—

1 “(1) the preventive controls identified under
2 subsection (c) have been validated as adequate to
3 control the hazards identified in the hazard analysis
4 under subsection (b)(3);

5 “(2) the facility is conducting monitoring in ac-
6 cordance with subsection (d);

7 “(3) the facility is taking effective corrective ac-
8 tions under subsection (e); and

9 “(4) the preventive controls are effectively pre-
10 venting, eliminating, or reducing to an acceptable
11 level the occurrence of identified hazards, including
12 through the use of environmental and product test-
13 ing programs and other appropriate means.

14 “(g) REQUIREMENT TO REANALYZE AND REVISE.—

15 “(1) REQUIREMENT.—The owner, operator, or
16 agent of a facility shall—

17 “(A) review the evaluation under sub-
18 section (b) for the facility and, as necessary, re-
19 vise the hazard analysis under subsection (b)(3)
20 for the facility—

21 “(i) not less than every 2 years;

22 “(ii) if there is a change in the proc-
23 ess or product that could affect the hazard
24 analysis; and

1 “(iii) if the Secretary determines that
2 it is appropriate to protect public health;
3 and

4 “(B) whenever there is a change in the
5 hazard analysis, revise the preventive controls
6 under subsection (c) for the facility as nec-
7 essary to ensure that all hazards that are rea-
8 sonably likely to occur are prevented, elimi-
9 nated, or reduced to an acceptable level, or doc-
10 ument the basis for the conclusion that no such
11 revision is needed.

12 “(2) NONDELEGATION.—Any revisions ordered
13 by the Secretary under this subsection shall be or-
14 dered by the Secretary or an official designated by
15 the Secretary. An official may not be so designated
16 unless the official is the director of the district
17 under this Act in which the article involved is lo-
18 cated, or is an official senior to such director.

19 “(h) RECORDKEEPING.—The owner, operator, or
20 agent of a facility shall maintain, for not less than 2 years,
21 records documenting the activities described in subsections
22 (a) through (g).

23 “(i) DEFINITIONS.—For purposes of this section:

1 “(1) FACILITY.—The term ‘facility’ means a
2 domestic facility or a foreign facility that is required
3 to be registered under section 415.

4 “(2) PREVENTIVE CONTROLS.—The term ‘pre-
5 ventive controls’ means those risk-based procedures,
6 practices, and processes that a person knowledgeable
7 about the safe manufacturing, processing, packing,
8 transporting, or holding of food would employ to
9 prevent, eliminate, or reduce to an acceptable level
10 the hazards identified in the hazard analysis under
11 subsection (b)(3) and that are consistent with the
12 current scientific understanding of safe food manu-
13 facturing, processing, packing, transporting, or hold-
14 ing at the time of the analysis. Those procedures,
15 practices, and processes shall include the following,
16 as appropriate:

17 “(A) Sanitation procedures and practices.

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

20 “(C) Process controls.

21 “(D) An allergen control program to mini-
22 mize potential allergic reactions in humans
23 from ingestion of, or contact with, human and
24 animal food.

25 “(E) Good manufacturing practices.

1 “(F) Verification procedures, practices,
2 and processes for suppliers and incoming ingre-
3 dients, which may include onsite auditing of
4 suppliers and testing of incoming ingredients.

5 “(G) Other procedures, practices, and
6 processes established by the Secretary under
7 subsection (c)(2).

8 “(3) HAZARD THAT IS REASONABLY LIKELY TO
9 OCCUR.—A food safety hazard that is reasonably
10 likely to occur is one for which a prudent person
11 who, as applicable, manufactures, processes, packs,
12 transports, or holds food, would establish controls
13 because experience, illness data, scientific reports, or
14 other information provides a basis to conclude that
15 there is a reasonable possibility that the hazard will
16 occur in the type of food being manufactured, proc-
17 essed, packed, transported, or held in the absence of
18 those controls.

19 **“SEC. 418A. FOOD SAFETY PLAN.**

20 “(a) IN GENERAL.—Before a facility (as defined in
21 section 418(i)) introduces or delivers for introduction into
22 interstate commerce any shipment of food, the owner, op-
23 erator, or agent of the facility shall develop and implement
24 a written food safety plan (in this section referred to as
25 a ‘food safety plan’).

1 “(b) CONTENTS.—The food safety plan shall include
2 each of the following elements:

3 “(1) The hazard analysis and any reanalysis
4 conducted under section 418.

5 “(2) A description of the preventive controls
6 being implemented under subsection 418(c), includ-
7 ing those to address hazards or conditions identified
8 by the Secretary under subsection 418(b)(2).

9 “(3) A description of the procedures for moni-
10 toring preventive controls.

11 “(4) A description of the procedures for taking
12 corrective actions.

13 “(5) A description of verification activities for
14 the preventive controls, including validation, review
15 of monitoring and corrective action records, and pro-
16 cedures for determining whether the preventive con-
17 trols are effectively preventing, eliminating, or re-
18 ducing to an acceptable level the occurrence of iden-
19 tified hazards or conditions, including the use of en-
20 vironmental and product testing programs.

21 “(6) A description of the facility’s record-
22 keeping procedures.

23 “(7) A description of the facility’s procedures
24 for the recall of articles of food, whether voluntarily
25 or when required under section 422.

1 “(8) A description of the facility’s procedures
2 for tracing the distribution history of articles of
3 food, whether voluntarily or when required under
4 section 414.

5 “(9) A description of the facility’s procedures to
6 ensure a safe and secure supply chain for the ingre-
7 dients or components used in making the food man-
8 ufactured, processed, packed, transported, or held by
9 such facility.

10 “(10) A description of the facility’s procedures
11 to implement the science-based performance stand-
12 ards issued under section 419.”.

13 (3) GUIDANCE OR REGULATIONS.—

14 (A) IN GENERAL.—The Secretary of
15 Health and Human Services (referred to in this
16 subsection as the “Secretary”) shall issue guid-
17 ance or promulgate regulations to establish
18 science-based standards for conducting a haz-
19 ard analysis, documenting hazards, identifying
20 and implementing preventive controls, and doc-
21 umenting the implementation of the preventive
22 controls, including verification and corrective
23 actions under sections 418 and 418A of the
24 Federal Food, Drug, and Cosmetic Act (as
25 added by paragraph (2)).

1 (B) INTERNATIONAL STANDARDS.—In
2 issuing guidance or regulations under subpara-
3 graph (A), the Secretary shall review inter-
4 national hazard analysis and preventive control
5 standards that are in existence on the date of
6 the enactment of this Act and relevant to such
7 guidelines or regulations to ensure that the pro-
8 grams under sections 418 and 418A of the Fed-
9 eral Food, Drug, and Cosmetic Act (as added
10 by paragraph (2) are consistent, to the extent
11 the Secretary determines practicable and appro-
12 priate, with such standards.

13 (C) AUTHORITY WITH RESPECT TO CER-
14 TAIN FACILITIES.—The Secretary may, by regu-
15 lation, exempt or modify the requirements for
16 compliance under this section and the amend-
17 ments made by this section with respect to fa-
18 cilities that are solely engaged in—

19 (i) the production of food for animals
20 other than man or the storage of packaged
21 foods that are not exposed to the environ-
22 ment; or

23 (ii) the storage of raw agricultural
24 commodities for further processing.

1 (D) SMALL BUSINESSES.—The Sec-
2 retary—

3 (i) shall consider the impact of any
4 guidance or regulations under this section
5 on small businesses; and

6 (ii) shall issue guidance to assist small
7 businesses in complying with the require-
8 ments of this section and the amendments
9 made by this section.

10 (4) NO EFFECT ON EXISTING HACCP AUTHORI-
11 TIES.—Nothing in this section or the amendments
12 made by this section limits the authority of the Sec-
13 retary under the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 301 et seq.) or the Public Health
15 Service Act (42 U.S.C. 201 et seq.), as in effect on
16 the day before the date of the enactment of this Act,
17 to revise, issue, or enforce product- and category-
18 specific regulations, such as the Seafood Hazard
19 Analysis Critical Controls Points Program, the Juice
20 Hazard Analysis Critical Control Program, and the
21 Thermally Processed Low-Acid Foods Packaged in
22 Hermetically Sealed Containers standards.

23 (5) CONSIDERATION.—When implementing sec-
24 tions 418 and 418A of the Federal Food, Drug, and
25 Cosmetic Act, as added by paragraph (2), the Sec-

1 retary may take into account differences between
2 food intended for human consumption and food in-
3 tended for consumption by animals other than man.

4 (6) EFFECTIVE DATE.—

5 (A) GENERAL RULE.—The amendments
6 made by subsection (a) and this subsection
7 shall take effect 18 months after the date of the
8 enactment of this Act.

9 (B) EXCEPTIONS.—Notwithstanding sub-
10 paragraph (A)—

11 (i) the amendments made by sub-
12 section (a) and this subsection shall apply
13 to a small business (as defined by the Sec-
14 retary) after the date that is 2 years after
15 the date of the enactment of this Act; and

16 (ii) the amendments made by sub-
17 section (a) and this subsection shall apply
18 to a very small business (as defined by the
19 Secretary) after the date that is 3 years
20 after the date of the enactment of this Act.

21 (b) FINISHED PRODUCT TEST RESULTS FROM CAT-
22 EGORY 1 FACILITIES.—

23 (1) ADULTERATION.—Section 402 (21 U.S.C.
24 342), as amended by subsection (a), is amended by
25 adding at the end the following:

1 “(k) If it is manufactured or processed in a facility
2 that is in violation of section 418B.”

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

6 **“SEC. 418B. FINISHED PRODUCT TEST RESULTS FROM CAT-**
7 **EGORY 1 FACILITIES.**

8 “(a) AUTHORITY.—Beginning on the date specified
9 in subsection (c), the Secretary shall require, after public
10 notice and an opportunity for comment, the submission
11 to the Secretary of finished product test results by the
12 owner, operator, or agent of each category 1 facility sub-
13 ject to good manufacturing practices regulations docu-
14 menting the presence of contaminants in food in the pos-
15 session or control of such facility posing a risk of severe
16 adverse health consequences or death.

17 “(b) CONSIDERATIONS.—The Secretary shall require
18 submissions under subsection (a)—

19 “(1) as the Secretary determines feasible and
20 appropriate; and

21 “(2) taking into consideration available data
22 and information on the potential risks posed by the
23 facility.

24 “(c) BEGINNING DATE.—The date specified in this
25 subsection is the sooner of—

1 “(1) the date of completion of the pilot projects
2 and feasibility study under subsections (d) and (e);
3 and

4 “(2) the date that is 2 years after the date of
5 the enactment of this section.

6 “(d) PILOT PROJECTS.—The Secretary shall conduct
7 2 or more pilot projects to evaluate the feasibility of col-
8 lecting positive finished product testing results from cat-
9 egory 1 facilities, including the value and feasibility of re-
10 porting corrective actions taken when positive finished
11 product test results are reported to the Secretary.

12 “(e) FEASIBILITY STUDY.—The Secretary shall as-
13 sess the feasibility and benefits of the reporting by facili-
14 ties subject to good manufacturing practices regulations
15 of appropriate finished product testing results from cat-
16 egory 1 facilities to the Secretary, including the extent to
17 which the collection of such finished product testing re-
18 sults will help the Secretary assess the risk presented by
19 a facility or product category.

20 “(f) LIMITATIONS.—Nothing in this section shall be
21 construed—

22 “(1) to require the Secretary to mandate test-
23 ing or submission of test results that the Secretary
24 determines would not provide useful information in

1 assessing the potential risk presented by a facility or
2 product category; or

3 “(2) to limit the Secretary’s authority under
4 any other provisions of law to require any person to
5 provide access, or to submit information or test re-
6 sults, to the Secretary, including the ability of the
7 Secretary to require field or other testing and to ob-
8 tain test results in the course of an investigation of
9 a potential food-borne illness or contamination inci-
10 dent.

11 “(g) DEFINITION.—In this section, the term ‘cat-
12 egory 1 facility’ means a category 1 facility within the
13 meaning of section 704(h).”.

14 **SEC. 103. PERFORMANCE STANDARDS.**

15 (a) ADULTERATED FOOD.—Section 402 (21 U.S.C.
16 342), as amended by section 102, is amended by adding
17 at the end the following:

18 “(l) If it has been manufactured, processed, packed,
19 transported, or held under conditions that do not meet the
20 standards issued under section 419.”.

21 (b) REQUIREMENTS.—Chapter IV (21 U.S.C. 341 et
22 seq.), as amended by section 102(b), is further amended
23 by adding at the end the following:

1 **“SEC. 419. PERFORMANCE STANDARDS.**

2 “(a) PERFORMANCE STANDARDS.—The Secretary
3 shall, not less frequently than every 2 years, review and
4 evaluate epidemiological data and other appropriate
5 sources of information, including research under section
6 123 of the Food Safety Enhancement Act of 2009, to
7 identify the most significant food-borne contaminants and
8 the most significant resulting hazards. The Secretary shall
9 issue, as soon as practicable, through guidance or by regu-
10 lation, science-based performance standards (which may
11 include action levels) applicable to foods or food classes,
12 as appropriate, to minimize to an acceptable level, prevent,
13 or eliminate the occurrence of such hazards. Such stand-
14 ards shall be applicable to foods and food classes.

15 “(b) LIST OF CONTAMINANTS.—Following each re-
16 view under subsection (a), the Secretary shall publish in
17 the Federal Register a list of food-borne contaminants
18 that have the greatest adverse impact on public health.
19 In determining whether a particular food-borne contami-
20 nant should be added to such list, the Secretary shall con-
21 sider the number and severity of illnesses and the number
22 of deaths associated with the foods associated with such
23 contaminants.

24 “(c) REVOCATION BY SECRETARY.—All performance
25 standards of the Food and Drug Administration applicable
26 to foods or food classes in effect on the date of the enact-

1 ment of this section, or issued under this section, shall
2 remain in effect until revised or revoked by the Sec-
3 retary.”.

4 (c) REPORT TO CONGRESS.—The Secretary of Health
5 and Human Services shall submit to the Congress by
6 March 30th of the year following each review under sec-
7 tion 419 of the Federal Food, Drug, and Cosmetic Act,
8 as added by subsection (b), a report on the results of such
9 review and the Secretary’s plans to address the significant
10 food-borne hazards identified, or the basis for not address-
11 ing any significant food-borne hazards identified, includ-
12 ing any resource limitations or limitations in data that
13 preclude further action at that time.

14 **SEC. 104. SAFETY STANDARDS FOR PRODUCE AND CERTAIN**
15 **OTHER RAW AGRICULTURAL COMMODITIES.**

16 (a) ADULTERATED FOOD.—Section 402 (21 U.S.C.
17 342), as amended by sections 102 and 103(a), is amended
18 by adding at the end the following:

19 “(m) If it has been grown, harvested, processed,
20 packed, sorted, transported, or held under conditions that
21 do not meet the standards established under section
22 419A.”.

23 (b) STANDARDS.—Chapter IV (21 U.S.C. 341 et
24 seq.), as amended by sections 102(b) and 103(b), is
25 amended by adding at the end the following:

1 **“SEC. 419A. SAFETY STANDARDS FOR PRODUCE AND CER-**
2 **TAIN OTHER RAW AGRICULTURAL COMMOD-**
3 **ITIES.**

4 “(a) STANDARDS.—The Secretary shall establish by
5 regulation scientific and risk-based standards for the safe
6 growing, harvesting, processing, packing, sorting, trans-
7 porting, and holding of those types of raw agricultural
8 commodities—

9 “(1) that are from a plant or a fungus; and

10 “(2) for which the Secretary has determined
11 that such standards are reasonably necessary to
12 minimize the risk of serious adverse health con-
13 sequences or death to humans or animals.

14 “(b) CONTENTS.—The regulations under subsection
15 (a)—

16 “(1) may set forth such procedures, processes,
17 and practices as the Secretary determines to be rea-
18 sonably necessary—

19 “(A) to prevent the introduction of known
20 or reasonably foreseeable biological, chemical,
21 and physical hazards, including hazards that
22 occur naturally, may be unintentionally intro-
23 duced, or may be intentionally introduced, in-
24 cluding by acts of terrorism, into raw agricul-
25 tural commodities that are from a plant or a
26 fungus; and

1 “(B) to provide reasonable assurances that
2 such commodity is not adulterated under sec-
3 tion 402;

4 “(2) may include, with respect to growing, har-
5 vesting, processing, packing, sorting, transporting,
6 and storage operations, standards for safety as the
7 Secretary determines to be reasonably necessary;

8 “(3) may include standards addressing manure
9 use, water quality, employee hygiene, sanitation and
10 animal control, and temperature controls, as the
11 Secretary determines to be reasonably necessary;

12 “(4) may include standards for such other ele-
13 ments as the Secretary determines necessary to
14 carry out subsection (a);

15 “(5) shall provide a reasonable period of time
16 for compliance, taking into account the needs of
17 small businesses for additional time to comply;

18 “(6) may provide for coordination of education
19 and enforcement activities;

20 “(7) shall take into consideration, consistent
21 with ensuring enforceable public health protection,
22 the impact on small-scale and diversified farms, and
23 on wildlife habitat, conservation practices, water-
24 shed-protection efforts, and organic production
25 methods;

1 “(8) may provide for coordination of education
2 and training with other government agencies, univer-
3 sities, private entities, and others with experience
4 working directly with farmers; and

5 “(9) may provide for recognition through guid-
6 ance of other existing publicly available procedures,
7 processes, and practices that the Secretary deter-
8 mines to be equivalent to those established under
9 paragraph (1).

10 “(c) ENFORCEMENT.—The Secretary may coordinate
11 with the Secretary of Agriculture and may contract and
12 coordinate with the agency or department designated by
13 the Governor of each State to perform activities to ensure
14 compliance with this section.”.

15 (c) TIMING.—

16 (1) PROPOSED RULE.—Not later than 18
17 months after the date of enactment of this Act, the
18 Secretary of Health and Human Services shall issue
19 a proposed rule to carry out section 419A of the
20 Federal Food, Drug, and Cosmetic Act, as added by
21 subsection (b).

22 (2) FINAL RULE.—Not later than 3 years after
23 such date, the Secretary of Health and Human
24 Services shall issue a final rule under such section.

1 (d) NO EFFECT ON EXISTING HACCP AUTHORI-
2 TIES.—Nothing in this section or the amendments made
3 by this section limits the authority of the Secretary under
4 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
5 et seq.) or the Public Health Service Act (42 U.S.C. 201
6 et seq.), as in effect on the day before the date of the
7 enactment of this Act, to revise, issue, or enforce product-
8 and category-specific regulations, such as the Seafood
9 Hazard Analysis Critical Controls Points Program, the
10 Juice Hazard Analysis Critical Control Program, and the
11 Thermally Processed Low-Acid Foods Packaged in Her-
12 metically Sealed Containers standards.

13 (e) UPDATE EXISTING GUIDANCE.—Not later than
14 1 year after the date of the enactment of this Act, the
15 Secretary of Health and Human Services shall update the
16 guidance document entitled “Guidance For Industry:
17 Guide To Minimize Microbial Food Safety Hazards For
18 Fresh Fruits And Vegetables” (issued on October 26,
19 1998) in accordance with this section and the amendments
20 made by this section.

21 **SEC. 105. RISK-BASED INSPECTION SCHEDULE.**

22 (a) IN GENERAL.—Section 704 (21 U.S.C. 374) is
23 amended by adding at the end the following:

24 “(h)(1) Each facility registered under section 415
25 shall be inspected—

1 “(A)(i) by one or more officers duly designated
2 under section 702 or other statutory authority by
3 the Secretary;

4 “(ii) for domestic facilities, by a Federal, State,
5 or local official recognized by the Secretary under
6 paragraph (2); or

7 “(iii) for foreign facilities, by an agency or a
8 representative of a country that is recognized by the
9 Secretary under paragraph (2); and

10 “(B) at a frequency determined pursuant to a
11 risk-based schedule.

12 “(2) For purposes of paragraph (1)(A), the Sec-
13 retary—

14 “(A) may recognize Federal, State, and local of-
15 ficials and agencies and representatives of foreign
16 countries as meeting standards established by the
17 Secretary for conducting inspections under this Act;
18 and

19 “(B) may limit such recognition to inspections
20 of specific commodities or food types.

21 “(3) The risk-based schedule under paragraph (1)(B)
22 shall be implemented beginning not later than 18 months
23 after the date of the enactment of this subsection.

24 “(4) Such risk-based schedule shall provide for a fre-
25 quency of inspections commensurate with the risk pre-

1 sented by the facility and shall be based on the following
2 categories and inspection frequencies:

3 “(A) CATEGORY 1.—A category 1 food facility
4 is a high-risk facility that manufactures or processes
5 food. The Secretary shall randomly inspect a cat-
6 egory 1 food facility at least every 6 to 12 months.

7 “(B) CATEGORY 2.—A category 2 food facility
8 is a low-risk facility that manufactures or processes
9 food or a facility that packs or labels food. The Sec-
10 retary shall randomly inspect a category 2 facility at
11 least every 18 months to 3 years.

12 “(C) CATEGORY 3.—A category 3 food facility
13 is a facility that holds food. The Secretary shall ran-
14 domly inspect a category 3 facility at least every 5
15 years.

16 “(5) The Secretary—

17 “(A) may, by guidance, modify the types of
18 food facilities within a category under paragraph
19 (4);

20 “(B) may alter the inspection frequencies speci-
21 fied in paragraph (4) based on the need to respond
22 to food-borne illness outbreaks and food recalls; and

23 “(C) may inspect a facility more frequently
24 than the inspection frequency provided by paragraph
25 (4);

1 “(D) beginning 6 months after submitting the
2 report required by section 105(b)(2) of the Food
3 Safety Enhancement Act of 2009, may—

4 “(i) publish in the Federal Register adjust-
5 ments to the inspection frequencies specified in
6 subparagraphs (B) and (C) of paragraph (4)
7 for category 2 and category 3 food facilities,
8 which adjustments shall be in accordance with
9 the Secretary’s recommendations in such re-
10 port; and

11 “(ii) after such publication, implement the
12 adjustments; and

13 “(E) except as provided in subparagraphs (B)
14 and (C), may not alter the inspection frequency
15 specified in paragraph (4)(A) for category 1 food fa-
16 cilities.

17 “(6) In determining the appropriate frequency of in-
18 spection, the Secretary shall consider—

19 “(A) the type of food manufactured, processed,
20 packed, or held at the facility;

21 “(B) the compliance history of the facility;

22 “(C) whether the facility importing or offering
23 for import into the United States food is certified by
24 a qualified certifying entity in accordance with sec-
25 tion 801(p); and

1 “(D) such other factors as the Secretary deter-
2 mines by guidance to be relevant to assessing the
3 risk presented by the facility.”.

4 (b) REPORTS ON RISK-BASED INSPECTIONS OF
5 FOOD FACILITIES.—

6 (1) ANNUAL REPORT.—Not later than Decem-
7 ber 31 of each year, the Secretary of Health and
8 Human Services shall submit a report to the Com-
9 mittee on Energy and Commerce of the House of
10 Representatives and the Committee on Health, Edu-
11 cation, Labor, and Pensions of the Senate describ-
12 ing—

13 (A) the number of foreign and domestic fa-
14 cilities, by risk category, inspected under the
15 risk-based inspection schedule established under
16 section 704(h) of the Federal Food, Drug, and
17 Cosmetic Act, as added by subsection (a), in
18 the preceding fiscal year; and

19 (B) the costs of implementing the risk-
20 based inspection schedule for the preceding 12
21 months.

22 (2) THIRD-YEAR REPORT.—Not later than 3
23 years after the date of the enactment of this Act, the
24 Secretary of Health and Human Services shall sub-
25 mit a report to the Committee on Energy and Com-

1 merce of the House of Representatives and the Com-
2 mittee on Health, Education, Labor, and Pensions
3 of the Senate describing recommendations on the
4 risk-based inspection schedule under section 704(h)
5 of the Federal Food, Drug, and Cosmetic Act, as
6 added by subsection (a), including recommendations
7 for adjustments to the timing of the schedule and
8 other ways to improve the risk-based allocation of
9 resources by the Food and Drug Administration. In
10 making such recommendations, the Secretary shall
11 consider the following—

12 (A) the nature of the food products being
13 processed, stored, or transported;

14 (B) the manner in which food products are
15 processed, stored, or transported;

16 (C) the inherent likelihood that the prod-
17 ucts will contribute to the risk of food-borne ill-
18 ness;

19 (D) the best available evidence concerning
20 reported illnesses associated with the foods
21 processed, stored, held, or transported in the
22 category of facilities; and

23 (E) the overall record of compliance with
24 food safety law among facilities in the category,

1 including compliance with applicable perform-
2 ance standards and the frequency of recalls.

3 **SEC. 106. ACCESS TO RECORDS.**

4 (a) RECORDS ACCESS.—Subsection (a) of section 414
5 (21 U.S.C. 350c) is amended to read as follows:

6 “(a) RECORDS ACCESS.—

7 “(1) RECORDS ACCESS DURING AN INSPEC-
8 TION.—

9 “(A) IN GENERAL.—Each person who pro-
10 duces, manufactures, processes, packs, trans-
11 ports, distributes, receives, or holds an article of
12 food in the United States or for import into the
13 United States shall, at the request of an officer
14 or employee duly designated by the Secretary,
15 permit such officer or employee, upon presen-
16 tation of appropriate credentials, at reasonable
17 times and within reasonable limits and in a rea-
18 sonable manner, to have access to and copy all
19 records relating to such article bearing on
20 whether the food may be adulterated, mis-
21 branded, or otherwise in violation of this Act,
22 including all records collected or developed to
23 comply with section 418 or 418A.

24 “(B) SCOPE OF RECORDS.—The require-
25 ment under subparagraph (A) applies to all

1 records relating to the production, manufacture,
2 processing, packing, transporting, distribution,
3 receipt, holding, or importation of such article
4 maintained by or on behalf of such person in
5 any format (including paper and electronic for-
6 mats) and at any location.

7 “(C) IMMEDIATE AVAILABILITY WITH NO-
8 TICE.—Records not required to be made avail-
9 able immediately on commencement of an in-
10 spection under subparagraph (A) shall nonethe-
11 less be made available immediately on com-
12 mencement of such an inspection if, by a rea-
13 sonable time before such inspection, the Sec-
14 retary by letter to the person identifies the
15 records to be made available during such in-
16 spection.

17 “(2) ADDITIONAL AUTHORITIES TO ACCESS
18 RECORDS REMOTELY; SUBMISSION OF RECORDS TO
19 THE SECRETARY.—

20 “(A) REMOTE ACCESS IN EMERGENCIES.—
21 If the Secretary has a reasonable belief that an
22 article of food presents a threat of serious ad-
23 verse health consequences or death to humans
24 or animals, the Secretary may require each per-
25 son who manufactures, processes, packs, trans-

1 ports, distributes, receives, holds, or imports
2 such article of food, or any article of food that
3 the Secretary determines may be affected in a
4 similar manner, to submit to the Secretary all
5 records reasonably related to such article of
6 food as soon as is reasonably practicable, after
7 receiving written notice (including by notice
8 served personally and outside normal business
9 hours to an agent identified under subpara-
10 graph (E) or (F) of section 415(a)(2)) of such
11 requirement.

12 “(B) REMOTE ACCESS TO RECORDS RE-
13 LATED TO FOOD SAFETY PLANS.—With respect
14 to a facility subject to section 418 and 418A,
15 the Secretary may require the owner, operator,
16 or agent of such facility to submit to the Sec-
17 retary, as soon as reasonably practicable after
18 receiving written notice of such requirement,
19 the food safety plan, supporting information re-
20 lied on by the facility to select the preventive
21 controls to include in its food safety plan, and
22 documentation of corrective actions, if any,
23 taken under section 418(e) within the preceding
24 2 years

1 “(C) ELECTRONIC SUBMISSION.—If the
2 records required to be submitted to the Sec-
3 retary under subparagraph (A) or (B) are avail-
4 able in electronic format, such records shall be
5 submitted electronically unless the Secretary
6 specifies otherwise in the notice under such sub-
7 paragraph.”.

8 (b) REGULATIONS CONCERNING RECORDKEEPING.—

9 (1) AMENDMENT.—Subsection (b) of section
10 414 (21 U.S.C. 350c) is amended to read as follows:

11 “(b) REGULATIONS CONCERNING RECORD-
12 KEEPING.—The Secretary, in consultation and coordina-
13 tion, as appropriate, with other Federal departments and
14 agencies with responsibilities for regulating food safety,
15 may by regulation establish requirements regarding the es-
16 tablishment and maintenance, for not longer than 3 years,
17 of records by persons who produce, manufacture, process,
18 pack, transport, distribute, receive, or hold food in the
19 United States or for import into the United States. The
20 Secretary shall take into account the size of a business
21 in promulgating regulations under this section. The only
22 distribution records which may be required of restaurants
23 under this subsection are those showing the restaurant’s
24 suppliers and subsequent distribution other than to con-
25 sumers.”.

1 (2) APPLICATION.—The Secretary of Health
2 and Human Services shall promulgate revised regu-
3 lations to implement section 414(b) of the Federal
4 Food, Drug, and Cosmetic Act, as amended by this
5 subsection. Section 414(b) of the Federal Food,
6 Drug, and Cosmetic Act and regulations thereunder,
7 as in effect on the day before the date of the enact-
8 ment of this Act, shall apply to acts and omissions
9 occurring before the effective date of such revised
10 regulations.

11 (c) CONFORMING AMENDMENTS.—Section 704(a)(1)
12 (21 U.S.C. 374(a)(1)) is amended—

13 (1) in the first sentence—

14 (A) by inserting “farm,” before “factory”
15 each place it appears; and

16 (B) by inserting “produced,” before “man-
17 ufactured”;

18 (2) in the second sentence—

19 (A) by striking “(excluding farms or res-
20 taurants)”;

21 (B) by inserting “produces,” before “man-
22 ufactures”;

23 (C) by inserting “receives,” before “holds”;

1 (D) by striking “described in section 414”
2 and inserting “described in or required under
3 section 414”; and

4 (E) by striking “when the Secretary has a
5 reasonable belief that an article of food is adul-
6 terated and presents a threat of serious adverse
7 health consequences or death to humans or ani-
8 mals” and inserting “bearing on whether such
9 food is adulterated, misbranded, or otherwise in
10 violation of this Act, including all records col-
11 lected or developed to comply with section 418
12 or 418A”; and

13 (3) in the fourth sentence—

14 (A) by striking “the preceding sentence”
15 and inserting “either of the preceding two sen-
16 tences”; and

17 (B) by inserting “recipes for food,” before
18 “financial data,”.

19 **SEC. 107. TRACEABILITY OF FOOD.**

20 (a) PROHIBITED ACT.—Section 301(e) (21 U.S.C.
21 331(e)) is amended by inserting “, the violation of any
22 requirement of the food tracing system under section
23 414(e);” before “or the refusal to permit access to or
24 verification or copying of any such required record”.

1 (b) IMPORTS.—Section 801(a) (21 U.S.C. 381(a)) is
2 amended by inserting “or (4) the requirements of section
3 414 have not been complied with regarding such article,”
4 before “then such article shall be refused admission”.

5 (c) PRODUCT TRACING FOR FOOD.—Section 414 (21
6 U.S.C. 350c), as amended by section 106, is amended—

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

9 (2) by inserting after subsection (b) the fol-
10 lowing:

11 “(c) TRACING SYSTEM FOR FOOD.—

12 “(1) IN GENERAL.—The Secretary shall by reg-
13 ulation establish a tracing system for food that is lo-
14 cated in the United States or is for import into the
15 United States.

16 “(2) INFORMATION GATHERING.—

17 “(A) TRACING TECHNOLOGIES.—Before
18 issuing a proposed regulation under this sub-
19 section, the Secretary shall—

20 “(i) identify technologies and meth-
21 odologies for tracing the distribution his-
22 tory of a food that are, or may be, used by
23 members of different sectors of the food in-
24 dustry, including technologies and meth-
25 odologies to enable each person who pro-

1 duces, manufactures, processes, pack,
2 transports, or holds a food to—

3 “(I) maintain the full pedigree of
4 the origin and previous distribution
5 history of the food;

6 “(II) link that history with the
7 subsequent distribution of the food;

8 “(III) establish and maintain a
9 system for tracing the food that is
10 interoperable with the systems estab-
11 lished and maintained by other such
12 persons; and

13 “(IV) use a unique identifier for
14 each facility owned or operated by
15 such person for such purpose, as spec-
16 ified under section 911; and

17 “(ii) to the extent practicable, as-
18 sess—

19 “(I) the costs and benefits associ-
20 ated with the adoption and use of
21 such technologies;

22 “(II) the feasibility of such tech-
23 nologies for different sectors of the
24 food industry; and

1 “(III) whether such technologies
2 are compatible with the requirements
3 of this subsection.

4 “(B) PUBLIC MEETINGS.—Before issuing a
5 proposed regulation under this subsection, the
6 Secretary shall conduct not less than 2 public
7 meetings in diverse geographical areas of the
8 United States to provide persons in different re-
9 gions an opportunity to provide input and infor-
10 mation to the Secretary.

11 “(C) PILOT PROJECTS.—Before issuing a
12 proposed regulation under this subsection, the
13 Secretary shall conduct 1 or more pilot projects
14 in coordination with 1 or more sectors of the
15 food industry to explore and evaluate tracing
16 systems for food.

17 “(3) REGULATION.—Taking into account infor-
18 mation obtained through information gathering
19 under paragraph (2), the Secretary shall issue regu-
20 lations establishing a tracing system that enables the
21 Secretary to identify each person who grows, pro-
22 duces, manufactures, processes, packs, transports,
23 holds, or sells such food in as short a timeframe as
24 practicable but no longer than 2 business days. The
25 Secretary may include in such regulation—

1 “(A) the establishment and maintenance of
2 lot numbers;

3 “(B) a standardized format for pedigree
4 information; and

5 “(C) the use of a common nomenclature
6 for food.

7 “(4) EXEMPTIONS.—

8 “(A) DIRECT SALES BY FARMS.—Food is
9 exempt from the requirements of this sub-
10 section if such food is—

11 “(i) produced on a farm or fishery
12 (including an oyster bed, a wild fishery, an
13 aquaculture facility, a fresh water fishery,
14 and a saltwater fishery); and

15 “(ii) sold by the owner, operator, or
16 agent in charge of such farm or fishery di-
17 rectly to a consumer or to a restaurant or
18 grocery store.

19 “(B) OTHER FOODS.—The Secretary may
20 by notice in the Federal Register exempt a food
21 or a type of facility, farm, or restaurant from,
22 or modify the requirements with respect to, the
23 requirements of this subsection if the Secretary
24 determines that a tracing system for such food

1 or type of facility, farm, or restaurant is not
2 necessary to protect the public health.

3 “(C) PREVIOUS SOURCES AND SUBSE-
4 QUENT RECIPIENTS.—For a food covered by an
5 exemption under subparagraph (B), the Sec-
6 retary shall require each person who produces,
7 manufactures, processes, packs, transports, or
8 holds such food to maintain records to identify
9 the immediate previous sources of such food
10 and its ingredients and the immediate subse-
11 quent recipients of such food.

12 “(D) RESTAURANTS AND GROCERY
13 STORES.—For a food covered by an exemption
14 under subparagraph (A), restaurants and gro-
15 cery stores shall keep records documenting the
16 farm that was the source of the food.

17 “(E) FARMS AND FISHERIES.—For a food
18 covered by an exemption under subparagraph
19 (A), farms and fisheries shall keep records, in
20 electronic or non-electronic format, for at least
21 6 months documenting the restaurant or gro-
22 cery store to which the food was sold”.

1 **SEC. 108. REINSPECTION AND FOOD RECALL FEES APPLI-**
2 **CABLE TO FACILITIES.**

3 (a) IN GENERAL.—Part 6 of subchapter C of chapter
4 VII (21 U.S.C. 371 et seq.), as added by section 101(c),
5 is amended by adding at the end the following:

6 **“SEC. 743A. REINSPECTION AND FOOD RECALL FEES APPLI-**
7 **CABLE TO FACILITIES.**

8 “(a) IN GENERAL.—The Secretary shall assess and
9 collect fees from each entity in a fiscal year—

10 “(1) that—

11 “(A) during such fiscal year commits a vio-
12 lation of any requirement of this Act relating to
13 food, including any such requirement relating to
14 good manufacturing practices; and

15 “(B) because of such violation, undergoes
16 additional inspection by the Food and Drug Ad-
17 ministration; or

18 “(2) during such fiscal year is subject to a food
19 recall.

20 “(b) AMOUNT OF FEES.—The Secretary shall set the
21 amount of the fees under this section to fully cover the
22 costs of—

23 “(1) in the case of fees collected under sub-
24 section (a)(1), conducting the additional inspections
25 referred to in such subsection; and

1 “(2) in the case of fees collected under sub-
2 section (a)(2), conducting food recall activities, in-
3 cluding technical assistance, follow-up effectiveness
4 checks, and public notifications, during the fiscal
5 year involved.

6 “(c) CREDITING AND AVAILABILITY OF FEES.—

7 “(1) IN GENERAL.—Fees authorized under sub-
8 section (a) shall be collected and available for obliga-
9 tion only to the extent and in the amount provided
10 in advance in appropriations Acts. Such fees are au-
11 thorized to remain available until expended. Such
12 sums as may be necessary may be transferred from
13 the Food and Drug Administration salaries and ex-
14 penses appropriation account without fiscal year lim-
15 itation to such appropriation account for salaries
16 and expenses with such fiscal year limitation.

17 “(2) COLLECTIONS AND APPROPRIATIONS
18 ACTS.—The fees authorized by this section—

19 “(A) shall be retained in each fiscal year in
20 an amount not to exceed the amount specified
21 in appropriation Acts, or otherwise made avail-
22 able for obligation, for such fiscal year; and

23 “(B) shall only be collected and available
24 to defray the costs referred to in subsection (b).

1 “(3) AUTHORIZATION OF APPROPRIATIONS.—
2 For each of fiscal years 2010 through 2014, there
3 are authorized to be appropriated for fees under this
4 section such sums as may be necessary.

5 “(d) WAIVER.—The Secretary shall waive and, if ap-
6 plicable, refund the amount of any fee collected under this
7 section from an entity as a result of a food recall that
8 the Secretary determines was inappropriately ordered.”.

9 (b) EFFECTIVE DATE.—The amendment made by
10 subsection (a) shall apply to additional inspections and
11 food recall activities occurring after the date of the enact-
12 ment of this Act.

13 **SEC. 109. CERTIFICATION AND ACCREDITATION.**

14 (a) MISBRANDING.—

15 (1) IN GENERAL.—Section 403 (21 U.S.C.
16 343), as amended by section 101(a), is amended by
17 adding at the end the following:

18 “(aa) If it is part of a shipment offered for import
19 into the United States and such shipment is in violation
20 of section 801(p) (requiring a certification to accompany
21 certain food shipments).”.

22 (2) EFFECTIVE DATE.—The amendment made
23 by paragraph (1) shall apply to shipments offered
24 for import on or after the date that is 3 years after
25 the date of the enactment of this Act.

1 (b) CERTIFICATION OF COMPLIANCE FOR IM-
2 PORTS.—Chapter VIII (21 U.S.C. 381 et seq.) is amend-
3 ed—

4 (1) in section 801(a), as amended by section
5 107(b), by inserting after the third sentence the fol-
6 lowing: “If an article of food being imported or of-
7 fered for import into the United States is not in
8 compliance with the requirement of subsection (p)
9 (relating to certifications of compliance with this
10 Act), then such article shall be refused admission.”;

11 (2) in the second sentence of section 801(b), by
12 striking “the fourth sentence” and inserting “the
13 fifth sentence”; and

14 (3) by adding at the end of section 801 the fol-
15 lowing:

16 “(p) CERTIFICATIONS CONCERNING IMPORTED ARTI-
17 CLES.—

18 “(1) IN GENERAL.—

19 “(A) REQUIREMENT.—The Secretary shall
20 require, as an additional condition of granting
21 admission to an article of food being imported
22 or offered for import into the United States,
23 that a qualified certifying entity provide a cer-
24 tification that the article complies with specified
25 requirements of this Act if—

1 “(i) for food imported from a par-
2 ticular country or region, based on the
3 adequacy of government controls in such
4 country or region or other information rel-
5 evant to such food, certification would as-
6 sist the Secretary in determining whether
7 to refuse to admit such article under sub-
8 section (a);

9 “(ii) for a type of food that could pose
10 a significant risk to health, certification
11 would assist the Secretary in determining
12 whether such article poses such risk; or

13 “(iii) for an article imported from a
14 particular country, there is an agreement
15 between the Secretary and the government
16 of such country providing for such certifi-
17 cation.

18 “(B) CONTENTS OF CERTIFICATION.—
19 Such certification shall include such informa-
20 tion regarding compliance as the Secretary may
21 specify, and may be provided in the form of
22 shipment-specific certificates, a listing of cer-
23 tified facilities or other entities, or in such other
24 form as the Secretary may specify.

1 “(C) NOTICE OF CANCELLATION OR SUS-
2 PENSION OF CERTIFICATION.—As a condition
3 on acceptance of certifications from a qualified
4 certifying entity, the Secretary shall require the
5 qualified certifying entity to notify the Sec-
6 retary whenever the qualified certifying entity
7 cancels or suspends the certification of any fa-
8 cility or other entity included in a listing under
9 subparagraph (B).

10 “(2) QUALIFIED CERTIFYING ENTITY.—For
11 purposes of this subsection, the term ‘qualified certi-
12 fying entity’ means—

13 “(A) an agency or a representative of the
14 government of the country from which the arti-
15 cle originated, as designated by such govern-
16 ment or the Secretary; or

17 “(B) an individual or entity determined by
18 the Secretary or an accredited body recognized
19 by the Secretary to be qualified to provide a
20 certification under paragraph (1).

21 “(3) NO CONFLICTS OF INTEREST.—

22 “(A) IN GENERAL.—The Secretary shall
23 issue regulations to ensure that any qualified
24 certifying entity and its auditors are free from
25 conflicts of interest.

1 “(B) REGULATIONS.—Such regulations
2 shall require that—

3 “(i) the qualified certifying entity
4 shall have a committee or management
5 structure for safeguarding impartiality;

6 “(ii) conflict of interest policies for a
7 qualified certifying entity and auditors act-
8 ing for the qualified certifying entity shall
9 be written;

10 “(iii) the qualified certifying entity
11 shall not be owned, operated, or controlled
12 by a producer, manufacturer, processor,
13 packer, holder, supplier, or vendor of any
14 article of the type it certifies;

15 “(iv) the qualified certifying entity
16 shall not have any ownership or financial
17 interest in any product, producer, manu-
18 facturer, processor, packer, holder, supplier
19 or vendor of the type it certifies;

20 “(v) no auditor acting for the quali-
21 fied certifying entity (or spouse or minor
22 children) shall have any significant owner-
23 ship or other financial interest regarding
24 any product of the type it certifies;

1 “(vi) the qualified certifying entity
2 shall maintain records pertaining to the fi-
3 nancial interests of the personnel involved
4 in audits;

5 “(vii) neither the qualified certifying
6 entity nor any of its auditors acting for the
7 qualified certifying entity shall participate
8 in the production, manufacture, processing,
9 packing, holding, promotion, or sale of any
10 product of the type it certifies;

11 “(viii) neither the qualified certifying
12 entity nor any of its auditors shall provide
13 consultative services to any facility cer-
14 tified by the qualified certifying entity, or
15 the owner, operator, or agent in charge of
16 such a facility, unless the qualified certi-
17 fying entity has procedures in place, ap-
18 proved by the Secretary, to ensure separa-
19 tion of functions between auditors pro-
20 viding consultative services and auditors
21 providing certification services under this
22 subsection;

23 “(ix) no auditors acting for the quali-
24 fied certifying entity shall participate in an

1 audit of a facility they were employed by
2 within the last 12 months;

3 “(x) fees charged or accepted shall
4 not be contingent or based upon the report
5 made by the qualified certifying entity or
6 any personnel involved in the audit pro-
7 cess;

8 “(xi) neither the qualified certifying
9 entity nor any of its auditors shall accept
10 anything of value from anyone in connec-
11 tion with the facility being audited other
12 than the audit fee;

13 “(xii) the qualified certifying entity
14 shall not be owned, operated, or controlled
15 by a trade association whose member com-
16 panies operate facilities that it certifies;

17 “(xiii) the qualified certifying entity
18 and its auditors shall be free from any
19 other conflicts of interest that threaten im-
20 partiality;

21 “(xiv) the qualified certifying entity
22 and its auditors shall sign a statement at-
23 testing to compliance with the conflict of
24 interests requirements under this para-
25 graph; and

1 “(xv) the qualified certifying entity
2 shall ensure that any subcontractors that
3 might be used (such as laboratories and
4 sampling services) provide similar assur-
5 ances, except that it shall not be a viola-
6 tion of this subsection to the extent such
7 subcontractors perform additional nutri-
8 tional testing services unrelated to the test-
9 ing under this subsection.

10 “(C) ANYTHING OF VALUE.—In this para-
11 graph, the term ‘anything of value’ includes
12 gifts, gratuities, reimbursement of expenses, en-
13 tertainment, loans, or any other form of com-
14 pensation in cash or in kind.

15 “(4) RENEWAL AND REFUSAL OF CERTIFI-
16 CATIONS.—The Secretary shall—

17 “(A) require that, to the extent applicable,
18 any certification provided by a qualified certi-
19 fying entity be renewed by such entity at such
20 times as the Secretary determines appropriate;
21 and

22 “(B) refuse to accept any certification if
23 the Secretary determines that such certification
24 is no longer valid or reliable.

1 “(5) ELECTRONIC SUBMISSION.—The Secretary
2 shall provide for the electronic submission of certifi-
3 cations under this subsection.

4 “(6) NO LIMIT ON AUTHORITY.—This sub-
5 section shall not be construed to limit the authority
6 of the Secretary to conduct random inspections of
7 imported articles or facilities of importers, issue im-
8 port alerts for detention without physical examina-
9 tion, require submission to the Secretary of docu-
10 mentation or other information about an article im-
11 ported or offered for import, or to take such other
12 steps as the Secretary deems appropriate to deter-
13 mine the admissibility of imported articles.”.

14 **SEC. 110. TESTING BY ACCREDITED LABORATORIES.**

15 (a) PROHIBITED ACT.—Section 301 (21 U.S.C. 331)
16 is amended by adding at the end the following:

17 “(oo) The violation of any requirement of section 714
18 (relating to testing by accredited laboratories).”.

19 (b) LABORATORY ACCREDITATION.—Subchapter A of
20 chapter VII (21 U.S.C. 371 et seq.) is amended by adding
21 at the end the following:

22 **“SEC. 714. TESTING BY ACCREDITED LABORATORIES.**

23 “(a) IN GENERAL.—

24 “(1) REQUIREMENT.—Whenever analytical test-
25 ing of an article of food is conducted as part of testi-

1 mony for the purposes of section 801(a), or for such
2 other purposes as the Secretary deems appropriate
3 through regulation or guidance, such testing shall be
4 conducted by a laboratory that—

5 “(A) is accredited, for the analytical meth-
6 od used, by a laboratory accreditation body that
7 has been recognized by the Secretary; and

8 “(B) samples such article with adequate
9 controls for ensuring the integrity of the sam-
10 ples analyzed.

11 “(2) INDEPENDENCE OF LABORATORY.—

12 “(A) CERTAIN TESTS.—Tests required for
13 purposes of section 801(a) or in response to a
14 finding of noncompliance by the Secretary shall
15 be conducted by a laboratory independent of the
16 person on whose behalf such testing is con-
17 ducted and analyzed.

18 “(B) CERTAIN PRODUCTS.—The Secretary
19 may require that testing for certain products
20 under paragraph (1) be conducted by a labora-
21 tory independent of the person on whose behalf
22 such testing is conducted.

23 “(b) RECOGNITION OF LABORATORY ACCREDITATION
24 BODIES.—The Secretary shall establish and implement a
25 program for the recognition, based on standards the Sec-

1 retary deems appropriate, of laboratory accreditation bod-
2 ies that accredit laboratories to perform analytical testing
3 for the purposes of this section. The Secretary shall issue
4 regulations or guidance to implement this program.

5 “(c) ONSITE AUDITS.—In evaluating whether an ac-
6 creditation body meets, or continues to meet, the stand-
7 ards for recognition under subsection (b), the Secretary
8 may—

9 “(1) observe onsite audits of laboratories by
10 such accreditation bodies; or

11 “(2) for any laboratory that is accredited by
12 such accreditation body under this section, upon re-
13 quest of an officer or employee designated by the
14 Secretary and upon presentation of appropriate cre-
15 dentials, at reasonable times and within reasonable
16 limits and in a reasonable manner, conduct an onsite
17 audit of the laboratory, which shall include access to,
18 and copying and verification of, any related records.

19 “(d) PUBLICATION OF LIST OF RECOGNIZED AC-
20 CREDITATION BODIES.—The Secretary shall publish and
21 maintain on the public Web site of the Food and Drug
22 Administration a list of accreditation bodies recognized by
23 the Secretary under subsection (b).

24 “(e) NOTIFICATION OF ACCREDITATION OF LABORA-
25 TORY.—An accreditation body that has been recognized

1 pursuant to this section shall promptly notify the Sec-
2 retary whenever it accredits a laboratory for the purposes
3 of this section and whenever it withdraws or suspends
4 such accreditation.

5 “(f) ADVANCE NOTICE.—Whenever analytical testing
6 is conducted pursuant to subsection (a), the person on
7 whose behalf the testing is conducted shall notify the Sec-
8 retary before any sample of the article is collected. Such
9 notice shall contain information the Secretary determines
10 is appropriate to identify the article, the location of the
11 article, and each laboratory that will analyze the sample
12 on the person’s behalf.

13 “(g) CONTENTS OF LABORATORY PACKAGES.—
14 Whenever analytical testing is conducted pursuant to sub-
15 section (a), the laboratory conducting such testing shall
16 submit, directly to the Secretary—

17 “(1) the results of all analyses conducted by the
18 laboratory on each sample of such article; and

19 “(2) all information the Secretary deems appro-
20 priate to—

21 “(A) determine whether the laboratory is
22 accredited by a recognized laboratory accredita-
23 tion body;

24 “(B) identify the article tested;

25 “(C) evaluate the analytical results; and

1 “(D) determine whether the requirements
2 of this section have been met.

3 “(h) EXIGENT CIRCUMSTANCES.—The Secretary
4 may waive the requirement of subsection (a)(1)(A) (relat-
5 ing to analytical methods) on a laboratory or method basis
6 due to exigent or other circumstances.

7 “(i) NO LIMIT ON AUTHORITY.—Nothing in this sec-
8 tion shall be construed to limit—

9 “(1) the ability of the Secretary to review and
10 act upon information from the analytical testing of
11 food (including under this section), including deter-
12 mining the sufficiency of such information and test-
13 ing; or

14 “(2) the authority of the Secretary to conduct,
15 require, or consider the results of analytical testing
16 pursuant to any other provision of law.”.

17 **SEC. 111. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
18 **OF ADULTERATED OR MISBRANDED FOOD.**

19 (a) PROHIBITED ACTS.—Section 301 (21 U.S.C.
20 331), as amended by section 110, is amended by adding
21 at the end the following:

22 “(pp)(1) The failure to notify the Secretary in viola-
23 tion of section 420(a).

24 “(2) The failure to comply with any order issued
25 under section 420.”.

1 (b) NOTIFICATION, NONDISTRIBUTION, AND RECALL
2 OF ADULTERATED OR MISBRANDED FOOD.—Chapter IV
3 (21 U.S.C. 341 et seq.), as amended by sections 102, 103,
4 and 104, is amended by adding at the end the following:
5 **“SEC. 420. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
6 **OF ADULTERATED OR MISBRANDED FOOD.**

7 “(a) NOTIFICATION, NONDISTRIBUTION, AND RE-
8 CALL OF ADULTERATED OR MISBRANDED FOOD.—

9 “(1) IN GENERAL.—A responsible party as that
10 term is defined in section 417(a)(1) or a person re-
11 quired to register under section 801(r) that has rea-
12 son to believe that an article of food when intro-
13 duced into or while in interstate commerce, or while
14 held for sale (regardless of whether the first sale)
15 after shipment in interstate commerce, is adulter-
16 ated or misbranded in a manner that presents a rea-
17 sonable probability that the use or consumption of,
18 or exposure to, the article (or an ingredient or com-
19 ponent used in any such article) will cause a threat
20 of serious adverse health consequences or death to
21 humans or animals shall, as soon as practicable, no-
22 tify the Secretary of the identity and location of the
23 article.

24 “(2) MANNER OF NOTIFICATION.—Notification
25 under paragraph (1) shall be made in such manner

1 and by such means as the Secretary may require by
2 regulation or guidance.

3 “(b) VOLUNTARY RECALL.—The Secretary may re-
4 quest that any person who distributes an article of food
5 that the Secretary has reason to believe is adulterated,
6 misbranded, or otherwise in violation of this Act volun-
7 tarily—

8 “(1) recall such article; and

9 “(2) provide for notice, including to individuals
10 as appropriate, to persons who may be affected by
11 the recall.

12 “(c) ORDER TO CEASE DISTRIBUTION.—If the Sec-
13 retary has reason to believe that the use or consumption
14 of, or exposure to, an article of food may cause serious
15 adverse health consequences or death to humans or ani-
16 mals, the Secretary shall have the authority to issue an
17 order requiring any person who distributes such article to
18 immediately cease distribution of such article.

19 “(d) ACTION FOLLOWING ORDER.—Any person who
20 is subject to an order under subsection (c) shall imme-
21 diately cease distribution of such article and provide notifi-
22 cation as required by such order, and may appeal within
23 24 hours of issuance such order to the Secretary. Such
24 appeal may include a request for an informal hearing and
25 a description of any efforts to recall such article under-

1 taken voluntarily by the person, including after a request
2 under subsection (b). Except as provided in subsection (f),
3 an informal hearing shall be held within as soon as prac-
4 ticable, but not later than 5 calendar days, or less as de-
5 termined by the Secretary, after such an appeal is filed,
6 unless the parties jointly agree to an extension. After af-
7 fording an opportunity for an informal hearing, the Sec-
8 retary shall determine whether the order should be amend-
9 ed to require a recall of such article. If, after providing
10 an opportunity for such a hearing, the Secretary deter-
11 mines that inadequate grounds exist to support the actions
12 required by the order, the Secretary shall vacate the order.

13 “(e) ORDER TO RECALL.—

14 “(1) AMENDMENT.—Except as provided under
15 subsection (f), if after providing an opportunity for
16 an informal hearing under subsection (d), the Sec-
17 retary determines that the order should be amended
18 to include a recall of the article with respect to
19 which the order was issued, the Secretary shall
20 amend the order to require a recall.

21 “(2) CONTENTS.—An amended order under
22 paragraph (1) shall—

23 “(A) specify a timetable in which the recall
24 will occur;

1 “(B) require periodic reports to the Sec-
2 retary describing the progress of the recall; and

3 “(C) provide for notice, including to indi-
4 viduals as appropriate, to persons who may be
5 affected by the recall.

6 In providing for such notice, the Secretary may
7 allow for the assistance of health professionals, State
8 or local officials, or other individuals designated by
9 the Secretary.

10 “(3) NONDELEGATION.—An amended order
11 under this subsection shall be ordered by the Sec-
12 retary or an official designated by the Secretary. An
13 official may not be so designated unless the official
14 is the director of the district under this Act in which
15 the article involved is located, or is an official senior
16 to such director.

17 “(f) EMERGENCY RECALL ORDER.—

18 “(1) IN GENERAL.—If the Secretary has a rea-
19 sonable belief that an article of food subject to an
20 order under subsection (e) presents an imminent
21 threat of serious adverse health consequences or
22 death to humans or animals, the Secretary may
23 issue an order requiring any person who distributes
24 such article—

25 “(A) to immediately recall such article; and

1 “(B) to provide for notice, including to in-
2 dividuals as appropriate, to persons who may be
3 affected by the recall.

4 “(2) ACTION FOLLOWING ORDER.—Any person
5 who is subject to an emergency recall order under
6 this subsection shall immediately recall such article
7 and provide notification as required by such order,
8 and may appeal within 24 hours after issuance such
9 order to the Secretary. An informal hearing shall be
10 held within as soon as practicable but not later than
11 5 calendar days, or less as determined by the Sec-
12 retary, after such an appeal is filed, unless the par-
13 ties jointly agree to an extension. After affording an
14 opportunity for an informal hearing, the Secretary
15 shall determine whether the order should be amend-
16 ed pursuant to subsection (e)(1). If, after providing
17 an opportunity for such a hearing, the Secretary de-
18 termines that inadequate grounds exist to support
19 the actions required by the order, the Secretary shall
20 vacate the order.

21 “(3) NONDELEGATION.—An order under this
22 subsection shall be issued by the Commissioner of
23 Food and Drugs, the Principal Deputy Commis-
24 sioner, or the Associate Commissioner for Regu-
25 latory Affairs of the Food and Drug Administration.

1 “(g) NOTICE TO CONSUMERS AND HEALTH OFFI-
2 CIALS.—The Secretary shall, as the Secretary determines
3 to be necessary, provide notice of a recall order under this
4 section to consumers to whom the article was, or may have
5 been, distributed and to appropriate State and local health
6 officials.

7 “(h) SAVINGS CLAUSE.—Nothing contained in this
8 section shall be construed as limiting—

9 “(1) the authority of the Secretary to issue an
10 order to cease distribution of, or to recall, an article
11 under any other provision of this Act or the Public
12 Health Service Act; or

13 “(2) the ability of the Secretary to request any
14 person to perform a voluntary activity related to any
15 article subject to this Act or the Public Health Serv-
16 ice Act.”.

17 (c) ARTICLES SUBJECT TO REFUSAL.—The third
18 sentence of subsection (a) of section 801 (21 U.S.C. 381),
19 as amended by section 107(b), is amended by inserting
20 “or (5) such article is subject to an order under section
21 420 to cease distribution of or recall the article,” before
22 “then such article shall be refused admission”.

23 (d) EFFECTIVE DATE.—Sections 301(pp)(1) and 420
24 of the Federal Food, Drug, and Cosmetic Act, as added
25 by subsections (a) and (b), shall apply with respect to arti-

1 cles of food as of such date, not later than 1 year after
2 the date of the enactment of this Act, as the Secretary
3 of Health and Human Services shall specify.

4 **SEC. 112. REPORTABLE FOOD REGISTRY; EXCHANGE OF IN-**
5 **FORMATION.**

6 (a) REPORTABLE FOOD REGISTRY.—Section 417 (21
7 U.S.C. 350f) is amended—

8 (1) in subsection (a)(1), by striking “means a
9 person” and all that follows through the end of
10 paragraph (1) and inserting the following: “means—

11 “(A) a person who submits the registration
12 under section 415(a) for a food facility that is
13 required to be registered under section 415(a),
14 at which such food is manufactured, processed,
15 packed, or held;

16 “(B) a person who owns, operates, is an
17 agent of, or is otherwise responsible for such
18 food on a farm (as such term is defined in sec-
19 tion 1.227(b)(3) of title 21, Code of Federal
20 Regulations, or successor regulations) at which
21 such food is produced for sale or distribution in
22 interstate commerce;

23 “(C) a person who owns, operates, or is an
24 agent of a restaurant or other retail food estab-
25 lishment (as such terms are defined in section

1 1.227(b)(11) and (12), respectively, of title 21,
2 Code of Federal Regulations, or successor regu-
3 lations) at which such food is offered for sale;
4 or

5 “(D) a person that is required to register
6 pursuant to section 801(r) with respect to im-
7 portation of such food.”;

8 (2) in subsection (b), by adding at the end the
9 following:

10 “(3) REPORTING BY RESTAURANTS AND RETAIL
11 FOOD ESTABLISHMENTS.—In addition to the elec-
12 tronic portal described in paragraph (1), the Sec-
13 retary shall make available alternative means of re-
14 porting under this section with respect to res-
15 taurants and other retail food establishments with
16 limited ability for such reporting.”;

17 (3) in subsection (d)(1)—

18 (A) in the matter preceding subparagraph
19 (A), by inserting “following a timely review of
20 any reasonably available data and information,”
21 after “reportable food,”;

22 (B) in subparagraph (A), by striking
23 “and” at the end;

24 (C) by redesignating subparagraph (B) as
25 subparagraph (C); and

1 (D) by inserting after subparagraph (A)
2 the following:

3 “(B) submit, with such report, through the
4 electronic portal, documentation of results from
5 any sampling and testing of such article, includ-
6 ing—

7 “(i) analytical results from testing of
8 such article conducted by or on behalf of
9 the responsible party under section 418,
10 418A, 419, 419A, or 714;

11 “(ii) analytical results from testing
12 conducted by or on behalf of such respon-
13 sible party of a component of such article;

14 “(iii) analytical results of environ-
15 mental testing of any facility at which such
16 article, or a component of such article, is
17 manufactured, processed, packed, or held;
18 and

19 “(iv) any other information the Sec-
20 retary determines is necessary to evaluate
21 the adulteration of such article, any com-
22 ponent of such article, any other article of
23 food manufactured, processed, packed or
24 held in the same manner as, or at the
25 same facility as, such article, or any other

1 article containing a component from the
2 same source as a component of such arti-
3 cle; and”; and

4 (4) in subsection (e)—

5 (A) in paragraph (1), by inserting “if the
6 responsible party is required to register” after
7 “415(a)(3)”; and

8 (B) by adding at the end the following:

9 “(12) Such additional information as the Sec-
10 retary deems appropriate.”.

11 (b) EXCHANGE OF INFORMATION.—Section 708 (21
12 U.S.C. 379) is amended—

13 (1) by striking “The Secretary” and inserting
14 “(a) The Secretary”; and

15 (2) by adding at the end the following:

16 “(b)(1)(A) The Secretary may provide to any Federal
17 agency acting within the scope of its jurisdiction any infor-
18 mation relating to food that is exempt from disclosure pur-
19 suant to subsection (a) of section 552 of title 5, United
20 States Code, by reason of subsection (b)(4) of such sec-
21 tion, or that is referred to in section 301(j) or 415(a)(4).

22 “(B) Any such information provided to another Fed-
23 eral agency shall not be disclosed by such agency except
24 in any action or proceeding under the laws of the United

1 States to which the receiving agency or the United States
2 is a party.

3 “(2)(A) In carrying out this Act, the Secretary may
4 provide to a State or local government agency any infor-
5 mation relating to food that is exempt from disclosure pur-
6 suant to section 552(a) of title 5, United States Code, by
7 reason of subsection (b)(4) of such section, or that is re-
8 ferred to in section 301(j) or 415(a)(4).

9 “(B) Any such information provided to a State or
10 local government agency shall not be disclosed by such
11 agency.

12 “(3) In carrying out this Act, the Secretary may pro-
13 vide to any person any information relating to food that
14 is exempt from disclosure pursuant to section 552(a) of
15 title 5, United States Code, by reason of subsection (b)(4)
16 of such section, if the Secretary determines that providing
17 the information to the person is appropriate under the cir-
18 cumstances and the recipient provides adequate assur-
19 ances to the Secretary that the recipient will preserve the
20 confidentiality of the information.

21 “(4) In carrying out this Act, the Secretary may pro-
22 vide any information relating to food that is exempt from
23 disclosure pursuant to section 552(a) of title 5, United
24 States Code, by reason of subsection (b)(4) of such sec-
25 tion, or that is referred to in section 301(j)—

1 “(A) to any foreign government agency; or

2 “(B) any international organization established
3 by law, treaty, or other governmental action and
4 having responsibility—

5 “(i) to facilitate global or regional harmo-
6 nization of standards and requirements in an
7 area of responsibility of the Food and Drug Ad-
8 ministration; or

9 “(ii) to promote and coordinate public
10 health efforts,

11 if the agency or organization provides adequate as-
12 surances to the Secretary that the agency or organi-
13 zation will preserve the confidentiality of the infor-
14 mation.

15 “(c) Except where specifically prohibited by statute,
16 the Secretary may disclose to the public any information
17 relating to food that is exempt from disclosure pursuant
18 to section 552(a) of title 5, United States Code, by reason
19 of subsection (b)(4) of such section, if the Secretary deter-
20 mines that such disclosure is necessary to protect the pub-
21 lic health.

22 “(d) Except as provided in subsection (e), the Sec-
23 retary shall not be required to disclose under section 552
24 of title 5, United States Code, or any other provision of
25 law any information relating to food obtained from a Fed-

1 eral, State, or local government agency, or from a foreign
2 government agency, or from an international organization
3 described in subsection (b)(4), if the agency or organiza-
4 tion has requested that the information be kept confiden-
5 tial, or has precluded such disclosure under other use limi-
6 tations, as a condition of providing the information.

7 “(e) Nothing in subsection (d) authorizes the Sec-
8 retary to withhold information from the Congress or pre-
9 vents the Secretary from complying with an order of a
10 court of the United States.

11 “(f) This section shall not affect the authority of the
12 Secretary to provide or disclose information under any
13 other provision of law.”.

14 (c) CONFORMING AMENDMENT.—Section 301(j) (21
15 U.S.C. 331(j)) is amended by striking “or to the courts
16 when relevant in any judicial proceeding under this Act,”
17 and inserting “to the courts when relevant in any judicial
18 proceeding under this Act, or as specified in section 708,”.

19 **SEC. 113. SAFE AND SECURE FOOD IMPORTATION PRO-**
20 **GRAM.**

21 Chapter VIII (21 U.S.C. 381 et seq.) is amended by
22 adding at the end the following:

1 **“SEC. 805. SAFE AND SECURE FOOD IMPORTATION PRO-**
2 **GRAM.**

3 “(a) IN GENERAL.—The Secretary may establish by
4 regulation or guidance a program that facilitates the
5 movement of food through the importation process under
6 this Act if the importer of such food—

7 “(1) verifies that each facility involved in the
8 production, manufacture, processing, packaging, and
9 holding of the food is in compliance with the food
10 safety and security guidelines developed under sub-
11 section (b) with respect to such food;

12 “(2) ensures that appropriate safety and secu-
13 rity controls are in place throughout the supply
14 chain for such food; and

15 “(3) provides supporting information to the
16 Secretary.

17 “(b) GUIDELINES.—

18 “(1) DEVELOPMENT.—For purposes of the pro-
19 gram established under subsection (a), the Secretary
20 shall develop safety and security guidelines applica-
21 ble to the importation of food.

22 “(2) FACTORS.—Such guidelines shall take into
23 account the following factors:

24 “(A) The personnel of the person import-
25 ing the food.

1 “(B) The physical and procedural safety
2 and security of such person’s food supply chain.

3 “(C) The sufficiency of preventive controls
4 for food and ingredients purchased by such per-
5 son.

6 “(D) Vendor and supplier information.

7 “(E) Other programs for certification or
8 verification by a qualified certifying entity used
9 by the importer.

10 “(F) Such other factors as the Secretary
11 determines necessary.”.

12 **SEC. 114. INFANT FORMULA.**

13 (a) MISBRANDING.—Section 403 of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 343) as amend-
15 ed by sections 101(a) and 109(a), is amended by adding
16 at the end the following:

17 “(bb) If it is a new infant formula and it is not the
18 subject of a letter from the Secretary provided pursuant
19 to section 412(c)(1)(C).”.

20 (b) REQUIREMENTS.—Section 412 of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 350a) is
22 amended—

23 (1) in subsection (b)(1), by adding at the end
24 the following: “The quality factor requirements es-
25 tablished under this paragraph may include require-

1 ments for one or more clinical studies to dem-
2 onstrate that the new infant formula supports nor-
3 mal physical growth of infants.”;

4 (2) in subsection (b)(4), by amending subpara-
5 graph (B) to read as follows:

6 “(B) Records required under subparagraph (A) with
7 respect to an infant formula shall be retained for at least
8 one year after the expiration of the shelf life of such infant
9 formula. Such records shall be made available to the Sec-
10 retary for review and duplication upon request of the Sec-
11 retary.”;

12 (3) in subsection (c)(1)—

13 (A) in subparagraph (A), by striking
14 “and” at the end;

15 (B) in subparagraph (B), by striking
16 “(c)(1).” at the end and inserting “(d)(1),
17 and”;

18 (C) by adding at the end the following:

19 “(C) the Secretary has by letter informed such
20 person that the registration requirements and the
21 requirements in subsection (d)(1) have been satis-
22 fied.”; and

23 (4) in subsection (d)(1), by striking subpara-
24 graphs (C) and (D) and inserting the following:

1 “(C) scientific evidence and other evidence, as
2 identified in regulations promulgated by the Sec-
3 retary, that demonstrates that the infant formula
4 satisfies the requirements of subsection (b)(1), and,
5 as demonstrated by the testing required under sub-
6 section (b)(3), that it satisfies the requirements of
7 subsection (i), and

8 “(D) scientific evidence and other evidence, as
9 identified in regulations promulgated by the Sec-
10 retary, that demonstrate that the processing of the
11 infant formula complies with the requirements of
12 subsection (b)(2).”.

13 **Subtitle B—Intervention**

14 **SEC. 121. SURVEILLANCE.**

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

19 (b) **FOOD-BORNE ILLNESS SURVEILLANCE SYS-**
20 **TEMS.**—The Secretary, acting through the Director of the
21 Centers for Disease Control and Prevention, shall enhance
22 food-borne illness surveillance systems to improve the col-
23 lection, analysis, reporting, and usefulness of data on food-
24 borne illnesses by—

1 (1) coordinating Federal, State, and local food-
2 borne illness surveillance systems, including com-
3 plaint systems, and increasing participation in na-
4 tional networks of public health and food regulatory
5 agencies and laboratories;

6 (2) facilitating sharing of findings on a more
7 timely basis among governmental agencies, including
8 the Food and Drug Administration, the Department
9 of Agriculture, and State and local agencies, and
10 with the public;

11 (3) developing improved epidemiological tools
12 for obtaining quality exposure data, and micro-
13 biological methods for classifying cases;

14 (4) augmenting such systems to improve attri-
15 bution of a food-borne illness outbreak to a specific
16 food;

17 (5) expanding capacity of such systems, includ-
18 ing fingerprinting and other detection strategies for
19 food-borne infectious agents, in order to identify new
20 or rarely documented causes of food-borne illness;

21 (6) allowing timely public access to aggregated,
22 de-identified surveillance data;

23 (7) at least annually, publishing current reports
24 on findings from such systems;

1 (8) establishing a flexible mechanism for rapidly
2 initiating scientific research by academic institu-
3 tions;

4 (9) integrating food-borne illness surveillance
5 systems and data with other biosurveillance and
6 public health situational awareness capabilities at
7 the Federal, State, and local levels; and

8 (10) other activities as determined appropriate
9 by the Secretary.

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

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

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

18 (B) Accelerate food-borne illness surveil-
19 lance and outbreak investigation, including
20 rapid shipment of clinical isolates from clinical
21 laboratories to appropriate State laboratories,
22 and conducting more standardized illness out-
23 break interviews.

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

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

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

12 (2) REVIEW.—In developing of the strategies
13 required by paragraph (1), the Secretary shall, not
14 later than 1 year after the date of enactment of this
15 Act, complete a review of State and local capacities,
16 and needs for enhancement, which may include a
17 survey with respect to—

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

20 (B) laboratory capacity to support surveil-
21 lance, outbreak response, inspection, and en-
22 forcement activities;

23 (C) information systems to support data
24 management and sharing of food safety and de-
25 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 **SEC. 122. PUBLIC EDUCATION AND ADVISORY SYSTEM.**

7 (a) PUBLIC EDUCATION.—The Secretary, in coopera-
8 tion with private and public organizations, including the
9 appropriate State entities, shall design and implement a
10 national public education program on food safety. The
11 program shall provide—

12 (1) information to the public so that individuals
13 can understand the potential impact and risk of
14 food-borne illness, take action to reduce their risk of
15 food-borne illness and injury, and make healthy die-
16 tary choices;

17 (2) information to health professionals so that
18 they may improve diagnosis and treatment of food-
19 related illness and advise individuals whose health
20 conditions place them in particular risk; and

21 (3) such other information or advice to con-
22 sumers and other persons as the Secretary deter-
23 mines will promote the purposes of this Act.

24 (b) HEALTH ADVISORIES.—The Secretary shall work
25 with the States and other appropriate entities to—

1 (1) develop and distribute regional and national
2 advisories concerning food safety;

3 (2) develop standardized formats for written
4 and broadcast advisories; and

5 (3) incorporate State and local advisories into
6 the national public education program required
7 under subsection (a).

8 **SEC. 123. RESEARCH.**

9 The Secretary shall conduct research to assist in the
10 implementation of this Act, including studies to—

11 (1) improve sanitation and food safety practices
12 in the production, harvesting, and processing of food
13 products;

14 (2) develop improved techniques for the moni-
15 toring of food and inspection of food products;

16 (3) develop efficient, rapid, and sensitive meth-
17 ods for determining and detecting the presence of
18 contaminants in food products;

19 (4) determine the sources of contamination of
20 food and food products, including critical points of
21 risk for fresh produce and other raw agricultural
22 commodities;

23 (5) develop consumption data with respect to
24 food products;

1 (6) draw upon research and educational pro-
2 grams that exist at the State and local level;

3 (7) utilize the DNA matching system and other
4 processes to identify and control pathogens;

5 (8) address common and emerging zoonotic dis-
6 eases;

7 (9) develop methods to reduce or destroy patho-
8 gens before, during, and after processing;

9 (10) analyze the incidence of antibiotic resist-
10 ance as it pertains to the food supply and evaluate
11 methods to reduce the transfer of antibiotic resist-
12 ance to humans; and

13 (11) conduct other research that supports the
14 purposes of this Act.

15 **Subtitle C—Response**

16 **SEC. 131. PROCEDURES FOR SEIZURE.**

17 Section 304(b) (21 U.S.C. 334(b)) is amended by in-
18 serting “and except that, with respect to proceedings relat-
19 ing to food, Rule G of the Supplemental Rules of Admi-
20 ralty or Maritime Claims and Asset Forfeiture Actions
21 shall not apply in any such case, exigent circumstances
22 shall be deemed to exist for all seizures brought under this
23 section, and the summons and arrest warrant shall be
24 issued by the clerk of the court without court review in

1 any such case” after “in any such case shall be tried by
2 jury”.

3 **SEC. 132. ADMINISTRATIVE DETENTION.**

4 (a) AMENDMENTS.—Section 304(h) (21 U.S.C.
5 334(h)) is amended—

6 (1) in paragraph (1)(A), by striking “credible
7 evidence or information indicating” and inserting
8 “reason to believe”;

9 (2) in paragraph (1)(A), by striking “presents
10 a threat of serious adverse health consequences or
11 death to humans or animals” and inserting “is adul-
12 terated, misbranded, or otherwise in violation of this
13 Act”;

14 (3) in paragraph (2), by striking “30” and in-
15 serting “60”;

16 (4) in paragraph (3), by striking the third sen-
17 tence; and

18 (5) in paragraph (4)(A) by striking the terms
19 “five” and “five-day” and inserting “fifteen” and
20 “fifteen-day”, respectively.

21 (b) REGULATIONS.—The Secretary shall issue regula-
22 tions or guidance to implement the amendments made by
23 this section.

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

4 **SEC. 133. QUARANTINE AUTHORITY FOR FOODS.**

5 (a) PROHIBITED ACT.—Section 301 (21 U.S.C. 331),
6 as amended by sections 110 and 111, is amended by add-
7 ing at the end by adding the following:

8 “(qq) The violation of a quarantine under section
9 304(i).”.

10 (b) IN GENERAL.—Section 304 (21 U.S.C. 334) is
11 amended by adding at the end the following:

12 “(i) QUARANTINE OF GEOGRAPHIC LOCATION.—

13 “(1) AUTHORITY TO QUARANTINE.—If the Sec-
14 retary determines that there is credible evidence or
15 information that an article of food presents an immi-
16 nent threat of serious adverse health consequences
17 or death to humans or animals, the Secretary may
18 quarantine any geographic area within the United
19 States where the Secretary reasonably believes such
20 food is located or from which such food originated.
21 The authority to quarantine includes prohibiting or
22 restricting the movement of food or of any vehicle
23 being used or that has been used to transport or
24 hold such food within the geographic area. Any
25 quarantine under this paragraph shall be no greater

1 than is appropriate, as determined by the Secretary,
2 to protect the public health.

3 “(2) NOTIFICATION PROCEDURES.—Before any
4 quarantine action is taken in any State under this
5 subsection, the Secretary shall notify an appropriate
6 official of the State affected and shall issue a public
7 announcement of—

8 “(A) the Secretary’s findings that support
9 the quarantine action;

10 “(B) the area affected by the intended
11 quarantine action;

12 “(C) the reasons for the intended quar-
13 antine action; and

14 “(D) where practicable, an estimate of the
15 anticipated duration of the quarantine.

16 The Secretary is not required to make such an-
17 nouncement by publication in the Federal Register,
18 but may use a newspaper, radio or television, the
19 Internet, or any reasonable means to make such an-
20 nouncement.

21 “(3) NONDELEGATION.—The authority to quar-
22 antine under this subsection is limited to the Com-
23 missioner of Food and Drugs, the Principal Deputy
24 Commissioner, and the Associate Commissioner for

1 Regulatory Affairs of the Food and Drug Adminis-
2 tration.”.

3 **SEC. 134. CRIMINAL PENALTIES.**

4 Section 303(a) (21 U.S.C. 333) is amended—

5 (1) in paragraph (1), by striking “Any” and in-
6 serting “Except as provided in paragraph (2) or (3),
7 any”; and

8 (2) by adding at the end the following:

9 “(3) Notwithstanding paragraph (1), any person who
10 knowingly violates paragraph (a), (b), (c), (k), or (v) of
11 section 301 with respect to any food that is misbranded
12 or adulterated shall be imprisoned for not more than 10
13 years or fined in accordance with title 18, United States
14 Code, or both.”.

15 **SEC. 135. CIVIL PENALTIES FOR VIOLATIONS RELATING TO**
16 **FOOD.**

17 (a) IN GENERAL.—Paragraph (2) of section 303(f)
18 (21 U.S.C. 331 et seq.) is amended to read as follows:

19 “(2)(A) Any person who violates a provision of
20 section 301 relating to food shall be subject to a civil
21 penalty for each such violation of not more than—

22 “(i) \$20,000 in the case of an individual,
23 not to exceed \$50,000 in a single proceeding;
24 and

1 “(ii) \$250,000 in the case of any other
2 person, not to exceed \$1,000,000 in a single
3 proceeding.

4 “(B) Any person who knowingly violates a pro-
5 vision of section 301 relating to food shall be subject
6 to a civil penalty for each such violation of not more
7 than—

8 “(i) \$50,000 in the case of an individual,
9 not to exceed \$100,000 in a single proceeding;
10 and

11 “(ii) \$500,000 in the case of any other
12 person, not to exceed \$7,500,000 in a single
13 proceeding.

14 “(C) Each violation described in subparagraph
15 (A) or (B) and each day during which the violation
16 continues shall be considered to be a separate of-
17 fense.”.

18 (b) EFFECTIVE DATE.—The amendment made by
19 subsection (a) applies to violations committed on or after
20 the date of the enactment of this Act.

21 **SEC. 136. IMPROPER IMPORT ENTRY FILINGS.**

22 (a) PROHIBITED ACTS.—Section 301 (21 U.S.C.
23 331), as amended by sections 110, 111, and 133, is
24 amended by adding at the end the following:

1 “(rr) The submission of information relating to food
2 that is required by or under section 801 that is inaccurate
3 or incomplete.

4 “(ss) The failure to submit information relating to
5 food that is required by or under section 801.”.

6 (b) DOCUMENTATION FOR IMPORTS.—Section 801
7 (21 U.S.C. 381), as amended by section 109, is amended
8 by adding at the end the following:

9 “(q) DOCUMENTATION.—

10 “(1) SUBMISSION.—The Secretary may require
11 by regulation or guidance the submission of docu-
12 mentation or other information for articles of food
13 that are imported or offered for import into the
14 United States.

15 “(2) FORMAT.—A regulation or guidance under
16 paragraph (1) may specify the format for submission
17 of the documentation or other information.”.

18 **TITLE II—MISCELLANEOUS**

19 **SEC. 201. FOOD SUBSTANCES GENERALLY RECOGNIZED AS** 20 **SAFE.**

21 Section 409 (21 U.S.C. 348) is amended by adding
22 at the end the following:

23 “Substances Generally Recognized as Safe

24 “(k)(1) Not later than 60 days after the date of re-
25 ceipt by the Secretary, after the date of the enactment

1 of this subsection, of a determination that a substance is
2 a GRAS food substance, the Secretary shall post notice
3 of such determination and the supporting scientific jus-
4 tifications on the Food and Drug Administration's public
5 Web site.

6 “(2) Not later than 60 days after the date of receipt
7 of a request under paragraph (1), the Secretary shall ac-
8 knowledge receipt of such request by informing the re-
9 quester in writing of the date on which the request was
10 received.

11 “(3) In this subsection, the term ‘GRAS food sub-
12 stance’ means a substance excluded from the definition of
13 the term ‘food additive’ in section 201(s) because such
14 substance is generally recognized, among experts qualified
15 by scientific training and experience to evaluate its safety,
16 as having been adequately shown through scientific proce-
17 dures (or, in the case of a substance used in food prior
18 to January 1, 1958, through either scientific procedures
19 or experience based on common use in food) to be safe
20 under the conditions of its intended use.”.

21 **SEC. 202. COUNTRY OF ORIGIN LABELING; DISCLOSURE OF**
22 **SOURCE OF INGREDIENTS.**

23 (a) MISBRANDING.—Section 403 (21 U.S.C. 343), as
24 amended by sections 101(a), 109(a), and 114(a), is
25 amended by adding at the end the following:

1 “(cc) In the case of a processed food, if the labeling
2 of the food fails to identify the country in which the final
3 processing of the food occurs.

4 “(dd) In the case of nonprocessed food, if the labeling
5 of the food fails to identify the country of origin of the
6 food.”.

7 (b) REGULATIONS.—

8 (1) PROMULGATION.—Not later than 180 days
9 after the date of the enactment of this Act, the Sec-
10 retary of Health and Human Services shall promul-
11 gate final regulations to carry out paragraphs (cc)
12 and (dd) of section 403 of the Federal Food, Drug,
13 and Cosmetic Act, as added by subsection (a).

14 (2) RELATION TO OTHER REQUIREMENTS.—
15 Regulations promulgated under paragraph (1) shall
16 provide that labeling meets the requirements of
17 paragraphs (cc) and (dd) of section 403 of the Fed-
18 eral Food, Drug, and Cosmetic Act, as added by
19 subsection (a), if—

20 (A) in the case of a processed food, the
21 label of the food informs the consumer of the
22 country where the final processing of the food
23 occurred in accordance with labeling require-
24 ments of the United States Customs and Bor-
25 der Protection; or

1 (B) in the case of a nonprocessed food, the
2 label of the food informs the consumer of the
3 country of origin of the food in accordance with
4 labeling requirements of the Department of Ag-
5 riculture.

6 (c) EFFECTIVE DATE.—The requirements of para-
7 graphs (cc) and (dd) of section 403 of the Federal Food,
8 Drug, and Cosmetic Act, as added by subsection (a), take
9 effect on the date that is 2 years after the date of the
10 enactment of this Act.

11 **SEC. 203. EXPORTATION CERTIFICATE PROGRAM.**

12 Section 801(e)(4) (21 U.S.C. 381) is amended—

13 (1) in the matter preceding clause (i) in sub-
14 paragraph (A)—

15 (A) by inserting “from the United States”
16 after “exports”; and

17 (B) by striking “a drug, animal drug, or
18 device” and inserting “a food (including animal
19 feed), drug, animal drug, or device”;

20 (2) in subparagraph (A)(i)—

21 (A) by striking “in writing”; and

22 (B) by striking “exported drug, animal
23 drug, or device” and inserting “exported food,
24 drug, animal drug, or device”;

25 (3) in subparagraph (A)(ii)—

1 (A) by striking “in writing”;

2 (B) by striking “the drug, animal drug, or
3 device” and inserting “the food, drug, animal
4 drug, or device”; and

5 (C) by striking “the drug or device” and
6 inserting “the food, drug, or device”;

7 (4) by redesignating subparagraph (B) as sub-
8 paragraph (C);

9 (5) by inserting after subparagraph (A) the fol-
10 lowing:

11 “(B) For purposes of this paragraph, a
12 certification by the Secretary shall be made on
13 such basis and in such form (such as a publicly
14 available listing) as the Secretary determines
15 appropriate.”; and

16 (6) by adding at the end the following:

17 “(D) Notwithstanding subparagraph (C), if the Sec-
18 retary issues an export certification within the 20 days
19 prescribed by subparagraph (A) with respect to the export
20 of food, a fee for such certification shall not exceed such
21 amount as the Secretary determines is reasonably related
22 to the cost of issuing certificates under subparagraph (A)
23 with respect to the export of food. The Secretary may ad-
24 just this fee annually to account for inflation and other
25 cost adjustments. Fees collected for a fiscal year pursuant

1 to this subparagraph shall be credited to the appropriation
2 account for salaries and expenses of the Food and Drug
3 Administration and shall be available in accordance with
4 appropriations Acts until expended, without fiscal year
5 limitation. Such fees shall be collected in each fiscal year
6 in an amount equal to the amount specified in appropria-
7 tions Acts for such fiscal year and shall only be collected
8 and available for the costs of the Food and Drug Adminis-
9 tration to cover the cost of issuing such certifications.
10 Such sums as necessary may be transferred from such ap-
11 propriation account for salaries and expenses of the Food
12 and Drug Administration without fiscal year limitation to
13 such appropriation account for salaries and expenses with
14 fiscal year limitation.”.

15 **SEC. 204. REGISTRATION FOR COMMERCIAL IMPORTERS**
16 **OF FOOD; FEE.**

17 (a) REGISTRATION.—

18 (1) PROHIBITIONS.—Section 301 (21 U.S.C.
19 331), as amended by sections 110, 111, 133, and
20 136, is amended by adding at the end the following:

21 “(tt) The failure to register in accordance with sec-
22 tion 801(r).”.

23 (2) MISBRANDING.—Section 403 (21 U.S.C.
24 343) as amended by sections 101(a), 109(a), 114(a),

1 and 202, is amended by adding at the end the fol-
2 lowing:

3 “(ee) If it is imported or offered for import by an
4 importer not duly registered under section 801(r).”.

5 (3) REGISTRATION.—Section 801, as amended
6 by sections 109 and 136, is amended by adding at
7 the end the following:

8 “(r) REGISTRATION OF IMPORTERS.—

9 “(1) REGISTRATION.—The Secretary shall re-
10 quire an importer of food—

11 “(A) to be registered with the Secretary in
12 a form and manner specified by the Secretary;
13 and

14 “(B) consistent with section 911, to submit
15 appropriate unique facility identifiers as a con-
16 dition of registration.

17 “(2) GOOD IMPORTER PRACTICES.—The main-
18 tenance of registration under this subsection is con-
19 ditioned on compliance with good importer practices.
20 Good importer practices shall include the verification
21 of good manufacturing practices and preventive con-
22 trols of the importer’s foreign suppliers, as applica-
23 ble.

24 “(3) SUSPENSION OF REGISTRATION.—

1 “(A) IN GENERAL.—Registration under
2 this subsection is subject to suspension upon a
3 finding by the Secretary, after notice and an
4 opportunity for an informal hearing, of—

5 “(i) a violation of this Act; or

6 “(ii) the knowing or repeated making
7 of an inaccurate or incomplete statement
8 or submission of information relating to
9 the importation of food.

10 “(B) REQUEST.—The importer whose reg-
11 istration is suspended may request that the
12 Secretary vacate the suspension of registration
13 when such importer has corrected the violation
14 that is the basis for such suspension.

15 “(C) VACATING OF SUSPENSION.—If the
16 Secretary determines that adequate reasons do
17 not exist to continue the suspension of a reg-
18 istration, the Secretary shall vacate such sus-
19 pension.

20 “(4) CANCELLATION OF REGISTRATION.—

21 “(A) IN GENERAL.—Not earlier than 10
22 days after providing the notice under subpara-
23 graph (B), the Secretary may cancel a registra-
24 tion that the Secretary determines was not up-
25 dated in accordance with this section or other-

1 wise contains false, incomplete, or inaccurate
2 information.

3 “(B) NOTICE OF CANCELLATION.—Can-
4 cellation shall be preceded by notice to the im-
5 porter of the intent to cancel the registration
6 and the basis for such cancellation.

7 “(C) TIMELY UPDATE OR CORRECTION.—
8 If the registration for the importer is updated
9 or corrected no later than 7 days after notice
10 is provided under subparagraph (B), the Sec-
11 retary shall not cancel such registration.

12 “(5) EXEMPTIONS.—The Secretary, by notice
13 published in the Federal Register—

14 “(A) shall establish an exemption from the
15 requirements of this subsection for importations
16 for personal use; and

17 “(B) may establish other exemptions from
18 the requirements of this subsection.”.

19 (4) REGULATIONS.—Not later than 24 months
20 after the date of the enactment of this Act, the Sec-
21 retary of Health and Human Services shall promul-
22 gate the regulations required to carry out section
23 801(r) of the Federal Food, Drug, and Cosmetic
24 Act, as added by paragraph (3).

1 (5) EFFECTIVE DATE.—The amendments made
2 by this subsection shall take effect on the date that
3 is 24 months after the date of enactment of this Act.

4 (b) FEE.—Subchapter C of chapter VII (21 U.S.C.
5 379f et seq.) as added and amended by sections 101 and
6 108, is amended by adding at the end the following:

7 **“PART 7—IMPORTERS OF FOOD**

8 **“SEC. 744. IMPORTERS OF FOOD.**

9 “**(a) IMPORTERS.**—The Secretary shall assess and
10 collect an annual fee for the registration of an importer
11 of food under section 801(r).

12 “**(b) AMOUNT OF FEE.**—

13 “(1) **BASE AMOUNTS.**—The registration fee
14 under subsection (a) shall be—

15 “(A) for fiscal year 2010, \$500; and

16 “(B) for fiscal year 2011 and each subse-
17 quent fiscal year, the fee for fiscal year 2010 as
18 adjusted under paragraph (2).

19 “(2) **ADJUSTMENT.**—For fiscal year 2011 and
20 subsequent fiscal years, the fees established pursu-
21 ant to paragraph (1) shall be adjusted by the Sec-
22 retary by notice, published in the Federal Register,
23 for a fiscal year to reflect the greater of—

24 “(A) the total percentage change that oc-
25 curred in the Consumer Price Index for all

1 urban consumers (all items; United States city
2 average), for the 12-month period ending June
3 30 preceding the fiscal year for which fees are
4 being established;

5 “(B) the total percentage change for the
6 previous fiscal year in basic pay under the Gen-
7 eral Schedule in accordance with section 5332
8 of title 5, United States Code, as adjusted by
9 any locality-based comparability payment pur-
10 suant to section 5304 of such title for Federal
11 employees stationed in the District of Columbia;
12 or

13 “(C) the average annual change in the
14 cost, per full-time equivalent position of the
15 Food and Drug Administration, of all personnel
16 compensation and benefits paid with respect to
17 such positions for the first 5 years of the pre-
18 ceding 6 fiscal years.

19 “(3) COMPOUNDED BASIS.—The adjustment
20 made each fiscal year pursuant this subsection shall
21 be added on a compounded basis to the sum of all
22 adjustments made each fiscal year after fiscal year
23 2010 under this subsection.

24 “(4) WAIVER FOR IMPORTERS REQUIRED TO
25 PAY REGISTRATION FEE.—In the case of a person

1 who is required to pay both a fee under section 743
2 for registration of one or more facilities under sec-
3 tion 415 and a fee under this section for registration
4 as an importer of food under section 801(r), the
5 Secretary shall waive the fees applicable to such per-
6 son under section 743 or the fee applicable to such
7 person under this section.

8 “(c) CREDITING AND AVAILABILITY OF FEES.—

9 “(1) IN GENERAL.—Fees authorized under sub-
10 section (a) shall be collected and available for obliga-
11 tion only to the extent and in the amount provided
12 in advance in appropriations Acts. Such fees are au-
13 thorized to remain available until expended. Such
14 sums as may be necessary may be transferred from
15 the Food and Drug Administration salaries and ex-
16 penses appropriation account without fiscal year lim-
17 itation to such appropriation account for salaries
18 and expenses with such fiscal year limitation.

19 “(2) COLLECTIONS AND APPROPRIATIONS
20 ACTS.—The fees authorized by this section—

21 “(A) shall be retained in each fiscal year in
22 an amount not to exceed the amount specified
23 in appropriation Acts, or otherwise made avail-
24 able for obligation, for such fiscal year; and

1 (2) MISBRANDING.—Section 403(ee) (21 U.S.C.
2 343), as added by section 204, is amended—

3 (A) by inserting “or a customs broker or
4 filer” after “by an importer”; and

5 (B) by inserting “or 801(s)” after
6 “801(r)”.

7 (3) REGISTRATION.—Section 801, as amended
8 by sections 109, 136, and 204, is amended by add-
9 ing at the end the following:

10 “(s) REGISTRATION OF CUSTOMS BROKERS AND FIL-
11 ERS.—

12 “(1) REGISTRATION.—The Secretary shall re-
13 quire a customs broker or filer, with respect to the
14 importation of food—

15 “(A) to be registered with the Secretary in
16 a form and manner specified by the Secretary;
17 and

18 “(B) consistent with section 911, to submit
19 appropriate unique facility identifiers as a con-
20 dition of registration.

21 “(3) SUSPENSION OF REGISTRATION.—

22 “(A) IN GENERAL.—Registration under
23 this subsection is subject to suspension upon a
24 finding by the Secretary, after notice and an
25 opportunity for an informal hearing, of—

1 “(i) a violation of this Act; or

2 “(ii) the knowing or repeated making
3 of an inaccurate or incomplete statement
4 or submission of information relating to
5 the importation of food.

6 “(B) REQUEST.—The customs broker or
7 filer whose registration is suspended may re-
8 quest that the Secretary vacate the suspension
9 of registration when such customs broker or
10 filer has corrected the violation that is the basis
11 for such suspension.

12 “(C) VACATING OF SUSPENSION.—If the
13 Secretary determines that adequate reasons do
14 not exist to continue the suspension of a reg-
15 istration, the Secretary shall vacate such sus-
16 pension.

17 “(4) CANCELLATION OF REGISTRATION.—

18 “(A) IN GENERAL.—Not earlier than 10
19 days after providing the notice under subpara-
20 graph (B), the Secretary may cancel a registra-
21 tion that the Secretary determines was not up-
22 dated in accordance with this section or other-
23 wise contains false, incomplete, or inaccurate
24 information.

1 “(B) NOTICE OF CANCELLATION.—Can-
2 cellation shall be preceded by notice to the cus-
3 toms broker or filer of the intent to cancel the
4 registration and the basis for such cancellation.

5 “(C) TIMELY UPDATE OR CORRECTION.—
6 If the registration for the customs broker or
7 filer is updated or corrected no later than 7
8 days after notice is provided under subpara-
9 graph (B), the Secretary shall not cancel such
10 registration.

11 “(5) EXEMPTIONS.—The Secretary, by notice
12 published in the Federal Register—

13 “(A) shall establish an exemption from the
14 requirements of this subsection for importations
15 for personal use; and

16 “(B) may establish other exemptions from
17 the requirements of this subsection.”.

18 “(4) REGULATIONS.—Not later than 24 months
19 after the date of the enactment of this Act, the Sec-
20 retary of Health and Human Services shall promul-
21 gate the regulations required to carry out section
22 801(s) of the Federal Food, Drug, and Cosmetic
23 Act, as added by paragraph (3).

1 (5) EFFECTIVE DATE.—The amendments made
2 by this subsection shall take effect on the date that
3 is 24 months after the date of enactment of this Act.

4 (b) INSPECTION.— Section 704 (21 U.S.C. 374), as
5 amended by sections 105 and 204, is amended by adding
6 at the end the following:

7 “(j) BROKERS AND FILERS.—Every person engaged
8 in the brokering for import or filing for import of any food
9 shall, upon request of an officer or employee designated
10 by the Secretary, permit such officer or employee at all
11 reasonable times to inspect the facilities of such person
12 and have access to, and to copy and verify, any related
13 records.”.

14 **SEC. 206. UNIQUE IDENTIFICATION NUMBER FOR FOOD FA-**
15 **CILITIES, IMPORTERS, CUSTOM BROKERS,**
16 **AND FILERS.**

17 Chapter IX (21 U.S.C. 391 et seq) is amended by
18 adding at the end the following:

19 **“SEC. 911. UNIQUE FACILITY IDENTIFIER.**

20 “(a) REGISTRATION OF FACILITY OR ESTABLISH-
21 MENT.—A person required to register a facility pursuant
22 to section 415 shall submit, at the time of registration,
23 a unique facility identifier for the facility or establishment.

24 “(b) REGISTRATION OF IMPORTERS, CUSTOM BRO-
25 KERS, AND FILERS.—A person required to register pursu-

1 ant to section 801(r) or 801(s) shall submit, at the time
2 of registration, a unique facility identifier for the principal
3 place of business for which such person is required to reg-
4 ister under section 801(r) or 801(s).

5 “(c) GUIDANCE.—The Secretary may, by guidance,
6 specify the unique numerical identifier system to be used
7 to meet the requirements of subsections (a) and (b) and
8 the form, manner, and timing of a submission under such
9 subsections.

10 “(d) IMPORTATION.—An article of food imported or
11 offered for import shall be refused admission unless the
12 appropriate unique facility identifiers, as specified by the
13 Secretary, are provided for such article.”.

14 **SEC. 207. PROHIBITION AGAINST DELAYING, LIMITING, OR**
15 **REFUSING INSPECTION.**

16 (a) ADULTERATION.—Section 402 (21 U.S.C. 342),
17 as amended by section 102, 103(a), and 104(a), is amend-
18 ed by adding at the end the following:

19 “(n) If it has been produced, manufactured, proc-
20 essed, packed, or held in any farm, factory, warehouse,
21 or establishment and the owner, operator, or agent of such
22 farm, factory, warehouse, or establishment, or any agent
23 of a governmental authority in the foreign country within
24 which such farm, factory, warehouse, or establishment is

1 located, delays or limits an inspection, or refuses to permit
2 entry or inspection, under section 414 or 704.”.

3 (b) FOREIGN INSPECTIONS.—Section 704(a)(1) (21
4 U.S.C. 374(a)(1)), as amended by section 106(c), is
5 amended—

6 (1) in the first sentence, by inserting “, includ-
7 ing any such food factory, warehouse, or establish-
8 ment whether foreign or domestic,” after “factory,
9 warehouse, or establishment”; and

10 (2) in the third sentence, by inserting “, includ-
11 ing any food factory, warehouse, establishment, or
12 consulting laboratory whether foreign or domestic,”
13 after “factory, warehouse, establishment, or con-
14 sulting laboratory”.

15 **SEC. 208. DEDICATED FOREIGN INSPECTORATE.**

16 Section 704 (21 U.S.C. 374), as amended by sections
17 105, 204, and 205, is amended by adding at the end the
18 following:

19 “(k) DEDICATED FOREIGN INSPECTORATE.—The
20 Secretary shall establish and maintain a corps of inspec-
21 tors dedicated to inspections of foreign food facilities. This
22 corps shall be staffed and funded by the Secretary at a
23 level sufficient to enable it to assist the Secretary in
24 achieving the frequency of inspections for food facilities
25 as described in this Act.”.

1 **SEC. 209. PLAN AND REVIEW OF CONTINUED OPERATION**
2 **OF FIELD LABORATORIES.**

3 (a) SUBMISSION OF PLAN.—Not later than 90 days
4 before the Secretary terminates or consolidates any lab-
5 oratory, district office, or the functions (including the in-
6 spection and compliance functions) of any such laboratory
7 or district office, specified in subsection (b), the Secretary
8 shall submit a reorganization plan to the Comptroller Gen-
9 eral of the United States, the Committee on Energy and
10 Commerce of the House of Representatives, and the Com-
11 mittee on Health, Education, Labor, and Pensions of the
12 Senate.

13 (b) SPECIFIED LABORATORIES AND OFFICES.—The
14 laboratories and offices specified in this subsection are the
15 following:

16 (1) Any of the 13 field laboratories responsible
17 for analyzing food that were operated by the Office
18 of Regulatory Affairs of the Food and Drug Admin-
19 istration as of January 1, 2007.

20 (2) Any of the 20 district offices of the Food
21 and Drug Administration with responsibility for food
22 safety functioning as of January 1, 2007.

23 (c) CONGRESSIONAL REVIEW.—A reorganization
24 plan described in subsection (a) is deemed to be a major
25 rule (as defined in section 804(2) of title 5, United States
26 Code) for purposes of chapter 8 of such title.

1 **SEC. 210. FALSE OR MISLEADING REPORTING TO FDA.**

2 (a) IN GENERAL.—Section 301(q)(2) (21 U.S.C.
3 331(q)(2)) is amended by inserting after “device” the fol-
4 lowing: “or food”.

5 (b) EFFECTIVE DATE.—The amendment made by
6 subsection (a) shall apply to submissions made on or after
7 the date of the enactment of this Act.

8 **SEC. 211. SUBPOENA AUTHORITY.**

9 (a) PROHIBITED ACT.—Section 301(f) is amended by
10 inserting before the period “or the failure or refusal to
11 obey a subpoena issued pursuant to section 311”.

12 (b) AMENDMENT.—Chapter III (21 U.S.C. 331 et
13 seq.) is amended by adding at the end the following:

14 **“SEC. 311. EXERCISE OF SUBPOENA AUTHORITY.**

15 “(a) IN GENERAL.—For the purpose of—

16 “(1) any hearing, investigation, or other pro-
17 ceeding respecting a violation of a provision of this
18 Act, the Public Health Service Act, or the Federal
19 Anti-Tampering Act, relating to food; or

20 “(2) any hearing, investigation, or other pro-
21 ceeding to determine if a person is in violation of a
22 specific provision of this Act, the Public Health
23 Service Act, or the Federal Anti-Tampering Act, re-
24 lating to food,

1 the Commissioner may issue subpoenas requiring the at-
2 tendance and testimony of witnesses and the production
3 of records and other things.

4 “(b) TIMING OF COMPLIANCE.—When the Commis-
5 sioner deems that immediate compliance with a subpoena
6 issued under this section is necessary to address a threat
7 of serious adverse health consequences or death, the sub-
8 poena may require immediate production.

9 “(c) SERVICE OF SUBPOENA.—

10 “(1) IN GENERAL.—Subpoenas of the Commis-
11 sioner shall be served by a person authorized by the
12 Commissioner by delivering a copy thereof to the
13 person named therein or by certified mail addressed
14 to such person at such person’s last known dwelling
15 place or principal place of business.

16 “(2) CORPORATIONS AND OTHER ENTITIES.—
17 Service on a domestic or foreign corporation, part-
18 nership, unincorporated association, or other entity
19 that is subject to suit under a common name may
20 be made by delivering the subpoena to an officer, a
21 managing or general agent, or any other agent au-
22 thorized by appointment or by law to receive service
23 of process.

24 “(3) PERSON OUTSIDE U.S. JURISDICTION.—
25 Service on any person not found within the terri-

1 torial jurisdiction of any court of the United States
2 may be made in any manner as the Federal Rules
3 of Civil Procedure prescribe for service in a foreign
4 nation.

5 “(4) PROOF OF SERVICE.—A verified return by
6 the person so serving the subpoena setting forth the
7 manner of service, or, in the case of service by cer-
8 tified mail, the return post office receipt therefor
9 signed by the person so served, shall be proof of
10 service.

11 “(d) PAYMENT OF WITNESSES.—Witnesses subpoe-
12 naed under subsection (a) shall be paid the same fees and
13 mileage as are paid witnesses in the district courts of the
14 United States.

15 “(e) ENFORCEMENT.—In the case of a refusal to
16 obey a subpoena duly served upon any person under sub-
17 section (a), any district court of the United States for the
18 judicial district in which such person charged with refusal
19 to obey is found, resides, or transacts business, upon ap-
20 plication by the Commissioner, shall have jurisdiction to
21 issue an order compelling compliance with the subpoena
22 and requiring such person to appear and give testimony
23 or to appear and produce records and other things, or
24 both. The failure to obey such order of the court may be
25 punished by the court as contempt thereof. If the person

1 charged with failure or refusal to obey is not found within
2 the territorial jurisdiction of the United States, the United
3 States District Court for the District of Columbia shall
4 have the same jurisdiction, consistent with due process,
5 to take any action respecting compliance with the sub-
6 poena by such person that such district court would have
7 if such person were personally within the jurisdiction of
8 such district court.

9 “(f) NONDISCLOSURE.—A United States district
10 court for the district in which the subpoena is or will be
11 served, upon application of the Commissioner, may issue
12 an ex parte order that no person or entity disclose to any
13 other person or entity (other than to an attorney to obtain
14 legal advice) the existence of such subpoena for a period
15 of up to 90 days. Such order may be issued on a showing
16 that the records or things being sought may be relevant
17 to the hearing, investigation, proceeding, or other matter
18 and that there is reason to believe that such disclosure
19 may result in—

20 “(1) furtherance of a potential violation under
21 investigation;

22 “(2) endangerment to the life or physical safety
23 of any person;

24 “(3) flight or other action to avoid prosecution
25 or other enforcement remedies;

1 “(4) destruction of or tampering with evidence;

2 or

3 “(5) intimidation of potential witnesses.

4 An order under this subsection may be renewed for addi-
5 tional periods of up to 90 days upon a showing that any
6 of the circumstances described in paragraphs (1) through
7 (5) continue to exist.

8 “(g) RELATION TO OTHER PROVISIONS.—The sub-
9 poena authority vested in the Commissioner and the dis-
10 trict courts of the United States by this section is in addi-
11 tion to any such authority vested in the Commissioner or
12 such courts by other provisions of law.

13 “(h) NONDELEGATION.—The authority to issue a
14 subpoena under this section is limited to the Secretary or
15 an official designated by the Secretary. An official may
16 not be so designated unless the official is the director of
17 the district under this Act in which the article involved
18 is located, or is an official senior to such director.”.

19 **SEC. 212. WHISTLEBLOWER PROTECTIONS.**

20 Chapter IX (21 U.S.C. 391 et seq.), as amended by
21 section 206, is amended by adding at the end the fol-
22 lowing:

1 **“SEC. 912. PROTECTIONS FOR EMPLOYEES WHO REFUSE TO**
2 **VIOLATE, OR WHO DISCLOSE VIOLATIONS OF,**
3 **THIS ACT OR SECTION 351 OF THE PUBLIC**
4 **HEALTH SERVICE ACT.**

5 “(a) IN GENERAL.—No person who submits or is re-
6 quired under this Act or the Public Health Service Act
7 to submit any information related to a food, or any officer,
8 employee, contractor, subcontractor, or agent of such per-
9 son may discharge, demote, suspend, threaten, harass, or
10 in any other manner discriminate against an employee in
11 the terms and conditions of employment because of any
12 lawful act done by the employee, including within the ordi-
13 nary course of the job duties of such employee—

14 “(1) to provide information, cause information
15 to be provided, or otherwise assist in any investiga-
16 tion regarding any conduct which the employee rea-
17 sonably believes constitutes a violation of this Act, or
18 any other provision of Federal law relating to the
19 safety of a food, if the information or assistance is
20 provided to, or an investigation stemming from the
21 provided information is conducted by—

22 “(A) a Federal regulatory or law enforce-
23 ment agency;

24 “(B) any Member of Congress or any com-
25 mittee of Congress; or

1 “(C) a person with supervisory authority
2 over the employee (or such other person work-
3 ing for the employer who has the authority to
4 investigate, discover, or terminate the mis-
5 conduct);

6 “(2) to file, cause to be filed, testify, participate
7 in, or otherwise assist in a proceeding filed, or about
8 to be filed (with any knowledge of the employer), in
9 any court or administrative forum relating to any
10 such alleged violation; or

11 “(3) to refuse to commit or assist in any such
12 violation.

13 “(b) ENFORCEMENT ACTION.—

14 “(1) IN GENERAL.—An employee who alleges
15 discharge or other discrimination in violation of sub-
16 section (a) may seek relief in accordance with the
17 provisions of subsection (c) by—

18 “(A) filing a complaint with the Secretary
19 of Labor; or

20 “(B) if the Secretary of Labor has not
21 issued a final decision within 210 days of the
22 filing of the complaint and there is no showing
23 that such delay is due to the bad faith of the
24 claimant, or within 90 days after receiving a
25 final decision or order from the Secretary,

1 bringing an action at law or equity for de novo
2 review in the appropriate district court of the
3 United States, which court shall have jurisdic-
4 tion over such action without regard to the
5 amount in controversy, and which action shall,
6 at the request of either party to such action, be
7 tried by the court with a jury.

8 “(2) PROCEDURE.—

9 “(A) IN GENERAL.—Any action under
10 paragraph (1) shall be governed under the rules
11 and procedures set forth in section 42121(b) of
12 title 49, United States Code.

13 “(B) EXCEPTION.—Notification in an ac-
14 tion under paragraph (1) shall be made in ac-
15 cordance with section 42121(b)(1) of title 49,
16 United States Code, except that such notifica-
17 tion shall be made to the person named in the
18 complaint and to the employer.

19 “(C) BURDENS OF PROOF.—An action
20 brought under paragraph (1)(B) shall be gov-
21 erned by the legal burdens of proof set forth in
22 section 42121(b) of title 49, United States
23 Code.

24 “(D) STATUTE OF LIMITATIONS.—An ac-
25 tion under paragraph (1) shall be commenced

1 not later than 180 days after the date on which
2 the violation occurs.

3 “(c) REMEDIES.—

4 “(1) IN GENERAL.—An employee prevailing in
5 any action under subsection (b)(1) shall be entitled
6 to all relief necessary to make the employee whole.

7 “(2) ISSUANCE OF ORDER.—If, in response to
8 a complaint filed under subsection (b)(1), the Sec-
9 retary of Labor or the district court, as applicable,
10 determines that a violation of subsection (a) has oc-
11 curred, the Secretary or the court shall order the
12 person who committed such violation—

13 “(A) to take affirmative action to abate
14 the violation;

15 “(B) to—

16 “(i) reinstate the complainant to his
17 or her former position together with com-
18 pensation (including backpay); and

19 “(ii) restore the terms, conditions,
20 and privileges associated with his or her
21 employment; and

22 “(C) to provide compensatory damages to
23 the complainant.

24 If such an order is issued under this paragraph, the
25 Secretary or the court, at the request of the com-

1 plainant, shall assess against the person against
2 whom the order is issued a sum equal to the aggregate
3 amount of all costs and expenses (including attorney
4 and expert witness fees) reasonably incurred,
5 as determined by the Secretary, by the complainant
6 for, or in connection with, the bringing of the complaint
7 upon which the order was issued.

8 “(d) RIGHTS RETAINED BY EMPLOYEE.—Nothing in
9 this section shall be deemed to diminish the rights, privileges,
10 or remedies of any employee under any Federal or
11 State law or under any collective bargaining agreement.
12 The rights and remedies in this section may not be waived
13 by any agreement, policy, form, or condition of employment.”.

15 **SEC. 213. EXTRATERRITORIAL JURISDICTION.**

16 (a) PROHIBITED ACT.—Section 301 (21 U.S.C. 331),
17 as amended by sections 110, 111, 133, 136, and 204, is
18 amended by adding at the end the following:

19 “(uu) The production, manufacture, processing, preparation,
20 packing, holding, or distribution of an adulterated
21 or misbranded food with the knowledge or intent that such
22 article will be imported into the United States.”.

23 (b) JURISDICTION.—Chapter III (21 U.S.C. 331 et
24 seq.), as amended by section 211, is amended by adding
25 at the end the following:

1 **“SEC. 312. EXTRATERRITORIAL JURISDICTION.**

2 “There is extraterritorial Federal jurisdiction over
3 any violation of this Act relating to any article of food
4 if such article was intended for import into the United
5 States or if any act in furtherance of the violation was
6 committed in the United States.”.

7 **SEC. 214. SUPPORT FOR TRAINING INSTITUTES.**

8 The Secretary of Health and Human Services, acting
9 through the Commissioner of Food and Drugs, shall pro-
10 vide financial and other assistance to appropriate entities
11 to establish and maintain one or more university-affiliated
12 food protection training institutes that—

13 (1) conduct training related to food protection
14 activities for Federal, State, local, territorial, and
15 tribal officials; and

16 (2) meet standards developed by the Secretary.

17 **SEC. 215. BISPHENOL A IN FOOD AND BEVERAGE CON-**
18 **TAINERS.**

19 (a) NOTICE OF DETERMINATION.—No later than De-
20 cember 31, 2009, the Secretary of Health and Human
21 Services shall notify the Congress whether the available
22 scientific data support a determination that there is a rea-
23 sonable certainty of no harm, for infants, young children,
24 pregnant women, and adults, for approved uses of
25 polycarbonate plastic and epoxy resin made with bisphenol
26 A in food and beverage containers, including reusable food

1 and beverage containers, under the conditions of use pre-
2 scribed in current Food and Drug Administration regula-
3 tions.

4 (b) NOTICE OF ACTIONS TO BE TAKEN.—If the Sec-
5 retary concludes that such a determination cannot be made
6 for any approved use, the Secretary shall notify the Con-
7 gress of the actions the Secretary intends to take under
8 the Secretary's authority to regulate food additives to pro-
9 tect the public health, which may include—

10 (1) revoking or modifying any of the approved
11 uses of bisphenol A in food and beverage containers,
12 including reusable food and beverage containers; and

13 (2) ensuring that the public is sufficiently in-
14 formed of such determination and the steps the pub-
15 lic may take in response to such determination.

16 (c) RULE OF CONSTRUCTION.—Nothing herein is in-
17 tended or shall be construed to modify existing Food and
18 Drug Administration authority, procedures, or policies for
19 assessing scientific data, making safety determinations, or
20 regulating the safe use of food additives.

