

111TH CONGRESS
1ST SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

Mr. WAXMAN introduced the following bill; which was referred to the Committee on _____

A BILL

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

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

3 **SECTION 1. SHORT TITLE.**

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

6 **SEC. 2. TABLE OF CONTENTS.**

7 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.

Subtitle D—Miscellaneous

- Sec. 141. Treatment of carbon monoxide used to preserve color of meat, poultry products, or seafood as color additive.
- Sec. 142. Food substances generally recognized as safe.
- Sec. 143. Country of origin labeling; disclosure of source of ingredients.
- Sec. 144. Exportation certificate program.

TITLE II—MISCELLANEOUS

- Sec. 201. Registration for commercial importers of food, drugs, and devices; fee.
- Sec. 202. Unique identification number for food facilities, drug and device establishments, and importers, custom brokers, and filers.
- Sec. 203. Prohibition against delaying, limiting, or refusing inspection.
- Sec. 204. Dedicated foreign inspectorate.
- Sec. 205. Plan and review of continued operation of field laboratories.
- Sec. 206. False or misleading reporting to FDA.
- Sec. 207. Subpoena authority.
- Sec. 208. Whistleblower protections.
- Sec. 209. 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
12 (2) the introduction of evidence of compliance
13 or noncompliance with the requirements of the Fed-
14 eral Food, Drug, and Cosmetic Act.

15 **TITLE I—FOOD SAFETY**

16 **Subtitle A—Prevention**

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

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

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

25 (b) ANNUAL REGISTRATION.—

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

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

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

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

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

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

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

1 istration has been canceled by the registrant,
2 canceled by the Secretary in accordance with
3 this section, or suspended by the Secretary in
4 accordance with this section.”.

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

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

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

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

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

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

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

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

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

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

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

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

22 “(5) SUSPENSION OF REGISTRATION.—

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

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

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

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

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

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

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

23 “(6) CANCELLATION OF REGISTRATION.—
24

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

8 “(B) NOTICE OF CANCELLATION.—Can-
9 cellation shall be preceded by notice to the facil-
10 ity of the intent to cancel the registration and
11 the basis for such cancellation.

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

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

22 “(A) The number of facilities registered
23 under section 415.

24 “(B) The number of such facilities that are
25 domestic.

1 “(C) The number of such facilities that are
2 foreign.

3 “(D) The number of such facilities that
4 are high-risk.

5 “(E) The number of such facilities that are
6 low-risk.

7 “(F) The number of such facilities that
8 hold food.”.

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

12 **“PART 6—FEES RELATING TO FOOD**

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

14 “(a) IN GENERAL.—

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

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

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

24 “(B) for any other facility—

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

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

7 “(b) FEE AMOUNTS.—

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

10 “(A) for fiscal year 2010, \$1,000; and

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

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

19 “(c) INFLATION ADJUSTMENT.—For fiscal year 2011
20 and each subsequent fiscal year, the fee amount under
21 subsection (b) shall be adjusted by the Secretary by notice,
22 published in the Federal Register, to reflect the greater
23 of—

24 “(1) the total percentage change that occurred
25 in the Consumer Price Index for all urban con-

1 sumers (all items; U.S. city average) for the 12-
2 month period ending June 30 preceding the fiscal
3 year for which fees are being established;

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

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

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

20 “(d) LIMITATIONS.—

21 “(1) IN GENERAL.—Fees under subsection (a)
22 shall be refunded for a fiscal year beginning after
23 fiscal year 2010 unless appropriations for salaries
24 and expenses of the Food and Drug Administration
25 for such fiscal year (excluding the amount of fees

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

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

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

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

23 “(1) IN GENERAL.—Fees authorized under sub-
24 section (a) shall be collected and available for obliga-
25 tion only to the extent and in the amount provided

1 in advance in appropriations Acts. Such fees are au-
2 thORIZED to remain available until expended. Such
3 sums as may be necessary may be transferred from
4 the Food and Drug Administration salaries and ex-
5 penses appropriation account without fiscal year lim-
6 itation to such appropriation account for salaries
7 and expenses with such fiscal year limitation.

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

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

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

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

20 “(f) COLLECTION OF UNPAID FEES.—In any case
21 where the Secretary does not receive payment of a fee as-
22 sessed under subsection (a) within 30 days after it is due,
23 such fee shall be treated as a claim of the United States
24 Government subject to subchapter II of chapter 37 of title
25 31, United States Code.

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

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

18 “(i) DEFINITIONS.—In this section:

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

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

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

3 “(B) laboratory capacity;

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

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

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

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

1 support, test development, product sampling, risk
2 communication, and administrative detention).”.

3 (d) TRANSITIONAL PROVISIONS.—

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

9 (2) MODIFICATION OF REGISTRATION FORM.—

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

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

22 (4) SUNSET DATE.—Section 743 of the Federal
23 Food, Drug, and Cosmetic Act, as added by sub-
24 section (c), does not authorize the assessment or col-
25 lection of a fee for registration under section 415 of

1 such Act (21 U.S.C. 360) occurring after fiscal year
2 2014.

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

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

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

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

12 **“SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVEN-**
13 **TIVE CONTROLS.**

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

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

18 “(2) identify, implement, and validate effective
19 preventive controls;

20 “(3) monitor preventive controls;

21 “(4) institute corrective actions when moni-
22 toring shows that preventive controls have not been
23 properly implemented or were ineffective;

24 “(5) conduct verification activities;

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

3 “(7) reanalyze for hazards.

4 “(b) IDENTIFICATION OF HAZARDS.—

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

13 “(A) biological, chemical, physical, and ra-
14 diological hazards, natural toxins, pesticides,
15 drug residues, filth, decomposition, parasites,
16 allergens, and unapproved food and color addi-
17 tives; and

18 “(B) hazards that occur naturally, may be
19 unintentionally introduced, or may be inten-
20 tionally introduced, including by acts of ter-
21 rorism.

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

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

6 “(c) PREVENTIVE CONTROLS.—

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

13 “(2) IDENTIFIED BY THE SECRETARY.—The
14 Secretary may establish by regulation or guidance
15 preventive controls for specific product types to pre-
16 vent intentional or unintentional contamination
17 throughout the supply chain. The owner, operator,
18 or agent of a facility shall implement any preventive
19 controls identified by the Secretary under this provi-
20 sion.

21 “(d) MONITORING.—The owner, operator, or agent of
22 a facility shall monitor the implementation of preventive
23 controls under subsection (c) to identify any circumstances
24 in which the preventive controls are not fully implemented

1 or were ineffective, including through the use of environ-
2 mental and product testing programs, as appropriate.

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

7 “(1) no product enters commerce; and

8 “(2) appropriate action is taken to reduce the
9 likelihood of recurrence of the implementation fail-
10 ure.

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

13 “(1) the preventive controls identified under
14 subsection (c) have been validated as adequate to
15 control the hazards identified under subsection (b);

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

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

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

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

1 “(1) HAZARD ANALYSIS.—The owner, operator,
2 or agent of a facility shall review the evaluation
3 under subsection (b) for the facility and, as nec-
4 essary, revise the hazard analysis under subsection
5 (b)(3) for the facility not less than every 2 years.

6 “(2) PREVENTIVE CONTROLS.—If there is a
7 change that could affect the hazard analysis for a
8 facility under subsection (b)(3) or if the Secretary
9 determines that it is appropriate to protect public
10 health, the owner, operator, or agent of the facility
11 shall revise the preventive controls under subsection
12 (c) for the facility to ensure that all hazards that are
13 reasonably likely to occur are prevented, eliminated,
14 or reduced to an acceptable level, or document the
15 basis for the conclusion that no such revision is
16 needed.

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

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

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

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

14 “(A) Sanitation procedures and practices.

15 “(B) Supervisor, manager, and employee
16 hygiene training.

17 “(C) Process controls.

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

22 “(E) Good manufacturing practices.

23 “(F) Verification procedures, practices,
24 and processes for suppliers and incoming ingre-

1 dients, which may include onsite auditing of
2 suppliers and testing of incoming ingredients.

3 “(G) Other procedures, practices, and
4 processes that the Secretary may deem appro-
5 priate under subsection (c)(2).

6 “(3) REASONABLY LIKELY TO OCCUR.—The
7 term ‘reasonably likely to occur’ means a hazard for
8 which a prudent person who, as applicable, manufac-
9 tures, processes, packs, transports, or holds food
10 would establish controls because experience, illness
11 data, scientific reports, or other information provide
12 a basis to conclude that there is a reasonable possi-
13 bility that, in the absence of those controls, the haz-
14 ard will occur in the type of food being manufac-
15 tured, processed, packed, transported, or held.

16 **“SEC. 418A. FOOD SAFETY PLAN.**

17 “(a) IMPLEMENTATION OF FOOD SAFETY PLAN.—

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

1 “(2) CONTENTS.—The food safety plan shall in-
2 clude each of the following elements:

3 “(A) The hazard analysis and any reanaly-
4 sis conducted under section 418.

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

10 “(C) A description of the procedures for
11 monitoring preventive controls.

12 “(D) A description of the procedures for
13 taking corrective actions.

14 “(E) A description of verification activities
15 for the preventive controls, including validation,
16 review of monitoring and corrective action
17 records, and procedures for determining wheth-
18 er the preventive controls are effectively pre-
19 venting, eliminating, or reducing to an accept-
20 able level the occurrence of identified hazards
21 or conditions.

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

1 “(G) A description of the facility’s proce-
2 dures for the recall of articles of food, whether
3 voluntarily or when required under section 422.

4 “(H) A description of the facility’s proce-
5 dures for the trace back of articles of food,
6 whether voluntarily or when required under sec-
7 tion 414.

8 “(I) A description of the facility’s proce-
9 dures to ensure a safe and secure supply chain
10 for the ingredients or components used in mak-
11 ing the food manufactured, processed, packed,
12 transported, or held by such facility.

13 “(J) A description of the facility’s proce-
14 dures to implement the science-based perform-
15 ance standards issued under section 419.”.

16 (c) GUIDANCE OR REGULATIONS.—

17 (1) IN GENERAL.—The Secretary of Health and
18 Human Services (referred to in this subsection as
19 the “Secretary”) shall issue guidance or promulgate
20 regulations to establish science-based standards for
21 conducting a hazard analysis, documenting hazards,
22 identifying and implementing preventive controls,
23 and documenting the implementation of the preven-
24 tive controls, including verification and corrective ac-
25 tions under sections 418 and 418A of the Federal

1 Food, Drug, and Cosmetic Act (as added by sub-
2 section (b)).

3 (2) CONSIDERATION.—In issuing guidance or
4 promulgating regulations under this section, the Sec-
5 retary shall consider the impact of such guidance or
6 regulations on small businesses.

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

19 (e) EFFECTIVE DATE.—

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

23 (2) EXCEPTIONS.—Notwithstanding paragraph
24 (1)—

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

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

9 **SEC. 103. PERFORMANCE STANDARDS.**

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

13 “(k) If it has been manufactured, processed, packed,
14 transported, or held under conditions that do not meet the
15 requirements of section 419.”.

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

19 **“SEC. 419. PERFORMANCE STANDARDS.**

20 “The Secretary shall, not less frequently than every
21 2 years, review and evaluate epidemiological data and
22 other appropriate sources of information, including re-
23 search under section 123 of the Food Safety Enhancement
24 Act of 2009, to identify the most significant food-borne
25 contaminants and the most significant resulting hazards.

1 The Secretary shall issue, as soon as practicable, through
2 guidance or by regulation, science-based performance
3 standards (which may include action levels) applicable to
4 foods or food classes, as appropriate to minimize to an
5 acceptable level, prevent, or eliminate the occurrence of
6 such hazards. Such standards shall be applicable to foods
7 and food classes.”.

8 (c) REPORT TO CONGRESS.—The Secretary of Health
9 and Human Services shall report to the Congress by
10 March 30th of the year following each review the results
11 of such review, the Secretary’s plans to address the signifi-
12 cant food-borne hazards identified, or the basis for not ad-
13 dressing any significant food-borne hazards identified, in-
14 cluding any resource limitations or limitations in data that
15 preclude further action at that time.

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

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

22 “(l) If it has been grown, harvested, packed, sorted,
23 transported, or held under conditions that do not meet the
24 requirements of section 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, packing, sorting, transporting, and holding of
10 raw agricultural commodities that—

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

12 “(2) for which the Secretary has determined
13 that such standards minimize the risk of serious ad-
14 verse health consequences or death to humans or
15 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 including 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, packing, sorting, transporting, and storage
9 operations, minimum 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; and

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

23 “(c) ENFORCEMENT.—The Secretary may coordinate
24 with the Secretary of Agriculture and may contract and
25 coordinate with the agency or department designated by

1 the Governor of each State to perform activities to ensure
2 compliance with this section.”.

3 (b) TIMING.—

4 (1) PROPOSED RULE.—Not later than 18
5 months after the date of enactment of this Act, the
6 Secretary of Health and Human Services shall issue
7 a proposed rule to carry out section 419A of the
8 Federal Food, Drug, and Cosmetic Act, as added by
9 subsection (a).

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

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

1 (e) UPDATE EXISTING GUIDANCE.—Not later than
2 one year after the date of the enactment of this Act, the
3 Secretary of Health and Human Services shall update the
4 guidance document entitled “Guidance For Industry:
5 Guide To Minimize Microbial Food Safety Hazards For
6 Fresh Fruits And Vegetables” (issued on October 26,
7 1998) in accordance with this section and the amendments
8 made by this section.

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

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

12 “(h)(1) Each facility registered under section 415
13 shall be inspected—

14 “(A)(i) by one or more officers duly designated
15 under section 702 or other statutory authority by
16 the Secretary;

17 “(ii) for domestic facilities, by a Federal, State,
18 or local official recognized by the Secretary under
19 paragraph (2); or

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

23 “(B) at a frequency determined pursuant to a
24 risk-based schedule.

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

3 “(A) may recognize Federal, State, and local of-
4 ficials and agencies and representatives of foreign
5 countries as meeting standards established by the
6 Secretary for conducting inspections under this Act;
7 and

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

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

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

17 “(A) CATEGORY 1.—A category 1 food facility
18 is a high-risk facility that manufactures or processes
19 food, including any facility that manufactures or
20 processes raw products of animal origin (including
21 fish and fisheries products) or other foods as des-
22 ignated by the Secretary. The Secretary shall ran-
23 domly inspect a category 1 food facility at least
24 every 6 to 18 months.

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

6 “(C) CATEGORY 3.—A category 3 food facility
7 is a facility that holds food. The Secretary shall ran-
8 domly inspect a category 3 facility at least every 3
9 to 4 years.

10 “(5) The Secretary—

11 “(A) may, by guidance, modify the types of
12 food facilities within a category under paragraph
13 (4);

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

17 “(C) may inspect a facility more frequently
18 than the inspection frequency provided by paragraph
19 (4).

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

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

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

1 “(C) whether the facility importing food is cer-
2 tified by a qualified certifying entity in accordance
3 with section 801(p); and

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

7 (b) REPORTS ON RISK-BASED INSPECTIONS OF
8 FOOD FACILITIES.—

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

16 (A) the number of foreign and domestic fa-
17 cilities, by risk category, inspected under the
18 risk-based inspection schedule established under
19 section 704(h) of the Federal Food, Drug, and
20 Cosmetic Act, as added by subsection (a), in
21 the preceding 12 months; and

22 (B) the costs of implementing the risk-
23 based inspection schedule for the preceding 12
24 months.

1 (2) THIRD-YEAR REPORT.—Not later than 3
2 years after the date of the enactment of this Act, the
3 Secretary of Health and Human Services shall sub-
4 mit a report to the Committee on Energy and Com-
5 merce of the House of Representatives and the Com-
6 mittee on Health, Education, Labor, and Pensions
7 of the Senate describing recommendations on the
8 risk-based inspection schedule under section 704(h)
9 of the Federal Food, Drug, and Cosmetic Act, as
10 added by subsection (a), including recommendations
11 for—

12 (A) adjustments to the timing of the
13 schedule and other ways to increase the effi-
14 ciency of inspections in order to enable the
15 Food and Drug Administration to conduct more
16 inspections; and

17 (B) other methods to contribute to assur-
18 ing the safety of food.

19 **SEC. 106. ACCESS TO RECORDS.**

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

22 “(a) RECORDS INSPECTION.—Each person who pro-
23 duces, manufactures, processes, packs, transports, distrib-
24 utes, receives, or holds an article of food in the United
25 States or for import into the United States shall, at the

1 request of an officer or employee duly designated by the
2 Secretary, permit such officer or employee, upon presen-
3 tation of appropriate credentials, at reasonable times and
4 within reasonable limits and in a reasonable manner, to
5 have access to and copy all records relating to such article
6 bearing on whether the food is adulterated, misbranded,
7 or otherwise in violation of this Act, including all records
8 collected or developed to comply with section 418 or 418A.
9 The requirement under the preceding sentence applies to
10 all records relating to the production, manufacture, proc-
11 essing, packing, transporting, distribution, receipt, hold-
12 ing, or importation of such article maintained by or on
13 behalf of such person in any format (including paper and
14 electronic formats) and at any location.”.

15 (b) REGULATIONS CONCERNING RECORDKEEPING.—

16 (1) AMENDMENT.—Subsection (b) of section
17 414 (21 U.S.C. 350c) is amended to read as follows:

18 “(b) REGULATIONS CONCERNING RECORD-
19 KEEPING.—The Secretary, in consultation and coordina-
20 tion, as appropriate, with other Federal departments and
21 agencies with responsibilities for regulating food safety,
22 may by regulation establish requirements regarding the es-
23 tablishment and maintenance, for not longer than 3 years,
24 of records by persons who produce, manufacture, process,
25 pack, transport, distribute, receive, or hold food in the

1 United States or for import into the United States. The
2 Secretary shall take into account the size of a business
3 in promulgating regulations under this section. The Sec-
4 retary may require such persons to maintain such records
5 in a standardized electronic format.”.

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

16 (c) CONFORMING AMENDMENTS.—Section 704(a)(1)
17 (21 U.S.C. 374(a)(1)) is amended—

18 (1) in the first sentence—

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

21 (B) by inserting “produced,” before “man-
22 ufactured”;

23 (2) in the second sentence—

24 (A) by striking “(excluding farms or res-
25 taurants)”;

1 (B) by inserting “produces,” before “man-
2 ufactures”;

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

4 (D) by striking “described in section 414”
5 and inserting “described in or required under
6 section 414”; and

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

16 (3) in the fourth sentence—

17 (A) by striking “the preceding sentence”
18 and inserting “either of the preceding two sen-
19 tences”; and

20 (B) by inserting “recipes for food,” before
21 “financial data,”.

22 **SEC. 107. TRACEABILITY OF FOOD.**

23 (a) PROHIBITED ACT.—Section 301(e) (21 U.S.C.
24 331(e)) is amended by inserting “, the violation of any
25 requirement of the food tracing system under section

1 414(c);” before “or the refusal to permit access to or
2 verification or copying of any such required record”.

3 (b) IMPORTS.—Section 801(a) (21 U.S.C. 381(a)) is
4 amended by inserting “or (4) the requirements of section
5 414 have not been complied with regarding such article,”
6 before “then such article shall be refused admission”.

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

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

11 (2) by inserting after subsection (b) the fol-
12 lowing:

13 “(c) TRACING SYSTEM FOR FOOD.—

14 “(1) IN GENERAL.—The Secretary shall by reg-
15 ulation establish a tracing system for food that is lo-
16 cated in the United States or is for import into the
17 United States. Such regulations shall require each
18 person who produces, manufactures, processes,
19 packs, transports, or holds such food—

20 “(A) to maintain the full pedigree of the
21 origin and previous distribution history of the
22 food;

23 “(B) to link that history with the subse-
24 quent distribution history of the food;

1 “(C) to establish and maintain a system
2 for tracing the food that is interoperable with
3 the systems established and maintained by
4 other such persons; and

5 “(D) to use a unique identifier for each fa-
6 cility owned or operated by such person for
7 such purpose, as specified under section 911.

8 “(2) INFORMATION GATHERING.—

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

12 “(i) identify technologies for tracing
13 the distribution history of a food that are,
14 or may be, used by members of different
15 sectors of the food industry; and

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

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

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

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

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

11 “(C) PILOT PROJECTS.—The Secretary
12 shall conduct 1 or more pilot projects in coordi-
13 nation with 1 or more sectors of the food indus-
14 try to explore and evaluate tracing systems for
15 food.

16 “(3) ADDITIONAL AUTHORITY.—In establishing
17 a tracing system for food, the Secretary shall re-
18 quire—

19 “(A) the establishment and maintenance of
20 such additional information, including lot num-
21 bers, as the Secretary deems appropriate;

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

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

1 “(4) EXEMPTIONS.—

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

5 “(i) produced on a farm; and

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

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

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

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

3 (a) IN GENERAL.—Part 5 of subchapter C of chapter
4 VII (21 U.S.C. 371 et seq.), as added by section
5 101(c)(2), is further amended by adding at the end the
6 following:

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

9 “(a) IN GENERAL.—The Secretary shall assess and
10 collect fees from each facility (as defined in section
11 415(b))—

12 “(1) that—

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

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

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

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

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

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

9 “(c) USE OF FEES.—The Secretary shall make all
10 of the fees collected pursuant to this section available sole-
11 ly to pay for the costs referred to in subsection (b).”.

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

16 **SEC. 109. CERTIFICATION AND ACCREDITATION.**

17 (a) MISBRANDING.—

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

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

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

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

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

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

18 (3) by adding at the end of section 801 the fol-
19 lowing:

20 “(p) CERTIFICATIONS CONCERNING IMPORTED ARTI-
21 CLES.—

22 “(1) IN GENERAL.—

23 “(A) REQUIREMENT.—The Secretary shall
24 require, as an additional condition of granting
25 admission to an article of food being imported

1 or offered for import into the United States,
2 that a qualified certifying entity provide a cer-
3 tification that the article complies with specified
4 requirements of this Act if—

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

13 “(ii) for a type of food that could pose
14 a significant risk to health, certification
15 would assist the Secretary in determining
16 whether such article poses such risk; or

17 “(iii) for an article imported from a
18 particular country, there is an agreement
19 between the Secretary and the government
20 of such country providing for such certifi-
21 cation.

22 “(B) CONTENTS OF CERTIFICATION.—
23 Such certification shall include such informa-
24 tion regarding compliance as the Secretary may
25 specify, and may be provided in the form of

1 shipment-specific certificates, a listing of cer-
2 tified facilities or other entities, or in such other
3 form as the Secretary may specify.

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

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

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

20 “(B) an individual or entity determined by
21 the Secretary to be qualified to provide a cer-
22 tification under paragraph (1).

23 “(3) NO CONFLICTS OF INTEREST.—

24 “(A) IN GENERAL.—The Secretary shall
25 issue regulations to ensure that any qualified

1 certifying entity and its auditors are free from
2 conflicts of interest.

3 “(B) REGULATIONS.—Such regulations
4 shall require that—

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

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

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

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

22 “(v) no auditor acting for the quali-
23 fied certifying entity (or spouse or minor
24 children) shall have any significant owner-

1 ship or other financial interest regarding
2 any product of the type it certifies;

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

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

13 “(viii) neither the qualified certifying
14 entity nor any of its auditors shall provide
15 consultative services to any facility cer-
16 tified by the qualified certifying entity, or
17 the owner, operator, or agent in charge of
18 such a facility;

19 “(ix) no auditors acting for the quali-
20 fied certifying entity shall participate in an
21 audit of a facility they were employed by
22 within the last 12 months;

23 “(x) fees charged or accepted shall
24 not be contingent or based upon the report
25 made by the qualified certifying entity or

1 any personnel involved in the audit proc-
2 ess;

3 “(xi) neither the qualified certifying
4 entity nor any of its auditors shall accept
5 anything of value from anyone in connec-
6 tion with the facility being audited other
7 than the audit fee;

8 “(xii) the qualified certifying entity
9 shall not be owned, operated, or controlled
10 by a trade association whose member com-
11 panies operate facilities that it certifies;

12 “(xiii) the qualified certifying entity
13 and its auditors shall be free from any
14 other conflicts of interest that threaten im-
15 partiality;

16 “(xiv) the qualified certifying entity
17 and its auditors shall sign a statement at-
18 testing to compliance with the conflict of
19 interests requirements under this para-
20 graph; and

21 “(xv) the qualified certifying entity
22 shall also ensure that any subcontractors
23 that might be used (such as laboratories
24 and sampling services) provide similar as-
25 surances.

1 “(C) ANYTHING OF VALUE.—In this para-
2 graph, the term ‘anything of value’ includes
3 gifts, gratuities, reimbursement of expenses, en-
4 tertainment, loans, or any other form of com-
5 pensation in cash or in kind.

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

8 “(A) require that, to the extent applicable,
9 any certification provided by an entity specified
10 in paragraph (2) be renewed by such entity at
11 such times as the Secretary determines appro-
12 priate; and

13 “(B) refuse to accept any certification if
14 the Secretary determines that such certification
15 is no longer valid or reliable.

16 “(5) ELECTRONIC SUBMISSION.—The Secretary
17 shall provide for the electronic submission of certifi-
18 cations under this subsection.

19 “(6) NO LIMIT ON AUTHORITY.—This sub-
20 section shall not be construed to limit the authority
21 of the Secretary to conduct random inspections of
22 imported articles or facilities of importers, issue im-
23 port alerts for detention without physical examina-
24 tion, require submission to the Secretary of docu-
25 mentation or other information about an article im-

1 ported or offered for import, or to take such other
2 steps as the Secretary deems appropriate to deter-
3 mine the admissibility of imported articles.”.

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

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

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

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

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

13 “(a) IN GENERAL.—Whenever analytical testing of
14 an article of food is conducted as part of testimony for
15 the purposes of section 801(a), or for other purposes as
16 the Secretary deems appropriate, such testing shall be
17 conducted by a laboratory that—

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

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

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

1 “(b) RECOGNITION OF LABORATORY ACCREDITATION
2 BODIES.—The Secretary shall establish and implement a
3 program for the recognition, based on standards the Sec-
4 retary deems appropriate, of laboratory accreditation bod-
5 ies that accredit laboratories to perform analytical testing
6 for the purposes of this section. The Secretary shall issue
7 regulations or guidance to implement this program.

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

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

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

23 “(d) PUBLICATION OF LIST OF RECOGNIZED AC-
24 CREDITATION BODIES.—The Secretary shall publish and
25 maintain on the public Web site of the Food and Drug

1 Administration a list of accreditation bodies recognized by
2 the Secretary under subsection (b).

3 “(e) NOTIFICATION OF ACCREDITATION OF LABORA-
4 TORY.—An accreditation body that has been recognized
5 pursuant to this section shall promptly notify the Sec-
6 retary whenever it accredits a laboratory for the purposes
7 of this section and whenever it withdraws or suspends
8 such accreditation.

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

17 “(g) CONTENTS OF LABORATORY PACKAGES.—
18 Whenever analytical testing is conducted pursuant to sub-
19 section (a), the laboratory conducting such testing shall
20 submit, directly to the Secretary—

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

23 “(2) all information the Secretary deems appro-
24 priate to—

1 “(A) determine whether the laboratory is
2 accredited by a recognized laboratory accredita-
3 tion body;

4 “(B) identify the article tested;

5 “(C) evaluate the analytical results; and

6 “(D) determine whether the requirements
7 of this section have been met.

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

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

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

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

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

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

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

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

10 (b) NOTIFICATION, NONDISTRIBUTION, AND RECALL
11 OF ADULTERATED OR MISBRANDED FOOD.—Chapter IV
12 (21 U.S.C. 341 et seq.), as amended by sections 101, 102,
13 103, 104, 106, 107, and 109, is amended by adding at
14 the end the following:

15 **“SEC. 420. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
16 **OF ADULTERATED OR MISBRANDED FOOD.**

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

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

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

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

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

17 “(1) recall such article, and

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

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

1 Secretary shall have the authority to issue an order requir-
2 ing any person who distributes such article—

3 “(1) to immediately cease distribution of such
4 article; and

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

7 In providing for notice under paragraph (2), the Secretary
8 may, as appropriate, allow such notice to be provided with
9 the assistance of health care professionals, State or local
10 health officials, or other persons designated by the Sec-
11 retary.

12 “(d) ACTION FOLLOWING ORDER.—Any person who
13 is subject to an order under subsection (c) shall imme-
14 diately cease distribution of such article and provide notifi-
15 cation as required by such order, and may appeal within
16 24 hours of issuance such order to the Secretary. Such
17 appeal may include a request for an informal hearing and
18 a description of any efforts to recall such article under-
19 taken voluntarily by the person, including after a request
20 under subsection (b). Except as provided in subsection (f),
21 an informal hearing, if granted, shall be held within 10
22 business days, or less as determined by the Secretary,
23 after such an appeal is filed, unless the parties jointly
24 agree to an extension. After affording an opportunity for
25 an informal hearing, the Secretary shall determine wheth-

1 er the order should be amended to require a recall of such
2 article. If, after providing an opportunity for such a hear-
3 ing, the Secretary determines that inadequate grounds
4 exist to support the actions required by the order, the Sec-
5 retary shall vacate the order.

6 “(e) ORDER TO RECALL.—

7 “(1) AMENDMENT.—Except as provided under
8 subsection (f), if after providing an opportunity for
9 an informal hearing under subsection (d), the Sec-
10 retary determines that the order should be amended
11 to include a recall of the article with respect to
12 which the order was issued, the Secretary shall
13 amend the order to require a recall.

14 “(2) CONTENTS.—An amended order under
15 paragraph (1) shall—

16 “(A) specify a timetable in which the recall
17 will occur;

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

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

23 In providing for such notice, the Secretary may
24 allow for the assistance of health professionals, State

1 or local officials, or other individuals designated by
2 the Secretary.

3 “(f) EMERGENCY RECALL ORDER.—

4 “(1) IN GENERAL.—If the Secretary has a rea-
5 sonable belief that an article of food subject to an
6 order under subsection (c) presents a threat of seri-
7 ous adverse health consequences or death to humans
8 or animals, the Secretary may issue an order requir-
9 ing any person who distributes such article—

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

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

14 “(2) ACTION FOLLOWING ORDER.—Any person
15 who is subject to an emergency recall order under
16 this subsection shall immediately recall such article
17 and provide notification as required by such order,
18 and may appeal within 24 hours after issuance such
19 order to the Secretary. An informal hearing, if
20 granted, shall be held within 10 business days, or
21 less as determined by the Secretary, after such an
22 appeal is filed, unless the parties jointly agree to an
23 extension. After affording an opportunity for an in-
24 formal hearing, the Secretary shall determine wheth-
25 er the order should be amended pursuant to sub-

1 section (e)(1). If, after providing an opportunity for
2 such a hearing, the Secretary determines that inad-
3 equate grounds exist to support the actions required
4 by the order, the Secretary shall vacate the order.

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

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

13 “(1) the authority of the Secretary to issue an
14 order to cease distribution of, or to recall, an article
15 under any other provision of this Act or the Public
16 Health Service Act; or

17 “(2) the ability of the Secretary to request any
18 person to perform a voluntary activity related to any
19 article subject to this Act or the Public Health Serv-
20 ice Act.”.

21 (c) ARTICLES SUBJECT TO REFUSAL.—The third
22 sentence of subsection (a) of section 801 (21 U.S.C. 381)
23 is amended by inserting “or (5) such article is subject to
24 an order under section 420 to cease distribution of or re-

1 call the article,” before “then such article shall be refused
2 admission”.

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

9 **SEC. 112. REPORTABLE FOOD REGISTRY; EXCHANGE OF IN-**
10 **FORMATION.**

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

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

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

21 “(B) a person who owns, operates, is an
22 agent of, or is otherwise responsible for such
23 food on a farm (as such term is defined in sec-
24 tion 1.227(b)(3) of title 21, Code of Federal
25 Regulations, or successor regulations) at which

1 such food is produced for sale or distribution in
2 interstate commerce;

3 “(C) a person who owns, operates, or is an
4 agent of a restaurant or other retail food estab-
5 lishment (as such terms are defined in section
6 1.227(b)(11) and (12), respectively, of title 21,
7 Code of Federal Regulations, or successor regu-
8 lations) at which such food is offered for sale;
9 or

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

13 (2) in subsection (d)(1)—

14 (A) in the matter preceding subparagraph
15 (A)—

16 (i) by inserting “information reason-
17 ably available to” after “after”; and

18 (ii) by striking “determines” and in-
19 serting “indicates”;

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

22 (C) by redesignating subparagraph (B) as
23 subparagraph (C); and

24 (D) by inserting after subparagraph (A)
25 the following:

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

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

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

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

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

1 same source as a component of such arti-
2 cle; and”; and

3 (3) in subsection (e)—

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

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

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

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

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

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

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

21 “(B) Any such information provided to another Fed-
22 eral agency shall not be disclosed by such agency except
23 in any action or proceeding under the laws of the United
24 States to which the receiving agency or the United States
25 is a party.

1 “(2)(A) In carrying out this Act, the Secretary may
2 provide to a State or local government agency any infor-
3 mation that is exempt from disclosure pursuant to section
4 552(a) of title 5, United States Code, by reason of sub-
5 section (b)(4) of such section, or that is referred to in sec-
6 tion 301(j) or 415(a)(4).

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

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

19 “(4) In carrying out this Act, the Secretary may pro-
20 vide any information that is exempt from disclosure pursu-
21 ant to section 552(a) of title 5, United States Code, by
22 reason of subsection (b)(4) of such section, or that is re-
23 ferred to in section 301(j)—

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

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

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

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

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

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

20 “(d) Except as provided in subsection (e), the Sec-
21 retary shall not be required to disclose under section 552
22 of title 5, United States Code, or any other provision of
23 law any information obtained from a Federal, State, or
24 local government agency, or from a foreign government
25 agency, or from an international organization described in

1 subsection (b)(4), if the agency or organization has re-
2 quested that the information be kept confidential, or has
3 precluded such disclosure under other use limitations, as
4 a condition of providing the information.

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

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

12 (c) CONFORMING AMENDMENTS.—

13 (1) Section 301(j) (21 U.S.C. 331(j)) is amend-
14 ed by striking “or to the courts when relevant in any
15 judicial proceeding under this Act,” and inserting
16 “to the courts when relevant in any judicial pro-
17 ceeding under this Act, or as specified in section
18 708,”.

19 (2) Section 520(c) (21 U.S.C. 360j(c)) is
20 amended—

21 (A) in the heading, by striking “Trade se-
22 crets” and inserting “Use of confidential device
23 information”;

24 (B) by inserting “about a device” before
25 “under section 513”; and

1 (C) by striking “except (1) in accordance”
2 and all that follows through the period and in-
3 serting “except in accordance with section
4 708(b), or as specified in section 301(j).”.

5 **SEC. 113. SAFE AND SECURE FOOD IMPORTATION PRO-**
6 **GRAM.**

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

9 **“SEC. 805. SAFE AND SECURE FOOD IMPORTATION PRO-**
10 **GRAM.**

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

15 “(1) verifies that each facility involved in the
16 production, manufacture, processing, packaging, and
17 holding of the food is in compliance with the food
18 safety and security guidelines developed under sub-
19 section (b) with respect to such food;

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

23 “(3) provides supporting information to the
24 Secretary.

25 “(b) GUIDELINES.—

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

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

7 “(A) The personnel of the person import-
8 ing the food.

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

11 “(C) The sufficiency of preventive controls
12 for food and ingredients purchased by such per-
13 son.

14 “(D) Vendor and supplier information.

15 “(E) Such other factors as the Secretary
16 determines necessary.”.

17 **SEC. 114. INFANT FORMULA.**

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

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

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

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

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

12 “(B) Records required under subparagraph (A) with
13 respect to an infant formula shall be retained for at least
14 one year after the expiration of the shelf life of such infant
15 formula. Such records shall be made available to the Sec-
16 retary for review and duplication upon request of the Sec-
17 retary.”;

18 (3) in subsection (c)(1)—

19 (A) in subparagraph (A), by striking
20 “and” at the end;

21 (B) in subparagraph (B), by striking
22 “(c)(1).” at the end and inserting “(d)(1),
23 and”;

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

1 “(C) the Secretary has by letter informed such
2 person that the registration requirements and the
3 requirements in section 412(d)(1) have been satis-
4 fied.”; and

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

7 “(C) scientific evidence and other evidence, as
8 identified in regulations promulgated by the Sec-
9 retary, that demonstrates that the infant formula
10 satisfies the requirements of subsection (b)(1), and,
11 as demonstrated by the testing required under sub-
12 section (b)(3), that it satisfies the requirements of
13 subsection (i), and

14 “(D) scientific evidence and other evidence, as
15 identified in regulations promulgated by the Sec-
16 retary, that demonstrates that the processing of the
17 infant formula complies with the requirements of
18 subsection (b)(2).”.

19 **Subtitle B—Intervention**

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

21 (a) SURVEILLANCE SYSTEM.—The Secretary of
22 Health and Human Services (in this subtitle referred to
23 as the “Secretary”) shall build upon the existing surveil-
24 lance system for food, based on a representative propor-
25 tion of the population of the United States, to assess the

1 frequency and sources of human illness in the United
2 States associated with the consumption of food.

3 (b) SAMPLING AND ASSESSMENT.—

4 (1) IN GENERAL.—The Secretary shall utilize,
5 as appropriate, samples of food collected and ana-
6 lyzed by, or on behalf of, the Secretary in carrying
7 out the Secretary's duties under this Act and the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 301 et seq.) and may collect and analyze additional
10 samples of food to assess the nature, frequency of
11 occurrence, and amounts of contaminants in food.

12 (2) REQUIREMENTS.—Assessment by the Sec-
13 retary under this section may employ, in the Sec-
14 retary's discretion, statistically valid monitoring, in-
15 cluding market-basket studies, on the nature, fre-
16 quency of occurrence, and amounts of contaminants
17 in food available to consumers, and at the request of
18 the Secretary such other information as the Sec-
19 retary determines may be useful.

20 (c) PUBLIC AVAILABILITY OF ASSESSMENT.—To the
21 extent it does not impede the ability of the United States
22 to protect against terrorist threats and other intentional
23 attacks against the food supply, the Secretary may make
24 publicly available, by posting on the Web site of the De-
25 partment of Health and Human Services, the results of

1 any assessment conducted under this section. To the ex-
2 tent feasible with the data and information available, the
3 assessment may rank food categories based on their haz-
4 ard to human health and may address—

5 (1) the safety of commercial harvesting and
6 processing, as compared with the health hazards as-
7 sociated with food products that are harvested for
8 recreational or subsistence purposes and prepared
9 noncommercially;

10 (2) the safety of food products that are domes-
11 tically harvested and processed, as compared with
12 the health hazards associated with food products
13 that are harvested or processed outside the United
14 States; and

15 (3) contamination originating from handling
16 practices that occur prior to or after sale of food
17 products to consumers.

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

19 (a) PUBLIC EDUCATION.—The Secretary, in coopera-
20 tion with private and public organizations, including the
21 appropriate State entities, shall design and implement a
22 national public education program on food safety. The
23 program shall provide—

1 (1) information to the public so that individuals
2 can reduce their risk of foodborne illness and injury
3 and make healthy dietary choices;

4 (2) information to health professionals so that
5 they may improve diagnosis and treatment of food-
6 related illness and advise individuals whose health
7 conditions place them in particular risk; and

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

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

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

15 (2) develop standardized formats for written
16 and broadcast advisories; and

17 (3) incorporate State and local advisories into
18 the national public education program required
19 under subsection (a).

20 **SEC. 123. RESEARCH.**

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

24 (1) improve sanitation and food safety practices
25 in the processing of food products;

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

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

6 (4) determine the sources of contamination of
7 food and food products;

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

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

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

14 (8) address common and emerging zoonotic dis-
15 eases;

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

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

22 (11) conduct other research that supports the
23 purposes of this Act.

24 (b) CONTRACT AUTHORITY.—The Secretary is au-
25 thorized to enter into contracts and agreements with any

1 State, university, government agency, or other person to
2 carry out this section.

3 **Subtitle C—Response**

4 **SEC. 131. PROCEDURES FOR SEIZURE.**

5 Section 304(b) (21 U.S.C. 334(b)) is amended by
6 striking “except that on demand of either party any issue
7 of fact joined in any such case shall be tried by jury” and
8 inserting “except that on demand of either party any issue
9 of fact joined in any such case shall be tried by jury, Rule
10 G of the Supplemental Rules of Admiralty or Maritime
11 Claims and Asset Forfeiture Actions shall not apply in any
12 such case, exigent circumstances shall be deemed to exist
13 for all seizures brought under this section, and the sum-
14 mons and arrest warrant shall be issued by the clerk of
15 the court without court review in any such case”.

16 **SEC. 132. ADMINISTRATIVE DETENTION.**

17 (a) AMENDMENTS.—Section 304(h) (21 U.S.C.
18 334(h)) is amended—

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

22 (2) in paragraph (1)(A), by striking “presents
23 a threat of serious adverse health consequences or
24 death to humans or animals” and inserting “is adul-

1 terated, misbranded, or otherwise in violation of this
2 Act”;

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

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

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

10 (b) REGULATIONS.—The Secretary shall issue regula-
11 tions or guidance to implement the amendments made by
12 this section.

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

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

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

20 “(qq) The violation of a quarantine under section
21 304(i).”.

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

24 “(i) QUARANTINE OF GEOGRAPHIC LOCATION.—

1 “(1) AUTHORITY TO QUARANTINE.—If the Sec-
2 retary determines that there is credible evidence or
3 information that an article of food presents a threat
4 of serious adverse health consequences or death to
5 humans or animals, the Secretary may quarantine
6 any geographic area within the United States where
7 the Secretary reasonably believes such food is lo-
8 cated or from which such food originated. The au-
9 thority to quarantine includes prohibiting or restrict-
10 ing the movement of food or of any vehicle being
11 used or that has been used to transport or hold such
12 food within the geographic area.

13 “(2) NOTIFICATION PROCEDURES.—Before any
14 quarantine action is taken in any State under this
15 subsection, the Secretary shall notify an appropriate
16 official of the State affected and shall issue a public
17 announcement of—

18 “(A) the Secretary’s findings that support
19 the quarantine action;

20 “(B) the area affected by the intended
21 quarantine action;

22 “(C) the reasons for the intended quar-
23 antine action; and

24 “(D) where practicable, an estimate of the
25 anticipated duration of the quarantine.

1 The Secretary is not required to make such announcement
2 by publication in the Federal Register, but may use a
3 newspaper, radio or television, the Internet, or any reason-
4 able means to make such announcement.”

5 **SEC. 134. CRIMINAL PENALTIES.**

6 (a) INCREASED CRIMINAL PENALTIES.—Section
7 303(a) (21 U.S.C. 333) is amended—

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

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

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

18 (b) SENTENCING GUIDELINES.—The United States
19 Sentencing Guidelines shall be revised to reflect the seri-
20 ousness of violations of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 301 et seq.), including the penalties
22 for the violations cited in the amendments to such Act
23 made by this section.

1 **SEC. 135. CIVIL PENALTIES FOR VIOLATIONS RELATING TO**
2 **FOOD.**

3 (a) IN GENERAL.—Paragraph (2) of section 303(f)
4 (21 U.S.C. 331 et seq.) is amended to read as follows:

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

8 “(i) \$100,000, in the case of an individual;
9 and

10 “(ii) \$500,000, in the case of any other
11 person.

12 “(B) Each violation described in subparagraph
13 (A) and each day during which the violation con-
14 tinues shall be considered to be a separate offense.”.

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

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

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

22 “(rr) The submission of information required by or
23 under section 801, 802, or 804 that is inaccurate or in-
24 complete.

25 “(ss) The failure to submit information required by
26 or under section 801, 802, or 804.”.

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 drugs, devices, or cosmetics that are imported or of-
9 fered for import into the 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 **Subtitle D—Miscellaneous**

14 **SEC. 141. 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 section 201(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 721of 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. 142. 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 request for a substance to be deter-
9 mined by the Secretary to be a GRAS food substance, the
10 Secretary shall post notice of such request and the sup-
11 porting scientific justifications on the Food and Drug Ad-
12 ministration’s public website.

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. 143. 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—

9 “(1) the labeling of the food fails to identify the
10 country in which the final processing of the food oc-
11 curs; and

12 “(2) the website for the manufacturer of the
13 food fails to identify the country (or countries) of or-
14 igin for each ingredient in the food.

15 “(dd) In the case of non-processed food if—

16 “(1) the labeling of the food fails to identify the
17 country of origin of the food; and

18 “(2) the website for the original packer of the
19 food fails to identify the country of origin for the
20 food.”.

21 (b) REGULATIONS.—Not later than 180 days after
22 the date of the enactment of this Act, the Secretary of
23 Health and Human Services shall promulgate final regula-
24 tions to carry out paragraphs (bb) and (cc) of section 403

1 of the Federal Food, Drug, and Cosmetic Act, as added
2 by subsection (a).

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

8 **SEC. 144. EXPORTATION CERTIFICATE PROGRAM.**

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

10 (1) in the matter preceding clause (i) in sub-
11 paragraph (A)—

12 (A) by inserting “from the United States”
13 after “exports”; and

14 (B) by striking “a drug, animal drug, or
15 device” and inserting “a food (including animal
16 feed), drug, animal drug, or device”;

17 (2) in subparagraph (A)(i)—

18 (A) by striking “in writing”; and

19 (B) by striking “exported drug, animal
20 drug, or device” and inserting “exported food,
21 drug, animal drug, or device”;

22 (3) in subparagraph (A)(ii)—

23 (A) by striking “in writing”;

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

4 (C) by striking “the drug or device” and
5 inserting “the food, drug, animal drug, or de-
6 vice”;

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

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

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

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

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

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

15 **TITLE II—MISCELLANEOUS**

16 **SEC. 201. REGISTRATION FOR COMMERCIAL IMPORTERS** 17 **OF FOOD, DRUGS, AND DEVICES; FEE.**

18 (a) REGISTRATION.—

19 (1) PROHIBITIONS.—Section 301 (21 U.S.C.
20 331), as amended by sections 110, 111, 133, and
21 136, is amended by adding at the end the following:
22 “(tt) The failure to register in accordance with sec-
23 tion 801(r).”.

1 (2) MISBRANDING.—Section 403 (21 U.S.C.
2 343) as amended by sections 101(a), 109(a), 114(a),
3 and 143 is amended by adding at the end:

4 “(dd) If it is imported or offered for import by an
5 importer or a customs broker or filer not duly registered
6 under section 801(r).”.

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

10 “(r) REGISTRATION OF IMPORTERS AND CUSTOMS
11 BROKERS AND FILERS.—

12 “(1) IMPORTERS.—

13 “(A) REGISTRATION.—The Secretary shall
14 require an importer of food, drugs, or devices—

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

18 “(ii) consistent with section 911, to
19 submit appropriate unique facility identi-
20 fiers as a condition of registration.

21 “(B) GOOD IMPORTER PRACTICES.—The
22 maintenance of registration under this para-
23 graph is conditioned on compliance with good
24 importer practices. Good importer practices
25 shall include the verification of good manufac-

1 turing practices and preventive controls of the
2 importer’s foreign suppliers, as applicable.

3 “(2) CUSTOMS BROKERS AND FILERS.—The
4 Secretary shall require a customs broker or filer—

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

8 “(B) consistent with section 911, to submit
9 appropriate unique facility identifiers as a con-
10 dition of registration.

11 “(3) SUSPENSION OF REGISTRATION.—

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

16 “(i) a violation of this Act; or

17 “(ii) the making of an inaccurate or
18 incomplete statement or submission of in-
19 formation relating to the importation of
20 food, drugs, or devices.

21 “(B) REQUEST.—The importer, customs
22 broker, or filer whose registration is suspended
23 may request that the Secretary vacate the sus-
24 pension of registration when such importer,

1 customs broker, or filer has corrected the viola-
2 tion that is the basis for such suspension.

3 “(C) VACATING OF SUSPENSION.—If the
4 Secretary determines that adequate reasons do
5 not exist to continue the suspension of a reg-
6 istration, the Secretary shall vacate such sus-
7 pension.

8 “(4) CANCELLATION OF REGISTRATION.—

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

16 “(B) NOTICE OF CANCELLATION.—Can-
17 cellation shall be preceded by notice to the im-
18 porter, customs broker, or filer of the intent to
19 cancel the registration and the basis for such
20 cancellation.

21 “(C) TIMELY UPDATE OR CORRECTION.—
22 If the registration for the importer, customs
23 broker, or filer is updated or corrected no later
24 than 7 days after notice is provided under sub-

1 paragraph (B), the Secretary shall not cancel
2 such registration.

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

5 “(A) shall establish an exemption for im-
6 portations for personal use; and

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

9 (4) REGULATIONS.—Not later than 24 months
10 after the date of the enactment of this Act, the Sec-
11 retary of Health and Human Services shall promul-
12 gate the regulations required to carry out section
13 801(r).

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

17 (b) FEE.—Subchapter C of chapter VII (21 U.S.C.
18 379f et seq.) as amended by sections 101 and 108, is
19 amended by adding at the end the following:

20 **“PART VI—IMPORTERS OF FOOD, DRUGS, AND**
21 **DEVICES**

22 **“SEC. 742. IMPORTERS OF FOOD, DRUGS, AND DEVICES.**

23 “(a) IMPORTERS.—The Secretary shall assess and
24 collect an annual fee for the registration of an importer
25 of food, drugs, or devices under section 801(r).

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

4 “(c) AMOUNT OF FEE.—

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

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

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

20 “(B) the total percentage change for the
21 previous fiscal year in basic pay under the Gen-
22 eral Schedule in accordance with section 5332
23 of title 5, United States Code, as adjusted by
24 any locality-based comparability payment pur-
25 suant to section 5304 of such title for Federal

1 employees stationed in the District of Columbia;
2 or

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

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

14 “(4) COLLECTIONS AND APPROPRIATIONS
15 ACTS.—

16 “(A) IN GENERAL.—The fees authorized
17 by this section—

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

23 “(ii) shall only be collected and avail-
24 able to cover the costs associated with reg-
25 istering importers, customs brokers, and

1 filers under section 801(r) and with ensur-
2 ing compliance with good importer prac-
3 tices.

4 “(B) LIMIT.—The total amount of fees
5 charged, as adjusted under paragraphs (2) and
6 (3), for a fiscal year may not exceed the total
7 costs described in subparagraph (A)(ii) for such
8 fiscal year.”.

9 (c) INSPECTION.— Section 704 (21 U.S.C. 374), as
10 amended by sections 104 and 106(c), is amended by add-
11 ing at the end the following:

12 “(i) IMPORTERS, BROKERS, AND FILERS.—Every
13 person engaged in the importing, brokering for import, or
14 filing for import of any food, drug, or device shall, upon
15 request of an officer or employee designated by the Sec-
16 retary, permit such officer or employee at all reasonable
17 times to inspect the facilities of such person and have ac-
18 cess to, and to copy and verify, any related records.”.

19 **SEC. 202. UNIQUE IDENTIFICATION NUMBER FOR FOOD FA-**
20 **CILITIES, DRUG AND DEVICE ESTABLISH-**
21 **MENTS, AND IMPORTERS, CUSTOM BROKERS,**
22 **AND FILERS.**

23 (a) IN GENERAL.—Chapter IX (21 U.S.C. 391 et
24 seq) is amended by adding at the end the following:

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

2 “(a) REGISTRATION OF FACILITY OR ESTABLISH-
3 MENT.—A person required to register a facility or estab-
4 lishment pursuant to section 415 or 510 shall submit, at
5 the time of registration, a unique facility identifier for the
6 facility or establishment.

7 “(b) REGISTRATION OF IMPORTERS, CUSTOM BRO-
8 KERS, AND FILERS.—A person required to register pursu-
9 ant to section 801(r) shall submit, at the time of registra-
10 tion, a unique facility identifier for the principal place of
11 business for which such person is required to register
12 under section 801(r).

13 “(c) GUIDANCE.—The Secretary may, by guidance,
14 specify the unique numerical identifier system to be used
15 to meet the requirements of subsections (a) and (b) and
16 the form, manner, and timing of a submission under such
17 subsections. In the absence of a specification by the Sec-
18 retary, a Dunn & Bradstreet Universal Numbering System
19 (DUNS) number shall be used as the required numerical
20 identifier for purposes of such subsections.

21 “(d) IMPORTATION.—An article of food, a drug, or
22 a device imported or offered for import shall be refused
23 admission unless the appropriate unique facility identi-
24 fiers, as specified by the Secretary, are provided for such
25 article.”.

1 (b) UNIQUE FACILITY IDENTIFIERS RELATING TO
2 DRUG AND DEVICE ESTABLISHMENTS.—

3 (1) MISBRANDING.—Section 502(o) (21 U.S.C.
4 352(o)) is amended by striking “in any State”.

5 (2) REGISTRATION.—Section 510 (21 U.S.C.
6 360) is amended—

7 (A) by amending subsections (b) through
8 (d) to read as follows:

9 “(b) ANNUAL REGISTRATION.—

10 “(1) On or before December 31 of each year,
11 every person who owns or operates any establish-
12 ment in any State engaged in the manufacture,
13 preparation, propagation, compounding, or proc-
14 essing of a drug or drugs shall register with the Sec-
15 retary the person’s name, places of business, and all
16 such establishments, and for each such establish-
17 ment shall submit the unique facility identifier as
18 specified in section 911.

19 “(2) During the period beginning on October 1
20 and ending on December 31 of each year, every per-
21 son who owns or operates any establishment in any
22 State engaged in the manufacture, preparation,
23 propagation, compounding, or processing of a device
24 or devices shall register with the Secretary the per-
25 son’s name, places of business, and all such estab-

1 lishments, and for each such establishment shall
2 submit the unique facility identifier as specified in
3 section 911.

4 “(c) NEW PRODUCERS.—Every person upon first en-
5 gaging in the manufacture, preparation, propagation,
6 compounding, or processing of a drug or drugs or a device
7 or devices in any establishment which the person owns or
8 operates in any State shall immediately register with the
9 Secretary the person’s name, place of business, and such
10 establishment, and for each such establishment shall sub-
11 mit the unique facility identifier as specified in section
12 911.

13 “(d) ADDITIONAL ESTABLISHMENTS.—Every person
14 duly registered in accordance with the foregoing sub-
15 sections of this section shall immediately register with the
16 Secretary any additional establishment which the person
17 owns or operates in any State and in which the person
18 begins the manufacture, preparation, propagation,
19 compounding, or processing of a drug or drugs or a device
20 or devices, and for each such establishment shall submit
21 the unique facility identifier as specified in section 911.”;

22 (B) by amending subsection (i) to read as
23 follows:

24 “(i) REGISTRATION OF FOREIGN ESTABLISH-
25 MENTS.—

1 “(1) Any establishment within any foreign
2 country engaged in the manufacture, preparation,
3 propagation, compounding, or processing of a drug
4 or device that is imported or offered for import into
5 the United States shall, through electronic means in
6 accordance with the criteria of the Secretary—

7 “(A) upon first engaging in any such activ-
8 ity, immediately register with the Secretary the
9 name and place of business of the establish-
10 ment, the name of the United States agent for
11 the establishment, the name of each importer of
12 such drug or device in the United States that
13 is known to the establishment, and the name of
14 each person who imports or offers for import
15 such drug or device to the United States, and
16 for each such establishment or person, submit
17 the unique facility identifier as specified in sec-
18 tion 911; and

19 “(B) each establishment subject to the re-
20 quirements of subparagraph (A) shall—

21 “(i) with respect to drugs, register
22 with the Secretary on or before December
23 31 of each year, and for each such estab-
24 lishment or person shall submit the unique

1 facility identifier as specified in section
2 911; and

3 “(ii) with respect to devices, register
4 with the Secretary during the period begin-
5 ning on October 1 and ending on Decem-
6 ber 31 of each year, and for each such es-
7 tablishment or person shall submit the
8 unique facility identifier as specified in sec-
9 tion 911.

10 “(2) The establishment shall also provide the
11 information required by subsection (j).

12 “(3) The Secretary is authorized to enter into
13 cooperative arrangements with officials of foreign
14 countries to ensure that adequate and effective
15 means are available for purposes of determining,
16 from time to time, whether drugs or devices manu-
17 factured, prepared, propagated, compounded, or
18 processed by an establishment described in para-
19 graph (1), if imported or offered for import into the
20 United States, shall be refused admission on any of
21 the grounds set forth in section 801(a)”; and

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

23 “(q) Any person or establishment that is required to
24 submit a unique facility identifier pursuant to subsection
25 (b), (c), (d), or (i) shall notify the Secretary within 30

1 days of changes affecting the use of the unique facility
2 identifier, including discontinuance or cessation of use of
3 the identifier involved.”.

4 **SEC. 203. PROHIBITION AGAINST DELAYING, LIMITING, OR**
5 **REFUSING INSPECTION.**

6 (a) ADULTERATION.—

7 (1) FOR FOODS.—Section 402 (21 U.S.C. 342),
8 as amended by section 102(a), 103(a), and 104(a),
9 is amended by adding at the end the following:

10 “(m) If it has been produced manufactured, proc-
11 essed, packed, or held in any farm, factory, warehouse,
12 or establishment and the owner, operator, or agent of such
13 farm, factory, warehouse, or establishment, or any agent
14 of a governmental authority in the foreign country within
15 which such farm, factory, warehouse, or establishment is
16 located, delays or limits an inspection, or refuses to permit
17 entry or inspection, under section 414 or 704.”

18 (2) FOR DRUGS AND DEVICES.—Section 501
19 (21 U.S.C. 351) is amended by adding at the end
20 the following:

21 “(j) If it has been manufactured, processed, packed,
22 or held in any factory, warehouse, or establishment and
23 the owner, operator, or agent of such factory, warehouse,
24 or establishment, or any agent of a governmental author-
25 ity in the foreign country within which such factory, ware-

1 house, or establishment is located, delays or limits an in-
2 spection, or refuses to permit entry or inspection, under
3 section 510(h) or 704.”

4 (3) FOR COSMETICS.—Section 601 (21 U.S.C.
5 361) is amended by adding at the end the following:

6 “(f) If it has been manufactured, processed, packed,
7 or held in any factory, warehouse, or establishment and
8 the owner, operator, or agent of such factory, warehouse,
9 or establishment, or any agent of a governmental author-
10 ity in the foreign country within which such factory, ware-
11 house, or establishment is located, delays limits an inspec-
12 tion, or refuses to permit entry or inspection, under sec-
13 tion 704.”.

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

17 (1) in subparagraph (A), by inserting “, wheth-
18 er foreign or domestic,” after “factory, warehouse,
19 or establishment”.

20 (2) in the third sentence, by inserting “, wheth-
21 er foreign or domestic,” after “factory, warehouse,
22 establishment, or consulting laboratory”.

23 **SEC. 204. DEDICATED FOREIGN INSPECTORATE.**

24 Section 704 (21 U.S.C. 374) is amended by adding
25 at the end the following:

1 “(j) DEDICATED FOREIGN INSPECTORATE.—The
2 Secretary shall establish and maintain a corps of inspec-
3 tors dedicated to inspections of foreign food, drug, device,
4 and cosmetics facilities and establishments. This corps
5 shall be staffed and funded by the Secretary at a level
6 sufficient to enable it to assist the Secretary in achieving
7 the frequency of inspections for food, drug, device, and
8 cosmetic facilities as described in this Act.”.

9 **SEC. 205. PLAN AND REVIEW OF CONTINUED OPERATION**
10 **OF FIELD LABORATORIES.**

11 (a) SUBMISSION OF PLAN.—Not later than 90 days
12 before the Secretary terminates or consolidates any lab-
13 oratory, district office, or the functions of any such labora-
14 tory or district office, specified in subsection (b), the Sec-
15 retary shall submit a reorganization plan to the Comp-
16 troller General of the United States, the Committee on
17 Energy and Commerce of the House of Representatives,
18 and the Committee on Health, Education, Labor, and
19 Pensions of the Senate.

20 (b) SPECIFIED LABORATORIES AND OFFICES.—The
21 laboratories and offices specified in this subsection are the
22 following:

23 (1) Any of the 13 field laboratories that were
24 operated by the Office of Regulatory Affairs of the

1 Food and Drug Administration as of January 1,
2 2007.

3 (2) Any of the 20 district offices or any of the
4 inspection or compliance functions of any of the 20
5 district offices of the Food and Drug Administration
6 functioning as of January 1, 2007.

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

11 **SEC. 206. FALSE OR MISLEADING REPORTING TO FDA.**

12 (a) IN GENERAL.—Section 301(q)(2) (21 U.S.C.
13 331(q)(2)) is amended by inserting after “device” the fol-
14 lowing: “food, drug, or biological product”.

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

18 **SEC. 207. SUBPOENA AUTHORITY.**

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

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

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

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

1 “(1) any hearing, investigation, or other pro-
2 ceeding respecting a violation of the Act;

3 “(2) any hearing, investigation, or other pro-
4 ceeding to determine if a person is in violation of a
5 specific provision of the Act; or

6 “(3) any other matter relative to the Commis-
7 sioner’s jurisdiction under this Act, the Public
8 Health Service Act, or the Federal Anti-Tampering
9 Act,

10 the Commissioner may issue subpoenas requiring the at-
11 tendance and testimony of witnesses and the production
12 of records and other things.

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

18 “(c) SERVICE OF SUBPOENA.—

19 “(1) IN GENERAL.—Subpoenas of the Commis-
20 sioner shall be served by a person authorized by the
21 Commissioner by delivering a copy thereof to the
22 person named therein or by certified mail addressed
23 to such person at such person’s last known dwelling
24 place or principal place of business.

1 “(2) CORPORATIONS AND OTHER ENTITIES.—
2 Service on a domestic or foreign corporation, part-
3 nership, unincorporated association, or other entity
4 that is subject to suit under a common name may
5 be made by delivering the subpoena to an officer, a
6 managing or general agent, or any other agent au-
7 thorized by appointment or by law to receive service
8 of process.

9 “(3) PERSON OUTSIDE U.S. JURISDICTION.—
10 Service on any person not found within the terri-
11 torial jurisdiction of any court of the United States
12 may be made in any manner as the Federal Rules
13 of Civil Procedure prescribe for service in a foreign
14 nation.

15 “(4) PROOF OF SERVICE.—A verified return by
16 the person so serving the subpoena setting forth the
17 manner of service, or, in the case of service by cer-
18 tified mail, the return post office receipt therefor
19 signed by the person so served, shall be proof of
20 service.

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

1 “(e) ENFORCEMENT.—In the case of a refusal to
2 obey a subpoena duly served upon any person under sub-
3 section (a), any district court of the United States for the
4 judicial district in which such person charged with refusal
5 to obey is found, resides, or transacts business, upon ap-
6 plication by the Commissioner, shall have jurisdiction to
7 issue an order compelling compliance with the subpoena
8 and requiring such person to appear and give testimony
9 or to appear and produce records and other things, or
10 both. The failure to obey such order of the court may be
11 punished by the court as contempt thereof. If the person
12 charged with failure or refusal to obey is not found within
13 the territorial jurisdiction of the United States, the United
14 States District Court for the District of Columbia shall
15 have the same jurisdiction, consistent with due process,
16 to take any action respecting compliance with the sub-
17 poena by such person that such district court would have
18 if such person were personally within the jurisdiction of
19 such district court.

20 “(f) NONDISCLOSURE.—A United States district
21 court for the district in which the subpoena is or will be
22 served, upon application of the Commissioner, may issue
23 an ex parte order that no person or entity disclose to any
24 other person or entity (other than to an attorney to obtain
25 legal advice) the existence of such subpoena for a period

1 of up to 90 days. Such order may be issued on a showing
2 that the records or things being sought may be relevant
3 to the hearing, investigation, proceeding, or other matter
4 and that there is reason to believe that such disclosure
5 may result in—

6 “(1) furtherance of a potential violation under
7 investigation;

8 “(2) endangerment to the life or physical safety
9 of any person;

10 “(3) flight or other action to avoid prosecution
11 or other enforcement remedies;

12 “(4) destruction of or tampering with evidence;
13 or

14 “(5) intimidation of potential witnesses.

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

19 “(g) RELATION TO OTHER PROVISIONS.—The sub-
20 poena authority vested in the Commissioner and the dis-
21 trict courts of the United States by this section is in addi-
22 tion to any such authority vested in the Commissioner or
23 such courts by other provisions of law.”.

1 (c) Section 801 (21 U.S.C. 381), as amended by sec-
2 tions 109, 136, and 201, is amended by adding at the end
3 the following:

4 “(s) FAILURE OR REFUSAL TO OBEY A SUBPOENA.—
5 An article of food, a drug, a device, an electronic product,
6 or a cosmetic shall be refused admission if any person who
7 manufactures, processes, packs, holds, or ships such arti-
8 cle before it is imported or offered for import into the
9 United States fails or refuses to obey a subpoena issued
10 pursuant to section 311 and such subpoena was issued,
11 in whole or in part, for the purpose of determining wheth-
12 er such article is adulterated, misbranded, or an unap-
13 proved new drug. No article shall be refused admission
14 under this section based on the failure or refusal to obey
15 a subpoena that has been withdrawn by the Commissioner
16 or quashed by a United States District Court.”.

17 **SEC. 208. WHISTLEBLOWER PROTECTIONS.**

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

20 **“SEC. 911 PROTECTIONS FOR EMPLOYEES WHO REFUSE TO**
21 **VIOLATE, OR WHO DISCLOSE VIOLATIONS OF,**
22 **THIS ACT OR SECTION 351 OF THE PUBLIC**
23 **HEALTH SERVICE ACT.**

24 “(a) IN GENERAL.—No person who submits or is re-
25 quired under this Act or the Public Health Service Act

1 to submit any information related to a food, drug, device,
2 or cosmetic, or any officer, employee, contractor, subcon-
3 tractor, or agent of such person may discharge, demote,
4 suspend, threaten, harass, or in any other manner dis-
5 criminate against an employee in the terms and conditions
6 of employment because of any lawful act done by the em-
7 ployee, including within the ordinary course of the job du-
8 ties of such employee—

9 “(1) to provide information, cause information
10 to be provided, or otherwise assist in any investiga-
11 tion regarding any conduct which the employee rea-
12 sonably believes constitutes a violation of this Act or
13 section 351 of the Public Health Service Act, any
14 other provision of Federal law relating to the safety
15 or effectiveness of a drug, biological product, or de-
16 vice or to the safety of a food or cosmetic, or any
17 provision of Federal law prohibiting fraud against
18 the Food and Drug Administration, if the informa-
19 tion or assistance is provided to, or an investigation
20 stemming from the provided information is con-
21 ducted 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, or within 90 days after
23 receiving a final decision or order from the Sec-
24 retary, and there is no showing that such delay
25 is due to the bad faith of the claimant, bringing

1 an action at law or equity for de novo review in
2 the appropriate district court of the United
3 States, which court shall have jurisdiction over
4 such action without regard to the amount in
5 controversy, and which action shall, at the re-
6 quest of either party to such action, be tried by
7 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 aggre-
3 gate amount of all costs and expenses (including at-
4 torney 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 com-
7 plaint upon which the order was issued.

8 “(d) RIGHTS RETAINED BY EMPLOYEE.—Nothing in
9 this section shall be deemed to diminish the rights, privi-
10 leges, 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 employ-
14 ment.”.

15 **SEC. 209. EXTRATERRITORIAL JURISDICTION.**

16 (a) PROHIBITED ACT.—Section 301 (21 U.S.C. 331),
17 as amended by sections 110, 111, 133, 136, and 201, is
18 amended by adding at the end the following:

19 “(uu) The production, manufacture, processing, prep-
20 aration, packing, holding, or distribution of an adulterated
21 or misbranded food, drug, device, or cosmetic with the
22 knowledge or intent that such article will be imported into
23 the United States, or the manufacture, processing, prepa-
24 ration, packing, holding, or distribution of a drug with the

1 knowledge or intent that the drug will be imported into
2 the United States in violation of section 505.”.

3 (b) JURISDICTION.—Chapter III (21 U.S.C. 331 et
4 seq.), as amended by section 207, is amended by adding
5 at the end the following:

6 **“SEC. 312. EXTRATERRITORIAL JURISDICTION.**

7 “There is extraterritorial Federal jurisdiction over
8 any violation of this Act relating to any food, drug, device,
9 or cosmetic if such article was intended for import into
10 the United States or if any act in furtherance of the viola-
11 tion was committed in the United States.”.