

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 2749
OFFERED BY MR. PALLONE OF NEW JERSEY**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE.

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

4 SEC. 2. TABLE OF CONTENTS.

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

- Sec. 1. Short title.
- Sec. 2. Table of contents.
- Sec. 3. References.
- Sec. 4. Rule of construction.

TITLE I—FOOD SAFETY

Subtitle A—Prevention

- Sec. 101. Changes in registration of food facilities.
- Sec. 102. Hazard analysis, risk-based preventive controls, and food safety plan.
- Sec. 103. Performance standards.
- Sec. 104. Safety standards for fresh produce and certain other raw agricultural commodities.
- Sec. 105. Risk-based inspection schedule.
- Sec. 106. Access to records.
- Sec. 107. Traceability of food.
- Sec. 108. Reinspection and food recall fees applicable to facilities.
- Sec. 109. Certification and accreditation.
- Sec. 110. Testing by accredited laboratories.
- Sec. 111. Notification, nondistribution, and recall of adulterated or misbranded food.
- Sec. 112. Reportable food registry; exchange of information.
- Sec. 113. Safe and secure food importation program.
- Sec. 114. Infant formula.

Subtitle B—Intervention

- Sec. 121. Public health assessment system.

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

Subtitle C—Response

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

TITLE II—MISCELLANEOUS

- Sec. 201. Treatment of carbon monoxide used to preserve color of meat, poultry products, or seafood as color additive.
- Sec. 202. Food substances generally recognized as safe.
- Sec. 203. Country of origin labeling; disclosure of source of ingredients.
- Sec. 204. Exportation certificate program.
- Sec. 205. Registration for commercial importers of food; fee.
- Sec. 206. Unique identification number for food facilities, importers, custom brokers, and filers.
- Sec. 207. Prohibition against delaying, limiting, or refusing inspection.
- Sec. 208. Dedicated foreign inspectorate.
- Sec. 209. Plan and review of continued operation of field laboratories.
- Sec. 210. False or misleading reporting to FDA.
- Sec. 211. Subpoena authority.
- Sec. 212. Whistleblower protections.
- Sec. 213. Extraterritorial jurisdiction.

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. RULE OF CONSTRUCTION.**

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

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

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

5 **TITLE I—FOOD SAFETY**

6 **Subtitle A—Prevention**

7 **SEC. 101. CHANGES IN REGISTRATION OF FOOD FACILI-** 8 **TIES.**

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

11 “(z) If it was manufactured, processed, packed, or
12 held in a facility that is not duly registered under section
13 415, including a facility whose registration is canceled or
14 suspended under such section.”.

15 (b) ANNUAL REGISTRATION.—

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

18 (A) in the first sentence of paragraph

19 (1)—

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

23 (ii) by striking “food for consumption
24 in the United States” and inserting “food

1 for consumption in the United States or
2 for export from the United States”;

3 (B) in subparagraphs (A) and (B) of para-
4 graph (1), by inserting “and pay the registra-
5 tion fee required under section 743” after “sub-
6 mit a registration to the Secretary” each place
7 it appears;

8 (C) in the first sentence of paragraph (2),
9 by inserting “in electronic format” after “sub-
10 mit”; and

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

21 (2) CONTENTS OF REGISTRATION.—Paragraph
22 (2) of section 415(a) (21 U.S.C. 350d(a)), as
23 amended by paragraph (1), is amended by striking
24 “containing information” and all that follows and in-

1 serting the following: “containing information that
2 identifies the following:

3 “(A) The name, address, and emergency
4 contact information of the facility being reg-
5 istered.

6 “(B) The primary purpose and business
7 activity of the facility, including the dates of op-
8 eration if the facility is seasonal.

9 “(C) The general food category (as defined
10 by the Secretary by guidance) of each food
11 manufactured, processed, packed, or held at the
12 facility.

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

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

22 “(F) If the facility is located outside of the
23 United States, the name, address, and emer-
24 gency contact information for a United States
25 agent.

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

3 “(H) Such additional information per-
4 taining to the facility as the Secretary may re-
5 quire by regulation.

6 The registrant shall notify the Secretary of any
7 change in the submitted information not later than
8 30 days after the date of such change, unless other-
9 wise specified by the Secretary.”.

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

14 “(5) SUSPENSION OF REGISTRATION.—

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

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

22 “(i) notice to the facility of the intent
23 to suspend the registration; and

24 “(ii) an opportunity for an informal
25 hearing, as defined in guidance or regula-

1 tions issued by the Secretary, concerning
2 the suspension of such registration for
3 such facility.

4 “(C) REQUEST.—The owner, operator, or
5 agent in charge of a facility whose registration
6 is suspended may request that the Secretary va-
7 cate the suspension of registration when such
8 owner, operator, or agent has corrected the vio-
9 lation that is the basis for such suspension.

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

16 “(6) CANCELLATION OF REGISTRATION.—

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

21 “(i) the registration was not updated
22 in accordance with this section or other-
23 wise contains false, incomplete, or inac-
24 curate information; or

1 “(ii) the required registration fee has
2 not been paid within 30 days after the date
3 due.

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

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

13 “(7) REPORT TO CONGRESS.—Not later than
14 March 30th of each year, the Secretary shall submit
15 to the Congress a report, based on the registrations
16 on or before December 31 of the previous year, on
17 the following:

18 “(A) The number of facilities registered
19 under this section.

20 “(B) The number of such facilities that are
21 domestic.

22 “(C) The number of such facilities that are
23 foreign.

24 “(D) The number of such facilities that
25 are high-risk.

1 “(E) The number of such facilities that are
2 low-risk.

3 “(F) The number of such facilities that
4 hold food.”.

5 (c) REGISTRATION FEE.—Chapter VII (21 U.S.C.
6 371 et seq.) is amended by adding at the end of sub-
7 chapter C the following:

8 **“PART 6—FEES RELATING TO FOOD**

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

10 “(a) IN GENERAL.—

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

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

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

20 “(B) for any other facility—

21 “(i) for fiscal year 2010, not later
22 than the sooner of 90 days after the date
23 of the enactment of this part or December
24 31, 2009; and

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

3 “(b) FREE AMOUNTS.—

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

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

7 “(B) for fiscal year 2011 and each subse-
8 quent fiscal year, the fee for fiscal year 2010 as
9 adjusted under subsection (c).

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

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

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

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

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

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

18 The adjustment made each fiscal year under this sub-
19 section shall be added on a compounded basis to the sum
20 of all adjustments made each fiscal year after fiscal year
21 2010 under this subsection.

22 “(d) LIMITATIONS.—

23 “(1) IN GENERAL.—Fees under subsection (a)
24 shall be refunded for a fiscal year beginning after
25 fiscal year 2010 unless appropriations for salaries

1 and expenses of the Food and Drug Administration
2 for such fiscal year (excluding the amount of fees
3 appropriated for such fiscal year) are equal to or
4 greater than the amount of appropriations for the
5 salaries and expenses of the Food and Drug Admin-
6 istration for fiscal year 2010 (excluding the amount
7 of fees appropriated for such fiscal year) multiplied
8 by the adjustment factor applicable to the fiscal year
9 involved.

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

18 “(3) ADJUSTMENT FACTOR.—In this sub-
19 section, the term ‘adjustment factor’ applicable to a
20 fiscal year is the Consumer Price Index for all urban
21 consumers (all items; United States city average) for
22 October of the preceding fiscal year divided by such
23 Index for October 2009.

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

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

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

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

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

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

23 “(4) PUBLIC MEETINGS.—For each fiscal year,
24 the Secretary shall hold a public meeting on how
25 fees collected under this section will be used to de-

1 fray the costs of food safety activities in order to so-
2 licit the views of the regulated industry, consumers,
3 and other interested stakeholders.

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

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

17 “(h) ANNUAL FISCAL REPORTS.—Beginning with
18 fiscal year 2011, not later than 120 days after the end
19 of each fiscal year for which fees are collected under this
20 section, the Secretary shall prepare and submit to the
21 Committee on Energy and Commerce of the House of
22 Representatives and the Committee on Health, Education,
23 Labor, and Pensions of the Senate a report on the imple-
24 mentation of the authority for such fees during such fiscal

1 year and the use, by the Food and Drug Administration,
2 of the fees collected for such fiscal year.

3 “(i) DEFINITIONS.—In this section:

4 “(1) The term ‘costs of food safety activities’
5 means the expenses incurred in connection with food
6 safety activities for—

7 “(A) officers and employees of the Food
8 and Drug Administration, contractors of the
9 Food and Drug Administration, advisory com-
10 mittees, and costs related to such officers, em-
11 ployees, and committees and to contracts with
12 such contractors;

13 “(B) laboratory capacity;

14 “(C) management of information, and the
15 acquisition, maintenance, and repair of tech-
16 nology resources;

17 “(D) leasing, maintenance, renovation, and
18 repair of facilities and acquisition, maintenance,
19 and repair of fixtures, furniture, scientific
20 equipment, and other necessary materials and
21 supplies; and

22 “(E) collecting fees under this section and
23 accounting for resources allocated for food safe-
24 ty activities.

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

12 (d) TRANSITIONAL PROVISIONS.—

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

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

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

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

13 **SEC. 102. HAZARD ANALYSIS, RISK-BASED PREVENTIVE**
14 **CONTROLS, AND FOOD SAFETY PLAN.**

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

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

20 (b) REQUIREMENTS.—Chapter IV (21 U.S.C. 341 et
21 seq.) is amended by adding at the end the following:

22 **“SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVEN-**
23 **TIVE CONTROLS.**

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

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

3 “(2) identify, implement, and validate effective
4 preventive controls;

5 “(3) monitor preventive controls;

6 “(4) institute corrective actions when—

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

9 “(B) monitoring and verification show that
10 such controls were ineffective;

11 “(5) conduct verification activities;

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

14 “(7) reanalyze for hazards.

15 “(b) IDENTIFICATION OF HAZARDS.—

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

24 “(A) biological, chemical, physical, and ra-
25 diological hazards, natural toxins, pesticides,

1 drug residues, filth, decomposition, parasites,
2 allergens, and unapproved food and color addi-
3 tives; and

4 “(B) hazards that occur naturally, may be
5 unintentionally introduced, or may be inten-
6 tionally introduced, including by acts of ter-
7 rorism.

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

12 “(3) HAZARD ANALYSIS.—The owner, operator,
13 or agent of a facility shall identify and describe the
14 hazards evaluated under paragraph (1) or identified
15 under paragraph (2), to the extent applicable to the
16 facility, in a hazard analysis.

17 “(c) PREVENTIVE CONTROLS.—

18 “(1) IN GENERAL.—The owner, operator, or
19 agent of a facility shall identify, implement, and vali-
20 date effective preventive controls to prevent, elimi-
21 nate, or reduce to acceptable levels the occurrence of
22 any hazards identified in the hazard analysis under
23 subsection (b)(3)

24 “(2) IDENTIFIED BY THE SECRETARY.—The
25 Secretary may establish by regulation or guidance

1 preventive controls for specific product types to pre-
2 vent intentional or unintentional contamination
3 throughout the supply chain. The owner, operator,
4 or agent of a facility shall implement any preventive
5 controls identified by the Secretary under this para-
6 graph.

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

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

16 “(1) no product from such facility enters com-
17 merce; and

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

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

23 “(1) the preventive controls identified under
24 subsection (c) have been validated as adequate to

1 control the hazards identified in the hazard analysis
2 under subsection (b)(3);

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

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

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

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

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

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

19 “(i) not less than every 2 years;

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

23 “(iii) if the Secretary determines that
24 it is appropriate to protect public health;
25 and

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

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

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

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

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

24 “(2) PREVENTIVE CONTROLS.—The term ‘pre-
25 ventive controls’ means those risk-based procedures,

1 practices, and processes that a person knowledgeable
2 about the safe manufacturing, processing, packing,
3 transporting, or holding of food would employ to
4 prevent, eliminate, or reduce to an acceptable level
5 the hazards identified in the hazard analysis under
6 subsection (b)(3) and that are consistent with the
7 current scientific understanding of safe food manu-
8 facturing, processing, packing, transporting, or hold-
9 ing at the time of the analysis. Those procedures,
10 practices, and processes shall include the following,
11 as appropriate:

12 “(A) Sanitation procedures and practices.

13 “(B) Supervisor, manager, and employee
14 hygiene training.

15 “(C) Process controls.

16 “(D) An allergen control program to mini-
17 mize potential allergic reactions in humans
18 from ingestion of, or contact with, human and
19 animal food.

20 “(E) Good manufacturing practices.

21 “(F) Verification procedures, practices,
22 and processes for suppliers and incoming ingre-
23 dients, which may include onsite auditing of
24 suppliers and testing of incoming ingredients.

1 “(G) Other procedures, practices, and
2 processes established by the Secretary under
3 subsection (c)(2).

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

15 **“SEC. 418A. FOOD SAFETY PLAN.**

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

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

24 “(1) The hazard analysis and any reanalysis
25 conducted under section 418.

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

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

7 “(4) A description of the procedures for taking
8 corrective actions.

9 “(5) A description of verification activities for
10 the preventive controls, including validation, review
11 of monitoring and corrective action records, and pro-
12 cedures for determining whether the preventive con-
13 trols are effectively preventing, eliminating, or re-
14 ducing to an acceptable level the occurrence of iden-
15 tified hazards or conditions.

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

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

21 “(8) A description of the facility’s procedures
22 for tracing the distribution history of articles of
23 food, whether voluntarily or when required under
24 section 414.

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

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

9 (c) GUIDANCE OR REGULATIONS.—

10 (1) IN GENERAL.—The Secretary of Health and
11 Human Services (referred to in this subsection as
12 the “Secretary”) shall issue guidance or promulgate
13 regulations to establish science-based standards for
14 conducting a hazard analysis, documenting hazards,
15 identifying and implementing preventive controls,
16 and documenting the implementation of the preven-
17 tive controls, including verification and corrective ac-
18 tions under sections 418 and 418A of the Federal
19 Food, Drug, and Cosmetic Act (as added by sub-
20 section (b)).

21 (2) INTERNATIONAL STANDARDS.—In issuing
22 guidance or regulations under paragraph (1), the
23 Secretary shall review international hazard analysis
24 and preventive control standards that are in exist-
25 ence on the date of the enactment of this Act and

1 relevant to such guidelines or regulations to ensure
2 that the programs under sections 418 and 418A of
3 the Federal Food, Drug, and Cosmetic Act (as
4 added by subsection (b)) are consistent, to the ex-
5 tent the Secretary determines practicable and appro-
6 priate, with such standards.

7 (3) AUTHORITY WITH RESPECT TO CERTAIN
8 FACILITIES.—The Secretary may, by regulation, ex-
9 empt or modify the requirements for compliance
10 under this section and the amendments made by this
11 section with respect to facilities that are solely en-
12 gaged in—

13 (A) the production of food for animals
14 other than man or the storage of packaged
15 foods that are not exposed to the environment;
16 or

17 (B) the storage of raw agricultural com-
18 modities for further processing.

19 (4) SMALL BUSINESSES.—The Secretary—

20 (A) shall consider the impact of any guid-
21 ance or regulations under this section on small
22 businesses; and

23 (B) shall issue guidance to assist small
24 businesses in complying with the requirements

1 of this section and the amendments made by
2 this section.

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

15 (e) EFFECTIVE DATE.—

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

19 (2) EXCEPTIONS.—Notwithstanding paragraph
20 (1)—

21 (A) the amendments made by this section
22 shall apply to a small business (as defined by
23 the Secretary) after the date that is 2 years
24 after the date of the enactment of this Act; and

1 (B) the amendments made by this section
2 shall apply to a very small business (as defined
3 by the Secretary) after the date that is 3 years
4 after the date of the enactment of this Act.

5 **SEC. 103. PERFORMANCE STANDARDS.**

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

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

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

15 **“SEC. 419. PERFORMANCE STANDARDS.**

16 “The Secretary shall, not less frequently than every
17 2 years, review and evaluate epidemiological data and
18 other appropriate sources of information, including re-
19 search under section 123 of the Food Safety Enhancement
20 Act of 2009, to identify the most significant food-borne
21 contaminants and the most significant resulting hazards.
22 The Secretary shall issue, as soon as practicable, through
23 guidance or by regulation, science-based performance
24 standards (which may include action levels) applicable to
25 foods or food classes, as appropriate to minimize to an

1 acceptable level, prevent, or eliminate the occurrence of
2 such hazards. Such standards shall be applicable to foods
3 and food classes.”.

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

14 **SEC. 104. SAFETY STANDARDS FOR FRESH PRODUCE AND**
15 **CERTAIN OTHER RAW AGRICULTURAL COM-**
16 **MODITIES.**

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

20 “(1) If it has been grown, harvested, processed,
21 packed, sorted, transported, or held under conditions that
22 do not meet the standards established under section
23 419A.”.

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

4 **“SEC. 419A. SAFETY STANDARDS FOR PRODUCE AND CER-**
5 **TAIN OTHER RAW AGRICULTURAL COMMOD-**
6 **ITIES.**

7 “(a) STANDARDS.—The Secretary shall establish by
8 regulation science-based standards for the safe growing,
9 harvesting, processing, packing, sorting, transporting, and
10 holding of raw agricultural commodities—

11 “(1) that are from a plant or a fungus; 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-

1 cluding by acts of terrorism, into raw agricul-
2 tural commodities that are from a plant or a
3 fungus; and

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

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

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

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

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

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

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

1 on wildlife habitat, conservation practices, water-
2 shed-protection efforts, and organic production
3 methods;

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

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

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

18 (b) TIMING.—

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

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 one 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, including any facility that manufactures or
11 processes raw products of animal origin (including
12 fish and fisheries products) or other foods as des-
13 ignated by the Secretary. The Secretary shall ran-
14 domly inspect a category 1 food facility at least
15 every 6 to 18 months.

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

21 “(C) CATEGORY 3.—A category 3 food facility
22 is a facility that holds food. The Secretary shall ran-
23 domly inspect a category 3 facility at least every 3
24 to 4 years.

25 “(5) The Secretary—

1 “(A) may, by guidance, modify the types of
2 food facilities within a category under paragraph
3 (4);

4 “(B) may alter the inspection frequencies speci-
5 fied in paragraph (4) based on the need to respond
6 to foodborne illness outbreaks and food recalls; and

7 “(C) may inspect a facility more frequently
8 than the inspection frequency provided by paragraph
9 (4).

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

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

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

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

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

22 (b) REPORTS ON RISK-BASED INSPECTIONS OF
23 FOOD FACILITIES.—

24 (1) ANNUAL REPORT.—Not later than Decem-
25 ber 31 of each year, the Secretary of Health and

1 Human Services shall submit a report to the Com-
2 mittee on Energy and Commerce of the House of
3 Representatives and the Committee on Health, Edu-
4 cation, Labor, and Pensions of the Senate describ-
5 ing—

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

12 (B) the costs of implementing the risk-
13 based inspection schedule for the preceding 12
14 months.

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

1 (A) adjustments to the timing of the
2 schedule and other ways to increase the effi-
3 ciency of inspections in order to enable the
4 Food and Drug Administration to conduct more
5 inspections; and

6 (B) other methods to contribute to assur-
7 ing the safety of food.

8 **SEC. 106. ACCESS TO RECORDS.**

9 (a) RECORDS INSPECTION.—Subsection (a) of section
10 414 (21 U.S.C. 350c) is amended to read as follows:

11 “(a) RECORDS INSPECTION.—Each person who pro-
12 duces, manufactures, processes, packs, transports, distrib-
13 utes, receives, or holds an article of food in the United
14 States or for import into the United States shall, at the
15 request of an officer or employee duly designated by the
16 Secretary, permit such officer or employee, upon presen-
17 tation of appropriate credentials, at reasonable times and
18 within reasonable limits and in a reasonable manner, to
19 have access to and copy all records relating to such article
20 bearing on whether the food is adulterated, misbranded,
21 or otherwise in violation of this Act, including all records
22 collected or developed to comply with section 418 or 418A.
23 The requirement under the preceding sentence applies to
24 all records relating to the production, manufacture, proc-
25 essing, packing, transporting, distribution, receipt, hold-

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

4 (b) REGULATIONS CONCERNING RECORDKEEPING.—

5 (1) AMENDMENT.—Subsection (b) of section
6 414 (21 U.S.C. 350c) is amended to read as follows:

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

23 (2) APPLICATION.—The Secretary of Health
24 and Human Services shall promulgate revised regu-
25 lations to implement section 414(b) of the Federal

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

8 (c) CONFORMING AMENDMENTS.—Section 704(a)(1)
9 (21 U.S.C. 374(a)(1)) is amended—

10 (1) in the first sentence—

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

13 (B) by inserting “produced,” before “man-
14 ufactured”;

15 (2) in the second sentence—

16 (A) by striking “(excluding farms or res-
17 taurants)”;

18 (B) by inserting “produces,” before “man-
19 ufactures”;

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

21 (D) by striking “described in section 414”
22 and inserting “described in or required under
23 section 414”; and

24 (E) by striking “when the Secretary has a
25 reasonable belief that an article of food is adul-

1 terated and presents a threat of serious adverse
2 health consequences or death to humans or ani-
3 mals” and inserting “bearing on whether such
4 food is adulterated, misbranded, or otherwise in
5 violation of this Act, including all records col-
6 lected or developed to comply with section 418
7 or 418A”; and

8 (3) in the fourth sentence—

9 (A) by striking “the preceding sentence”
10 and inserting “either of the preceding two sen-
11 tences”; and

12 (B) by inserting “recipes for food,” before
13 “financial data,”.

14 **SEC. 107. TRACEABILITY OF FOOD.**

15 (a) **PROHIBITED ACT.**—Section 301(e) (21 U.S.C.
16 331(e)) is amended by inserting “, the violation of any
17 requirement of the food tracing system under section
18 414(e);” before “or the refusal to permit access to or
19 verification or copying of any such required record”.

20 (b) **IMPORTS.**—Section 801(a) (21 U.S.C. 381(a)) is
21 amended by inserting “or (4) the requirements of section
22 414 have not been complied with regarding such article,”
23 before “then such article shall be refused admission”.

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

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

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

5 “(c) TRACING SYSTEM FOR FOOD.—

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

10 “(2) INFORMATION GATHERING.—

11 “(A) TRACING TECHNOLOGIES.—Before
12 issuing a proposed regulation under this sub-
13 section, the Secretary shall—

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

22 “(I) maintain the full pedigree of
23 the origin and previous distribution
24 history of the food;

1 “(II) link that history with the
2 subsequent distribution of the food;

3 “(III) establish and maintain a
4 system for tracing the food that is
5 interoperable with the systems estab-
6 lished and maintained by other such
7 persons; and

8 “(IV) use a unique identifier for
9 each facility owned or operated by
10 such person for such purpose, as spec-
11 ified under section 911; and

12 “(ii) to the extent practicable, as-
13 sess—

14 “(I) the costs and benefits associ-
15 ated with the adoption and use of
16 such technologies;

17 “(II) the feasibility of such tech-
18 nologies for different sectors of the
19 food industry; and

20 “(III) whether such technologies
21 are compatible with the requirements
22 of this subsection.

23 “(B) PUBLIC MEETINGS.—Before issuing a
24 proposed regulation under this subsection, the
25 Secretary shall conduct not less than 2 public

1 meetings in diverse geographical areas of the
2 United States to provide persons in different re-
3 gions an opportunity to provide input and infor-
4 mation to the Secretary.

5 “(C) PILOT PROJECTS.—The Secretary
6 shall conduct 1 or more pilot projects in coordi-
7 nation with 1 or more sectors of the food indus-
8 try to explore and evaluate tracing systems for
9 food.

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

19 “(A) the establishment and maintenance of
20 lot numbers;

21 “(B) a standardized format for pedigree
22 information; and

23 “(C) the use of a common nomenclature
24 for food.

25 “(4) EXEMPTIONS.—

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

4 “(i) produced on a farm; and

5 “(ii) sold by the owner, operator, or
6 agent in charge of such farm directly to a
7 consumer or to a restaurant or grocery
8 store.

9 “(B) OTHER FOODS.—The Secretary may
10 by notice in the Federal Register exempt a food
11 or a type of facility, farm, or restaurant from,
12 or modify the requirements with respect to, the
13 requirements of this subsection if the Secretary
14 determines that a tracing system for such food
15 or type of facility, farm, or restaurant is not
16 necessary to protect the public health.

17 “(C) PREVIOUS SOURCES AND SUBSE-
18 QUENT RECIPIENTS.—For a food covered by an
19 exemption under subparagraph (B), the Sec-
20 retary shall require each person who produces,
21 manufactures, processes, packs, transports, or
22 holds such food to maintain records to identify
23 the immediate previous sources of such food
24 and its ingredients and the immediate subse-
25 quent recipients of such food.

1 “(D) RESTAURANTS AND GROCERY
2 STORES.—For a food covered by an exemption
3 under subparagraph (A), restaurants and gro-
4 cery stores shall keep records documenting the
5 farm that was the source of the food.”.

6 **SEC. 108. REINSPECTION AND FOOD RECALL FEES APPLI-**
7 **CABLE TO FACILITIES.**

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

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

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

15 “(1) that—

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

20 “(B) because of such violation, undergoes
21 additional inspection by the Food and Drug Ad-
22 ministration; or

23 “(2) during such fiscal year is subject to a food
24 recall.

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

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

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

12 “(c) USE OF FEES.—The Secretary shall make all
13 fees collected pursuant to this section available solely to
14 pay for the costs referred to in subsection (b).

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

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

23 **SEC. 109. CERTIFICATION AND ACCREDITATION.**

24 (a) MISBRANDING.—

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

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

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

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

15 (1) in section 801(a), as amended by section
16 107(b), by inserting after the third sentence the fol-
17 lowing: “If an article of food being imported or of-
18 fered for import into the United States is not in
19 compliance with the requirement of subsection (p)
20 (relating to certifications of compliance with this
21 Act), then such article shall be refused admission.”;

22 (2) in the second sentence of section 801(b), by
23 striking “the fourth sentence” and inserting “the
24 fifth sentence”; and

1 (3) by adding at the end of section 801 the fol-
2 lowing:

3 “(p) CERTIFICATIONS CONCERNING IMPORTED ARTI-
4 CLES.—

5 “(1) IN GENERAL.—

6 “(A) REQUIREMENT.—The Secretary shall
7 require, as an additional condition of granting
8 admission to an article of food being imported
9 or offered for import into the United States,
10 that a qualified certifying entity provide a cer-
11 tification that the article complies with specified
12 requirements of this Act if—

13 “(i) for food imported from a par-
14 ticular country or region, based on the
15 adequacy of government controls in such
16 country or region or other information rel-
17 evant to such food, certification would as-
18 sist the Secretary in determining whether
19 to refuse to admit such article under sub-
20 section (a);

21 “(ii) for a type of food that could pose
22 a significant risk to health, certification
23 would assist the Secretary in determining
24 whether such article poses such risk; or

1 “(iii) for an article imported from a
2 particular country, there is an agreement
3 between the Secretary and the government
4 of such country providing for such certifi-
5 cation.

6 “(B) CONTENTS OF CERTIFICATION.—
7 Such certification shall include such informa-
8 tion regarding compliance as the Secretary may
9 specify, and may be provided in the form of
10 shipment-specific certificates, a listing of cer-
11 tified facilities or other entities, or in such other
12 form as the Secretary may specify.

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

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

1 “(A) an agency or a representative of the
2 government of the country from which the arti-
3 cle originated, as designated by such govern-
4 ment or the Secretary; or

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

9 “(3) NO CONFLICTS OF INTEREST.—

10 “(A) IN GENERAL.—The Secretary shall
11 issue regulations to ensure that any qualified
12 certifying entity and its auditors are free from
13 conflicts of interest.

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 maintain records pertaining to the fi-
15 nancial interests of the personnel involved
16 in audits;

17 “(vii) neither the qualified certifying
18 entity nor any of its auditors acting for the
19 qualified certifying entity shall participate
20 in the production, manufacture, processing,
21 packing, holding, promotion, or sale of any
22 product of the type it certifies;

23 “(viii) neither the qualified certifying
24 entity nor any of its auditors shall provide
25 consultative services to any facility cer-

1 tified by the qualified certifying entity, or
2 the owner, operator, or agent in charge of
3 such a facility;

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

8 “(x) fees charged or accepted shall
9 not be contingent or based upon the report
10 made by the qualified certifying entity or
11 any personnel involved in the audit pro-
12 cess;

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

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

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

1 “(xiv) the qualified certifying entity
2 and its auditors shall sign a statement at-
3 testing to compliance with the conflict of
4 interests requirements under this para-
5 graph; and

6 “(xv) the qualified certifying entity
7 shall also ensure that any subcontractors
8 that might be used (such as laboratories
9 and sampling services) provide similar as-
10 surances.

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

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

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

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

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

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

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

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

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

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

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

23 “(a) IN GENERAL.—Whenever analytical testing of
24 an article of food is conducted as part of testimony for
25 the purposes of section 801(a), or for other purposes as

1 the Secretary deems appropriate, such testing shall be
2 conducted by a laboratory that—

3 “(1) is independent of the person on whose be-
4 half such testing is conducted;

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

8 “(3) samples such article, itself or through an
9 independent third party, with adequate controls for
10 ensuring the integrity of the samples analyzed.

11 “(b) RECOGNITION OF LABORATORY ACCREDITATION
12 BODIES.—The Secretary shall establish and implement a
13 program for the recognition, based on standards the Sec-
14 retary deems appropriate, of laboratory accreditation bod-
15 ies that accredit laboratories to perform analytical testing
16 for the purposes of this section. The Secretary shall issue
17 regulations or guidance to implement this program.

18 “(c) ON-SITE AUDITS.—In evaluating whether an ac-
19 creditation body meets, or continues to meet, the stand-
20 ards for recognition under subsection (b), the Secretary
21 may—

22 “(1) observe on-site audits of laboratories by
23 such accreditation bodies; or

24 “(2) for any laboratory that is accredited by
25 such accreditation body under this section, upon re-

1 quest of an officer or employee designated by the
2 Secretary and upon presentation of appropriate cre-
3 dentials, at reasonable times and within reasonable
4 limits and in a reasonable manner, conduct an on-
5 site audit of the laboratory, which shall include ac-
6 cess to, and copying and verification of, any related
7 records.

8 “(d) PUBLICATION OF LIST OF RECOGNIZED AC-
9 CREDITATION BODIES.—The Secretary shall publish and
10 maintain on the public Web site of the Food and Drug
11 Administration a list of accreditation bodies recognized by
12 the Secretary under subsection (b).

13 “(e) NOTIFICATION OF ACCREDITATION OF LABORA-
14 TORY.—An accreditation body that has been recognized
15 pursuant to this section shall promptly notify the Sec-
16 retary whenever it accredits a laboratory for the purposes
17 of this section and whenever it withdraws or suspends
18 such accreditation.

19 “(f) ADVANCE NOTICE.—Whenever analytical testing
20 is conducted pursuant to subsection (a), the person on
21 whose behalf the testing is conducted shall notify the Sec-
22 retary before any sample of the article is collected. Such
23 notice shall contain information the Secretary determines
24 is appropriate to identify the article, the location of the

1 article, and each laboratory that will analyze the sample
2 on the person's behalf.

3 “(g) CONTENTS OF LABORATORY PACKAGES.—

4 Whenever analytical testing is conducted pursuant to sub-
5 section (a), the laboratory conducting such testing shall
6 submit, directly to the Secretary—

7 “(1) the results of all analyses conducted by the
8 laboratory on each sample of such article;

9 “(2) all information the Secretary deems appro-
10 priate to—

11 “(A) determine whether the laboratory is
12 accredited by a recognized laboratory accredita-
13 tion body;

14 “(B) identify the article tested;

15 “(C) evaluate the analytical results; and

16 “(D) determine whether the requirements
17 of this section have been met.

18 “(h) EXIGENT CIRCUMSTANCES.—The Secretary
19 may waive the requirement of subsection (a)(2) (relating
20 to analytical methods) on a laboratory- or method-basis
21 due to exigent or other circumstances.

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

24 “(1) the ability of the Secretary to review and
25 act upon information from the analytical testing of

1 food (including under this section), including deter-
2 mining the sufficiency of such information and test-
3 ing; or

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

7 **SEC. 111. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
8 **OF ADULTERATED OR MISBRANDED FOOD.**

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

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

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

16 (b) NOTIFICATION, NONDISTRIBUTION, AND RECALL
17 OF ADULTERATED OR MISBRANDED FOOD.—Chapter IV
18 (21 U.S.C. 341 et seq.), as amended by sections 102, 103,
19 and 104, is amended by adding at the end the following:

20 **“SEC. 420. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
21 **OF ADULTERATED OR MISBRANDED FOOD.**

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

24 “(1) IN GENERAL.—A responsible party as that
25 term is defined in section 417(a)(1) or a person re-

1 quired to register under section 801(r) that has rea-
2 son to believe that an article of food when intro-
3 duced into or while in interstate commerce, or while
4 held for sale (regardless of whether the first sale)
5 after shipment in interstate commerce, is adulter-
6 ated or misbranded in a manner that presents a rea-
7 sonable probability that the use or consumption of,
8 or exposure to, the article (or an ingredient or com-
9 ponent used in any such article) will cause a threat
10 of serious adverse health consequences or death to
11 humans or animals shall, as soon as practicable, no-
12 tify the Secretary of the identity and location of the
13 article.

14 “(2) MANNER OF NOTIFICATION.—Notification
15 under paragraph (1) shall be made in such manner
16 and by such means as the Secretary may require by
17 regulation or guidance.

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

23 “(1) recall such article, and

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

4 “(c) ORDER TO CEASE DISTRIBUTION.—If the Sec-
5 retary has reason to believe that the use or consumption
6 of, or exposure to, an article of food may cause adverse
7 health consequences or death to humans or animals, the
8 Secretary shall have the authority to issue an order requir-
9 ing any person who distributes such article—

10 “(1) to immediately cease distribution of such
11 article; and

12 “(2) to immediately notify any person to whom
13 the article was distributed of the order.

14 In providing for notice under paragraph (2), the Secretary
15 may, as appropriate, allow such notice to be provided with
16 the assistance of health care professionals, State or local
17 health officials, or other persons designated by the Sec-
18 retary.

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

1 taken voluntarily by the person, including after a request
2 under subsection (b). Except as provided in subsection (f),
3 an informal hearing shall be held within 10 business days,
4 or less as determined by the Secretary, after such an ap-
5 peal is filed, unless the parties jointly agree to an exten-
6 sion. After affording an opportunity for an informal hear-
7 ing, the Secretary shall determine whether the order
8 should be amended to require a recall of such article. If,
9 after providing an opportunity for such a hearing, the Sec-
10 retary determines that inadequate grounds exist to sup-
11 port the actions required by the order, the Secretary shall
12 vacate the order.

13 “(e) ORDER TO RECALL.—

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

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

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

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

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

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

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

17 “(f) EMERGENCY RECALL ORDER.—

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

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

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

4 “(2) ACTION FOLLOWING ORDER.—Any person
5 who is subject to an emergency recall order under
6 this subsection shall immediately recall such article
7 and provide notification as required by such order,
8 and may appeal within 24 hours after issuance such
9 order to the Secretary. An informal hearing shall be
10 held within 10 business days, or less as determined
11 by the Secretary, after such an appeal is filed, un-
12 less the parties jointly agree to an extension. After
13 affording an opportunity for an informal hearing,
14 the Secretary shall determine whether the order
15 should be amended pursuant to subsection (e)(1). If,
16 after providing an opportunity for such a hearing,
17 the Secretary determines that inadequate grounds
18 exist to support the actions required by the order,
19 the Secretary shall vacate the order.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 (2) in subsection (d)(1)—

9 (A) in the matter preceding subparagraph
10 (A), by inserting “following a timely review of
11 any reasonably available data and information,”
12 after “reportable food,”;

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

15 (C) by redesignating subparagraph (B) as
16 subparagraph (C); and

17 (D) by inserting after subparagraph (A)
18 the following:

19 “(B) submit, with such report, through the
20 electronic portal, documentation of results from
21 any sampling and testing of such article, includ-
22 ing—

23 “(i) analytical results from testing of
24 such article conducted by or on behalf of

1 the responsible party under section 418,
2 418A, 419, 419A, or 714;

3 “(ii) analytical results from testing
4 conducted by or on behalf of such respon-
5 sible party of a component of such article;

6 “(iii) analytical results of environ-
7 mental testing of any facility at which such
8 article, or a component of such article, is
9 manufactured, processed, packed, or held;
10 and

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

21 (3) in subsection (e)—

22 (A) in paragraph (1), by inserting “if the
23 responsible party is required to register” after
24 “415(a)(3)”;

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

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

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

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

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

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

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

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

1 “(B) Any such information provided to a State or
2 local government agency shall not be disclosed by such
3 agency.

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

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

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

19 “(B) any international organization established
20 by law, treaty, or other governmental action and
21 having responsibility—

22 “(i) to facilitate global or regional harmo-
23 nization of standards and requirements in an
24 area of responsibility of the Food and Drug Ad-
25 ministration; or

1 “(ii) to promote and coordinate public
2 health efforts,
3 if the agency or organization provides adequate as-
4 surances to the Secretary that the agency or organi-
5 zation will preserve the confidentiality of the infor-
6 mation.

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

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

24 “(e) Nothing in subsection (d) authorizes the Sec-
25 retary to withhold information from the Congress or pre-

1 vents the Secretary from complying with an order of a
2 court of the United States.

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

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

11 **SEC. 113. SAFE AND SECURE FOOD IMPORTATION PRO-**
12 **GRAM.**

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

15 **“SEC. 805. SAFE AND SECURE FOOD IMPORTATION PRO-**
16 **GRAM.**

17 “(a) IN GENERAL.—The Secretary may establish by
18 regulation or guidance a program that facilitates the
19 movement of food through the importation process under
20 this Act if the importer of such 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 safety and security guidelines applica-
10 ble to the importation of food.

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

13 “(A) The personnel of the person import-
14 ing the food.

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

17 “(C) The sufficiency of preventive controls
18 for food and ingredients purchased by such per-
19 son.

20 “(D) Vendor and supplier information.

21 “(E) Other programs for certification or
22 verification by a qualified certifying entity used
23 by the importer.

24 “(F) Such other factors as the Secretary
25 determines necessary.”.

1 **SEC. 114. INFANT FORMULA.**

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

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

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

12 (1) in subsection (b)(1), by adding at the end
13 the following: “The quality factor requirements es-
14 tablished under this paragraph may include require-
15 ments for one or more clinical studies to dem-
16 onstrate that the new infant formula supports nor-
17 mal physical growth of infants.”;

18 (2) in subsection (b)(4), amend subparagraph
19 (B) to read as follows:

20 “(B) Records required under subparagraph (A) with
21 respect to an infant formula shall be retained for at least
22 one year after the expiration of the shelf life of such infant
23 formula. Such records shall be made available to the Sec-
24 retary for review and duplication upon request of the Sec-
25 retary.”;

26 (3) in subsection (c)(1)—

1 (A) in subparagraph (A), by striking
2 “and” at the end;

3 (B) in subparagraph (B), by striking
4 “(e)(1).” at the end and inserting “(d)(1),
5 and”; and

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

7 “(C) the Secretary has by letter informed such
8 person that the registration requirements and the
9 requirements in subsection (d)(1) have been satis-
10 fied.”; and

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

13 “(C) scientific evidence and other evidence, as
14 identified in regulations promulgated by the Sec-
15 retary, that demonstrates that the infant formula
16 satisfies the requirements of subsection (b)(1), and,
17 as demonstrated by the testing required under sub-
18 section (b)(3), that it satisfies the requirements of
19 subsection (i), and

20 “(D) scientific evidence and other evidence, as
21 identified in regulations promulgated by the Sec-
22 retary, that demonstrates that the processing of the
23 infant formula complies with the requirements of
24 subsection (b)(2).”.

1 **Subtitle B—Intervention**

2 **SEC. 121. PUBLIC HEALTH ASSESSMENT SYSTEM.**

3 (a) SURVEILLANCE SYSTEM.—The Secretary of
4 Health and Human Services (in this subtitle referred to
5 as the “Secretary”) shall build upon the existing surveil-
6 lance system for food, based on a representative propor-
7 tion of the population of the United States, to assess the
8 frequency and sources of human illness in the United
9 States associated with the consumption of food. In car-
10 rying out this subsection, the Secretary shall establish—

11 (1) means for integrating and linking multiple
12 diverse data sources within the Department of
13 Health and Human Services; and

14 (2) mechanisms for sharing data across agen-
15 cies and with the public to maximize the potential
16 use of the data to create a more accurate picture of
17 the trends, sources, demographic distribution, and
18 outcomes of food-borne illness.

19 (b) SAMPLING AND ASSESSMENT.—

20 (1) IN GENERAL.—The Secretary shall utilize,
21 as appropriate, samples of food collected and ana-
22 lyzed by, or on behalf of, the Secretary in carrying
23 out the Secretary’s duties under this Act and the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 301 et seq.) and may collect and analyze additional

1 samples of food to assess the nature, frequency of
2 occurrence, and amounts of contaminants in food.

3 (2) REQUIREMENTS.—Assessment by the Sec-
4 retary under this section may employ, in the Sec-
5 retary's discretion, statistically valid monitoring, in-
6 cluding market-basket studies, on the nature, fre-
7 quency of occurrence, and amounts of contaminants
8 in food available to consumers, and at the request of
9 the Secretary such other information as the Sec-
10 retary determines may be useful.

11 (c) PUBLIC AVAILABILITY OF ASSESSMENT.—To the
12 extent it does not impede the ability of the United States
13 to protect against terrorist threats and other intentional
14 attacks against the food supply, the Secretary may make
15 publicly available, by posting on the Web site of the De-
16 partment of Health and Human Services, the results of
17 any assessment conducted under this section. To the ex-
18 tent feasible with the data and information available, the
19 assessment may rank food categories based on their haz-
20 ard to human health and may address—

21 (1) the safety of commercial harvesting and
22 processing, as compared with the health hazards as-
23 sociated with food products that are harvested for
24 recreational or subsistence purposes and prepared
25 noncommercially;

1 (2) the safety of food products that are domes-
2 tically harvested and processed, as compared with
3 the health hazards associated with food products
4 that are harvested or processed outside the United
5 States; and

6 (3) contamination originating from handling
7 practices that occur prior to or after sale of food
8 products to consumers.

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

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

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

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

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

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

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

8 (2) develop standardized formats for written
9 and broadcast advisories; and

10 (3) incorporate State and local advisories into
11 the national public education program required
12 under subsection (a).

13 **SEC. 123. RESEARCH.**

14 (a) IN GENERAL.—The Secretary shall conduct re-
15 search to assist in the implementation of this Act, includ-
16 ing studies to—

17 (1) improve sanitation and food safety practices
18 in the production, harvesting, and processing of food
19 products;

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

22 (3) develop efficient, rapid, and sensitive meth-
23 ods for determining and detecting the presence of
24 contaminants in food products;

1 (4) determine the sources of contamination of
2 food and food products, including critical points of
3 risk for fresh produce and other raw agricultural
4 commodities;

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

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

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

11 (8) address common and emerging zoonotic dis-
12 eases;

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

15 (10) analyze the incidence of antibiotic resist-
16 ance as it pertains to the food supply and develop
17 new methods to reduce the transfer of antibiotic re-
18 sistance to humans; and

19 (11) conduct other research that supports the
20 purposes of this Act.

21 (b) CONTRACT AUTHORITY.—The Secretary is au-
22 thorized to enter into contracts and agreements with any
23 State, university, government agency, or other person to
24 carry out this section.

1 **Subtitle C—Response**

2 **SEC. 131. PROCEDURES FOR SEIZURE.**

3 Section 304(b) (21 U.S.C. 334(b)) is amended by in-
4 serting “and except that, with respect to proceedings relat-
5 ing to food, Rule G of the Supplemental Rules of Admi-
6 rality or Maritime Claims and Asset Forfeiture Actions
7 shall not apply in any such case, exigent circumstances
8 shall be deemed to exist for all seizures brought under this
9 section, and the summons and arrest warrant shall be
10 issued by the clerk of the court without court review in
11 any such case” after “in any such case shall be tried by
12 jury”.

13 **SEC. 132. ADMINISTRATIVE DETENTION.**

14 (a) AMENDMENTS.—Section 304(h) (21 U.S.C.
15 334(h)) is amended—

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

19 (2) in paragraph (1)(A), by striking “presents
20 a threat of serious adverse health consequences or
21 death to humans or animals” and inserting “is adul-
22 terated, misbranded, or otherwise in violation of this
23 Act”;

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

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

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

6 (b) REGULATIONS.—The Secretary shall issue regula-
7 tions or guidance to implement the amendments made by
8 this section.

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

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

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

16 “(qq) The violation of a quarantine under section
17 304(i).”.

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

20 “(i) QUARANTINE OF GEOGRAPHIC LOCATION.—

21 “(1) AUTHORITY TO QUARANTINE.—If the Sec-
22 retary determines that there is credible evidence or
23 information that an article of food presents a threat
24 of serious adverse health consequences or death to
25 humans or animals, the Secretary may quarantine

1 any geographic area within the United States where
2 the Secretary reasonably believes such food is lo-
3 cated or from which such food originated. The au-
4 thority to quarantine includes prohibiting or restrict-
5 ing the movement of food or of any vehicle being
6 used or that has been used to transport or hold such
7 food within the geographic area.

8 “(2) NOTIFICATION PROCEDURES.—Before any
9 quarantine action is taken in any State under this
10 subsection, the Secretary shall notify an appropriate
11 official of the State affected and shall issue a public
12 announcement of—

13 “(A) the Secretary’s findings that support
14 the quarantine action;

15 “(B) the area affected by the intended
16 quarantine action;

17 “(C) the reasons for the intended quar-
18 antine action; and

19 “(D) where practicable, an estimate of the
20 anticipated duration of the quarantine.

21 The Secretary is not required to make such an-
22 nouncement by publication in the Federal Register,
23 but may use a newspaper, radio or television, the
24 Internet, or any reasonable means to make such an-
25 nouncement.

1 “(3) NONDELEGATION.—The authority to quar-
2 antine under this subsection is limited to the Com-
3 missioner of Food and Drugs, the Principal Deputy
4 Commissioner, and the Associate Commissioner for
5 Regulatory Affairs of the Food and Drug Adminis-
6 tration.”

7 **SEC. 134. CRIMINAL PENALTIES.**

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

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

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

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

19 **SEC. 135. CIVIL PENALTIES FOR VIOLATIONS RELATING TO**
20 **FOOD.**

21 (a) IN GENERAL.—Paragraph (2) of section 303(f)
22 (21 U.S.C. 331 et seq.) is amended to read as follows:

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

1 “(i) \$100,000, in the case of an individual;
2 and
3 “(ii) \$500,000, in the case of any other
4 person.
5 “(B) Each violation described in subparagraph
6 (A) and each day during which the violation con-
7 tinues shall be considered to be a separate offense.

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

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

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

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

22 “(ss) The failure to submit information relating to
23 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 “(q) 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.

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

13 **TITLE II—MISCELLANEOUS**

14 **SEC. 201. TREATMENT OF CARBON MONOXIDE USED TO** 15 **PRESERVE COLOR OF MEAT, POULTRY PROD-** 16 **UCTS, OR SEAFOOD AS COLOR ADDITIVE.**

17 (a) IN GENERAL.—Paragraph (t) of section 201 (21
18 U.S.C. 321) is amended by adding at the end the fol-
19 lowing:

20 “(4) In the case of food that is meat within the mean-
21 ing of the Federal Meat Inspection Act, a poultry product
22 within the meaning of the Poultry Products Inspection
23 Act, or seafood (including all fresh or saltwater fish,
24 molluscan shellfish, crustaceans, and other forms of
25 aquatic animal life) intended for human consumption as

1 food within the meaning of paragraph (f) (referred to col-
2 lectively in this paragraph as ‘seafood’), the term ‘color
3 additive’ shall include carbon monoxide under conditions
4 of use that may impart, maintain, preserve, stabilize, fix,
5 or otherwise affect the color of fresh meat, poultry prod-
6 ucts, or seafood.”.

7 (b) ACTION BY SECRETARY.—The Secretary of
8 Health and Human Services shall—

9 (1) promulgate a final regulation in accordance
10 with section 721 of the Federal Food, Drug, and
11 Cosmetic Act (21 U.S.C. 379e) for use of carbon
12 monoxide in or on meat, poultry products, and sea-
13 food; or

14 (2) publish in the Federal Register a decision
15 against promulgating such a regulation.

16 (c) APPLICATION.—Section 201(t)(4) of the Federal
17 Food, Drug, and Cosmetic Act, as added by subsection
18 (a), applies to the use of carbon monoxide in or on meat,
19 poultry products, and seafood beginning on the date on
20 which the Secretary of Health and Human Services pro-
21 mulgates a final regulation under subsection (b)(1) or
22 publishes a decision under subsection (b)(2).

1 **SEC. 202. FOOD SUBSTANCES GENERALLY RECOGNIZED AS**
2 **SAFE.**

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

5 “Substances Generally Recognized as Safe

6 “(k)(1) Not later than 60 days after the date of re-
7 ceipt by the Secretary, after the date of the enactment
8 of this subsection, of a determination that a substance is
9 a GRAS food substance, the Secretary shall post notice
10 of such determination and the supporting scientific jus-
11 tifications on the Food and Drug Administration’s public
12 Web site.

13 “(2) Not later than 60 days after the date of receipt
14 of a request under paragraph (1), the Secretary shall ac-
15 knowledge receipt of such request by informing the re-
16 quester in writing of the date on which the request was
17 received.

18 “(3) In this subsection, the term ‘GRAS food sub-
19 stance’ means a substance excluded from the definition of
20 the term ‘food additive’ in section 201(s) because such
21 substance is generally recognized, among experts qualified
22 by scientific training and experience to evaluate its safety,
23 as having been adequately shown through scientific proce-
24 dures (or, in the case of a substances used in food prior
25 to January 1, 1958, through either scientific procedures

1 or experience based on common use in food) to be safe
2 under the conditions of its intended use.”.

3 **SEC. 203. COUNTRY OF ORIGIN LABELING; DISCLOSURE OF**
4 **SOURCE OF INGREDIENTS.**

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

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

11 “(dd) In the case of non-processed food, if the label-
12 ing of the food fails to identify the country of origin of
13 the food.”.

14 (b) REGULATIONS.—

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

21 (2) RELATION TO OTHER REQUIREMENTS.—
22 Regulations promulgated under paragraph (1) shall
23 provide that labeling meets the requirements of
24 paragraphs (cc) and (dd) of section 403 of the Fed-

1 eral Food, Drug, and Cosmetic Act, as added by
2 subsection (a), if—

3 (A) in the case of a processed food, the
4 label of the food informs the consumer of the
5 country where the final processing of the food
6 occurred in accordance with labeling require-
7 ments of the United States Customs and Bor-
8 der Protection; or

9 (B) in the case of a non-processed food,
10 the label of the food informs the consumer of
11 the country of origin of the food in accordance
12 with labeling requirements of the Department
13 of Agriculture.

14 (c) **EFFECTIVE DATE.**—The requirements of para-
15 graphs (cc) and (dd) of section 403 of the Federal Food,
16 Drug, and Cosmetic Act, as added by subsection (a), take
17 effect on the date that is 2 years after the date of the
18 enactment of this Act.

19 **SEC. 204. EXPORTATION CERTIFICATE PROGRAM.**

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

21 (1) in the matter preceding clause (i) in sub-
22 paragraph (A)—

23 (A) by inserting “from the United States”
24 after “exports”; and

1 (B) by striking “a drug, animal drug, or
2 device” and inserting “a food (including animal
3 feed), drug, animal drug, or device”;

4 (2) in subparagraph (A)(i)—

5 (A) by striking “in writing”; and

6 (B) by striking “exported drug, animal
7 drug, or device” and inserting “exported food,
8 drug, animal drug, or device”;

9 (3) in subparagraph (A)(ii)—

10 (A) by striking “in writing”;

11 (B) by striking “the drug, animal drug, or
12 device” and inserting “the food, drug, animal
13 drug, or device”; and

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

16 (4) by redesignating subparagraph (B) as sub-
17 paragraph (C);

18 (5) by inserting after subparagraph (A) the fol-
19 lowing:

20 “(B) For purposes of this paragraph, a
21 certification by the Secretary shall be made on
22 such basis and in such form (such as a publicly
23 available listing) as the Secretary determines
24 appropriate.”; and

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

1 “(D) Notwithstanding subparagraph (C), if the Sec-
2 retary issues an export certification within the 20 days
3 prescribed by subparagraph (A) with respect to the export
4 of food, a fee for such certification shall not exceed such
5 amount as the Secretary determines is reasonably related
6 to the cost of issuing certificates under subparagraph (A)
7 with respect to the export of food. The Secretary may ad-
8 just this fee annually to account for inflation and other
9 cost adjustments. Fees collected for a fiscal year pursuant
10 to this subparagraph shall be credited to the appropriation
11 account for salaries and expenses of the Food and Drug
12 Administration and shall be available in accordance with
13 appropriations Acts until expended, without fiscal year
14 limitation. Such fees shall be collected in each fiscal year
15 in an amount equal to the amount specified in appropria-
16 tions Acts for such fiscal year and shall only be collected
17 and available for the costs of the Food and Drug Adminis-
18 tration to cover the cost of issuing such certifications.
19 Such sums as necessary may be transferred from such ap-
20 propriation account for salaries and expenses of the Food
21 and Drug Administration without fiscal year limitation to
22 such appropriation account for salaries and expenses with
23 fiscal year limitation.”.

1 **SEC. 205. REGISTRATION FOR COMMERCIAL IMPORTERS**
2 **OF FOOD; FEE.**

3 (a) REGISTRATION.—

4 (1) PROHIBITIONS.—Section 301 (21 U.S.C.
5 331), as amended by sections 110, 111, 133, and
6 136, is amended by adding at the end the following:

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

9 (2) MISBRANDING.—Section 403 (21 U.S.C.
10 343) as amended by sections 101(a), 109(a), 114(a),
11 and 203, is amended by adding at the end:

12 “(ee) If it is imported or offered for import by an
13 importer or a customs broker or filer not duly registered
14 under section 801(r).”.

15 (3) REGISTRATION.—Section 801, as amended
16 by sections 109 and 136, is amended by adding at
17 the end the following:

18 “(r) REGISTRATION OF IMPORTERS AND CUSTOMS
19 BROKERS AND FILERS.—

20 “(1) IMPORTERS.—

21 “(A) REGISTRATION.—The Secretary shall
22 require an importer of food—

23 “(i) to be registered with the Sec-
24 retary in a form and manner specified by
25 the Secretary; and

1 “(ii) consistent with section 911, to
2 submit appropriate unique facility identi-
3 fiers as a condition of registration.

4 “(B) GOOD IMPORTER PRACTICES.—The
5 maintenance of registration under this para-
6 graph is conditioned on compliance with good
7 importer practices. Good importer practices
8 shall include the verification of good manufac-
9 turing practices and preventive controls of the
10 importer’s foreign suppliers, as applicable.

11 “(2) CUSTOMS BROKERS AND FILERS.—The
12 Secretary shall require a customs broker or filer,
13 with respect to the importation of food—

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

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

20 “(3) SUSPENSION OF REGISTRATION.—

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

25 “(i) a violation of this Act; or

1 “(ii) the making of an inaccurate or
2 incomplete statement or submission of in-
3 formation relating to the importation of
4 food

5 “(B) REQUEST.—The importer, customs
6 broker, or filer whose registration is suspended
7 may request that the Secretary vacate the sus-
8 pension of registration when such importer,
9 customs broker, or filer has corrected the viola-
10 tion that is the basis for such suspension.

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

16 “(4) CANCELLATION OF REGISTRATION.—

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

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

1 porter, customs broker, or filer of the intent to
2 cancel the registration and the basis for such
3 cancellation.

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

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

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

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

17 (4) REGULATIONS.—Not later than 24 months
18 after the date of the enactment of this Act, the Sec-
19 retary of Health and Human Services shall promul-
20 gate the regulations required to carry out section
21 801(r).

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

1 (b) FEE.—Subchapter C of chapter VII (21 U.S.C.
2 379f et seq.) as added and amended by sections 101 and
3 108, is amended by adding at the end the following:

4 **“PART 7—IMPORTERS OF FOOD**

5 **“SEC. 744. IMPORTERS OF FOOD.**

6 “(a) IMPORTERS.—The Secretary shall assess and
7 collect an annual fee for the registration of an importer
8 of food under section 801(r).

9 “(b) CUSTOMS BROKERS AND FILERS.—The Sec-
10 retary shall assess and collect an annual fee for the reg-
11 istration of a customs broker or filer under section 801(r).

12 “(c) AMOUNT OF FEE.—

13 “(1) BASE AMOUNTS.—For fiscal year 2010,
14 the Secretary shall, subject to paragraph (4), deter-
15 mine the amount of the fees under this section for
16 importers, customs brokers, and filers.

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

22 “(A) the total percentage change that oc-
23 curred in the Consumer Price Index for all
24 urban consumers (all items; United States city
25 average), for the 12-month period ending June

1 30 preceding the fiscal year for which fees are
2 being established;

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

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

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

22 “(4) WAIVER FOR IMPORTERS REQUIRED TO
23 PAY REGISTRATION FEE.—In the case of a person
24 who is required to pay both a fee under section 743
25 for registration of one or more facilities under sec-

1 tion 415 and a fee under this section for registration
2 as an importer of food under section 801(r), the
3 Secretary shall waive the fees applicable to such per-
4 son under section 743 or the fee applicable to such
5 person under this section, whichever fees or fee is
6 lesser in amount.

7 “(5) COLLECTIONS AND APPROPRIATIONS
8 ACTS.—

9 “(A) IN GENERAL.—The fees authorized
10 by this section—

11 “(i) shall be retained in each fiscal
12 year in an amount not to exceed the
13 amount specified in appropriation Acts, or
14 otherwise made available for obligation, for
15 such fiscal year; and

16 “(ii) shall only be collected and avail-
17 able to cover the costs associated with reg-
18 istering importers, customs brokers, and
19 filers under section 801(r) and with ensur-
20 ing compliance with good importer prac-
21 tices respecting food.

22 “(B) LIMIT.—The total amount of fees
23 charged, as adjusted under paragraphs (2) and
24 (3), for a fiscal year may not exceed the total

1 costs described in subparagraph (A)(ii) for such
2 fiscal year.”.

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

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

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

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

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

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

23 “(b) REGISTRATION OF IMPORTERS, CUSTOM BRO-
24 KERS, AND FILERS.—A person required to register pursu-
25 ant to section 801(r) shall submit, at the time of registra-

1 tion, a unique facility identifier for the principal place of
2 business for which such person is required to register
3 under section 801(r).

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

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

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

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

18 “(m) If it has been produced manufactured, proc-
19 essed, packed, or held in any farm, factory, warehouse,
20 or establishment and the owner, operator, or agent of such
21 farm, factory, warehouse, or establishment, or any agent
22 of a governmental authority in the foreign country within
23 which such farm, factory, warehouse, or establishment is
24 located, delays or limits an inspection, or refuses to permit
25 entry or inspection, under section 414 or 704.”.

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

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

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

13 **SEC. 208. DEDICATED FOREIGN INSPECTORATE.**

14 Section 704 (21 U.S.C. 374), as amended by sections
15 105 and 205, is amended by adding at the end the fol-
16 lowing:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 “(c) SERVICE OF SUBPOENA.—

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

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

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

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

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

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

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

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

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

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

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

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

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

2 or

3 “(5) intimidation of potential witnesses.

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

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

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

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

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

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

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

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

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

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

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

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

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

13 “(b) ENFORCEMENT ACTION.—

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

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

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

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

8 “(2) PROCEDURE.—

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

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

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

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

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

3 “(c) REMEDIES.—

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

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

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

15 “(B) to—

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

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

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

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

1 plainant, shall assess against the person against
2 whom the order is issued a sum equal to the aggregate
3 amount of all costs and expenses (including attorney
4 and expert witness fees) reasonably incurred,
5 as determined by the Secretary, by the complainant
6 for, or in connection with, the bringing of the complaint
7 upon which the order was issued.

8 “(d) **RIGHTS RETAINED BY EMPLOYEE.**—Nothing in
9 this section shall be deemed to diminish the rights, privileges,
10 or remedies of any employee under any Federal or
11 State law or under any collective bargaining agreement.
12 The rights and remedies in this section may not be waived
13 by any agreement, policy, form, or condition of employment.”

15 **SEC. 213. EXTRATERRITORIAL JURISDICTION.**

16 (a) **PROHIBITED ACT.**—Section 301 (21 U.S.C. 331),
17 as amended by sections 110, 111, 133, 136, and 205, is
18 amended by adding at the end the following:

19 “(uu) The production, manufacture, processing, preparation,
20 packing, holding, or distribution of an adulterated
21 or misbranded food with the knowledge or intent that such
22 article will be imported into the United States.”

23 (b) **JURISDICTION.**—Chapter III (21 U.S.C. 331 et
24 seq.), as amended by section 211, is amended by adding
25 at the end the following:

1 **“SEC. 312. EXTRATERRITORIAL JURISDICTION.**

2 “There is extraterritorial Federal jurisdiction over
3 any violation of this Act relating to any article of food
4 if such article was intended for import into the United
5 States or if any act in furtherance of the violation was
6 committed in the United States.”.

