

111TH CONGRESS
1ST SESSION

H. R. 2749

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food in the global market, and for other purposes.

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

1 **SECTION 1. SHORT TITLE.**

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.
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- Sec. 107. Traceability of food.
- Sec. 108. Reinspection and food recall fees applicable to facilities.
- Sec. 109. Certification and accreditation.
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- 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.
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Subtitle C—Response

- Sec. 131. Procedures for seizure.
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TITLE II—MISCELLANEOUS

- Sec. 201. Food substances generally recognized as safe.

- Sec. 202. Country of origin labeling.
- Sec. 203. Exportation certificate program.
- Sec. 204. Registration for commercial importers of food; fee.
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- 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.
- Sec. 216. Lead content labeling requirement for ceramic tableware and cookware.

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.).

8 **SEC. 4. RULES OF CONSTRUCTION.**

9 (a) Nothing in this Act or the amendments made by
10 this Act shall be construed to prohibit or limit—

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

12 (2) the introduction of evidence of compliance
13 or noncompliance with the requirements of the Fed-
14 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301
15 et seq.).

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

1 (1) alter the jurisdiction between the Secretary
2 of Agriculture and the Secretary of Health and
3 Human Services, under applicable statutes and regu-
4 lations;

5 (2) limit the authority of the Secretary of
6 Health and Human Services to issue regulations re-
7 lated to the safety of food under—

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

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

15 (3) impede, minimize, or affect the authority of
16 the Secretary of Agriculture to prevent, control, or
17 mitigate a plant or animal health emergency, or a
18 food emergency involving products regulated under
19 the Federal Meat Inspection Act (21 U.S.C. 601 et
20 seq.), the Poultry Products Inspection Act (21
21 U.S.C. 451 et seq.), or the Egg Products Inspection
22 Act (21 U.S.C. 1031 et seq.).

23 **SEC. 5. USDA EXEMPTIONS.**

24 (a) **USDA-REGULATED PRODUCTS.**—Food is exempt
25 from the requirements of this Act to the extent that such

1 food is regulated by the Secretary of Agriculture under
2 the Federal Meat Inspection Act (21 U.S.C. 601 et seq.),
3 the Poultry Products Inspection Act (21 U.S.C. 451 et
4 seq.), or the Egg Products Inspection Act (21 U.S.C. 1031
5 et seq.).

6 (b) LIVESTOCK AND POULTRY.—Livestock and poul-
7 try that are intended to be presented for slaughter pursu-
8 ant to the regulations by the Secretary of Agriculture
9 under the Federal Meat Inspection Act or the Poultry
10 Products Inspection Act are exempt from the require-
11 ments of this Act. A cow, sheep, or goat that is used for
12 the production of milk is exempt from the requirements
13 of this Act.

14 (c) USDA-REGULATED FACILITIES.—A facility is ex-
15 empt from the requirements of this Act to the extent such
16 facility is regulated as an official establishment by the Sec-
17 retary of Agriculture under the Federal Meat Inspection
18 Act, the Poultry Products Inspection Act, or the Egg
19 Products Inspection Act or under a program recognized
20 by the Secretary of Agriculture as at least equal to Fed-
21 eral regulation under the Federal Meat Inspection Act, the
22 Poultry Products Inspection Act, or the Egg Products In-
23 spection Act.

24 (d) FARMS.—A farm is exempt from the require-
25 ments of this Act to the extent such farm raises animals

1 from which food is derived that is regulated under the
2 Federal Meat Inspection Act, the Poultry Products In-
3 spection Act, or the Egg Products Inspection Act.

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

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

9 (1) under the Federal Alcohol Administration
10 Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle
11 E of the Internal Revenue Code of 1986 (26 U.S.C.
12 5291 et seq.) is required to obtain a permit or to
13 register with the Secretary of the Treasury as a con-
14 dition of doing business in the United States; and

15 (2) under section 415 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 350d), as
17 amended by this Act, is required to register as a fa-
18 cility because such facility is engaged in manufac-
19 turing, processing, packing, or holding 1 or more al-
20 coholic beverages.

21 (b) LIMITED RECEIPT AND DISTRIBUTION OF NON-
22 ALCOHOL FOOD.—Subsection (a) shall not apply to a fa-
23 cility engaged in the distributing of any non-alcohol food,
24 except that subsection (a) shall apply to a facility de-
25 scribed in paragraphs (1) and (2) of subsection (a) that

1 receives and distributes non-alcohol food provided such
2 food is received and distributed—

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

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

8 (c) **RULE OF CONSTRUCTION.**—This section shall not
9 be construed to exempt any food, apart from distilled spir-
10 its, wine, and malt beverages, as defined in section 211
11 of the Federal Alcohol Administration Act (27 U.S.C.
12 211), from the requirements of this Act and the amend-
13 ments made by this Act.

14 **TITLE I—FOOD SAFETY**

15 **Subtitle A—Prevention**

16 **SEC. 101. CHANGES IN REGISTRATION OF FOOD FACILI-**
17 **TIES.**

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

20 “(z) If it was manufactured, processed, packed, or
21 held in a facility that is not duly registered under section
22 415, including a facility whose registration is canceled or
23 suspended under such section.”.

24 (b) **ANNUAL REGISTRATION.**—

1 (1) DEFINITION OF FACILITY.—Paragraph (1)
2 of section 415(b) (21 U.S.C. 350d(b)) is amended to
3 read as follows:

4 “(1)(A) The term ‘facility’ means any factory,
5 warehouse, or establishment (including a factory,
6 warehouse, or establishment of an importer) that
7 manufactures, processes, packs, or holds food.

8 “(B) Such term does not include farms; private
9 residences of individuals; restaurants; other retail
10 food establishments; nonprofit food establishments
11 in which food is prepared for or served directly to
12 the consumer; or fishing vessels (except such vessels
13 engaged in processing as defined in section 123.3(k)
14 of title 21, Code of Federal Regulations, or any suc-
15 cessor regulations).

16 “(C)(i) The term ‘retail food establishment’
17 means an establishment that, as its primary func-
18 tion, sells food products (including those food prod-
19 ucts that it manufactures, processes, packs, or
20 holds) directly to consumers (including by Internet
21 or mail order).

22 “(ii) Such term includes—

23 “(I) grocery stores;

24 “(II) convenience stores;

25 “(III) vending machine locations; and

1 “(IV) stores that sell bagged feed, pet
2 food, and feed ingredients or additives
3 over-the-counter directly to consumers and
4 final purchasers for their own personal ani-
5 mals.

6 “(iii) A retail food establishment’s primary
7 function is to sell food directly to consumers if
8 the annual monetary value of sales of food
9 products directly to consumers exceeds the an-
10 nual monetary value of sales of food products to
11 all other buyers.

12 “(D)(i) The term ‘farm’ means an operation in
13 one general physical location devoted to the growing
14 and harvesting of crops, the raising of animals (in-
15 cluding seafood), or both.

16 “(ii) Such term includes—

17 “(I) such an operation that packs or holds
18 food, provided that all food used in such activi-
19 ties is grown, raised, or consumed on such farm
20 or another farm under the same ownership;

21 “(II) such an operation that manufactures
22 or processes food, provided that all food used in
23 such activities is consumed on such farm or an-
24 other farm under the same ownership;

1 “(III) such an operation that sells food di-
2 rectly to consumers if the annual monetary
3 value of sales of the food products from the
4 farm or by an agent of the farm to consumers
5 exceeds the annual monetary value of sales of
6 the food products to all other buyers;

7 “(IV) such an operation that manufactures
8 grains or other feed stuffs that are grown and
9 harvested on such farm or another farm under
10 the same ownership and are distributed directly
11 to 1 or more farms for consumption as food by
12 humans or animals on such farm; and

13 “(V) a fishery, including a wild fishery, an
14 aquaculture operation or bed, a fresh water
15 fishery, and a saltwater fishery.

16 “(iii) Such term does not include such an oper-
17 ation that receives manufactured feed from another
18 farm as described in clause (ii)(IV) if the receiving
19 farm releases the feed to another farm or facility
20 under different ownership.

21 “(iv) The term ‘harvesting’ includes washing,
22 trimming of outer leaves of, and cooling produce.

23 “(E) The term ‘consumer’ does not include a
24 business.”.

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

3 (A) in the first sentence of paragraph
4 (1)—

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

8 (ii) by striking “food for consumption
9 in the United States” and inserting “food
10 for consumption in the United States or
11 for export from the United States”;

12 (B) in subparagraphs (A) and (B) of para-
13 graph (1), by inserting “and pay the registra-
14 tion fee required under section 743” after “sub-
15 mit a registration to the Secretary” each place
16 it appears;

17 (C) in the first sentence of paragraph (2),
18 by inserting “in electronic format” after “sub-
19 mit”; and

20 (D) in paragraph (4), by inserting after
21 the first sentence the following: “The Secretary
22 shall remove from such list the name of any fa-
23 cility that fails to reregister in accordance with
24 this section, that fails to pay the registration
25 fee required under section 743, or whose reg-

1 istration is canceled by the registrant, canceled
2 by the Secretary in accordance with this sec-
3 tion, or suspended by the Secretary in accord-
4 ance with this section.”.

5 (3) CONTENTS OF REGISTRATION.—Paragraph
6 (2) of section 415(a) (21 U.S.C. 350d(a)), as
7 amended by paragraph (1), is amended by striking
8 “containing information” and all that follows and in-
9 serting the following: “containing information that
10 identifies the following:

11 “(A) The name, address, and emergency
12 contact information of the facility being reg-
13 istered.

14 “(B) The primary purpose and business
15 activity of the facility, including the dates of op-
16 eration if the facility is seasonal.

17 “(C) The general food category (as defined
18 by the Secretary by guidance) of each food
19 manufactured, processed, packed, or held at the
20 facility.

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

23 “(E) The name, address, and 24-hour
24 emergency contact information of the United
25 States distribution agent for the facility, which

1 agent shall have access to the information re-
2 quired to be maintained under section 414(d)
3 for food that is manufactured, processed,
4 packed, or held at the facility.

5 “(F) If the facility is located outside of the
6 United States, the name, address, and emer-
7 gency contact information for a United States
8 agent.

9 “(G) The unique facility identifier of the
10 facility, as specified under section 1011.

11 “(H) Such additional information per-
12 taining to the facility as the Secretary may re-
13 quire by regulation.

14 The registrant shall notify the Secretary of any
15 change in the submitted information not later than
16 30 days after the date of such change, unless other-
17 wise specified by the Secretary.”.

18 (4) SUSPENSION AND CANCELLATION AUTHOR-
19 ITY.—Section 415(a) (21 U.S.C. 350d(a)), as
20 amended by paragraphs (1) and (2), is further
21 amended by adding at the end the following:

22 “(5) SUSPENSION OF REGISTRATION.—

23 “(A) IN GENERAL.—The Secretary may
24 suspend the registration of any facility reg-
25 istered under this section for a violation of this

1 Act that could result in serious adverse health
2 consequences or death to humans or animals.

3 “(B) NOTICE OF SUSPENSION.—Suspension of a registration shall be preceded by—

4 “(i) notice to the facility of the intent
5 to suspend the registration; and

6 “(ii) an opportunity for an informal
7 hearing, as defined in guidance or regula-
8 tions issued by the Secretary, concerning
9 the suspension of such registration for
10 such facility.

11 “(C) REQUEST.—The owner, operator, or
12 agent in charge of a facility whose registration
13 is suspended may request that the Secretary va-
14 cate the suspension of registration when such
15 owner, operator, or agent has corrected the vio-
16 lation that is the basis for such suspension.

17 “(D) VACATING OF SUSPENSION.—If,
18 based on an inspection of the facility or other
19 information, the Secretary determines that ade-
20 quate reasons do not exist to continue the sus-
21 pension of a registration, the Secretary shall va-
22 cate such suspension.

23 “(6) CANCELLATION OF REGISTRATION.—
24

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

5 “(i) the registration was not updated
6 in accordance with this section or other-
7 wise contains false, incomplete, or inac-
8 curate information; or

9 “(ii) the required registration fee has
10 not been paid within 30 days after the date
11 due.

12 “(B) NOTICE OF CANCELLATION.—Can-
13 cellation shall be preceded by notice to the facil-
14 ity of the intent to cancel the registration and
15 the basis for such cancellation.

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

21 “(7) REPORT TO CONGRESS.—Not later than
22 March 30th of each year, the Secretary shall submit
23 to the Congress a report, based on the registrations
24 on or before December 31 of the previous year, on
25 the following:

1 “(A) The number of facilities registered
2 under this section.

3 “(B) The number of such facilities that are
4 domestic.

5 “(C) The number of such facilities that are
6 foreign.

7 “(D) The number of such facilities that
8 are high-risk.

9 “(E) The number of such facilities that are
10 low-risk.

11 “(F) The number of such facilities that
12 hold food.

13 “(8) LIMITATION ON DELEGATION.—The au-
14 thority conferred by this subsection to issue an order
15 to suspend a registration or cancel a registration
16 shall not be delegated to any officer or employee
17 other than the Commissioner of Food and Drugs,
18 the Principal Deputy Commissioner, the Associate
19 Commissioner for Regulatory Affairs, or the Direc-
20 tor for the Center for Food Safety and Applied Nu-
21 trition, of the Food and Drug Administration.”.

22 (c) REGISTRATION FEE.—Chapter VII (21 U.S.C.
23 371 et seq.) is amended by adding at the end of sub-
24 chapter C the following:

1 **“PART 6—FEES RELATING TO FOOD**

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

3 “(a) IN GENERAL.—

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

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

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

13 “(B) for any other facility—

14 “(i) for fiscal year 2010, not later
15 than the sooner of 90 days after the date
16 of the enactment of this part or December
17 31, 2009; and

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

20 “(b) FEE AMOUNTS.—

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

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

24 “(B) for fiscal year 2011 and each subse-
25 quent fiscal year, the fee for fiscal year 2010 as
26 adjusted under subsection (c).

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

6 “(3) MAXIMUM AMOUNT.—Notwithstanding
7 paragraph (1), a person who owns or operates mul-
8 tiple facilities for which a fee must be paid under
9 this section for a fiscal year shall be liable for not
10 more than \$175,000 in aggregate fees under this
11 section for such fiscal year.

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

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

22 “(2) the total percentage change for the pre-
23 vious fiscal year in basic pay under the General
24 Schedule in accordance with section 5332 of title 5,
25 United States Code, as adjusted by any locality-

1 based comparability payment pursuant to section
2 5304 of such title for Federal employees stationed in
3 the District of Columbia; or

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

9 The adjustment made each fiscal year under this sub-
10 section shall be added on a compounded basis to the sum
11 of all adjustments made each fiscal year after fiscal year
12 2010 under this subsection.

13 “(d) LIMITATIONS.—

14 “(1) IN GENERAL.—Fees under subsection (a)
15 shall be refunded for a fiscal year beginning after
16 fiscal year 2010 unless appropriations for salaries
17 and expenses of the Food and Drug Administration
18 for such fiscal year (excluding the amount of fees
19 appropriated for such fiscal year) are equal to or
20 greater than the amount of appropriations for the
21 salaries and expenses of the Food and Drug Admin-
22 istration for fiscal year 2010 (excluding the amount
23 of fees appropriated for such fiscal year) multiplied
24 by the adjustment factor applicable to the fiscal year
25 involved.

1 “(2) AUTHORITY.—If the Secretary does not
2 assess fees under subsection (a) during any portion
3 of a fiscal year because of paragraph (1) and if at
4 a later date in such fiscal year the Secretary may as-
5 sess such fees, the Secretary may assess and collect
6 such fees, without any modification in the rate, for
7 registration under section 415 at any time in such
8 fiscal year.

9 “(3) ADJUSTMENT FACTOR.—In this sub-
10 section, the term ‘adjustment factor’ applicable to a
11 fiscal year is the Consumer Price Index for all urban
12 consumers (all items; United States city average) for
13 October of the preceding fiscal year divided by such
14 Index for October 2009.

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

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

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

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

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

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

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

19 “(f) COLLECTION OF UNPAID FEES.—In any case
20 where the Secretary does not receive payment of a fee as-
21 sessed under subsection (a) within 30 days after it is due,
22 such fee shall be treated as a claim of the United States
23 Government subject to subchapter II of chapter 37 of title
24 31, United States Code.

1 “(g) CONSTRUCTION.—This section may not be con-
2 strued to require that the number of full-time equivalent
3 positions in the Department of Health and Human Serv-
4 ices, for officers, employees, and advisory committees not
5 engaged in food safety activities, be reduced to offset the
6 number of officers, employees, and advisory committees so
7 engaged.

8 “(h) ANNUAL FISCAL REPORTS.—Beginning with
9 fiscal year 2011, not later than 120 days after the end
10 of each fiscal year for which fees are collected under this
11 section, the Secretary shall prepare and submit to the
12 Committee on Energy and Commerce of the House of
13 Representatives and the Committee on Health, Education,
14 Labor, and Pensions of the Senate a report on the imple-
15 mentation of the authority for such fees during such fiscal
16 year and the use, by the Food and Drug Administration,
17 of the fees collected for such fiscal year.

18 “(i) DEFINITIONS.—In this section:

19 “(1) The term ‘costs of food safety activities’
20 means the expenses incurred in connection with food
21 safety activities for—

22 “(A) officers and employees of the Food
23 and Drug Administration, contractors of the
24 Food and Drug Administration, advisory com-
25 mittees, and costs related to such officers, em-

1 employees, and committees and to contracts with
2 such contractors;

3 “(B) laboratory capacity;

4 “(C) management of information, and the
5 acquisition, maintenance, and repair of tech-
6 nology resources;

7 “(D) leasing, maintenance, renovation, and
8 repair of facilities and acquisition, maintenance,
9 and repair of fixtures, furniture, scientific
10 equipment, and other necessary materials and
11 supplies; and

12 “(E) collecting fees under this section and
13 accounting for resources allocated for food safe-
14 ty activities.

15 “(2) The term ‘food safety activities’ means ac-
16 tivities related to compliance by facilities registered
17 under section 415 with the requirements of this Act
18 relating to food (including research related to and
19 the development of standards (such as performance
20 standards and preventive controls), risk assessments,
21 hazard analyses, inspection planning and inspec-
22 tions, third-party inspections, compliance review and
23 enforcement, import review, information technology
24 support, test development, product sampling, risk
25 communication, and administrative detention).”.

1 (d) TRANSITIONAL PROVISIONS.—

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

7 (2) MODIFICATION OF REGISTRATION FORM.—
8 Not later than 180 days after the date of the enact-
9 ment of this Act, the Secretary of Health and
10 Human Services shall modify the registration form
11 under section 415 of the Federal Food, Drug, and
12 Cosmetic Act (21 U.S.C. 350d) to comply with the
13 amendments made by this section.

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

20 (4) SUNSET DATE.—Section 743 of the Federal
21 Food, Drug, and Cosmetic Act, as added by sub-
22 section (c), does not authorize the assessment or col-
23 lection of a fee for registration under section 415 of
24 such Act (21 U.S.C. 360) occurring after fiscal year
25 2014.

1 **SEC. 102. HAZARD ANALYSIS, RISK-BASED PREVENTIVE**
2 **CONTROLS, FOOD SAFETY PLAN, FINISHED**
3 **PRODUCT TEST RESULTS FROM CATEGORY 1**
4 **FACILITIES.**

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

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

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

13 (2) REQUIREMENTS.—Chapter IV (21 U.S.C.
14 341 et seq.) is amended by adding at the end the
15 following:

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

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

20 “(1) conduct a hazard analysis (or more than
21 one if appropriate);

22 “(2) identify and implement effective preventive
23 controls;

24 “(3) monitor preventive controls;

25 “(4) institute corrective actions when—

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

3 “(B) monitoring and verification show that
4 such controls were ineffective;

5 “(5) conduct verification activities;

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

8 “(7) reanalyze for hazards.

9 “(b) IDENTIFICATION OF HAZARDS.—

10 “(1) IN GENERAL.—The owner, operator, or
11 agent of a facility shall evaluate whether there are
12 any hazards, including hazards due to the source of
13 the ingredients, that are reasonably likely to occur
14 in the absence of preventive controls that may affect
15 the safety, wholesomeness, or sanitation of the food
16 manufactured, processed, packed, transported, or
17 held by the facility, including—

18 “(A) biological, chemical, physical, and ra-
19 diological hazards, natural toxins, pesticides,
20 drug residues, filth, decomposition, parasites,
21 allergens, and unapproved food and color addi-
22 tives; and

23 “(B) hazards that occur naturally or that
24 may be unintentionally introduced.

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

5 “(3) HAZARD ANALYSIS.—The owner, operator,
6 or agent of a facility shall identify and describe the
7 hazards evaluated under paragraph (1) or identified
8 under paragraph (2), to the extent applicable to the
9 facility, in a hazard analysis.

10 “(c) PREVENTIVE CONTROLS.—

11 “(1) IN GENERAL.—The owner, operator, or
12 agent of a facility shall identify and implement effec-
13 tive preventive controls to prevent, eliminate, or re-
14 duce to acceptable levels the occurrence of any haz-
15 ards identified in the hazard analysis under sub-
16 section (b)(3).

17 “(2) IDENTIFIED BY THE SECRETARY.—

18 “(A) ESTABLISHMENT.—The Secretary
19 may establish by regulation or guidance preven-
20 tive controls for specific product types to pre-
21 vent unintentional contamination throughout
22 the supply chain. The owner, operator, or agent
23 of a facility shall implement any preventive con-
24 trols identified by the Secretary under this
25 paragraph.

1 “(B) ALTERNATIVE CONTROLS.—Such reg-
2 ulation or guidance shall allow the owner, oper-
3 ator, or agent of a facility to implement an al-
4 ternative preventive control to one established
5 by the Secretary, provided that, in response to
6 a request by the Secretary, the owner, operator,
7 or agent can present to the Secretary data or
8 other information sufficient to demonstrate that
9 the alternative control effectively addresses the
10 hazard, including meeting any applicable per-
11 formance standard.

12 “(C) LIMITATION.—Subparagraph (B)
13 shall not apply to any preventive control de-
14 scribed in subparagraph (A), (B), or (E) of
15 subsection (i)(2).

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

21 “(e) CORRECTIVE ACTIONS.—The owner, operator,
22 or agent of a facility shall establish and implement proce-
23 dures to ensure that, if the preventive controls under sub-
24 section (c) are not fully implemented or are not found ef-
25 fective—

1 “(1) no affected product from such facility en-
2 ters commerce; and

3 “(2) appropriate action is taken to reduce the
4 likelihood of recurrence of the implementation fail-
5 ure.

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

8 “(1) the system of preventive controls identified
9 under subsection (c) has been validated as scientif-
10 ically and technically sound so that, if such system
11 is implemented, the hazards identified in the hazard
12 analysis under subsection (b)(3) will be prevented,
13 eliminated, or reduced to an acceptable level;

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

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

18 “(4) the preventive controls are effectively pre-
19 venting, eliminating, or reducing to an acceptable
20 level the occurrence of identified hazards, including
21 through the use of environmental and product test-
22 ing programs and other appropriate means.

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

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

1 “(A) review the evaluation under sub-
2 section (b) for the facility and, as necessary, re-
3 vise the hazard analysis under subsection (b)(3)
4 for the facility—

5 “(i) not less than every 2 years;

6 “(ii) if there is a change in the proc-
7 ess or product that could affect the hazard
8 analysis; and

9 “(iii) if the Secretary determines that
10 it is appropriate to protect public health;
11 and

12 “(B) whenever there is a change in the
13 hazard analysis, revise the preventive controls
14 under subsection (c) for the facility as nec-
15 essary to ensure that all hazards that are rea-
16 sonably likely to occur are prevented, elimi-
17 nated, or reduced to an acceptable level, or doc-
18 ument the basis for the conclusion that no such
19 revision is needed.

20 “(2) NONDELEGATION.—Any revisions ordered
21 by the Secretary under this subsection shall be or-
22 dered by the Secretary or an official designated by
23 the Secretary. An official may not be so designated
24 unless the official is the director of the district

1 under this Act in which the facility involved is lo-
2 cated, or is an official senior to such director.

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

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

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

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

24 “(A) Sanitation procedures and practices.

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

3 “(C) Process controls.

4 “(D) An allergen control program to mini-
5 mize potential allergic reactions in humans
6 from ingestion of, or contact with, human and
7 animal food.

8 “(E) Good manufacturing practices.

9 “(F) Verification procedures, practices,
10 and processes for suppliers and incoming ingre-
11 dients, which may include onsite auditing of
12 suppliers and testing of incoming ingredients.

13 “(G) Other procedures, practices, and
14 processes established by the Secretary under
15 subsection (c)(2).

16 “(3) HAZARD THAT IS REASONABLY LIKELY TO
17 OCCUR.—A food safety hazard that is reasonably
18 likely to occur is one for which a prudent person
19 who, as applicable, manufactures, processes, packs,
20 transports, or holds food, would establish controls
21 because experience, illness data, scientific reports, or
22 other information provides a basis to conclude that
23 there is a reasonable possibility that the hazard will
24 occur in the type of food being manufactured, proc-

1 essed, packed, transported, or held in the absence of
2 those controls.

3 **“SEC. 418A. FOOD SAFETY PLAN.**

4 “(a) IN GENERAL.—Before a facility (as defined in
5 section 418(i)) introduces or delivers for introduction into
6 interstate commerce any shipment of food, the owner, op-
7 erator, or agent of the facility shall develop and implement
8 a written food safety plan (in this section referred to as
9 a ‘food safety plan’).

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

12 “(1) The hazard analysis and any reanalysis
13 conducted under section 418.

14 “(2) A description of the preventive controls
15 being implemented under subsection 418(c), includ-
16 ing those to address hazards identified by the Sec-
17 retary under subsection 418(b)(2).

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

20 “(4) A description of the procedures for taking
21 corrective actions.

22 “(5) A description of verification activities for
23 the preventive controls, including validation that the
24 system of controls, if implemented, will prevent,
25 eliminate, or reduce to an acceptable level the identi-

1 fied hazards, review of monitoring and corrective ac-
2 tion records, and procedures for determining wheth-
3 er the system of controls as implemented is effec-
4 tively preventing, eliminating, or reducing to an ac-
5 ceptable level the occurrence of identified hazards,
6 including the use of environmental and product test-
7 ing programs.

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

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

13 “(8) A description of the facility’s procedures
14 for tracing the distribution history of articles of
15 food, whether voluntarily or when required under
16 section 414.

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

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

25 (3) GUIDANCE OR REGULATIONS.—

1 (A) IN GENERAL.—The Secretary of
2 Health and Human Services (referred to in this
3 subsection as the “Secretary”) shall issue guid-
4 ance or promulgate regulations to establish
5 science-based standards for conducting a haz-
6 ard analysis, documenting hazards, identifying
7 and implementing preventive controls, and doc-
8 umenting the implementation of the preventive
9 controls, including verification and corrective
10 actions under sections 418 and 418A of the
11 Federal Food, Drug, and Cosmetic Act (as
12 added by paragraph (2)).

13 (B) INTERNATIONAL STANDARDS.—In
14 issuing guidance or regulations under subpara-
15 graph (A), the Secretary shall review inter-
16 national hazard analysis and preventive control
17 standards that are in existence on the date of
18 the enactment of this Act and relevant to such
19 guidelines or regulations to ensure that the pro-
20 grams under sections 418 and 418A of the Fed-
21 eral Food, Drug, and Cosmetic Act (as added
22 by paragraph (2) are consistent, to the extent
23 the Secretary determines practicable and appro-
24 priate, with such standards.

1 (C) AUTHORITY WITH RESPECT TO CER-
2 TAIN FACILITIES.—The Secretary may, by regu-
3 lation, exempt or modify the requirements for
4 compliance under this section and the amend-
5 ments made by this section with respect to fa-
6 cilities that are solely engaged in—

7 (i) the production of food for animals
8 other than man or the storage of packaged
9 foods that are not exposed to the environ-
10 ment; or

11 (ii) the storage of raw agricultural
12 commodities for further distribution or
13 processing.

14 (D) SMALL BUSINESSES.—The Sec-
15 retary—

16 (i) shall consider the impact of any
17 guidance or regulations under this section
18 on small businesses; and

19 (ii) shall issue guidance to assist small
20 businesses in complying with the require-
21 ments of this section and the amendments
22 made by this section.

23 (4) NO EFFECT ON EXISTING HACCP AUTHORI-
24 TIES.—Nothing in this section or the amendments
25 made by this section limits the authority of the Sec-

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

11 (5) CONSIDERATION.—When implementing sec-
12 tions 418 and 418A of the Federal Food, Drug, and
13 Cosmetic Act, as added by paragraph (2), the Sec-
14 retary may take into account differences between
15 food intended for human consumption and food in-
16 tended for consumption by animals other than man.

17 (6) EFFECTIVE DATE.—

18 (A) GENERAL RULE.—The amendments
19 made by subsection (a) and this subsection
20 shall take effect 18 months after the date of the
21 enactment of this Act.

22 (B) EXCEPTIONS.—Notwithstanding sub-
23 paragraph (A)—

24 (i) the amendments made by sub-
25 section (a) and this subsection shall apply

1 to a small business (as defined by the Sec-
2 retary) after the date that is 2 years after
3 the date of the enactment of this Act; and

4 (ii) the amendments made by sub-
5 section (a) and this subsection shall apply
6 to a very small business (as defined by the
7 Secretary) after the date that is 3 years
8 after the date of the enactment of this Act.

9 (b) **FINISHED PRODUCT TEST RESULTS FROM CAT-**
10 **EGORY 1 FACILITIES.**—

11 (1) **ADULTERATION.**—Section 402 (21 U.S.C.
12 342), as amended by subsection (a), is amended by
13 adding at the end the following:

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

16 (2) **REQUIREMENTS.**—Chapter IV (21 U.S.C.
17 341 et seq.), as amended, is further amended by
18 adding at the end the following:

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

21 “(a) **AUTHORITY.**—Beginning on the date specified
22 in subsection (c), the Secretary shall require, after public
23 notice and an opportunity for comment, the submission
24 to the Secretary of finished product test results by the
25 owner, operator, or agent of each category 1 facility sub-

1 ject to good manufacturing practices regulations docu-
2 menting the presence of contaminants in food in the pos-
3 session or control of such facility posing a risk of severe
4 adverse health consequences or death.

5 “(b) CONSIDERATIONS.—The Secretary shall require
6 submissions under subsection (a)—

7 “(1) as the Secretary determines feasible and
8 appropriate; and

9 “(2) taking into consideration available data
10 and information on the potential risks posed by the
11 facility.

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

14 “(1) the date of completion of the pilot projects
15 and feasibility study under subsections (d) and (e);
16 and

17 “(2) the date that is 2 years after the date of
18 the enactment of this section.

19 “(d) PILOT PROJECTS.—The Secretary shall conduct
20 2 or more pilot projects to evaluate the feasibility of col-
21 lecting positive finished product testing results from cat-
22 egory 1 facilities, including the value and feasibility of re-
23 porting corrective actions taken when positive finished
24 product test results are reported to the Secretary.

1 “(e) FEASIBILITY STUDY.—The Secretary shall as-
2 sess the feasibility and benefits of the reporting by facili-
3 ties subject to good manufacturing practices regulations
4 of appropriate finished product testing results from cat-
5 egory 1 facilities to the Secretary, including the extent to
6 which the collection of such finished product testing re-
7 sults will help the Secretary assess the risk presented by
8 a facility or product category.

9 “(f) LIMITATIONS.—Nothing in this section shall be
10 construed—

11 “(1) to require the Secretary to mandate test-
12 ing or submission of test results that the Secretary
13 determines would not provide useful information in
14 assessing the potential risk presented by a facility or
15 product category; or

16 “(2) to limit the Secretary’s authority under
17 any other provisions of law to require any person to
18 provide access, or to submit information or test re-
19 sults, to the Secretary, including the ability of the
20 Secretary to require field or other testing and to ob-
21 tain test results in the course of an investigation of
22 a potential food-borne illness or contamination inci-
23 dent.

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

4 (c) FOOD DEFENSE.—

5 (1) ADULTERATION.—Section 402(j), as added
6 by subsection (a), is amended by striking “and
7 418A” and inserting “, 418A, or 418C”.

8 (2) REQUIREMENTS.—Chapter IV (21 U.S.C.
9 341 et seq.), as amended, is further amended by
10 adding at the end the following:

11 **“SEC. 418C. FOOD DEFENSE.**

12 “(a) IN GENERAL.—Before a facility (as defined in
13 section 418(i)) introduces or delivers for introduction into
14 interstate commerce any shipment of food, the owner, op-
15 erator, or agent of the facility shall develop and implement
16 a written food defense plan (in this section referred to as
17 a ‘food defense plan’).

18 “(b) CONTENTS.—The food defense plan shall in-
19 clude each of the following elements:

20 “(1) A food defense assessment to identify con-
21 ditions and practices that may permit a hazard that
22 may be intentionally introduced, including by an act
23 of terrorism. This assessment shall evaluate proc-
24 essing security, cybersecurity, material security (in-
25 cluding ingredients, finished product, and pack-

1 aging), personnel security, storage security, shipping
2 and receiving security, and utility security.

3 “(2) A description of the preventive measures
4 being implemented as a result of such assessment to
5 minimize the risk of intentional contamination.

6 “(3) A description of the procedures to check
7 for and identify any circumstances in which the pre-
8 ventive measures are not fully implemented or were
9 ineffective.

10 “(4) A description of the procedures for taking
11 corrective actions to ensure that when preventive
12 measures have not been properly implemented or
13 have been ineffective, appropriate action is taken—

14 “(A) to reduce the likelihood of recurrence
15 of the failure; and

16 “(B) to assess the consequences of the fail-
17 ure.

18 “(5) A description of evaluation activities for
19 the preventive measures, including a review of
20 records provided for under paragraph (6) and proce-
21 dures to periodically test the effectiveness of the
22 plan.

23 “(6) A description of the facility’s record-keep-
24 ing procedures, including records documenting im-

1 plementation of the procedures under paragraphs
2 (3), (4), and (5).

3 “(c) HAZARD.—For purposes of this section, the
4 term ‘hazard that may be intentionally introduced, includ-
5 ing by an act of terrorism’ means a hazard for which a
6 prudent person who, as applicable, manufactures, proc-
7 esses, packs, transports, or holds food, would establish
8 preventive measures because the hazard has been identi-
9 fied by a food defense assessment by application of—

10 “(1) a targeting assessment tool recommended
11 by the Secretary by guidance; or

12 “(2) a comparable targeting assessment tool.

13 “(d) FOOD DEFENSE HAZARDS IDENTIFIED BY THE
14 SECRETARY.—

15 “(1) ESTABLISHMENT.—The Secretary may es-
16 tablish by regulation or guidance preventive meas-
17 ures for specific product types to prevent intentional
18 contamination throughout the supply chain. The
19 owner, operator, or agent of a facility shall imple-
20 ment any preventive measures identified by the Sec-
21 retary under this paragraph.

22 “(2) ALTERNATIVE MEASURES.—Such regula-
23 tion or guidance shall allow the owner, operator, or
24 agent of a facility to implement an alternative pre-
25 ventive measure to one established by the Secretary,

1 provided that, in response to a request by the Sec-
2 retary, the owner, operator, or agent can present to
3 the Secretary data or other information sufficient to
4 demonstrate that the alternative measure effectively
5 addresses the hazard.

6 “(e) REQUIREMENT TO REASSESS AND REVISE.—

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

9 “(A) review the food defense assessment
10 under subsection (b)(1) for the facility and, as
11 necessary, revise the food defense assessment
12 under subsection (b)(1) for the facility—

13 “(i) not less than every 2 years;

14 “(ii) if there is a change in the proc-
15 ess or product that could affect the food
16 defense assessment; and

17 “(iii) if the Secretary determines that
18 it is appropriate to protect public health;
19 and

20 “(B) whenever there is a change in the
21 food defense assessment, revise the preventive
22 measures under subsection (b)(2) for the facil-
23 ity as necessary to ensure that for all hazards
24 identified, the risk is minimized, or document

1 the basis for the conclusion that no such revision is needed.

2
3 “(2) NONDELEGATION.—Any revisions ordered
4 by the Secretary under this subsection shall be ordered
5 by the Secretary or an official designated by
6 the Secretary. An official may not be so designated
7 unless the official is the director of the district
8 under this Act in which the facility involved is located,
9 or is an official senior to such director.

10 “(f) RECORDKEEPING.—The owner, operator, or
11 agent of a facility shall maintain, for not less than 2 years,
12 records documenting the activities described in subsections
13 (b) and (e).

14 “(g) ACCESS TO PLAN.—

15 “(1) ON INSPECTION.—An officer or employee
16 of the Secretary shall have access to the food defense
17 plan of a facility under section 414(a) only if
18 the Secretary, through an official who is the director
19 of the district under this Act in which the facility is
20 located or an official who is senior to such a director,
21 provides notice under section 414(a)(1)(C).

22 “(2) NONDISCLOSURE.—A food defense plan,
23 and any information derived from such a plan, shall
24 be exempt from disclosure under section 552 of title
25 5, United States Code.”.

1 (3) PROHIBITION.—Section 301(j) (21 U.S.C.
2 331(j)) is amended by inserting after “entitled to
3 protection” the following: “or a food defense plan, or
4 any information derived from such a plan, under
5 section 418C”.

6 **SEC. 103. PERFORMANCE STANDARDS.**

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

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

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

16 **“SEC. 419. PERFORMANCE STANDARDS.**

17 “(a) PERFORMANCE STANDARDS.—The Secretary
18 shall, not less frequently than every 2 years, review and
19 evaluate epidemiological data and other appropriate
20 sources of information, including research under section
21 123 of the Food Safety Enhancement Act of 2009, to
22 identify the most significant food-borne contaminants and
23 the most significant resulting hazards. The Secretary shall
24 issue, as soon as practicable, through guidance or by regu-
25 lation, science-based performance standards (which may

1 include action levels) applicable to foods or food classes,
2 as appropriate, to minimize to an acceptable level, prevent,
3 or eliminate the occurrence of such hazards. Such stand-
4 ards shall be applicable to foods and food classes. Notwith-
5 standing the timelines set forth in this paragraph, the Sec-
6 retary shall as appropriate establish such science-based
7 performance standards for identified contaminants as nec-
8 essary to protect the public health.

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

18 “(c) SAMPLING PROGRAM.—In conjunction with the
19 establishment of a performance standard under this sec-
20 tion, the Secretary may make recommendations to indus-
21 try for conducting product sampling.

22 “(d) REVOCATION BY SECRETARY.—All performance
23 standards of the Food and Drug Administration applicable
24 to foods or food classes in effect on the date of the enact-
25 ment of this section, or issued under this section, shall

1 remain in effect until revised or revoked by the Sec-
2 retary.”.

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

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

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

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

22 (b) STANDARDS.—Chapter IV (21 U.S.C. 341 et
23 seq.), as amended by sections 102(b) and 103(b), is
24 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, in coordination
5 with the Secretary of Agriculture, shall establish by regu-
6 lation scientific and risk-based food safety standards for
7 the growing, harvesting, processing, packing, sorting,
8 transporting, and holding of those types of raw agricul-
9 tural commodities—

10 “(1) that are a fruit, vegetable, nut, or fungus;
11 and

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

16 “(b) CONTENTS.—The regulations under subsection
17 (a)—

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

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

1 tural commodities that are a fruit, vegetable,
2 nut, or fungus; and

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

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

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

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

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

20 “(6) may provide for coordination of education
21 and enforcement activities;

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

1 shed-protection efforts, and organic production
2 methods;

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

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

12 “(c) EDUCATION AND COMPLIANCE.—The Secretary
13 shall coordinate with the Secretary of Agriculture to pro-
14 vide for effective implementation of education and compli-
15 ance activities. The Secretary may contract and coordinate
16 with the agency or department designated by the Governor
17 of each State to perform activities to ensure compliance
18 with this section.”.

19 (c) TIMING.—

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

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

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

16 (e) UPDATE EXISTING GUIDANCE.—Not later than
17 1 year after the date of the enactment of this Act, the
18 Secretary of Health and Human Services shall update the
19 guidance document entitled “Guidance For Industry:
20 Guide To Minimize Microbial Food Safety Hazards For
21 Fresh Fruits And Vegetables” (issued on October 26,
22 1998) in accordance with this section and the amendments
23 made by this section.

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

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

4 “(h)(1) Each facility registered under section 415
5 shall be inspected—

6 “(A)(i) by one or more officers duly designated
7 under section 702 or other statutory authority by
8 the Secretary;

9 “(ii) for domestic facilities, by a Federal, State,
10 or local official recognized by the Secretary under
11 paragraph (2); or

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

15 “(B) at a frequency determined pursuant to a
16 risk-based schedule.

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

19 “(A) may recognize Federal, State, and local of-
20 ficials and agencies and representatives of foreign
21 countries as meeting standards established by the
22 Secretary for conducting inspections under this Act;
23 and

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

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

4 “(4) Such risk-based schedule shall provide for a fre-
5 quency of inspections commensurate with the risk pre-
6 sented by the facility and shall be based on the following
7 categories and inspection frequencies:

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

12 “(B) CATEGORY 2.—A category 2 food facility
13 is a low-risk facility that manufactures or processes
14 food or a facility that packs or labels food. The Sec-
15 retary shall randomly inspect a category 2 facility at
16 least every 18 months to 3 years.

17 “(C) CATEGORY 3.—A category 3 food facility
18 is a facility that holds food. The Secretary shall ran-
19 domly inspect a category 3 facility at least every 5
20 years.

21 “(5) The Secretary—

22 “(A) may, by guidance, modify the types of
23 food facilities within a category under paragraph
24 (4);

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

4 “(C) may inspect a facility more frequently
5 than the inspection frequency provided by paragraph
6 (4);

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

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

17 “(ii) after such publication, implement the
18 adjustments; and

19 “(E) except as provided in subparagraphs (B)
20 and (C), may not alter the inspection frequency
21 specified in paragraph (4)(A) for category 1 food fa-
22 cilities.

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

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

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

4 “(C) whether the facility importing or offering
5 for import into the United States food is certified by
6 a qualified certifying entity in accordance with sec-
7 tion 801(q); and

8 “(D) such other factors as the Secretary deter-
9 mines by guidance to be relevant to assessing the
10 risk presented by the facility.

11 “(7) Before establishing or modifying the categoriza-
12 tion under paragraph (4) of any food facility or type of
13 food facility, the Secretary shall publish a notice of the
14 proposed categorization in the Federal Register and pro-
15 vide a period of not less than 60 days for public comment
16 on the proposed categorization.”.

17 (b) REPORTS ON RISK-BASED INSPECTIONS OF FOOD
18 FACILITIES.—

19 (1) ANNUAL REPORT.—Not later than Decem-
20 ber 31 of each year, the Secretary of Health and
21 Human Services shall submit a report to the Com-
22 mittee on Energy and Commerce of the House of
23 Representatives and the Committee on Health, Edu-
24 cation, Labor, and Pensions of the Senate describ-
25 ing—

1 (A) the number of foreign and domestic fa-
2 cilities, by risk category, inspected under the
3 risk-based inspection schedule established under
4 section 704(h) of the Federal Food, Drug, and
5 Cosmetic Act, as added by subsection (a), in
6 the preceding fiscal year; and

7 (B) the costs of implementing the risk-
8 based inspection schedule for the preceding 12
9 months.

10 (2) THIRD-YEAR REPORT.—Not later than 3
11 years after the date of the enactment of this Act, the
12 Secretary of Health and Human Services shall sub-
13 mit a report to the Committee on Energy and Com-
14 merce of the House of Representatives and the Com-
15 mittee on Health, Education, Labor, and Pensions
16 of the Senate describing recommendations on the
17 risk-based inspection schedule under section 704(h)
18 of the Federal Food, Drug, and Cosmetic Act, as
19 added by subsection (a), including recommendations
20 for adjustments to the timing of the schedule and
21 other ways to improve the risk-based allocation of
22 resources by the Food and Drug Administration. In
23 making such recommendations, the Secretary shall
24 consider—

1 (A) the nature of the food products being
2 processed, stored, or transported;

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

5 (C) the inherent likelihood that the prod-
6 ucts will contribute to the risk of food-borne ill-
7 ness;

8 (D) the best available evidence concerning
9 reported illnesses associated with the foods
10 processed, stored, held, or transported in the
11 category of facilities; and

12 (E) the overall record of compliance with
13 food safety law among facilities in the category,
14 including compliance with applicable perform-
15 ance standards and the frequency of recalls.

16 **SEC. 106. ACCESS TO RECORDS.**

17 (a) RECORDS ACCESS.—Subsection (a) of section 414
18 (21 U.S.C. 350e) is amended to read as follows:

19 “(a) RECORDS ACCESS.—

20 “(1) RECORDS ACCESS DURING AN INSPEC-
21 TION.—

22 “(A) IN GENERAL.—Except as provided in
23 paragraph (3), each person who manufactures,
24 processes, packs, transports, distributes, re-
25 ceives, or holds an article of food in the United

1 States or for import into the United States
2 shall, at the request of an officer or employee
3 duly designated by the Secretary, permit such
4 officer or employee, upon presentation of appro-
5 priate credentials, at reasonable times and with-
6 in reasonable limits and in a reasonable man-
7 ner, to have access to and copy all records re-
8 lating to such article bearing on whether the
9 food may be adulterated, misbranded, or other-
10 wise in violation of this Act, including all
11 records collected or developed to comply with
12 section 418 or 418A.

13 “(B) SCOPE OF RECORDS.—The require-
14 ment under subparagraph (A) applies to all
15 records relating to the manufacture, processing,
16 packing, transporting, distribution, receipt,
17 holding, or importation of such article main-
18 tained by or on behalf of such person in any
19 format (including paper and electronic formats)
20 and at any location.

21 “(C) IMMEDIATE AVAILABILITY WITH NO-
22 TICE.—Records not required to be made avail-
23 able immediately on commencement of an in-
24 spection under subparagraph (A) shall nonethe-
25 less be made available immediately on com-

1 mencement of such an inspection if, by a rea-
2 sonable time before such inspection, the Sec-
3 retary by letter to the person identifies the
4 records to be made available during such in-
5 spection. Nothing in this subparagraph shall
6 be construed as permitting a person to refuse to
7 produce records required under and in accord-
8 ance with subparagraph (A) due to failure of
9 the Secretary to provide notice under this
10 paragraph.

11 “(2) ADDITIONAL AUTHORITIES TO ACCESS
12 RECORDS REMOTELY; SUBMISSION OF RECORDS TO
13 THE SECRETARY.—

14 “(A) REMOTE ACCESS IN EMERGENCIES.—

15 If the Secretary has a reasonable belief that an
16 article of food presents a threat of serious ad-
17 verse health consequences or death to humans
18 or animals, the Secretary may require each per-
19 son who manufactures, processes, packs, trans-
20 ports, distributes, receives, holds, or imports
21 such article of food, or any article of food that
22 the Secretary determines may be affected in a
23 similar manner, to submit to the Secretary all
24 records reasonably related to such article of
25 food as soon as is reasonably practicable, after

1 receiving written notice (including by notice
2 served personally and outside normal business
3 hours to an agent identified under subpara-
4 graph (E) or (F) of section 415(a)(2)) of such
5 requirement.

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

19 “(C) ELECTRONIC SUBMISSION.—If the
20 records required to be submitted to the Sec-
21 retary under subparagraph (A) or (B) are avail-
22 able in electronic format, such records shall be
23 submitted electronically unless the Secretary
24 specifies otherwise in the notice under such sub-
25 paragraph.

1 “(3) LIMITED RECORDS ACCESS ON FARMS.—

2 “(A) APPLICATION.—Paragraphs (1) and
3 (2) do not apply with respect to farms, except
4 as provided in this paragraph.

5 “(B) IN GENERAL.—A person who is the
6 owner, operator, or agent of a farm (as defined
7 in section 415) shall, at the request of an offi-
8 cer or employee duly designated by the Sec-
9 retary, permit such officer or employee, at rea-
10 sonable times and within reasonable limits and
11 in a reasonable manner, to have access to and
12 copy all records relating to an article of food
13 produced, manufactured, processed, packed, or
14 held on such farm as specified in paragraphs
15 (1) and (2) if—

16 “(i) such article of food is a fruit, veg-
17 etable, nut, or fungus that is the subject of
18 a standard issued under section 419A; or

19 “(ii) such article of food is the subject
20 of an active investigation by the Secretary
21 of a food borne illness outbreak and is not
22 a grain or similarly handled commodity as
23 defined in subsection (c)(4)(C)(ii).

24 “(C) RECORDS ACCESS ON FARMS PRIOR
25 TO RULEMAKING.—

1 “(i) IN GENERAL.—As soon as prac-
2 ticable after the enactment of this para-
3 graph, the Secretary shall, in coordination
4 with the Secretary of Agriculture, identify
5 1 or more fruits, vegetables, nuts, or fungi
6 for which the Secretary shall have access
7 to records on farms. Such identification
8 shall be made by guidance, following notice
9 and public comment.

10 “(ii) IDENTIFICATION OF RAW AGRI-
11 CULTURAL COMMODITIES.—The Secretary,
12 in coordination with the Secretary of Agri-
13 culture, shall make the identification in
14 clause (i), based on any past food borne ill-
15 ness outbreak attributed to the fruit, vege-
16 table, nut, or fungus—

17 “(I) in the United States and the
18 risk that a similar outbreak could
19 occur again in the United States; or

20 “(II) in a foreign country and
21 the risk that a similar outbreak could
22 occur in the United States.

23 “(iii) DURATION OF AUTHORITY.—
24 The authority to have access to records for
25 a fruit, vegetable, nut, or fungus under

1 this subparagraph shall begin on the date
2 on which the Secretary identifies such
3 fruit, vegetable, nut, or fungus under
4 clause (i) and shall terminate on the effec-
5 tive date of a final rule issued by the Sec-
6 retary under section 419A.

7 “(iv) SCOPE OF RECORDS ACCESS.—
8 In the guidance under clause (i), and for
9 the period specified in clause (iii), the Sec-
10 retary, in coordination with the Secretary
11 of Agriculture, shall determine the scope of
12 the records to which the Secretary shall
13 have access under this subparagraph.

14 “(D) RULE OF CONSTRUCTION.—This
15 paragraph shall not be construed as limiting ac-
16 cess to any records authorized under—

17 “(i) this Act or the Public Health
18 Service Act, as in effect on the day before
19 the date of the enactment of this para-
20 graph; or

21 “(ii) regulations issued under such
22 Acts on any date before the date of the en-
23 actment of this paragraph.”.

24 (b) REGULATIONS CONCERNING RECORDKEEPING.—

1 (1) AMENDMENT.—Subsection (b) of section
2 414 (21 U.S.C. 350c) is amended to read as follows:

3 “(b) REGULATIONS CONCERNING RECORD-
4 KEEPING.—The Secretary, in consultation and coordina-
5 tion, as appropriate, with other Federal departments and
6 agencies with responsibilities for regulating food safety,
7 shall by regulation establish requirements regarding the
8 establishment and maintenance, for not longer than 3
9 years, of records by persons who manufacture, process,
10 pack, transport, distribute, receive, or hold food in the
11 United States or for import into the United States. The
12 Secretary shall take into account the size of a business
13 in promulgating regulations under this subsection. The
14 Secretary shall consult with the Secretary of Agriculture
15 in promulgating regulations with respect to farms under
16 this subsection and shall take into account the nature of
17 and impact on farms in promulgating such regulations.
18 The only distribution records which may be required of
19 restaurants under this subsection are those showing the
20 restaurant’s suppliers and subsequent distribution other
21 than to consumers.”.

22 (2) APPLICATION.—The Secretary of Health
23 and Human Services shall promulgate revised regu-
24 lations to implement section 414(b) of the Federal
25 Food, Drug, and Cosmetic Act, as amended by this

1 subsection. Section 414(b) of the Federal Food,
2 Drug, and Cosmetic Act and regulations thereunder,
3 as in effect on the day before the date of the enact-
4 ment of this Act, shall apply to acts and omissions
5 occurring before the effective date of such revised
6 regulations.

7 (c) CONFORMING AMENDMENTS.—Section 704(a)(1)
8 (21 U.S.C. 374(a)(1)) is amended—

9 (1) in the second sentence—

10 (A) by striking “(excluding farms or res-
11 taurants)” and inserting “(excluding farms, ex-
12 cept as provided in section 414(a)(3))”;

13 (B) by inserting “receives,” before
14 “holds”;

15 (C) by striking “described in section 414”
16 and inserting “described in or required under
17 section 414”; and

18 (D) by striking “when the Secretary has a
19 reasonable belief that an article of food is adul-
20 terated and presents a threat of serious adverse
21 health consequences or death to humans or ani-
22 mals” and inserting “bearing on whether such
23 food is adulterated, misbranded, or otherwise in
24 violation of this Act, including all records col-

1 lected or developed to comply with section 418
2 or 418A”; and

3 (2) in the fourth sentence—

4 (A) by striking “the preceding sentence”
5 and inserting “either of the preceding two sen-
6 tences”; and

7 (B) by inserting “recipes for food,” before
8 “financial data,”.

9 **SEC. 107. TRACEABILITY OF FOOD.**

10 (a) PROHIBITED ACT.—Section 301(e) (21 U.S.C.
11 331(e)) is amended by inserting “, the violation of any
12 requirement of the food tracing system under section
13 414(c);” before “or the refusal to permit access to or
14 verification or copying of any such required record”.

15 (b) IMPORTS.—Section 801(a) (21 U.S.C. 381(a)) is
16 amended by inserting “or (4) the requirements of section
17 414 have not been complied with regarding such article,”
18 before “then such article shall be refused admission”.

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

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

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

25 “(c) TRACING SYSTEM FOR FOOD.—

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

5 “(2) INFORMATION GATHERING.—

6 “(A) TRACING TECHNOLOGIES.—Before
7 issuing a proposed regulation under this sub-
8 section, the Secretary shall—

9 “(i) identify technologies and meth-
10 odologies for tracing the distribution his-
11 tory of a food that are, or may be, used by
12 members of different sectors of the food in-
13 dustry, including technologies and meth-
14 odologies to enable each person who pro-
15 duces, manufactures, processes, pack,
16 transports, or holds a food to—

17 “(I) maintain the full pedigree of
18 the origin and previous distribution
19 history of the food;

20 “(II) link that history with the
21 subsequent distribution of the food;

22 “(III) establish and maintain a
23 system for tracing the food that is
24 interoperable with the systems estab-

1 lished and maintained by other such
2 persons; and

3 “(IV) use a unique identifier for
4 each facility owned or operated by
5 such person for such purpose, as spec-
6 ified under section 1011; and

7 “(ii) to the extent practicable, as-
8 sess—

9 “(I) the costs and benefits associ-
10 ated with the adoption and use of
11 such technologies;

12 “(II) the feasibility of such tech-
13 nologies for different sectors of the
14 food industry; and

15 “(III) whether such technologies
16 are compatible with the requirements
17 of this subsection.

18 “(B) PUBLIC MEETINGS.—Before issuing a
19 proposed regulation under this subsection, the
20 Secretary shall conduct not less than 2 public
21 meetings in diverse geographical areas of the
22 United States to provide persons in different re-
23 gions an opportunity to provide input and infor-
24 mation to the Secretary.

1 “(C) PILOT PROJECTS.—Before issuing a
2 proposed regulation under this subsection, the
3 Secretary shall conduct 1 or more pilot projects
4 in coordination with 1 or more sectors of the
5 food industry to explore and evaluate tracing
6 systems for food. The Secretary shall coordinate
7 with the Secretary of Agriculture in conducting
8 pilot projects with respect to farms under this
9 subsection.

10 “(3) REGULATION.—

11 “(A) IN GENERAL.—Taking into account
12 information obtained through information gath-
13 ering under paragraph (2), the Secretary shall
14 issue regulations establishing a tracing system
15 that enables the Secretary to identify each per-
16 son who grows, produces, manufactures, proc-
17 esses, packs, transports, holds, or sells such
18 food in as short a timeframe as practicable but
19 no longer than 2 business days.

20 “(B) SCOPE OF REGULATION.—The Sec-
21 retary may include in the regulations estab-
22 lishing a tracing system—

23 “(i) the establishment and mainte-
24 nance of lot numbers;

1 “(ii) a standardized format for pedi-
2 gree information; and

3 “(iii) the use of a common nomen-
4 clature for food.

5 “(C) COORDINATION REGARDING FARM IM-
6 PACT.—In issuing regulations under this para-
7 graph that will impact farms, the Secretary—

8 “(i) shall coordinate with the Sec-
9 retary of Agriculture; and

10 “(ii) take into account the nature of
11 the impact of the regulations on farms.

12 “(4) EXEMPTIONS AND LIMITATIONS.—

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

16 “(i) produced on a farm; and

17 “(ii) sold by the owner, operator, or
18 agent in charge of such farm directly to a
19 consumer or to a restaurant or grocery
20 store.

21 “(B) FISHING VESSELS.—Food is exempt
22 from the requirements of this subsection if such
23 food is produced through the use of a fishing
24 vessel as defined in section 3(18) of the Magnu-
25 son-Stevens Fishery Conservation and Manage-

1 ment Act until such time as the food is sold by
2 the owner, operator, or agent in charge of such
3 fishing vessel.

4 “(C) GRAINS AND SIMILARLY HANDLED
5 COMMODITIES.—

6 “(i) LIMITATION ON EXTENT OF
7 TRACING.—In addition to the exemption
8 under subparagraph (A), any tracing sys-
9 tem established under this subsection with
10 regard to any grain or similarly handled
11 commodity shall be limited to enabling the
12 Secretary to identify persons who received,
13 processed, packed, transported, distributed,
14 held, or sold the grain or similarly handled
15 commodity from the initial warehouse op-
16 erator that held the grain or similarly han-
17 dled commodity for any period of time to
18 the ultimate consumer.

19 “(ii) DEFINITIONS.—In this subpara-
20 graph:

21 “(I) The term ‘grain or similarly
22 handled commodity’ means wheat,
23 corn, grain sorghum, barley, oats,
24 rice, wild rice, rye, soybeans, legumes,
25 sugar cane, sugar beets, sunflower

1 seed, rapeseed, canola, safflower,
2 flaxseed, mustard seed, crambe, ses-
3 ame seed, camelina, cottonseed, cocoa
4 beans, grass hay, and honey. The
5 term may include any other com-
6 modity as determined by the Sec-
7 retary in coordination with the Sec-
8 retary of Agriculture.

9 “(II) The term ‘warehouse oper-
10 ator’ has the meaning given that term
11 in section 2 of the United States
12 Warehouse Act (7 U.S.C. 241), except
13 that the term also includes any person
14 or entity that handles or stores agri-
15 cultural products for other persons or
16 entities or, in the case of a coopera-
17 tive, handles or stores agricultural
18 products for its members, as deter-
19 mined by the Secretary in coordina-
20 tion with the Secretary of Agriculture.

21 “(D) EXEMPTION OF OTHER FOODS.—The
22 Secretary may by notice in the Federal Register
23 exempt a food or a type of facility, farm, or res-
24 taurant from, or modify the requirements with
25 respect to, the requirements of this subsection

1 if the Secretary determines that a tracing sys-
2 tem for such food or type of facility, farm, or
3 restaurant is not necessary to protect the public
4 health.

5 “(E) RECORDKEEPING REGARDING PRE-
6 VIOUS SOURCES AND SUBSEQUENT RECIPI-
7 ENTS.—For a food or person covered by a limi-
8 tation or exemption under subparagraph (B),
9 (C), or (D), the Secretary shall require each
10 person who produces, receives, manufactures,
11 processes, packs, transports, distributes, or
12 holds such food to maintain records to identify
13 the immediate previous sources of such food
14 and its ingredients and the immediate subse-
15 quent recipients of such food.

16 “(F) RECORDKEEPING BY RESTAURANTS
17 AND GROCERY STORES.—For a food covered by
18 an exemption under subparagraph (A), res-
19 taurants and grocery stores shall keep records
20 documenting the farm that was the source of
21 the food.

22 “(G) RECORDKEEPING BY FARMS.—For a
23 food covered by an exemption under subpara-
24 graph (A), farms shall keep records, in elec-
25 tronic or non-electronic format, for at least 6

1 months documenting the restaurant or grocery
2 store to which the food was sold.”.

3 **SEC. 108. REINSPECTION AND FOOD RECALL FEES APPLI-**
4 **CABLE TO FACILITIES.**

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

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

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

12 “(1) that—

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

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

20 “(2) during such fiscal year is subject to a food
21 recall.

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

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

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

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

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

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

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

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

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

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

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

15 **SEC. 109. CERTIFICATION AND ACCREDITATION.**

16 (a) MISBRANDING.—

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

20 “(aa) If it is part of a shipment offered for import
21 into the United States and such shipment is in violation
22 of section 801(q) (requiring a certification of compliance
23 for certain food shipments).”.

24 (2) EFFECTIVE DATE.—The amendment made
25 by paragraph (1) shall apply to shipments offered

1 for import on or after the date that is 3 years after
2 the date of the enactment of this Act.

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

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

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

16 (3) by adding at the end of section 801 the fol-
17 lowing:

18 “(q) CERTIFICATIONS CONCERNING IMPORTED ARTI-
19 CLES.—

20 “(1) IN GENERAL.—

21 “(A) REQUIREMENT.—The Secretary may
22 require, as an additional condition of granting
23 admission to an article of food being imported
24 or offered for import into the United States,
25 that a qualified certifying entity provide a cer-

1 tification that the article complies with require-
2 ments of this Act as specified by the Secretary
3 if—

4 “(i) for food imported from a par-
5 ticular country, territory, or region, the
6 Secretary finds, based on scientific, risk-
7 based evidence, that the government con-
8 trols in such country, territory, or region
9 are inadequate to ensure that the article is
10 safe and that certification would assist the
11 Secretary in determining whether to refuse
12 to admit such article under subsection (a);

13 “(ii) for a type of food for which there
14 is scientific evidence that there is a par-
15 ticular risk associated with the food that
16 presents a threat of serious adverse health
17 consequences or death, the Secretary finds
18 that certification would assist the Sec-
19 retary in determining whether to refuse to
20 admit such article under subsection (a); or

21 “(iii) for an article imported from a
22 particular country or territory, there is an
23 agreement between the Secretary and the
24 government of such country or territory
25 providing for such certification.

1 “(B) FORM OF CERTIFICATION.—A certifi-
2 cation under subparagraph (A) may take the
3 form of a statement that the article or the facil-
4 ity or farm that manufactured, processed,
5 packed, held, grew, harvested, sorted, or trans-
6 ported the article, as the case may be, complies
7 with requirements of this Act as specified by
8 the Secretary, or any other form as the Sec-
9 retary may specify, including a listing of cer-
10 tified facilities or other entities. The Secretary
11 may require that the certification include addi-
12 tional information regarding compliance.

13 “(C) ADEQUATE GOVERNMENT CON-
14 TROLS.—

15 “(i) PROCESS.—Before requiring a
16 certification under clause (ii) of subpara-
17 graph (A) with respect to a food, the Sec-
18 retary shall establish a process by which a
19 country or territory may demonstrate that
20 its government controls are adequate to
21 ensure that such food exported from its
22 territory to the United States is safe.

23 “(ii) DEMONSTRATION.—The Sec-
24 retary shall not require a certification
25 under clause (ii) of subparagraph (A) for

1 a food exported from a country or terri-
2 tory, if that country or territory has dem-
3 onstrated, pursuant to the process estab-
4 lished by the Secretary under clause (i),
5 that its government controls are adequate
6 to ensure that such food exported from its
7 territory to the United States is safe.

8 “(D) NOTICE OF CANCELLATION OR SUS-
9 PENSION OF CERTIFICATION.—As a condition
10 on acceptance of certifications from a qualified
11 certifying entity, the Secretary shall require the
12 qualified certifying entity to notify the Sec-
13 retary whenever the qualified certifying entity
14 cancels or suspends the certification of any fa-
15 cility or other entity included in a listing under
16 subparagraph (B).

17 “(E) CONSISTENCY WITH INTERNATIONAL
18 OBLIGATIONS.—The Secretary shall apply this
19 paragraph consistently with United States obli-
20 gations under international agreements.

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

24 “(A) an agency or a representative of the
25 government of the country from which the arti-

1 cle originated, as designated by such govern-
2 ment or the Secretary; or

3 “(B) an individual or entity determined by
4 the Secretary or an accredited body recognized
5 by the Secretary to be qualified to provide a
6 certification under paragraph (1).

7 “(3) NO CONFLICTS OF INTEREST.—

8 “(A) IN GENERAL.—The Secretary shall
9 issue regulations to ensure that any qualified
10 certifying entity and its auditors are free from
11 conflicts of interest. In issuing these regula-
12 tions, the Secretary may rely on or incorporate
13 international certification standards.

14 “(B) REGULATIONS.—Such regulations
15 shall require that—

16 “(i) the qualified certifying entity
17 shall have a committee or management
18 structure for safeguarding impartiality;

19 “(ii) conflict of interest policies for a
20 qualified certifying entity and auditors act-
21 ing for the qualified certifying entity shall
22 be written;

23 “(iii) the qualified certifying entity
24 shall not be owned, operated, or controlled
25 by a producer, manufacturer, processor,

1 packer, holder, supplier, or vendor of any
2 article of the type it certifies;

3 “(iv) the qualified certifying entity
4 shall not have any ownership or financial
5 interest in any product, producer, manu-
6 facturer, processor, packer, holder, supplier
7 or vendor of the type it certifies;

8 “(v) no auditor acting for the quali-
9 fied certifying entity (or spouse or minor
10 children) shall have any significant owner-
11 ship or other financial interest regarding
12 any product of the type it certifies;

13 “(vi) the qualified certifying entity
14 shall—

15 “(I) obtain and maintain annual
16 declarations from all personnel who
17 may be directly involved in the per-
18 formance of audits as to whether they
19 do or do not have direct financial in-
20 terests in any producer, manufacturer,
21 processor, packer, holder, supplier, or
22 vendor of foods, and a list of any such
23 companies in which they do have fi-
24 nancial interests or by which they
25 were employed in the past year; and

1 “(II) when an auditor is assigned
2 to audit a facility, require that indi-
3 vidual to affirm that he or she has no
4 financial interest in the company that
5 owns or operates that facility and was
6 not employed by that facility in the
7 previous year;

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

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

1 “(ix) no auditors acting for the quali-
2 fied certifying entity shall participate in an
3 audit of a facility they were employed by
4 within the last 12 months;

5 “(x) fees charged or accepted shall
6 not be contingent or based upon the report
7 made by the qualified certifying entity or
8 any personnel involved in the audit proc-
9 ess;

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

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

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

23 “(xiv) the qualified certifying entity
24 and its auditors shall sign a statement at-
25 testing to compliance with the conflict of

1 interests requirements under this para-
2 graph; and

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

12 “(C) DEFINITIONS.—In this paragraph:

13 “(i) The term ‘anything of value’ in-
14 cludes gifts, gratuities, reimbursement of
15 non-audit-related expenses, entertainment,
16 loans, or any other form of compensation
17 in cash or in kind.

18 “(ii) The term ‘direct financial inter-
19 est’ does not include any ownership of mu-
20 tual funds that have a financial interest in
21 a company.

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

24 “(A) require that, to the extent applicable,
25 any certification provided by a qualified certi-

1 fying entity be renewed by such entity at such
2 times as the Secretary determines appropriate;
3 and

4 “(B) refuse to accept any certification if
5 the Secretary determines that such certification
6 is no longer valid or reliable.

7 “(5) ON-SITE AUDITS.—In evaluating whether
8 an accreditation body meets, or continues to meet,
9 the standards for recognition under this subsection,
10 or whether to accept certifications from a qualified
11 certifying entity, the Secretary may—

12 “(A) observe on-site audits of qualified cer-
13 tifying entities by such accreditation body; or

14 “(B) for any facility that is certified by a
15 qualified certifying entity, upon request of an
16 officer or employee designated by the Secretary
17 and upon presentation of appropriate creden-
18 tials, at reasonable times and within reasonable
19 limits and in a reasonable manner, conduct an
20 on-site audit of the facility, which shall include
21 access to, and copying and verification of, any
22 related records.

23 “(6) ELECTRONIC SUBMISSION.—The Secretary
24 shall provide, in coordination with the Commissioner
25 responsible for Customs and Border Protection, for

1 the electronic submission of certifications under this
2 subsection.

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

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

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

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

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

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

22 “(a) IN GENERAL.—

23 “(1) REQUIREMENT.—Whenever analytical test-
24 ing of an article of food is conducted as part of testi-
25 mony for the purposes of section 801(a), or for such

1 other purposes as the Secretary deems appropriate
2 through regulation or guidance, such testing shall be
3 conducted by a laboratory that—

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

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

10 “(2) INDEPENDENCE OF LABORATORY.—

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

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

22 “(b) RECOGNITION OF LABORATORY ACCREDITATION
23 BODIES.—The Secretary shall establish and implement a
24 program for the recognition, based on standards the Sec-
25 retary deems appropriate, of laboratory accreditation bod-

1 ies that accredit laboratories to perform analytical testing
2 for the purposes of this section. The Secretary shall issue
3 regulations or guidance to implement this program.

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

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

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

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

23 “(e) NOTIFICATION OF ACCREDITATION OF LABORA-
24 TORY.—An accreditation body that has been recognized
25 pursuant to this section shall promptly notify the Sec-

1 retary whenever it accredits a laboratory for the purposes
2 of this section and whenever it withdraws or suspends
3 such accreditation.

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

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

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

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

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

23 “(B) identify the article tested;

24 “(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) FEDERAL LABORATORY TESTING.—If Customs
8 and Border Protection laboratory testing concludes that
9 an article of food is adulterated or misbranded, the Sec-
10 retary shall consider and utilize as appropriate the testing
11 results issued by the Customs and Border Protection lab-
12 oratories in making a decision about the admissibility of
13 the product.

14 “(j) NO LIMIT ON AUTHORITY.—Nothing in this sec-
15 tion shall be construed to limit—

16 “(1) the ability of the Secretary to review and
17 act upon information from the analytical testing of
18 food (including under this section), including deter-
19 mining the sufficiency of such information and test-
20 ing; or

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

1 **SEC. 111. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
2 **OF ADULTERATED OR MISBRANDED FOOD.**

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

6 “(v)(1) The failure to notify the Secretary in viola-
7 tion of section 420(a).

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

10 (b) NOTIFICATION, NONDISTRIBUTION, AND RECALL
11 OF ADULTERATED OR MISBRANDED FOOD.—Chapter IV
12 (21 U.S.C. 341 et seq.), as amended by sections 102, 103,
13 and 104, is amended by adding at the end the following:
14 **“SEC. 420. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
15 **OF ADULTERATED OR MISBRANDED FOOD.**

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

18 “(1) IN GENERAL.—A responsible party as that
19 term is defined in section 417(a)(1) or a person re-
20 quired to register under section 801(s) that has rea-
21 son to believe that an article of food when intro-
22 duced into or while in interstate commerce, or while
23 held for sale (regardless of whether the first sale)
24 after shipment in interstate commerce, is adulter-
25 ated or misbranded in a manner that presents a rea-
26 sonable probability that the use or consumption of,

1 or exposure to, the article (or an ingredient or com-
2 ponent used in any such article) will cause a threat
3 of serious adverse health consequences or death to
4 humans or animals shall, as soon as practicable, no-
5 tify the Secretary of the identity and location of the
6 article.

7 “(2) MANNER OF NOTIFICATION.—Notification
8 under paragraph (1) shall be made in such manner
9 and by such means as the Secretary may require by
10 regulation or guidance.

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

16 “(1) recall such article; and

17 “(2) provide for notice, including to individuals
18 as appropriate, to persons who may be affected by
19 the recall.

20 “(c) ORDER TO CEASE DISTRIBUTION.—If the Sec-
21 retary has reason to believe that the use or consumption
22 of, or exposure to, an article of food may cause serious
23 adverse health consequences or death to humans or ani-
24 mals, the Secretary shall have the authority to issue an

1 order requiring any person who distributes such article to
2 immediately cease distribution of such article.

3 “(d) ACTION FOLLOWING ORDER.—Any person who
4 is subject to an order under subsection (c) shall imme-
5 diately cease distribution of such article and provide notifi-
6 cation as required by such order, and may appeal within
7 24 hours of issuance such order to the Secretary. Such
8 appeal may include a request for an informal hearing and
9 a description of any efforts to recall such article under-
10 taken voluntarily by the person, including after a request
11 under subsection (b). Except as provided in subsection (f),
12 an informal hearing shall be held as soon as practicable,
13 but not later than 5 calendar days, or less as determined
14 by the Secretary, after such an appeal is filed, unless the
15 parties jointly agree to an extension. After affording an
16 opportunity for an informal hearing, the Secretary shall
17 determine whether the order should be amended to require
18 a recall of such article. If, after providing an opportunity
19 for such a hearing, the Secretary determines that inad-
20 equate grounds exist to support the actions required by
21 the order, the Secretary shall vacate the order.

22 “(e) ORDER TO RECALL.—

23 “(1) AMENDMENT.—Except as provided under
24 subsection (f), if after providing an opportunity for
25 an informal hearing under subsection (d), the Sec-

1 retary determines that the order should be amended
2 to include a recall of the article with respect to
3 which the order was issued, the Secretary shall
4 amend the order to require a recall.

5 “(2) CONTENTS.—An amended order under
6 paragraph (1) shall—

7 “(A) specify a timetable in which the recall
8 will occur;

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

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

14 In providing for such notice, the Secretary may
15 allow for the assistance of health professionals, State
16 or local officials, or other individuals designated by
17 the Secretary.

18 “(3) NONDELEGATION.—An amended order
19 under this subsection shall be ordered by the Sec-
20 retary or an official designated by the Secretary. An
21 official may not be so designated unless the official
22 is the director of the district under this Act in which
23 the article involved is located, or is an official senior
24 to such director.

25 “(f) EMERGENCY RECALL ORDER.—

1 “(1) IN GENERAL.—If the Secretary has cred-
2 ible evidence or information that an article of food
3 subject to an order under subsection (c) presents an
4 imminent threat of serious adverse health con-
5 sequences or death to humans or animals, the Sec-
6 retary may issue an order requiring any person who
7 distributes such article—

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

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

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

1 termines that inadequate grounds exist to support
2 the actions required by the order, the Secretary shall
3 vacate the order.

4 “(3) NONDELEGATION.—An order under this
5 subsection shall be issued by the Commissioner of
6 Food and Drugs, the Principal Deputy Commis-
7 sioner, or the Associate Commissioner for Regu-
8 latory Affairs of the Food and Drug Administration.

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

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

17 “(1) the authority of the Secretary to issue an
18 order to cease distribution of, or to recall, an article
19 under any other provision of this Act or the Public
20 Health Service Act; or

21 “(2) the ability of the Secretary to request any
22 person to perform a voluntary activity related to any
23 article subject to this Act or the Public Health Serv-
24 ice Act.”.

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

7 (d) EFFECTIVE DATE.—Sections 301(vv)(1) and 420
8 of the Federal Food, Drug, and Cosmetic Act, as added
9 by subsections (a) and (b), shall apply with respect to arti-
10 cles of food as of such date, not later than 1 year after
11 the date of the enactment of this Act, as the Secretary
12 of Health and Human Services shall specify.

13 **SEC. 112. REPORTABLE FOOD REGISTRY; EXCHANGE OF IN-**
14 **FORMATION.**

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

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

20 “(A) a person who submits the registration
21 under section 415(a) for a food facility that is
22 required to be registered under section 415(a),
23 at which such food is manufactured, processed,
24 packed, or held;

1 “(B) a person who owns, operates, is an
2 agent of, or is otherwise responsible for such
3 food on a farm (as such term is defined in sec-
4 tion 1.227(b)(3) of title 21, Code of Federal
5 Regulations, or successor regulations) at which
6 such food is produced for sale or distribution in
7 interstate commerce;

8 “(C) a person who owns, operates, or is an
9 agent of a restaurant or other retail food estab-
10 lishment (as such terms are defined in section
11 1.227(b)(11) and (12), respectively, of title 21,
12 Code of Federal Regulations, or successor regu-
13 lations) at which such food is offered for sale;
14 or

15 “(D) a person that is required to register
16 pursuant to section 801(s) with respect to im-
17 portation of such food.”;

18 (2) in subsection (b), by adding at the end the
19 following:

20 “(3) REPORTING BY FARMS, RESTAURANTS,
21 AND RETAIL FOOD ESTABLISHMENTS.—In addition
22 to the electronic portal described in paragraph (1),
23 the Secretary shall make available alternative means
24 of reporting under this section with respect to farms,

1 restaurants, and other retail food establishments
2 with limited ability for such reporting.”;

3 (3) in subsection (d)(1)—

4 (A) in the matter preceding subparagraph
5 (A), by inserting “following a timely review of
6 any reasonably available data and information,”
7 after “reportable food,”;

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

10 (C) by redesignating subparagraph (B) as
11 subparagraph (C); and

12 (D) by inserting after subparagraph (A)
13 the following:

14 “(B) submit, with such report, through the
15 electronic portal, documentation of results from
16 any sampling and testing of such article, includ-
17 ing—

18 “(i) analytical results from testing of
19 such article conducted by or on behalf of
20 the responsible party under section 418,
21 418A, 419, 419A, or 714;

22 “(ii) analytical results from testing
23 conducted by or on behalf of such respon-
24 sible party of a component of such article;

1 “(iii) analytical results of environ-
2 mental testing of any facility at which such
3 article, or a component of such article, is
4 manufactured, processed, packed, or held;
5 and

6 “(iv) any other information the Sec-
7 retary determines is necessary to evaluate
8 the adulteration of such article, any com-
9 ponent of such article, any other article of
10 food manufactured, processed, packed or
11 held in the same manner as, or at the
12 same facility as, such article, or any other
13 article containing a component from the
14 same source as a component of such arti-
15 cle; and”;

16 (4) in subsection (e)—

17 (A) in paragraph (1), by inserting “if the
18 responsible party is required to register” after
19 “415(a)(3)”;

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

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

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

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

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

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

10 “(B) Any such information provided to another Fed-
11 eral agency shall not be disclosed by such agency except
12 in any action or proceeding under the laws of the United
13 States to which the receiving agency or the United States
14 is a party.

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

21 “(B) Any such information provided to a State or
22 local government agency shall not be disclosed by such
23 agency.

24 “(3) In carrying out this Act, the Secretary may pro-
25 vide to any person any information relating to food that

1 is exempt from disclosure pursuant to section 552(a) of
2 title 5, United States Code, by reason of subsection (b)(4)
3 of such section, if the Secretary determines that providing
4 the information to the person is appropriate under the cir-
5 cumstances and the recipient provides adequate assur-
6 ances to the Secretary that the recipient will preserve the
7 confidentiality of the information.

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

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

14 “(B) any international organization established
15 by law, treaty, or other governmental action and
16 having responsibility—

17 “(i) to facilitate global or regional harmo-
18 nization of standards and requirements in an
19 area of responsibility of the Food and Drug Ad-
20 ministration; or

21 “(ii) to promote and coordinate public
22 health efforts,

23 if the agency or organization provides adequate as-
24 surances to the Secretary that the agency or organi-

1 zation will preserve the confidentiality of the infor-
2 mation.

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

10 “(d) Except as provided in subsection (e), the Sec-
11 retary shall not be required to disclose under section 552
12 of title 5, United States Code, or any other provision of
13 law any information relating to food obtained from a Fed-
14 eral, State, or local government agency, or from a foreign
15 government agency, or from an international organization
16 described in subsection (b)(4), if the agency or organiza-
17 tion has requested that the information be kept confiden-
18 tial, or has precluded such disclosure under other use limi-
19 tations, as a condition of providing the information.

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

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

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

9 **SEC. 113. SAFE AND SECURE FOOD IMPORTATION PRO-**
10 **GRAM.**

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

13 **“SEC. 805. SAFE AND SECURE FOOD IMPORTATION PRO-**
14 **GRAM.**

15 “(a) IN GENERAL.—The Secretary may establish by
16 regulation or guidance in coordination with the Commis-
17 sioner responsible for Customs and Border Protection a
18 program that facilitates the movement of food through the
19 importation process under this Act if the importer of such
20 food—

21 “(1) verifies that each facility involved in the
22 production, manufacture, processing, packaging, and
23 holding of the food is in compliance with the food
24 safety and security guidelines developed under sub-
25 section (b) with respect to such food;

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

4 “(3) provides supporting information to the
5 Secretary.

6 “(b) GUIDELINES.—

7 “(1) DEVELOPMENT.—For purposes of the pro-
8 gram established under subsection (a), the Secretary
9 shall develop in consultation with the Commissioner
10 responsible for Customs and Border Protection safe-
11 ty and security guidelines applicable to the importa-
12 tion of food taking into account, to the extent appro-
13 priate, other relevant Federal programs, such as the
14 Customs-Trade Partnership Against Terrorism (C-
15 TPAT) programs under section 211 of the Security
16 and Accountability for Every Port Act of 2006.

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

19 “(A) The personnel of the person import-
20 ing the food.

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

23 “(C) The sufficiency of preventive controls
24 for food and ingredients purchased by such per-
25 son.

1 “(D) Vendor and supplier information.

2 “(E) Other programs for certification or
3 verification by a qualified certifying entity used
4 by the importer.

5 “(F) Such other factors as the Secretary
6 determines necessary.”.

7 **SEC. 114. INFANT FORMULA.**

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

11 “(bb) If it is a new infant formula and—

12 “(1) it is not the subject of a registration made
13 pursuant to section 412(c)(1)(A);

14 “(2) it is not the subject of a submission made
15 pursuant to section 412(c)(1)(B), or

16 “(3) at least 90 days have not passed since the
17 making of such registration or of such submission to
18 the Secretary.”.

19 (b) REQUIREMENTS.—Section 412 (21 U.S.C. 350a)
20 is amended—

21 (1) in subsection (c)(1)(B), by striking “(c)(1)”
22 at the end and inserting “(d)(1), subject to sub-
23 section (d)(2)(B)”;

24 (2) in subsection (d)(1)—

1 (A) by striking “and” at the end of sub-
2 paragraph (C);

3 (B) by striking the period at the end of
4 subparagraph (D) and inserting “, and”; and

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

6 “(E) information on any new ingredient in
7 accordance with paragraph (2)(A).”;

8 (3) in subsection (d), by redesignating para-
9 graphs (2) and (3) as paragraphs (3) and (4), re-
10 spectively; and

11 (4) by inserting after paragraph (1) of sub-
12 section (d) the following:

13 “(2)(A) The description of any new infant formula
14 required under paragraph (1) shall include, for any new
15 ingredient for use in the formula—

16 “(i) a citation to a prior approval by the Sec-
17 retary of the new ingredient for use in infant for-
18 mula under section 409;

19 “(ii) a citation to or information showing a
20 prior consideration of the new ingredient for use in
21 infant formula under any program established by the
22 Secretary for the review of ingredients used in food;
23 or

24 “(iii) for a new ingredient that is not a food ad-
25 ditive or a color additive, information equivalent to

1 that provided under any program established by the
2 Secretary for the review of ingredients used in food.
3 “(B) If the information submitted under subpara-
4 graph (A) is the information described in clause (iii) of
5 such subparagraph, the 90 day period provided by sub-
6 section (c)(1)(B) shall not commence until the Secretary
7 has completed review of the information submitted under
8 such clause and has provided the submitter notice of the
9 results of such review.”.

10 **Subtitle B—Intervention**

11 **SEC. 121. SURVEILLANCE.**

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

16 (b) FOOD-BORNE ILLNESS SURVEILLANCE SYS-
17 TEMS.—The Secretary of Health and Human Services (in
18 this subtitle referred to as the “Secretary”), acting
19 through the Director of the Centers for Disease Control
20 and Prevention, shall enhance food-borne illness surveil-
21 lance systems to improve the collection, analysis, report-
22 ing, and usefulness of data on food-borne illnesses by—

23 (1) coordinating Federal, State, and local food-
24 borne illness surveillance systems, including com-
25 plaint systems, and increasing participation in na-

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

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

8 (3) developing improved epidemiological tools
9 for obtaining quality exposure data, and micro-
10 biological methods for classifying cases;

11 (4) augmenting such systems to improve attri-
12 bution of a food-borne illness outbreak to a specific
13 food;

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

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

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

22 (8) establishing a flexible mechanism for rapidly
23 initiating scientific research by academic institu-
24 tions;

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

5 (10) other activities as determined appropriate
6 by the Secretary.

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

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

13 (A) Improve food-borne illness outbreak re-
14 sponse and containment.

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

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

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

1 safety and defense resources and reduce the in-
2 cidence of food-borne illness.

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

7 (2) REVIEW.—In developing the strategies re-
8 quired by paragraph (1), the Secretary shall, not
9 later than 1 year after the date of enactment of this
10 Act, complete a review of State and local capacities,
11 and needs for enhancement, which may include a
12 survey with respect to—

13 (A) staffing levels and expertise available
14 to perform food safety and defense functions;

15 (B) laboratory capacity to support surveil-
16 lance, outbreak response, inspection, and en-
17 forcement activities;

18 (C) information systems to support data
19 management and sharing of food safety and de-
20 fense information among State and local agen-
21 cies and with counterparts at the Federal level;
22 and

23 (D) other State and local activities and
24 needs as determined appropriate by the Sec-
25 retary.

1 **SEC. 122. PUBLIC EDUCATION AND ADVISORY SYSTEM.**

2 (a) PUBLIC EDUCATION.—The Secretary, in coopera-
3 tion with private and public organizations, including the
4 appropriate State entities, shall design and implement a
5 national public education program on food safety. The
6 program shall provide—

7 (1) information to the public so that individuals
8 can understand the potential impact and risk of
9 food-borne illness, take action to reduce their risk of
10 food-borne illness and injury, and make healthy die-
11 tary choices;

12 (2) information to health professionals so that
13 they may improve diagnosis and treatment of food-
14 related illness and advise individuals whose health
15 conditions place them in particular risk; and

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

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

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

23 (2) develop standardized formats for written
24 and broadcast advisories; and

1 (3) incorporate State and local advisories into
2 the national public education program required
3 under subsection (a).

4 **SEC. 123. RESEARCH.**

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

7 (1) improve sanitation and food safety practices
8 in the production, harvesting, and processing of food
9 products;

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

12 (3) develop efficient, rapid, and sensitive meth-
13 ods for determining and detecting the presence of
14 contaminants in food products;

15 (4) determine the sources of contamination of
16 food and food products, including critical points of
17 risk for fresh produce and other raw agricultural
18 commodities;

19 (5) develop consumption data with respect to
20 food products;

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

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

1 (8) address common and emerging zoonotic dis-
2 eases;

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

5 (10) analyze the incidence of antibiotic resist-
6 ance as it pertains to the food supply and evaluate
7 methods to reduce the transfer of antibiotic resist-
8 ance to humans; and

9 (11) conduct other research that supports the
10 purposes of this Act.

11 **Subtitle C—Response**

12 **SEC. 131. PROCEDURES FOR SEIZURE.**

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

23 **SEC. 132. ADMINISTRATIVE DETENTION.**

24 (a) AMENDMENTS.—Section 304(h) (21 U.S.C.
25 334(h)) is amended—

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

4 (2) in paragraph (1)(A), by striking “presents
5 a threat of serious adverse health consequences or
6 death to humans or animals” and inserting “is adul-
7 terated, misbranded, or otherwise in violation of this
8 Act”;

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

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

13 (5) in paragraph (4)(A) by striking the terms
14 “five” and “five-day” and inserting “fifteen” and
15 “fifteen-day”, respectively.

16 (b) REGULATIONS.—The Secretary shall issue regula-
17 tions or guidance to implement the amendments made by
18 this section.

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

1 **SEC. 133. AUTHORITY TO PROHIBIT OR RESTRICT THE**
2 **MOVEMENT OF FOOD.**

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

6 “(ww) The violation of a prohibition or restriction
7 under section 304(i).”.

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

10 “(i) AUTHORITY TO PROHIBIT OR RESTRICT THE
11 MOVEMENT OF FOOD WITHIN A STATE OR PORTION OF
12 A STATE.—

13 “(1) AUTHORITY TO PROHIBIT OR RESTRICT
14 THE MOVEMENT OF FOOD.—

15 “(A) IN GENERAL.—

16 “(i) After consultation with the Gov-
17 ernor or other appropriate official of an af-
18 fected State, if the Secretary determines
19 that there is credible evidence that an arti-
20 cle of food presents an imminent threat of
21 serious adverse health consequences or
22 death to humans or animals, the Secretary
23 may prohibit or restrict the movement of
24 an article of food within a State or portion
25 of a State for which the Secretary has
26 credible evidence that such food is located

1 within, or originated from, such State or
2 portion thereof.

3 “(ii) In carrying out clause (i), the
4 Secretary may prohibit or restrict the
5 movement within a State or portion of a
6 State of any article of food or means of
7 conveyance of such article of food, if the
8 Secretary determines that the prohibition
9 or restriction is a necessary protection
10 from an imminent threat of serious adverse
11 health consequences or death to humans or
12 animals.

13 “(2) NOTIFICATION PROCEDURES.—Subject to
14 paragraph (3), before any action is taken in a State
15 under this subsection, the Secretary shall—

16 “(A) notify the Governor or other appro-
17 priate official of the State affected by the pro-
18 posed action;

19 “(B) issue a public announcement of the
20 proposed action; and

21 “(C) publish in the Federal Register—

22 “(i) the findings of the Secretary that
23 support the proposed action;

24 “(ii) a statement of the reasons for
25 the proposed action; and

1 “(iii) a description of the proposed ac-
2 tion, including—

3 “(I) the area affected; and

4 “(II) an estimate of the antici-
5 pated duration of the action.

6 “(3) NOTICE AFTER ACTION.—If it is not prac-
7 ticable to publish in the Federal Register the infor-
8 mation required under paragraph (2)(C) before tak-
9 ing action under paragraph (1), the Secretary shall
10 publish the information as soon as practicable, but
11 not later than 10 business days, after commence-
12 ment of the action.

13 “(4) APPLICATION OF LEAST DRASTIC AC-
14 TION.—No action shall be taken under paragraph
15 (1) unless, in the opinion of the Secretary, there is
16 no less drastic action that is feasible and that would
17 be adequate to prevent the imminent threat of seri-
18 ous adverse health consequences or death to humans
19 or animals.

20 “(5) NONDELEGATION.—An action under para-
21 graph (1) may only be ordered by the Secretary or
22 an official designated by the Secretary. An official
23 may not be so designated unless the official is the
24 Commissioner of Food and Drugs or the Principal
25 Deputy Commissioner.

1 “(6) DURATION.—Fourteen days after the initi-
2 ation of an action under paragraph (1), and each 14
3 days thereafter, if the Secretary determines that it
4 is necessary to continue the action, the Secretary
5 shall—

6 “(A) notify the Governor or other appro-
7 priate official of the State affected of the con-
8 tinuation of the action;

9 “(B) issue a public announcement of the
10 continuation of the action; and

11 “(C) publish in the Federal Register the
12 findings of the Secretary that support the con-
13 tinuation of the action, including an estimate of
14 the anticipated duration of the action.

15 “(7) RULEMAKING.—The Secretary shall, con-
16 sistent with national security interests and as appro-
17 priate for known hazards, establish by regulation
18 standards for conducting actions under paragraph
19 (1), including, as appropriate, sanitation standards
20 and procedures to restore any affected equipment or
21 means of conveyance to its status prior to an action
22 under paragraph (1).”.

23 **SEC. 134. CRIMINAL PENALTIES.**

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

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

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

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

11 **SEC. 135. CIVIL PENALTIES FOR VIOLATIONS RELATING TO**
12 **FOOD.**

13 (a) IN GENERAL.—Paragraph (2) of section 303(f)
14 (21 U.S.C. 331 et seq.) is amended to read as follows:

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

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

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

24 “(B) Any person who knowingly violates a pro-
25 vision of section 301 relating to food shall be subject

1 to a civil penalty for each such violation of not more
2 than—

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

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

9 “(C) Each violation described in subparagraph
10 (A) or (B) and each day during which the violation
11 continues shall be considered to be a separate of-
12 fense.”.

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

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

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

20 “(xx) The submission of information relating to food
21 that is required by or under section 801 that is inaccurate
22 or incomplete.

23 “(yy) The failure to submit information relating to
24 food that is required by or under section 801.”.

1 (b) DOCUMENTATION FOR IMPORTS.—Section 801
2 (21 U.S.C. 381), as amended by section 109, is amended
3 by adding at the end the following:

4 “(r) DOCUMENTATION.—

5 “(1) SUBMISSION.—The Secretary may require
6 by regulation or guidance the submission of docu-
7 mentation or other information for articles of food
8 that are imported or offered for import into the
9 United States. When developing any regulation or
10 guidance in accordance with this paragraph, to the
11 extent that the collection of documentation or other
12 information involves Customs and Border Protection
13 efforts or resources, the Secretary shall consult with
14 Customs and Border Protection.

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.**

22 (a) MISBRANDING.—Section 403 (21 U.S.C. 343), as
23 amended by sections 101(a), 109(a), and 114(a), is
24 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 country of origin
24 marking requirements of the United States
25 Customs and Border 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 “(zz) The failure to register in accordance with sec-
22 tion 801(s).”.

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(s).”.

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

8 “(s) 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 1011, to sub-
15 mit appropriate unique facility identifiers as a
16 condition 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 in accordance with the following:

21 “(A) The Secretary, in consultation with
22 Customs and Border Protection, shall promul-
23 gate regulations to establish good importer
24 practices that specify the measures an importer

1 shall take to ensure imported food is in compli-
2 ance with the requirements of this Act.

3 “(B) The measures under subparagraph
4 (A) shall ensure that the importer of a food—

5 “(i) has adequate information about
6 the food, its hazards, and the requirements
7 of this Act applicable to such food;

8 “(ii) has adequate information or pro-
9 cedures in place to verify that both the
10 food and each person that produced, man-
11 ufactured, processed, packed, transported,
12 or held the food, including components of
13 the food, are in compliance with the re-
14 quirements of this Act; and

15 “(iii) has adequate procedures in
16 place to take corrective action, such as the
17 ability to appropriately trace, withhold,
18 and recall articles of food, if a food im-
19 ported by the importer is not in compliance
20 with the requirements of this Act.

21 “(C) In promulgating good importer prac-
22 tices regulations, the Secretary may, as appro-
23 priate—

24 “(i) incorporate certification of com-
25 pliance under section 801(q) and participa-

1 tion in the safe and secure food importa-
2 tion program under section 805; and

3 “(ii) take into account differences
4 among importers and the types of imports,
5 including based on the level of risk posed
6 by the imported food.

7 “(3) SUSPENSION OF REGISTRATION.—

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

12 “(i) a violation of this Act; or

13 “(ii) the knowing or repeated making
14 of an inaccurate or incomplete statement
15 or submission of information relating to
16 the importation of food.

17 “(B) REQUEST.—The importer whose reg-
18 istration is suspended may request that the
19 Secretary vacate the suspension of registration
20 when such importer has corrected the violation
21 that is the basis for such suspension.

22 “(C) VACATING OF SUSPENSION.—If the
23 Secretary determines that adequate reasons do
24 not exist to continue the suspension of a reg-

1 istration, the Secretary shall vacate such sus-
2 pension.

3 “(4) CANCELLATION OF REGISTRATION.—

4 “(A) IN GENERAL.—Not earlier than 10
5 days after providing the notice under subpara-
6 graph (B), the Secretary may cancel a registra-
7 tion that the Secretary determines was not up-
8 dated in accordance with this section or other-
9 wise contains false, incomplete, or inaccurate
10 information.

11 “(B) NOTICE OF CANCELLATION.—Can-
12 cellation shall be preceded by notice to the im-
13 porter of the intent to cancel the registration
14 and the basis for such cancellation.

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

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

22 “(A) shall establish an exemption from the
23 requirements of this subsection for importations
24 for personal use; and

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

3 (4) REGULATIONS.—Not later than 36 months
4 after the date of the enactment of this Act, the Sec-
5 retary of Health and Human Services in consulta-
6 tion with the Commissioner responsible for Customs
7 and Border Protection shall promulgate the regula-
8 tions required to carry out section 801(s) of the
9 Federal Food, Drug, and Cosmetic Act, as added by
10 paragraph (3). In establishing the effective date of
11 a regulation promulgated under section 801(s), the
12 Secretary shall, in consultation with the Commis-
13 sioner responsible for Customs and Border Protec-
14 tion, as appropriate, provide a reasonable period of
15 time for importers of food to comply with good im-
16 porter practices, taking into account differences
17 among importers and the types of imports, including
18 based on the level of risk posed by the imported
19 food.

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

23 (b) FEE.—Subchapter C of chapter VII (21 U.S.C.
24 379f et seq.) as added and amended by sections 101 and
25 108, is amended by adding at the end the following:

1 **“PART 7—IMPORTERS OF FOOD**

2 **“SEC. 744. IMPORTERS OF FOOD.**

3 “(a) IMPORTERS.—The Secretary shall assess and
4 collect an annual fee for the registration of an importer
5 of food under section 801(s).

6 “(b) AMOUNT OF FEE.—

7 “(1) BASE AMOUNTS.—The registration fee
8 under subsection (a) shall be—

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

10 “(B) for fiscal year 2011 and each subse-
11 quent fiscal year, the fee for fiscal year 2010 as
12 adjusted under paragraph (2).

13 “(2) ADJUSTMENT.—For fiscal year 2011 and
14 subsequent fiscal years, the fees established pursu-
15 ant to paragraph (1) shall be adjusted by the Sec-
16 retary by notice, published in the Federal Register,
17 for a fiscal year to reflect the greater of—

18 “(A) the total percentage change that oc-
19 curred in the Consumer Price Index for all
20 urban consumers (all items; United States city
21 average), for the 12-month period ending June
22 30 preceding the fiscal year for which fees are
23 being established;

24 “(B) the total percentage change for the
25 previous fiscal year in basic pay under the Gen-
26 eral Schedule in accordance with section 5332

1 of title 5, United States Code, as adjusted by
2 any locality-based comparability payment pur-
3 suant to section 5304 of such title for Federal
4 employees stationed in the District of Columbia;
5 or

6 “(C) the average annual change in the
7 cost, per full-time equivalent position of the
8 Food and Drug Administration, of all personnel
9 compensation and benefits paid with respect to
10 such positions for the first 5 years of the pre-
11 ceding 6 fiscal years.

12 “(3) COMPOUNDED BASIS.—The adjustment
13 made each fiscal year pursuant this subsection shall
14 be added on a compounded basis to the sum of all
15 adjustments made each fiscal year after fiscal year
16 2010 under this subsection.

17 “(4) WAIVER FOR IMPORTERS REQUIRED TO
18 PAY REGISTRATION FEE.—In the case of a person
19 who is required to pay both a fee under section 743
20 for registration of one or more facilities under sec-
21 tion 415 and a fee under this section for registration
22 as an importer of food under section 801(s), the
23 Secretary shall waive the fees applicable to such per-
24 son under section 743 or the fee applicable to such
25 person under this section.

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

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

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

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

18 “(B) shall only be collected and available
19 to cover the costs associated with registering
20 importers under section 801(s) and with ensur-
21 ing compliance with good importer practices re-
22 specting food.

23 “(3) AUTHORIZATION OF APPROPRIATIONS.—
24 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 (c) INSPECTION.—Section 704 (21 U.S.C. 374), as
4 amended by section 105, is amended by adding at the end
5 the following:

6 “(i) IMPORTERS.—Every person engaged in the im-
7 porting of any food shall, upon request of an officer or
8 employee designated by the Secretary, permit such officer
9 or employee at all reasonable times to inspect the facilities
10 of such person and have access to, and to copy and verify,
11 any related records.”.

12 **SEC. 205. REGISTRATION FOR CUSTOMS BROKERS.**

13 (a) REGISTRATION.—

14 (1) PROHIBITIONS.—Section 301(zz) (21
15 U.S.C. 331), as added by section 204, is amended
16 by inserting “or 801(t)” after “801(s)”.

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

19 (A) by inserting “or a customs broker”
20 after “by an importer”; and

21 (B) by inserting “or 801(t)” after
22 “801(s)”.

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

1 “(t) REGISTRATION OF CUSTOMS BROKER.—

2 “(1) REGISTRATION.—The Secretary shall re-
3 quire a customs broker, with respect to the importa-
4 tion of food—

5 “(A) to be registered with the Secretary in
6 a form and manner specified by the Secretary;
7 and

8 “(B) consistent with section 1011, to sub-
9 mit appropriate unique facility identifiers as a
10 condition of registration.

11 “(2) 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 that the Secretary determines was not up-
16 dated in accordance with this section or other-
17 wise contains false, incomplete, or inaccurate
18 information.

19 “(B) NOTICE OF CANCELLATION.—Can-
20 cellation shall be preceded by notice to the cus-
21 toms broker of the intent to cancel the registra-
22 tion and the basis for such cancellation.

23 “(C) TIMELY UPDATE OR CORRECTION.—
24 If the registration for the customs broker is up-
25 dated or corrected no later than 7 days after

1 notice is provided under subparagraph (B), the
2 Secretary shall not cancel such registration.

3 “(3) NOTIFICATION.—The Secretary shall no-
4 tify the Commissioner responsible for Customs and
5 Border Protection whenever the Secretary cancels a
6 registration under this subsection.

7 “(4) EXEMPTIONS.—In consultation with the
8 Commissioner responsible for Customs and Border
9 Protection, the Secretary, by notice published in the
10 Federal Register—

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

14 “(B) may establish other exemptions from
15 the requirements of this subsection.

16 “(5) CIVIL PENALTIES.—Notwithstanding any
17 other provision in this Act, a customs broker who
18 violates section 301 because of a violation of section
19 403(ee), or who violates section 301(xx), 301(yy), or
20 301(zz), shall not be subject to a civil penalty under
21 section 303(f)(2).”.

22 (4) REGULATIONS.—Not later than 24 months
23 after the date of the enactment of this Act, the Sec-
24 retary of Health and Human Services, in consulta-
25 tion with the Commissioner responsible for Customs

1 and Border Protection, shall promulgate the regula-
2 tions required to carry out section 801(t) of the
3 Federal Food, Drug, and Cosmetic Act, as added by
4 paragraph (2).

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

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

11 “(j) BROKERS.—Every customs broker required to be
12 registered with the Secretary shall, upon request of an of-
13 ficer or employee designated by the Secretary, permit such
14 officer or employee at all reasonable times to inspect the
15 facilities of such person and have access to, and to copy
16 and verify, any related records.”.

17 **SEC. 206. UNIQUE IDENTIFICATION NUMBER FOR FOOD FA-**
18 **CILITIES, IMPORTERS, AND CUSTOM BRO-**
19 **KERS.**

20 Chapter X (21 U.S.C. 391 et seq) is amended by add-
21 ing at the end the following:

22 **“SEC. 1011. UNIQUE FACILITY IDENTIFIER.**

23 **“(a) REGISTRATION OF FACILITY OR ESTABLISH-**
24 **MENT.—A person required to register a facility pursuant**

1 to section 415 shall submit, at the time of registration,
2 a unique facility identifier for the facility or establishment.

3 “(b) REGISTRATION OF IMPORTERS AND CUSTOM
4 BROKERS.—A person required to register pursuant to sec-
5 tion 801(s) or 801(t) shall submit, at the time of registra-
6 tion, a unique facility identifier for the principal place of
7 business for which such person is required to register
8 under section 801(s) or 801(t).

9 “(c) GUIDANCE.—The Secretary may, by guidance,
10 and, with respect to importers and customs brokers, in
11 consultation with the Commissioner responsible for Cus-
12 toms and Border Protection, specify the unique numerical
13 identifier system to be used to meet the requirements of
14 subsections (a) and (b) and the form, manner, and timing
15 of a submission under such subsections. Development of
16 such guidelines shall take into account the utilization of
17 existing unique identification schemes and compatibility
18 with customs automated systems, such as integration with
19 the Automated Commercial Environment (ACE) and the
20 International Trade Data System (ITDS), and any suc-
21 cessor systems.

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

1 **SEC. 207. PROHIBITION AGAINST DELAYING, LIMITING, OR**
2 **REFUSING INSPECTION.**

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

6 “(n) If it has been produced, manufactured, proc-
7 essed, packed, or held in any farm, factory, warehouse,
8 or establishment and the owner, operator, or agent of such
9 farm, factory, warehouse, or establishment, or any agent
10 of a governmental authority in the foreign country within
11 which such farm, factory, warehouse, or establishment is
12 located, delays or limits an inspection, or refuses to permit
13 entry or inspection, under section 414 or 704.”.

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

17 (1) in the first sentence, by inserting “, includ-
18 ing any such food factory, warehouse, or establish-
19 ment whether foreign or domestic,” after “factory,
20 warehouse, or establishment”; and

21 (2) in the third sentence, by inserting “, includ-
22 ing any food factory, warehouse, establishment, or
23 consulting laboratory whether foreign or domestic,”
24 after “factory, warehouse, establishment, or con-
25 sulting laboratory”.

1 **SEC. 208. DEDICATED FOREIGN INSPECTORATE.**

2 Section 704 (21 U.S.C. 374), as amended by sections
3 105, 204, and 205, is amended by adding at the end the
4 following:

5 “(k) DEDICATED FOREIGN INSPECTORATE.—The
6 Secretary shall establish and maintain a corps of inspec-
7 tors dedicated to inspections of foreign food facilities. This
8 corps shall be staffed and funded by the Secretary at a
9 level sufficient to enable it to assist the Secretary in
10 achieving the frequency of inspections for food facilities
11 as described in this Act.”.

12 **SEC. 209. PLAN AND REVIEW OF CONTINUED OPERATION**
13 **OF FIELD LABORATORIES.**

14 (a) SUBMISSION OF PLAN.—Not later than 90 days
15 before the Secretary terminates or consolidates any lab-
16 oratory, district office, or the functions (including the in-
17 spection and compliance functions) of any such laboratory
18 or district office, specified in subsection (b), the Secretary
19 shall submit a reorganization plan to the Comptroller Gen-
20 eral of the United States, the Committee on Energy and
21 Commerce of the House of Representatives, and the Com-
22 mittee on Health, Education, Labor, and Pensions of the
23 Senate.

24 (b) SPECIFIED LABORATORIES AND OFFICES.—The
25 laboratories and offices specified in this subsection are the
26 following:

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

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

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

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

13 (a) IN GENERAL.—Section 301(q)(2) (21 U.S.C.
14 331(q)(2)) is amended by inserting after “device” the fol-
15 lowing: “, food,”.

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

19 **SEC. 211. SUBPOENA AUTHORITY.**

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

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

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

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

3 “(1) any hearing, investigation, or other pro-
4 ceeding respecting a violation of a provision of this
5 Act, the Public Health Service Act, or the Federal
6 Anti-Tampering Act, relating to food; or

7 “(2) any hearing, investigation, or other pro-
8 ceeding to determine if a person is in violation of a
9 specific provision of this Act, the Public Health
10 Service Act, or the Federal Anti-Tampering Act, re-
11 lating to food,

12 the Commissioner may issue subpoenas requiring the at-
13 tendance and testimony of witnesses and the production
14 of records and other things.

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

20 “(c) SERVICE OF SUBPOENA.—

21 “(1) IN GENERAL.—Subpoenas of the Commis-
22 sioner shall be served by a person authorized by the
23 Commissioner by delivering a copy thereof to the
24 person named therein or by certified mail addressed
25 to such person at such person’s last known dwelling
26 place or principal place of business.

1 “(2) CORPORATIONS AND OTHER ENTITIES.—
2 Service on a domestic or foreign corporation, part-
3 nership, unincorporated association, or other entity
4 that is subject to suit under a common name may
5 be made by delivering the subpoena to an officer, a
6 managing or general agent, or any other agent au-
7 thorized by appointment or by law to receive service
8 of process.

9 “(3) PERSON OUTSIDE U.S. JURISDICTION.—
10 Service on any person not found within the terri-
11 torial jurisdiction of any court of the United States
12 may be made in any manner as the Federal Rules
13 of Civil Procedure prescribe for service in a foreign
14 nation.

15 “(4) PROOF OF SERVICE.—A verified return by
16 the person so serving the subpoena setting forth the
17 manner of service, or, in the case of service by cer-
18 tified mail, the return post office receipt therefor
19 signed by the person so served, shall be proof of
20 service.

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

1 “(e) ENFORCEMENT.—In the case of a refusal to
2 obey a subpoena duly served upon any person under sub-
3 section (a), any district court of the United States for the
4 judicial district in which such person charged with refusal
5 to obey is found, resides, or transacts business, upon ap-
6 plication by the Commissioner, shall have jurisdiction to
7 issue an order compelling compliance with the subpoena
8 and requiring such person to appear and give testimony
9 or to appear and produce records and other things, or
10 both. The failure to obey such order of the court may be
11 punished by the court as contempt thereof. If the person
12 charged with failure or refusal to obey is not found within
13 the territorial jurisdiction of the United States, the United
14 States District Court for the District of Columbia shall
15 have the same jurisdiction, consistent with due process,
16 to take any action respecting compliance with the sub-
17 poena by such person that such district court would have
18 if such person were personally within the jurisdiction of
19 such district court.

20 “(f) NONDISCLOSURE.—A United States district
21 court for the district in which the subpoena is or will be
22 served, upon application of the Commissioner, may issue
23 an ex parte order that no person or entity disclose to any
24 other person or entity (other than to an attorney to obtain
25 legal advice) the existence of such subpoena for a period

1 of up to 90 days. Such order may be issued on a showing
2 that the records or things being sought may be relevant
3 to the hearing, investigation, proceeding, or other matter
4 and that there is reason to believe that such disclosure
5 may result in—

6 “(1) furtherance of a potential violation under
7 investigation;

8 “(2) endangerment to the life or physical safety
9 of any person;

10 “(3) flight or other action to avoid prosecution
11 or other enforcement remedies;

12 “(4) destruction of or tampering with evidence;
13 or

14 “(5) intimidation of potential witnesses.

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

19 “(g) RELATION TO OTHER PROVISIONS.—The sub-
20 poena authority vested in the Commissioner and the dis-
21 trict courts of the United States by this section is in addi-
22 tion to any such authority vested in the Commissioner or
23 such courts by other provisions of law, or as is otherwise
24 authorized by law.

1 sonably believes constitutes a violation of this Act, or
2 any other provision of Federal law relating to the
3 safety of a food, if the information or assistance is
4 provided to, or an investigation stemming from the
5 provided information is conducted by—

6 “(A) a Federal regulatory or law enforce-
7 ment agency;

8 “(B) any Member of Congress or any com-
9 mittee of Congress; or

10 “(C) a person with supervisory authority
11 over the employee (or such other person work-
12 ing for the employer who has the authority to
13 investigate, discover, or terminate the mis-
14 conduct);

15 “(2) to file, cause to be filed, testify, participate
16 in, or otherwise assist in a proceeding filed, or about
17 to be filed (with any knowledge of the employer), in
18 any court or administrative forum relating to any
19 such alleged violation; or

20 “(3) to refuse to commit or assist in any such
21 violation.

22 “(b) ENFORCEMENT ACTION.—

23 “(1) IN GENERAL.—An employee who alleges
24 discharge or other discrimination in violation of sub-

1 section (a) may seek relief in accordance with the
2 provisions of subsection (c) by—

3 “(A) filing a complaint with the Secretary
4 of Labor; or

5 “(B) if the Secretary of Labor has not
6 issued a final decision within 210 days of the
7 filing of the complaint and there is no showing
8 that such delay is due to the bad faith of the
9 claimant, or within 90 days after receiving a
10 final decision or order from the Secretary,
11 bringing an action at law or equity for de novo
12 review in the appropriate district court of the
13 United States, which court shall have jurisdic-
14 tion over such action without regard to the
15 amount in controversy, and which action shall,
16 at the request of either party to such action, be
17 tried by the court with a jury.

18 “(2) PROCEDURE.—

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

23 “(B) EXCEPTION.—Notification in an ac-
24 tion under paragraph (1) shall be made in ac-
25 cordance with section 42121(b)(1) of title 49,

1 United States Code, except that such notifica-
2 tion shall be made to the person named in the
3 complaint, the employer, and the Commissioner
4 of Food and Drugs.

5 “(C) BURDENS OF PROOF.—An action
6 brought under paragraph (1)(A) or (1)(B) shall
7 be governed by the legal burdens of proof set
8 forth in section 42121(b) of title 49, United
9 States Code.

10 “(D) STATUTE OF LIMITATIONS.—An ac-
11 tion under paragraph (1)(A) shall be com-
12 menced not later than 180 days after the date
13 on which the violation occurs.

14 “(c) REMEDIES.—

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

18 “(2) ISSUANCE OF ORDER.—If, in response to
19 a complaint filed under paragraph (b)(1), the Sec-
20 retary of Labor or the district court, as applicable,
21 determines that a violation of subsection (a) has oc-
22 curred, the Secretary or the court shall order the
23 person who committed such violation—

24 “(A) to take affirmative action to abate
25 the violation;

1 “(B) to—

2 “(i) reinstate the complainant to his
3 or her former position together with com-
4 pensation (including back pay); and

5 “(ii) restore the terms, conditions,
6 and privileges associated with his or her
7 employment; and

8 “(C) to provide compensatory damages to
9 the complainant.

10 If such an order is issued under this paragraph, the
11 Secretary or the court, at the request of the com-
12 plainant, shall assess against the person against
13 whom the order is issued a sum equal to the aggre-
14 gate amount of all costs and expenses (including at-
15 torney and expert witness fees) reasonably incurred,
16 as determined by the Secretary, by the complainant
17 for, or in connection with, the bringing of the com-
18 plaint upon which the order was issued.

19 “(d) RIGHTS RETAINED BY EMPLOYEE.—Nothing in
20 this section shall be deemed to diminish the rights, privi-
21 leges, or remedies of any employee under any Federal or
22 State law or under any collective bargaining agreement.
23 The rights and remedies in this section may not be waived
24 by any agreement, policy, form, or condition of employ-
25 ment.”.

1 **SEC. 213. EXTRATERRITORIAL JURISDICTION.**

2 (a) PROHIBITED ACT.—Section 301 (21 U.S.C. 331),
3 as amended by sections 110, 111, 133, 136, and 204, is
4 amended by adding at the end the following:

5 “(aaa) The production, manufacture, processing,
6 preparation, packing, holding, or distribution of an adul-
7 terated or misbranded food with the knowledge or intent
8 that such article will be imported into the United States.”.

9 (b) JURISDICTION.—Chapter III (21 U.S.C. 331 et
10 seq.), as amended by section 211, is amended by adding
11 at the end the following:

12 **“SEC. 312. EXTRATERRITORIAL JURISDICTION.**

13 “There is extraterritorial Federal jurisdiction over
14 any violation of this Act relating to any article of food
15 if such article was intended for import into the United
16 States or if any act in furtherance of the violation was
17 committed in the United States.”.

18 **SEC. 214. SUPPORT FOR TRAINING INSTITUTES.**

19 The Secretary of Health and Human Services, acting
20 through the Commissioner of Food and Drugs, shall pro-
21 vide financial and other assistance to appropriate entities
22 to establish and maintain one or more university-affiliated
23 food protection training institutes that—

24 (1) conduct training related to food protection
25 activities for Federal, State, local, territorial, and
26 tribal officials; and

1 (2) meet standards developed by the Secretary.

2 **SEC. 215. BISPHEENOL A IN FOOD AND BEVERAGE CON-**
3 **TAINERS.**

4 (a) NOTICE OF DETERMINATION.—No later than De-
5 cember 31, 2009, the Secretary of Health and Human
6 Services shall notify the Congress whether the available
7 scientific data support a determination that there is a rea-
8 sonable certainty of no harm, for infants, young children,
9 pregnant women, and adults, for approved uses of
10 polycarbonate plastic and epoxy resin made with bisphenol
11 A in food and beverage containers, including reusable food
12 and beverage containers, under the conditions of use pre-
13 scribed in current Food and Drug Administration regula-
14 tions.

15 (b) NOTICE OF ACTIONS TO BE TAKEN.—If the Sec-
16 retary concludes that such a determination cannot be
17 made for any approved use, the Secretary shall notify the
18 Congress of the actions the Secretary intends to take
19 under the Secretary's authority to regulate food additives
20 to protect the public health, which may include—

21 (1) revoking or modifying any of the approved
22 uses of bisphenol A in food and beverage containers,
23 including reusable food and beverage containers; and

1 (b) EFFECTIVE DATE.—Section 403(ff) of the Fed-
2 eral Food, Drug, and Cosmetic Act, as added by sub-
3 section (a), shall apply only to ceramic tableware or
4 cookware that is manufactured on or after the date that
5 is 1 year after the date of the enactment of this Act.

6 (c) CONSUMER EDUCATION.—Chapter IV (21 U.S.C.
7 341 et seq.), as amended by sections 102, 103, 104, and
8 111, is amended by adding at the end the following:

9 **“SEC. 421. CONSUMER EDUCATION ON THE CONTENT OF**
10 **LEAD IN CERAMICWARE AND APPLICABLE**
11 **LABELING REQUIREMENTS.**

12 “(a) IN GENERAL.—The Secretary shall educate con-
13 sumers on the safety of ceramicware for food use by post-
14 ing information on the Web site of the Food and Drug
15 Administration with regard to—

16 “(1) the content of lead in ceramicware and its
17 glaze;

18 “(2) existing Federal laws and regulations gov-
19 erning lead in ceramicware;

20 “(3) as appropriate, existing industry practices
21 and guidelines; and

22 “(4) the labeling requirements applicable under
23 this Act.

24 “(b) TOPICS.—The education under this section shall
25 address—

1 “(1) the broad range of ceramicware types, in-
2 cluding traditional pottery, ornamental and decora-
3 tive ceramicware, cookware, and everyday dinner-
4 ware;

5 “(2) the safety of ceramicware that is aged or
6 damaged;

7 “(3) the use of ceramicware in microwave
8 ovens;

9 “(4) the storage of foods in ceramicware;

10 “(5) the use of home lead test kits by con-
11 sumers;

12 “(6) the use of ceramicware by children and
13 women of childbearing age; and

14 “(7) issues that are especially relevant to sub-
15 populations of consumers who may preferentially use
16 certain types of ceramicware made with lead.”.

Passed the House of Representatives July 30, 2009.

Attest:

Clerk.

111TH CONGRESS
1ST SESSION

H. R. 2749

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food in the global market, and for other purposes.