

## Union Calendar No.

111<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 2749

[Report No. 111-]

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

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### IN THE HOUSE OF REPRESENTATIVES

JUNE 8, 2009

Mr. DINGELL (for himself, Mr. WAXMAN, Mr. PALLONE, Mr. STUPAK, Ms. DEGETTE, and Ms. SUTTON) introduced the following bill; which was referred to the Committee on Energy and Commerce

JULY --, 2009

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italics]

[For text of introduced bill, see copy of bill as introduced on June 8, 2009]

# **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. Rules of construction.*
- Sec. 5. USDA exemptions.*
- Sec. 6. Alcohol-related facilities.*

**TITLE I—FOOD SAFETY**

*Subtitle A—Prevention*

- Sec. 101. Changes in registration of food facilities.*
- Sec. 102. Hazard analysis, risk-based preventive controls, food safety plan, finished product test results from category 1 facilities.*
- Sec. 103. Performance standards.*
- Sec. 104. Safety standards for produce and certain other raw agricultural commodities.*
- Sec. 105. Risk-based inspection schedule.*
- Sec. 106. Access to records.*
- Sec. 107. Traceability of food.*
- Sec. 108. Reinspection and food recall fees applicable to facilities.*
- Sec. 109. Certification and accreditation.*
- Sec. 110. Testing by accredited laboratories.*
- Sec. 111. Notification, nondistribution, and recall of adulterated or misbranded food.*
- Sec. 112. Reportable food registry; exchange of information.*
- Sec. 113. Safe and secure food importation program.*
- Sec. 114. Infant formula.*

*Subtitle B—Intervention*

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

*Subtitle C—Response*

- Sec. 131. Procedures for seizure.*
- Sec. 132. Administrative detention.*
- Sec. 133. Quarantine authority for foods.*
- Sec. 134. Criminal penalties.*

*Sec. 135. Civil penalties for violations relating to food.*

*Sec. 136. Improper import entry filings.*

#### TITLE II—MISCELLANEOUS

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

*Sec. 202. Country of origin labeling; disclosure of source of ingredients.*

*Sec. 203. Exportation certificate program.*

*Sec. 204. Registration for commercial importers of food; fee.*

*Sec. 205. Registration for customs brokers and filers; fee.*

*Sec. 206. Unique identification number for food facilities, importers, custom brokers, and filers.*

*Sec. 207. Prohibition against delaying, limiting, or refusing inspection.*

*Sec. 208. Dedicated foreign inspectorate.*

*Sec. 209. Plan and review of continued operation of field laboratories.*

*Sec. 210. False or misleading reporting to FDA.*

*Sec. 211. Subpoena authority.*

*Sec. 212. Whistleblower protections.*

*Sec. 213. Extraterritorial jurisdiction.*

*Sec. 214. Support for training institutes.*

*Sec. 215. Bisphenol A in food and beverage containers.*

### 1 **SEC. 3. REFERENCES.**

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

### 7 **SEC. 4. RULES OF CONSTRUCTION.**

8 *(a) Nothing in this Act or any amendment made by*  
9 *this Act shall be construed to prohibit or limit—*

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

11 *(2) the introduction of evidence of compliance or*  
12 *noncompliance with the requirements of the Federal*  
13 *Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).*

14 *(b) Nothing in this Act or any amendment made by*  
15 *this Act shall be construed to—*

1           (1) *alter the jurisdiction between the Secretary of*  
2 *Agriculture and the Secretary of Health and Human*  
3 *Services, under applicable statutes and regulations;*

4           (2) *limit the authority of the Secretary of Health*  
5 *and Human Services to issue regulations related to*  
6 *the safety of food under—*

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

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

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

22 **SEC. 5. USDA EXEMPTIONS.**

23           (a) *USDA-REGULATED PRODUCTS.—Food is exempt*  
24 *from the requirements of this Act if such food is regulated*  
25 *by the Secretary of Agriculture under the Federal Meat In-*

1 *spection Act, the Poultry Products Inspection Act, or the*  
2 *Egg Products Inspection Act.*

3 (b) *USDA-REGULATED FACILITIES.*—*A facility is ex-*  
4 *empt from the requirements of this Act if such facility is*  
5 *regulated exclusively as an official establishment by the Sec-*  
6 *retary of Agriculture under the Federal Meat Inspection*  
7 *Act, the Poultry Products Inspection Act, or the Egg Prod-*  
8 *ucts Inspection Act.*

9 (c) *FARMS.*—*A farm is exempt from the requirements*  
10 *of this Act to the extent such farm raises animals from*  
11 *which food is derived that is regulated under the Federal*  
12 *Meat Inspection Act, the Poultry Products Inspection Act,*  
13 *or the Egg Products Inspection Act.*

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

15 (a) *IN GENERAL.*—*With the exception of the amend-*  
16 *ments made by section 101(a) and (b) and section 113 of*  
17 *this Act, nothing in this Act, or the amendments made by*  
18 *this Act, shall be construed to apply to a facility that—*

19 (1) *under the Federal Alcohol Administration*  
20 *Act or chapter 51 of subtitle E of the Internal Rev-*  
21 *enue Code, is required to obtain a permit or to reg-*  
22 *ister with the Secretary of the Treasury as a condi-*  
23 *tion of doing business in the United States; and*

24 (2) *under section 415 of the Federal Food, Drug,*  
25 *and Cosmetic Act, as amended by this Act, is required*

1       to register as a facility solely because such facility is  
2       engaged in manufacturing, processing, packing, or  
3       holding 1 or more alcoholic beverages.

4       (b) *RULE OF CONSTRUCTION.*—This section shall not  
5       be construed to exempt any food, apart from distilled spir-  
6       its, wine, and malt beverages, as defined in section 211 of  
7       the Federal Alcohol Administration Act, from the require-  
8       ments of this Act and the amendments made by this Act.

## 9                   **TITLE I—FOOD SAFETY**

### 10                   **Subtitle A—Prevention**

#### 11       **SEC. 101. CHANGES IN REGISTRATION OF FOOD FACILITIES.**

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

14               “(z) If it was manufactured, processed, packed, or held  
15       in a facility that is not duly registered under section 415,  
16       including a facility whose registration is canceled or sus-  
17       pended under such section.”.

18       (b) *ANNUAL REGISTRATION.*—

19               (1) *IN GENERAL.*—Section 415(a) (21 U.S.C.  
20       350d(a)) is amended—

21                   (A) in the first sentence of paragraph (1)—

22                               (i) by striking “require that” and in-  
23                               serting “require that, on or before December  
24                               31 of each year,”; and

1                   (ii) by striking “food for consumption  
2                   in the United States” and inserting “food  
3                   for consumption in the United States or for  
4                   export from the United States”;

5                   (B) in subparagraphs (A) and (B) of para-  
6                   graph (1), by inserting “and pay the registration  
7                   fee required under section 743” after “submit a  
8                   registration to the Secretary” each place it ap-  
9                   pears;

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

13                  (D) in paragraph (4), by inserting after the  
14                  first sentence the following: “The Secretary shall  
15                  remove from such list the name of any facility  
16                  that fails to reregister in accordance with this  
17                  section, that fails to pay the registration fee re-  
18                  quired under section 743, or whose registration  
19                  is canceled by the registrant, canceled by the Sec-  
20                  retary in accordance with this section, or sus-  
21                  pended by the Secretary in accordance with this  
22                  section.”.

23                  (2) *CONTENTS OF REGISTRATION.*—Paragraph  
24                  (2) of section 415(a) (21 U.S.C. 350d(a)), as amended  
25                  by paragraph (1), is amended by striking “containing



1        *information” and all that follows and inserting the*  
2        *following: “containing information that identifies the*  
3        *following:*

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

7                *“(B) The primary purpose and business ac-*  
8                *tivity of the facility, including the dates of oper-*  
9                *ation if the facility is seasonal.*

10               *“(C) The general food category (as defined*  
11               *by the Secretary by guidance) of each food man-*  
12               *ufactured, processed, packed, or held at the facil-*  
13               *ity.*

14               *“(D) All trade names under which the facil-*  
15               *ity conducts business related to food.*

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

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

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

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

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

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

14           “(5) *SUSPENSION OF REGISTRATION.—*

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

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

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

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

1                    *tions issued by the Secretary, concerning the*  
2                    *suspension of such registration for such fa-*  
3                    *cility.*

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

10                    “(D) *VACATING OF SUSPENSION.—If, based*  
11                    *on an inspection of the facility or other informa-*  
12                    *tion, the Secretary determines that adequate rea-*  
13                    *sons do not exist to continue the suspension of a*  
14                    *registration, the Secretary shall vacate such sus-*  
15                    *pension.*

16                    “(6) *CANCELLATION OF REGISTRATION.—*

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

21                    “(i) *the registration was not updated*  
22                    *in accordance with this section or otherwise*  
23                    *contains false, incomplete, or inaccurate in-*  
24                    *formation; or*

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

4                   “(B) *NOTICE OF CANCELLATION.—Cancell-*  
5                   *ation shall be preceded by notice to the facility of*  
6                   *the intent to cancel the registration and the basis*  
7                   *for such cancellation.*

8                   “(C) *TIMELY UPDATE OR CORRECTION.—If*  
9                   *the registration for the facility is updated or cor-*  
10                   *rected no later than 7 days after notice is pro-*  
11                   *vided under subparagraph (B), the Secretary*  
12                   *shall not cancel such registration.*

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

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

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

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

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

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

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

5           “(8) *LIMITATION ON DELEGATION.—The author-*  
6           *ity conferred by this subsection to issue an order to*  
7           *suspend a registration or cancel a registration shall*  
8           *not be delegated to any officer or employee other than*  
9           *the Commissioner of Food and Drugs, the Principal*  
10           *Deputy Commissioner, the Associate Commissioner*  
11           *for Regulatory Affairs, or the Director for the Center*  
12           *for Food Safety and Applied Nutrition, of the Food*  
13           *and Drug Administration.”.*

14           “(c) *REGISTRATION FEE.—Chapter VII (21 U.S.C. 371*  
15           *et seq.) is amended by adding at the end of subchapter C*  
16           *the following:*

17           **“PART 6—FEES RELATING TO FOOD**

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

19           “(a) *IN GENERAL.—*

20           “(1) *ASSESSMENT AND COLLECTION.—Beginning*  
21           *in fiscal year 2010, the Secretary shall assess and col-*  
22           *lect an annual fee for the registration of a facility*  
23           *under section 415.*

24           “(2) *PAYABLE DATE.—A fee under this section*  
25           *shall be payable—*

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

4           “(B) for any other facility—

5                 “(i) for fiscal year 2010, not later than  
6                 the sooner of 90 days after the date of the  
7                 enactment of this part or December 31,  
8                 2009; and

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

11       “(b) *FEE AMOUNTS.*—

12               “(1) *IN GENERAL.*—The registration fee under  
13               subsection (a) shall be—

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

15                     “(B) for fiscal year 2011 and each subse-  
16                     quent fiscal year, the fee for fiscal year 2010 as  
17                     adjusted under subsection (c).

18               “(2) *ANNUAL FEE SETTING.*—The Secretary  
19               shall, not later than 60 days before the start of fiscal  
20               year 2011 and each subsequent fiscal year, establish,  
21               for the next fiscal year, registration fees under sub-  
22               section (a), as described in paragraph (1).

23               “(3) *MAXIMUM AMOUNT.*—Notwithstanding  
24               paragraph (1), a person who owns or operates mul-  
25               tiple facilities for which a fee must be paid under this

1        *section for a fiscal year shall be liable for not more*  
2        *than \$175,000 in aggregate fees under this section for*  
3        *such fiscal year.*

4        *“(c) INFLATION ADJUSTMENT.—For fiscal year 2011*  
5        *and each subsequent fiscal year, the fee amount under sub-*  
6        *section (b)(1) shall be adjusted by the Secretary by notice,*  
7        *published in the Federal Register, to reflect the greater of—*

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

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

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

1 *The adjustment made each fiscal year under this subsection*  
2 *shall be added on a compounded basis to the sum of all*  
3 *adjustments made each fiscal year after fiscal year 2010*  
4 *under this subsection.*

5 “(d) *LIMITATIONS.—*

6 “(1) *IN GENERAL.—Fees under subsection (a)*  
7 *shall be refunded for a fiscal year beginning after fis-*  
8 *cal year 2010 unless appropriations for salaries and*  
9 *expenses of the Food and Drug Administration for*  
10 *such fiscal year (excluding the amount of fees appro-*  
11 *priated for such fiscal year) are equal to or greater*  
12 *than the amount of appropriations for the salaries*  
13 *and expenses of the Food and Drug Administration*  
14 *for fiscal year 2010 (excluding the amount of fees ap-*  
15 *propriated for such fiscal year) multiplied by the ad-*  
16 *justment factor applicable to the fiscal year involved.*

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



1           “(3) *ADJUSTMENT FACTOR.*—*In this subsection,*  
2           *the term ‘adjustment factor’ applicable to a fiscal*  
3           *year is the Consumer Price Index for all urban con-*  
4           *sumers (all items; United States city average) for Oc-*  
5           *tober of the preceding fiscal year divided by such*  
6           *Index for October 2009.*

7           “(e) *CREDITING AND AVAILABILITY OF FEES.*—

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

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

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

24           “(B) *shall only be collected and available to*  
25           *defray the costs of food safety activities.*

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

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

11          “(f) *COLLECTION OF UNPAID FEES.*—*In any case*  
12          *where the Secretary does not receive payment of a fee as-*  
13          *essed under subsection (a) within 30 days after it is due,*  
14          *such fee shall be treated as a claim of the United States*  
15          *Government subject to subchapter II of chapter 37 of title*  
16          *31, United States Code.*

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

24          “(h) *ANNUAL FISCAL REPORTS.*—*Beginning with fis-*  
25          *cal year 2011, not later than 120 days after the end of each*

1 *fiscal year for which fees are collected under this section,*  
2 *the Secretary shall prepare and submit to the Committee*  
3 *on Energy and Commerce of the House of Representatives*  
4 *and the Committee on Health, Education, Labor, and Pen-*  
5 *sions of the Senate a report on the implementation of the*  
6 *authority for such fees during such fiscal year and the use,*  
7 *by the Food and Drug Administration, of the fees collected*  
8 *for such fiscal year.*

9 “(i) *DEFINITIONS.—In this section:*

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

13 “(A) *officers and employees of the Food and*  
14 *Drug Administration, contractors of the Food*  
15 *and Drug Administration, advisory committees,*  
16 *and costs related to such officers, employees, and*  
17 *committees and to contracts with such contrac-*  
18 *tors;*

19 “(B) *laboratory capacity;*

20 “(C) *management of information, and the*  
21 *acquisition, maintenance, and repair of tech-*  
22 *nology resources;*

23 “(D) *leasing, maintenance, renovation, and*  
24 *repair of facilities and acquisition, maintenance,*  
25 *and repair of fixtures, furniture, scientific equip-*

1           *ment, and other necessary materials and sup-*  
2           *plies; and*

3           *“(E) collecting fees under this section and*  
4           *accounting for resources allocated for food safety*  
5           *activities.*

6           *“(2) The term ‘food safety activities’ means ac-*  
7           *tivities related to compliance by facilities registered*  
8           *under section 415 with the requirements of this Act*  
9           *relating to food (including research related to and the*  
10           *development of standards (such as performance stand-*  
11           *ards and preventive controls), risk assessments, haz-*  
12           *ard analyses, inspection planning and inspections,*  
13           *third-party inspections, compliance review and en-*  
14           *forcement, import review, information technology sup-*  
15           *port, test development, product sampling, risk com-*  
16           *munication, and administrative detention).”.*

17           *(d) TRANSITIONAL PROVISIONS.—*

18           *(1) FEES.—The Secretary of Health and Human*  
19           *Services shall first impose the fee established under*  
20           *section 743 of the Federal Food, Drug, and Cosmetic*  
21           *Act, as added by subsection (c), for fiscal years begin-*  
22           *ning with fiscal year 2010.*

23           *(2) MODIFICATION OF REGISTRATION FORM.—*  
24           *Not later than 180 days after the date of the enact-*  
25           *ment of this Act, the Secretary of Health and Human*

1        *Services shall modify the registration form under sec-*  
2        *tion 415 of the Federal Food, Drug, and Cosmetic Act*  
3        *(21 U.S.C. 350d) to comply with the amendments*  
4        *made by this section.*

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

11           (4) *SUNSET DATE.—Section 743 of the Federal*  
12       *Food, Drug, and Cosmetic Act, as added by subsection*  
13       *(c), does not authorize the assessment or collection of*  
14       *a fee for registration under section 415 of such Act*  
15       *(21 U.S.C. 360) occurring after fiscal year 2014.*

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

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

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

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

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

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

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

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

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

15           “(3) *monitor preventive controls;*

16           “(4) *institute corrective actions when—*

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

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

21           “(5) *conduct verification activities;*

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

24           “(7) *reanalyze for hazards.*

25       “(b) *IDENTIFICATION OF HAZARDS.*—

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

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

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

18           “(2) *IDENTIFIED BY THE SECRETARY.*—*The Sec-*  
19           *retary may, by regulation or guidance, identify haz-*  
20           *ards that are reasonably likely to occur in the absence*  
21           *of preventive controls.*

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

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

3        *“(c) PREVENTIVE CONTROLS.—*

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

10        *“(2) IDENTIFIED BY THE SECRETARY.—*

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

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



1           *information sufficient to demonstrate that the al-*  
2           *ternative control effectively addresses the hazard,*  
3           *including meeting any applicable performance*  
4           *standard.*

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

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

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

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

20                 “(2) *appropriate action is taken to reduce the*  
21                 *likelihood of recurrence of the implementation failure.*

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

24                 “(1) *the preventive controls identified under sub-*  
25                 *section (c) have been validated as adequate to control*

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

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

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

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

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

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

15             “(A) *review the evaluation under subsection*  
16       *(b) for the facility and, as necessary, revise the*  
17       *hazard analysis under subsection (b)(3) for the*  
18       *facility—*

19             “(i) *not less than every 2 years;*

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

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

1           “(B) whenever there is a change in the haz-  
2           ard analysis, revise the preventive controls under  
3           subsection (c) for the facility as necessary to en-  
4           sure that all hazards that are reasonably likely  
5           to occur are prevented, eliminated, or reduced to  
6           an acceptable level, or document the basis for the  
7           conclusion that no such revision is needed.

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

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

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

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

23                  “(2) PREVENTIVE CONTROLS.—The term ‘preven-  
24                  tive controls’ means those risk-based procedures, prac-  
25                  tices, and processes that a person knowledgeable about

1        *the safe manufacturing, processing, packing, trans-*  
2        *porting, or holding of food would employ to prevent,*  
3        *eliminate, or reduce to an acceptable level the hazards*  
4        *identified in the hazard analysis under subsection*  
5        *(b)(3) and that are consistent with the current sci-*  
6        *entific understanding of safe food manufacturing,*  
7        *processing, packing, transporting, or holding at the*  
8        *time of the analysis. Those procedures, practices, and*  
9        *processes shall include the following, as appropriate:*

10                *“(A) Sanitation procedures and practices.*

11                *“(B) Supervisor, manager, and employee*  
12                *hygiene training.*

13                *“(C) Process controls.*

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

18                *“(E) Good manufacturing practices.*

19                *“(F) Verification procedures, practices, and*  
20                *processes for suppliers and incoming ingredients,*  
21                *which may include onsite auditing of suppliers*  
22                *and testing of incoming ingredients.*

23                *“(G) Other procedures, practices, and proc-*  
24                *esses established by the Secretary under sub-*  
25                *section (c)(2).*

1           “(3) *HAZARD THAT IS REASONABLY LIKELY TO*  
2           *OCCUR.—A food safety hazard that is reasonably like-*  
3           *ly to occur is one for which a prudent person who,*  
4           *as applicable, manufactures, processes, packs, trans-*  
5           *ports, or holds food, would establish controls because*  
6           *experience, illness data, scientific reports, or other in-*  
7           *formation provides a basis to conclude that there is*  
8           *a reasonable possibility that the hazard will occur in*  
9           *the type of food being manufactured, processed,*  
10          *packed, transported, or held in the absence of those*  
11          *controls.*

12          **“SEC. 418A. FOOD SAFETY PLAN.**

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

19          “(b) *CONTENTS.—The food safety plan shall include*  
20          *each of the following elements:*

21                  “(1) *The hazard analysis and any reanalysis*  
22                  *conducted under section 418.*

23                  “(2) *A description of the preventive controls*  
24                  *being implemented under subsection 418(c), including*

1       *those to address hazards or conditions identified by*  
2       *the Secretary under subsection 418(b)(2).*

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

5               “(4) *A description of the procedures for taking*  
6       *corrective actions.*

7               “(5) *A description of verification activities for*  
8       *the preventive controls, including validation, review*  
9       *of monitoring and corrective action records, and pro-*  
10       *cedures for determining whether the preventive con-*  
11       *trols are effectively preventing, eliminating, or reduc-*  
12       *ing to an acceptable level the occurrence of identified*  
13       *hazards or conditions, including the use of environ-*  
14       *mental and product testing programs.*

15               “(6) *A description of the facility’s recordkeeping*  
16       *procedures.*

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

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

24               “(9) *A description of the facility’s procedures to*  
25       *ensure a safe and secure supply chain for the ingredi-*

1        *ents or components used in making the food manufac-*  
2        *tured, processed, packed, transported, or held by such*  
3        *facility.*

4                *“(10) A description of the facility’s procedures to*  
5        *implement the science-based performance standards*  
6        *issued under section 419.”.*

7                *(3) GUIDANCE OR REGULATIONS.—*

8                        *(A) IN GENERAL.—The Secretary of Health*  
9        *and Human Services (referred to in this sub-*  
10        *section as the “Secretary”) shall issue guidance*  
11        *or promulgate regulations to establish science-*  
12        *based standards for conducting a hazard anal-*  
13        *ysis, documenting hazards, identifying and im-*  
14        *plementing preventive controls, and documenting*  
15        *the implementation of the preventive controls, in-*  
16        *cluding verification and corrective actions under*  
17        *sections 418 and 418A of the Federal Food,*  
18        *Drug, and Cosmetic Act (as added by paragraph*  
19        *(2)).*

20                        *(B) INTERNATIONAL STANDARDS.—In*  
21        *issuing guidance or regulations under subpara-*  
22        *graph (A), the Secretary shall review inter-*  
23        *national hazard analysis and preventive control*  
24        *standards that are in existence on the date of the*  
25        *enactment of this Act and relevant to such guide-*

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

7                    (C) *AUTHORITY WITH RESPECT TO CERTAIN*  
8            *FACILITIES.—The Secretary may, by regulation,*  
9            *exempt or modify the requirements for compli-*  
10           *ance under this section and the amendments*  
11           *made by this section with respect to facilities*  
12           *that are solely engaged in—*

13                    (i) *the production of food for animals*  
14                    *other than man or the storage of packaged*  
15                    *foods that are not exposed to the environ-*  
16                    *ment; or*

17                    (ii) *the storage of raw agricultural*  
18                    *commodities for further processing.*

19                    (D) *SMALL BUSINESSES.—The Secretary—*

20                    (i) *shall consider the impact of any*  
21                    *guidance or regulations under this section*  
22                    *on small businesses; and*

23                    (ii) *shall issue guidance to assist small*  
24                    *businesses in complying with the require-*



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

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

16                  (5) *CONSIDERATION.*—When implementing sec-  
17                  tions 418 and 418A of the Federal Food, Drug, and  
18                  Cosmetic Act, as added by paragraph (2), the Sec-  
19                  retary may take into account differences between food  
20                  intended for human consumption and food intended  
21                  for consumption by animals other than man.

22                  (6) *EFFECTIVE DATE.*—

23                  (A) *GENERAL RULE.*—The amendments  
24                  made by subsection (a) and this subsection shall

1           *take effect 18 months after the date of the enact-*  
2           *ment of this Act.*

3           (B) *EXCEPTIONS.—Notwithstanding sub-*  
4           *paragraph (A)—*

5                   (i) *the amendments made by subsection*  
6                   (i) *and this subsection shall apply to a*  
7                   *small business (as defined by the Secretary)*  
8                   *after the date that is 2 years after the date*  
9                   *of the enactment of this Act; and*

10                   (ii) *the amendments made by sub-*  
11                   *section (a) and this subsection shall apply*  
12                   *to a very small business (as defined by the*  
13                   *Secretary) after the date that is 3 years*  
14                   *after the date of the enactment of this Act.*

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

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

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

22           (2) *REQUIREMENTS.—Chapter IV (21 U.S.C.*  
23           *341 et seq.) is amended by adding at the end the fol-*  
24           *lowing:*

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

3       “(a) *AUTHORITY.*—Beginning on the date specified in  
4 subsection (c), the Secretary shall require, after public no-  
5 tice and an opportunity for comment, the submission to the  
6 Secretary of finished product test results by the owner, oper-  
7 ator, or agent of each category 1 facility subject to good  
8 manufacturing practices regulations documenting the pres-  
9 ence of contaminants in food in the possession or control  
10 of such facility posing a risk of severe adverse health con-  
11 sequences or death.

12       “(b) *CONSIDERATIONS.*—The Secretary shall require  
13 submissions under subsection (a)—

14               “(1) as the Secretary determines feasible and ap-  
15 propriate; and

16               “(2) taking into consideration available data  
17 and information on the potential risks posed by the  
18 facility.

19       “(c) *BEGINNING DATE.*—The date specified in this  
20 subsection is the sooner of—

21               “(1) the date of completion of the pilot projects  
22 and feasibility study under subsections (d) and (e);  
23 and

24               “(2) the date that is 2 years after the date of the  
25 enactment of this section.

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

7           “(e) *FEASIBILITY STUDY.*—*The Secretary shall assess*  
8 *the feasibility and benefits of the reporting by facilities sub-*  
9 *ject to good manufacturing practices regulations of appro-*  
10 *priate finished product testing results from category 1 fa-*  
11 *cilities to the Secretary, including the extent to which the*  
12 *collection of such finished product testing results will help*  
13 *the Secretary assess the risk presented by a facility or prod-*  
14 *uct category.*

15           “(f) *LIMITATIONS.*—*Nothing in this section shall be*  
16 *construed—*

17                   “(1) *to require the Secretary to mandate testing*  
18 *or submission of test results that the Secretary deter-*  
19 *mines would not provide useful information in assess-*  
20 *ing the potential risk presented by a facility or prod-*  
21 *uct category; or*

22                   “(2) *to limit the Secretary’s authority under any*  
23 *other provisions of law to require any person to pro-*  
24 *vide access, or to submit information or test results,*  
25 *to the Secretary, including the ability of the Secretary*

1        *to require field or other testing and to obtain test re-*  
2        *sults in the course of an investigation of a potential*  
3        *food-borne illness or contamination incident.*

4        *“(g) DEFINITION.—In this section, the term ‘category*  
5        *1 facility’ means a category 1 facility within the meaning*  
6        *of section 704(h).”.*

7        **SEC. 103. PERFORMANCE STANDARDS.**

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

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

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

17       **“SEC. 419. PERFORMANCE STANDARDS.**

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

1 *tion, science-based performance standards (which may in-*  
2 *clude action levels) applicable to foods or food classes, as*  
3 *appropriate, to minimize to an acceptable level, prevent,*  
4 *or eliminate the occurrence of such hazards. Such standards*  
5 *shall be applicable to foods and food classes.*

6       “(b) *LIST OF CONTAMINANTS.*—*Following each review*  
7 *under subsection (a), the Secretary shall publish in the Fed-*  
8 *eral Register a list of food-borne contaminants that have*  
9 *the greatest adverse impact on public health. In deter-*  
10 *mining whether a particular food-borne contaminant*  
11 *should be added to such list, the Secretary shall consider*  
12 *the number and severity of illnesses and the number of*  
13 *deaths associated with the foods associated with such con-*  
14 *taminants.*

15       “(c) *REVOCAION BY SECRETARY.*—*All performance*  
16 *standards of the Food and Drug Administration applicable*  
17 *to foods or food classes in effect on the date of the enactment*  
18 *of this section, or issued under this section, shall remain*  
19 *in effect until revised or revoked by the Secretary.”.*

20       “(c) *REPORT TO CONGRESS.*—*The Secretary of Health*  
21 *and Human Services shall submit to the Congress by March*  
22 *30th of the year following each review under section 419*  
23 *of the Federal Food, Drug, and Cosmetic Act, as added by*  
24 *subsection (b), a report on the results of such review and*  
25 *the Secretary’s plans to address the significant food-borne*

1 *hazards identified, or the basis for not addressing any sig-*  
2 *nificant food-borne hazards identified, including any re-*  
3 *source limitations or limitations in data that preclude fur-*  
4 *ther action at that time.*

5 **SEC. 104. SAFETY STANDARDS FOR PRODUCE AND CERTAIN**  
6 **OTHER RAW AGRICULTURAL COMMODITIES.**

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

10 “(m) *If it has been grown, harvested, processed, packed,*  
11 *sorted, transported, or held under conditions that do not*  
12 *meet the standards established under section 419A.”.*

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

16 **“SEC. 419A. SAFETY STANDARDS FOR PRODUCE AND CER-**  
17 **TAIN OTHER RAW AGRICULTURAL COMMOD-**  
18 **ITIES.**

19 “(a) *STANDARDS.*—*The Secretary shall establish by*  
20 *regulation scientific and risk-based standards for the safe*  
21 *growing, harvesting, processing, packing, sorting, trans-*  
22 *porting, and holding of those types of raw agricultural com-*  
23 *modities—*

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

1           “(2) for which the Secretary has determined that  
2           such standards are reasonably necessary to minimize  
3           the risk of serious adverse health consequences or  
4           death to humans or animals.

5           “(b) CONTENTS.—The regulations under subsection  
6 (a)—

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

10           “(A) to prevent the introduction of known  
11           or reasonably foreseeable biological, chemical,  
12           and physical hazards, including hazards that  
13           occur naturally, may be unintentionally intro-  
14           duced, or may be intentionally introduced, in-  
15           cluding by acts of terrorism, into raw agricul-  
16           tural commodities that are from a plant or a  
17           fungus; and

18           “(B) to provide reasonable assurances that  
19           such commodity is not adulterated under section  
20           402;

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



1           “(3) may include standards addressing manure  
2           use, water quality, employee hygiene, sanitation and  
3           animal control, and temperature controls, as the Sec-  
4           retary determines to be reasonably necessary;

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

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

11          “(6) may provide for coordination of education  
12          and enforcement activities;

13          “(7) shall take into consideration, consistent  
14          with ensuring enforceable public health protection, the  
15          impact on small-scale and diversified farms, and on  
16          wildlife habitat, conservation practices, watershed-  
17          protection efforts, and organic production methods;

18          “(8) may provide for coordination of education  
19          and training with other government agencies, univer-  
20          sities, private entities, and others with experience  
21          working directly with farmers; and

22          “(9) may provide for recognition through guid-  
23          ance of other existing publicly available procedures,  
24          processes, and practices that the Secretary determines

1       to be equivalent to those established under paragraph  
2       (1).

3       “(c) *ENFORCEMENT.*—*The Secretary may coordinate*  
4 *with the Secretary of Agriculture and may contract and*  
5 *coordinate with the agency or department designated by the*  
6 *Governor of each State to perform activities to ensure com-*  
7 *pliance with this section.”.*

8       (c) *TIMING.*—

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

14           (2) *FINAL RULE.*—*Not later than 3 years after*  
15 *such date, the Secretary of Health and Human Serv-*  
16 *ices shall issue a final rule under such section.*

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

1 *ysis Critical Control Program, and the Thermally Processed*  
2 *Low-Acid Foods Packaged in Hermetically Sealed Con-*  
3 *tainers standards.*

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

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

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

15 *“(h)(1) Each facility registered under section 415 shall*  
16 *be inspected—*

17 *“(A)(i) by one or more officers duly designated*  
18 *under section 702 or other statutory authority by the*  
19 *Secretary;*

20 *“(ii) for domestic facilities, by a Federal, State,*  
21 *or local official recognized by the Secretary under*  
22 *paragraph (2); or*

23 *“(iii) for foreign facilities, by an agency or a*  
24 *representative of a country that is recognized by the*  
25 *Secretary under paragraph (2); and*

1           “(B) at a frequency determined pursuant to a  
2           risk-based schedule.

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

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

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

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

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

18                 “(A) CATEGORY 1.—A category 1 food facility is  
19                 a high-risk facility that manufactures or processes  
20                 food. The Secretary shall randomly inspect a category  
21                 1 food facility at least every 6 to 12 months.

22                 “(B) CATEGORY 2.—A category 2 food facility is  
23                 a low-risk facility that manufactures or processes food  
24                 or a facility that packs or labels food. The Secretary

1       *shall randomly inspect a category 2 facility at least*  
2       *every 18 months to 3 years.*

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

7       “(5) *The Secretary—*

8               “(A) *may, by guidance, modify the types of food*  
9       *facilities within a category under paragraph (4);*

10              “(B) *may alter the inspection frequencies speci-*  
11       *fied in paragraph (4) based on the need to respond*  
12       *to food-borne illness outbreaks and food recalls; and*

13              “(C) *may inspect a facility more frequently than*  
14       *the inspection frequency provided by paragraph (4);*

15              “(D) *beginning 6 months after submitting the re-*  
16       *port required by section 105(b)(2) of the Food Safety*  
17       *Enhancement Act of 2009, may—*

18                      “(i) *publish in the Federal Register adjust-*  
19       *ments to the inspection frequencies specified in*  
20       *subparagraphs (B) and (C) of paragraph (4) for*  
21       *category 2 and category 3 food facilities, which*  
22       *adjustments shall be in accordance with the Sec-*  
23       *retary’s recommendations in such report; and*

24                      “(ii) *after such publication, implement the*  
25       *adjustments; and*

1           “(E) *except as provided in subparagraphs (B)*  
2           *and (C), may not alter the inspection frequency speci-*  
3           *fied in paragraph (4)(A) for category 1 food facilities.*

4           “(6) *In determining the appropriate frequency of in-*  
5           *spection, the Secretary shall consider—*

6           “(A) *the type of food manufactured, processed,*  
7           *packed, or held at the facility;*

8           “(B) *the compliance history of the facility;*

9           “(C) *whether the facility importing or offering*  
10           *for import into the United States food is certified by*  
11           *a qualified certifying entity in accordance with sec-*  
12           *tion 801(p); and*

13           “(D) *such other factors as the Secretary deter-*  
14           *mines by guidance to be relevant to assessing the risk*  
15           *presented by the facility.”.*

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

18           ***(1) ANNUAL REPORT.—Not later than December***  
19           ***31 of each year, the Secretary of Health and Human***  
20           ***Services shall submit a report to the Committee on***  
21           ***Energy and Commerce of the House of Representa-***  
22           ***tives and the Committee on Health, Education,***  
23           ***Labor, and Pensions of the Senate describing—***

24                           ***(A) the number of foreign and domestic fa-***  
25                           ***cilities, by risk category, inspected under the***

1           *risk-based inspection schedule established under*  
2           *section 704(h) of the Federal Food, Drug, and*  
3           *Cosmetic Act, as added by subsection (a), in the*  
4           *preceding fiscal year; and*

5                     *(B) the costs of implementing the risk-based*  
6           *inspection schedule for the preceding 12 months.*

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

22                     *(A) the nature of the food products being*  
23           *processed, stored, or transported;*

24                     *(B) the manner in which food products are*  
25           *processed, stored, or transported;*

1           (C) *the inherent likelihood that the products*  
2           *will contribute to the risk of food-borne illness;*

3           (D) *the best available evidence concerning*  
4           *reported illnesses associated with the foods proc-*  
5           *essed, stored, held, or transported in the category*  
6           *of facilities; and*

7           (E) *the overall record of compliance with*  
8           *food safety law among facilities in the category,*  
9           *including compliance with applicable perform-*  
10          *ance standards and the frequency of recalls.*

11 **SEC. 106. ACCESS TO RECORDS.**

12          (a) *RECORDS ACCESS.*—*Subsection (a) of section 414*  
13 *(21 U.S.C. 350c) is amended to read as follows:*

14          “(a) *RECORDS ACCESS.*—

15               “(1) *RECORDS ACCESS DURING AN INSPEC-*  
16               *TION.*—

17                       “(A) *IN GENERAL.*—*Each person who pro-*  
18                       *duces, manufactures, processes, packs, transports,*  
19                       *distributes, receives, or holds an article of food in*  
20                       *the United States or for import into the United*  
21                       *States shall, at the request of an officer or em-*  
22                       *ployee duly designated by the Secretary, permit*  
23                       *such officer or employee, upon presentation of*  
24                       *appropriate credentials, at reasonable times and*  
25                       *within reasonable limits and in a reasonable*



1           *manner, to have access to and copy all records*  
2           *relating to such article bearing on whether the*  
3           *food may be adulterated, misbranded, or other-*  
4           *wise in violation of this Act, including all*  
5           *records collected or developed to comply with sec-*  
6           *tion 418 or 418A.*

7           “(B) *SCOPE OF RECORDS.*—*The require-*  
8           *ment under subparagraph (A) applies to all*  
9           *records relating to the production, manufacture,*  
10          *processing, packing, transporting, distribution,*  
11          *receipt, holding, or importation of such article*  
12          *maintained by or on behalf of such person in*  
13          *any format (including paper and electronic for-*  
14          *mats) and at any location.*

15          “(C) *IMMEDIATE AVAILABILITY WITH NO-*  
16          *TICE.*—*Records not required to be made avail-*  
17          *able immediately on commencement of an in-*  
18          *spection under subparagraph (A) shall nonethe-*  
19          *less be made available immediately on com-*  
20          *mencement of such an inspection if, by a reason-*  
21          *able time before such inspection, the Secretary by*  
22          *letter to the person identifies the records to be*  
23          *made available during such inspection.*

1           “(2) *ADDITIONAL AUTHORITIES TO ACCESS*  
2           *RECORDS REMOTELY; SUBMISSION OF RECORDS TO*  
3           *THE SECRETARY.*—

4                   “(A) *REMOTE ACCESS IN EMERGENCIES.*—*If*  
5           *the Secretary has a reasonable belief that an ar-*  
6           *ticl e of food presents a threat of serious adverse*  
7           *health consequences or death to humans or ani-*  
8           *mals, the Secretary may require each person who*  
9           *manufactures, processes, packs, transports, dis-*  
10           *tributes, receives, holds, or imports such article*  
11           *of food, or any article of food that the Secretary*  
12           *determines may be affected in a similar manner,*  
13           *to submit to the Secretary all records reasonably*  
14           *related to such article of food as soon as is rea-*  
15           *sonably practicable, after receiving written no-*  
16           *tice (including by notice served personally and*  
17           *outside normal business hours to an agent iden-*  
18           *tified under subparagraph (E) or (F) of section*  
19           *415(a)(2)) of such requirement.*

20                   “(B) *REMOTE ACCESS TO RECORDS RE-*  
21           *LATED TO FOOD SAFETY PLANS.*—*With respect to*  
22           *a facility subject to section 418 and 418A, the*  
23           *Secretary may require the owner, operator, or*  
24           *agent of such facility to submit to the Secretary,*  
25           *as soon as reasonably practicable after receiving*

1           *written notice of such requirement, the food safe-*  
2           *ty plan, supporting information relied on by the*  
3           *facility to select the preventive controls to in-*  
4           *clude in its food safety plan, and documentation*  
5           *of corrective actions, if any, taken under section*  
6           *418(e) within the preceding 2 years*

7           “(C) *ELECTRONIC SUBMISSION.—If the*  
8           *records required to be submitted to the Secretary*  
9           *under subparagraph (A) or (B) are available in*  
10          *electronic format, such records shall be submitted*  
11          *electronically unless the Secretary specifies other-*  
12          *wise in the notice under such subparagraph.”.*

13          ***(b) REGULATIONS CONCERNING RECORDKEEPING.—***

14                 ***(1) AMENDMENT.—Subsection (b) of section 414***  
15                 ***(21 U.S.C. 350c) is amended to read as follows:***

16                 ***“(b) REGULATIONS CONCERNING RECORDKEEPING.—***  
17                 ***The Secretary, in consultation and coordination, as appro-***  
18                 ***priate, with other Federal departments and agencies with***  
19                 ***responsibilities for regulating food safety, may by regula-***  
20                 ***tion establish requirements regarding the establishment and***  
21                 ***maintenance, for not longer than 3 years, of records by per-***  
22                 ***sons who produce, manufacture, process, pack, transport,***  
23                 ***distribute, receive, or hold food in the United States or for***  
24                 ***import into the United States. The Secretary shall take into***  
25                 ***account the size of a business in promulgating regulations***

1 *under this section. The only distribution records which may*  
2 *be required of restaurants under this subsection are those*  
3 *showing the restaurant's suppliers and subsequent distribu-*  
4 *tion other than to consumers.”.*

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

14 (c) *CONFORMING AMENDMENTS.—Section 704(a)(1)*  
15 *(21 U.S.C. 374(a)(1)) is amended—*

16 (1) *in the first sentence—*

17 (A) *by inserting “farm,” before “factory”*  
18 *each place it appears; and*

19 (B) *by inserting “produced,” before “manu-*  
20 *factured”;*

21 (2) *in the second sentence—*

22 (A) *by striking “(excluding farms and res-*  
23 *taurants)”;*

24 (B) *by inserting “produces,” before “manu-*  
25 *factures”;*

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

2           (D) by striking “described in section 414”

3 and inserting “described in or required under

4 section 414”; and

5           (E) by striking “when the Secretary has a

6 reasonable belief that an article of food is adul-

7 terated and presents a threat of serious adverse

8 health consequences or death to humans or ani-

9 mals” and inserting “bearing on whether such

10 food is adulterated, misbranded, or otherwise in

11 violation of this Act, including all records col-

12 lected or developed to comply with section 418 or

13 418A”; and

14 (3) in the fourth sentence—

15           (A) by striking “the preceding sentence”

16 and inserting “either of the preceding two sen-

17 tences”; and

18           (B) by inserting “recipes for food,” before

19 “financial data.”

20 **SEC. 107. TRACEABILITY OF FOOD.**

21       (a) *PROHIBITED ACT.*—Section 301(e) (21 U.S.C.

22 331(e)) is amended by inserting “, the violation of any re-

23 quirement of the food tracing system under section 414(c);”

24 before “or the refusal to permit access to or verification or

25 copying of any such required record”.

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

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

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

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

11           **“(c) TRACING SYSTEM FOR FOOD.**—

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

16                   **“(2) INFORMATION GATHERING.**—

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

20                                   **“(i) identify technologies and meth-**  
21 **odologies for tracing the distribution history**  
22 **of a food that are, or may be, used by mem-**  
23 **bers of different sectors of the food industry,**  
24 **including technologies and methodologies to**  
25 **enable each person who produces, manufac-**

1                    *tures, processes, pack, transports, or holds a*  
2                    *food to—*

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

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

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

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

17                   *“(ii) to the extent practicable, assess—*

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

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

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

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

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

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



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

3           “(B) *a standardized format for pedigree in-*  
4           *formation; and*

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

7           “(4) *EXEMPTIONS.—*

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

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

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

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

1           *type of facility, farm, or restaurant is not nec-*  
2           *essary to protect the public health.*

3           “(C) *PREVIOUS SOURCES AND SUBSEQUENT*  
4           *RECIPIENTS.—For a food covered by an exemp-*  
5           *tion under subparagraph (B), the Secretary shall*  
6           *require each person who produces, manufactures,*  
7           *processes, packs, transports, or holds such food to*  
8           *maintain records to identify the immediate pre-*  
9           *vious sources of such food and its ingredients*  
10           *and the immediate subsequent recipients of such*  
11           *food.*

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

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

1 **SEC. 108. REINSPECTION AND FOOD RECALL FEES APPLICA-**  
2 **BLE TO FACILITIES.**

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

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

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

10 “(1) that—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14          “(a) *MISBRANDING.*—

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

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

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

1           **(b) CERTIFICATION OF COMPLIANCE FOR IMPORTS.—**

2 *Chapter VIII (21 U.S.C. 381 et seq.) is amended—*

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

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

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

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

17           **“(1) IN GENERAL.—**

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

1           “(i) for food imported from a par-  
2           ticular country or region, based on the ade-  
3           quacy of government controls in such coun-  
4           try or region or other information relevant  
5           to such food, certification would assist the  
6           Secretary in determining whether to refuse  
7           to admit such article under subsection (a);

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

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

17          “(B) CONTENTS OF CERTIFICATION.—Such  
18          certification shall include such information re-  
19          garding compliance as the Secretary may speci-  
20          fy, and may be provided in the form of ship-  
21          ment-specific certificates, a listing of certified fa-  
22          cilities or other entities, or in such other form as  
23          the Secretary may specify.

24          “(C) NOTICE OF CANCELLATION OR SUSPEN-  
25          SION OF CERTIFICATION.—As a condition on ac-

1           *ceptance of certifications from a qualified certi-*  
2           *fying entity, the Secretary shall require the*  
3           *qualified certifying entity to notify the Secretary*  
4           *whenever the qualified certifying entity cancels*  
5           *or suspends the certification of any facility or*  
6           *other entity included in a listing under subpara-*  
7           *graph (B).*

8           “(2) *QUALIFIED CERTIFYING ENTITY.*—*For pur-*  
9           *poses of this subsection, the term ‘qualified certifying*  
10          *entity’ means—*

11                   “(A) *an agency or a representative of the*  
12                   *government of the country from which the article*  
13                   *originated, as designated by such government or*  
14                   *the Secretary; or*

15                   “(B) *an individual or entity determined by*  
16                   *the Secretary or an accredited body recognized*  
17                   *by the Secretary to be qualified to provide a cer-*  
18                   *tification under paragraph (1).*

19          “(3) *NO CONFLICTS OF INTEREST.*—

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

24                   “(B) *REGULATIONS.*—*Such regulations*  
25                   *shall require that—*



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

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

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

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

18                  “(v) no auditor acting for the qualified  
19                  certifying entity (or spouse or minor chil-  
20                  dren) shall have any significant ownership  
21                  or other financial interest regarding any  
22                  product of the type it certifies;

23                  “(vi) the qualified certifying entity  
24                  shall maintain records pertaining to the fi-

1            *nancial interests of the personnel involved*  
2            *in audits;*

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

9            *“(viii) neither the qualified certifying*  
10           *entity nor any of its auditors shall provide*  
11           *consultative services to any facility certified*  
12           *by the qualified certifying entity, or the*  
13           *owner, operator, or agent in charge of such*  
14           *a facility, unless the qualified certifying en-*  
15           *tity has procedures in place, approved by*  
16           *the Secretary, to ensure separation of func-*  
17           *tions between auditors providing consult-*  
18           *ative services and auditors providing cer-*  
19           *tification services under this subsection;*

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

24           *“(x) fees charged or accepted shall not*  
25           *be contingent or based upon the report made*

1           by the qualified certifying entity or any  
2           personnel involved in the audit process;

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 other  
14          conflicts of interest that threaten impar-  
15          tiality;

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

21          “(xv) the qualified certifying entity  
22          shall ensure that any subcontractors that  
23          might be used (such as laboratories and  
24          sampling services) provide similar assur-  
25          ances, except that it shall not be a violation

1           of this subsection to the extent such sub-  
2           contractors perform additional nutritional  
3           testing services unrelated to the testing  
4           under this subsection.

5           “(C) *ANYTHING OF VALUE.*—*In this para-*  
6           *graph, the term ‘anything of value’ includes*  
7           *gifts, gratuities, reimbursement of expenses, en-*  
8           *tertainment, loans, or any other form of com-*  
9           *ensation in cash or in kind.*

10          “(4) *RENEWAL AND REFUSAL OF CERTIFI-*  
11          *CATIONS.*—*The Secretary shall—*

12                 “(A) *require that, to the extent applicable,*  
13                 *any certification provided by a qualified certi-*  
14                 *fying entity be renewed by such entity at such*  
15                 *times as the Secretary determines appropriate;*  
16                 *and*

17                 “(B) *refuse to accept any certification if the*  
18                 *Secretary determines that such certification is no*  
19                 *longer valid or reliable.*

20          “(5) *ELECTRONIC SUBMISSION.*—*The Secretary*  
21          *shall provide for the electronic submission of certifi-*  
22          *cations under this subsection.*

23          “(6) *NO LIMIT ON AUTHORITY.*—*This subsection*  
24          *shall not be construed to limit the authority of the*  
25          *Secretary to conduct random inspections of imported*

1        *articles or facilities of importers, issue import alerts*  
2        *for detention without physical examination, require*  
3        *submission to the Secretary of documentation or other*  
4        *information about an article imported or offered for*  
5        *import, or to take such other steps as the Secretary*  
6        *deems appropriate to determine the admissibility of*  
7        *imported articles.”.*

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

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

11        *“(oo) The violation of any requirement of section 714*  
12       *(relating to testing by accredited laboratories).”.*

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

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

17        *“(a) IN GENERAL.—*

18                *“(1) REQUIREMENT.—Whenever analytical test-*  
19        *ing of an article of food is conducted as part of testi-*  
20        *mony for the purposes of section 801(a), or for such*  
21        *other purposes as the Secretary deems appropriate*  
22        *through regulation or guidance, such testing shall be*  
23        *conducted by a laboratory that—*

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

4           “(B) samples such article with adequate  
5           controls for ensuring the integrity of the samples  
6           analyzed.

7           “(2) INDEPENDENCE OF LABORATORY.—

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

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

19          “(b) RECOGNITION OF LABORATORY ACCREDITATION  
20          BODIES.—The Secretary shall establish and implement a  
21          program for the recognition, based on standards the Sec-  
22          retary deems appropriate, of laboratory accreditation bod-  
23          ies that accredit laboratories to perform analytical testing  
24          for the purposes of this section. The Secretary shall issue  
25          regulations or guidance to implement this program.

1           “(c) *ONSITE AUDITS.*—*In evaluating whether an ac-*  
2 *creditation body meets, or continues to meet, the standards*  
3 *for recognition under subsection (b), the Secretary may—*

4                   “(1) *observe onsite audits of laboratories by such*  
5 *accreditation bodies; or*

6                   “(2) *for any laboratory that is accredited by*  
7 *such accreditation body under this section, upon re-*  
8 *quest of an officer or employee designated by the Sec-*  
9 *retary and upon presentation of appropriate creden-*  
10 *tials, at reasonable times and within reasonable lim-*  
11 *its and in a reasonable manner, conduct an onsite*  
12 *audit of the laboratory, which shall include access to,*  
13 *and copying and verification of, any related records.*

14           “(d) *PUBLICATION OF LIST OF RECOGNIZED ACCREDI-*  
15 *TATION BODIES.*—*The Secretary shall publish and main-*  
16 *tain on the public Web site of the Food and Drug Adminis-*  
17 *tration a list of accreditation bodies recognized by the Sec-*  
18 *retary under subsection (b).*

19           “(e) *NOTIFICATION OF ACCREDITATION OF LABORA-*  
20 *TORY.*—*An accreditation body that has been recognized*  
21 *pursuant to this section shall promptly notify the Secretary*  
22 *whenever it accredits a laboratory for the purposes of this*  
23 *section and whenever it withdraws or suspends such accred-*  
24 *itation.*

1           “(f) *ADVANCE NOTICE.*—Whenever analytical testing  
2 is conducted pursuant to subsection (a), the person on whose  
3 behalf the testing is conducted shall notify the Secretary be-  
4 fore any sample of the article is collected. Such notice shall  
5 contain information the Secretary determines is appro-  
6 priate to identify the article, the location of the article, and  
7 each laboratory that will analyze the sample on the person’s  
8 behalf.

9           “(g) *CONTENTS OF LABORATORY PACKAGES.*—When-  
10 ever analytical testing is conducted pursuant to subsection  
11 (a), the laboratory conducting such testing shall submit, di-  
12 rectly to the Secretary—

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

15                   “(2) all information the Secretary deems appro-  
16 priate to—

17                           “(A) determine whether the laboratory is ac-  
18 credited by a recognized laboratory accreditation  
19 body;

20                           “(B) identify the article tested;

21                           “(C) evaluate the analytical results; and

22                           “(D) determine whether the requirements of  
23 this section have been met.

24           “(h) *EXIGENT CIRCUMSTANCES.*—The Secretary may  
25 waive the requirement of subsection (a)(1)(A) (relating to



1 *analytical methods) on a laboratory or method basis due*  
2 *to exigent or other circumstances.*

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

5 “(1) *the ability of the Secretary to review and*  
6 *act upon information from the analytical testing of*  
7 *food (including under this section), including deter-*  
8 *mining the sufficiency of such information and test-*  
9 *ing; or*

10 “(2) *the authority of the Secretary to conduct,*  
11 *require, or consider the results of analytical testing*  
12 *pursuant to any other provision of law.”.*

13 **SEC. 111. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
14 **OF ADULTERATED OR MISBRANDED FOOD.**

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

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

20 “(2) *The failure to comply with any order issued under*  
21 *section 420.”.*

22 (b) *NOTIFICATION, NONDISTRIBUTION, AND RECALL OF*  
23 *ADULTERATED OR MISBRANDED FOOD.*—*Chapter IV (21*  
24 *U.S.C. 341 et seq.), as amended by sections 102, 103, and*  
25 *104, is amended by adding at the end the following:*

1 **“SEC. 420. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
2 **OF ADULTERATED OR MISBRANDED FOOD.**

3 *“(a) NOTIFICATION, NONDISTRIBUTION, AND RECALL*  
4 *OF ADULTERATED OR MISBRANDED FOOD.—*

5 *“(1) IN GENERAL.—A responsible party as that*  
6 *term is defined in section 417(a)(1) or a person re-*  
7 *quired to register under section 801(r) that has reason*  
8 *to believe that an article of food when introduced into*  
9 *or while in interstate commerce, or while held for sale*  
10 *(regardless of whether the first sale) after shipment in*  
11 *interstate commerce, is adulterated or misbranded in*  
12 *a manner that presents a reasonable probability that*  
13 *the use or consumption of, or exposure to, the article*  
14 *(or an ingredient or component used in any such ar-*  
15 *ticle) will cause a threat of serious adverse health con-*  
16 *sequences or death to humans or animals shall, as*  
17 *soon as practicable, notify the Secretary of the iden-*  
18 *tity and location of the article.*

19 *“(2) MANNER OF NOTIFICATION.—Notification*  
20 *under paragraph (1) shall be made in such manner*  
21 *and by such means as the Secretary may require by*  
22 *regulation or guidance.*

23 *“(b) VOLUNTARY RECALL.—The Secretary may request*  
24 *that any person who distributes an article of food that the*  
25 *Secretary has reason to believe is adulterated, misbranded,*  
26 *or otherwise in violation of this Act voluntarily—*

1           “(1) recall such article; and

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

5           “(c) *ORDER TO CEASE DISTRIBUTION.*—If the Sec-  
6           retary has reason to believe that the use or consumption  
7           of, or exposure to, an article of food may cause serious ad-  
8           verse health consequences or death to humans or animals,  
9           the Secretary shall have the authority to issue an order re-  
10          quiring any person who distributes such article to imme-  
11          diately cease distribution of such article.

12          “(d) *ACTION FOLLOWING ORDER.*—Any person who is  
13          subject to an order under subsection (c) shall immediately  
14          cease distribution of such article and provide notification  
15          as required by such order, and may appeal within 24 hours  
16          of issuance such order to the Secretary. Such appeal may  
17          include a request for an informal hearing and a description  
18          of any efforts to recall such article undertaken voluntarily  
19          by the person, including after a request under subsection  
20          (b). Except as provided in subsection (f), an informal hear-  
21          ing shall be held within as soon as practicable, but not later  
22          than 5 calendar days, or less as determined by the Sec-  
23          retary, after such an appeal is filed, unless the parties joint-  
24          ly agree to an extension. After affording an opportunity for  
25          an informal hearing, the Secretary shall determine whether

1 *the order should be amended to require a recall of such arti-*  
2 *cle. If, after providing an opportunity for such a hearing,*  
3 *the Secretary determines that inadequate grounds exist to*  
4 *support the actions required by the order, the Secretary*  
5 *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 to*  
11 *include a recall of the article with respect to which*  
12 *the order was issued, the Secretary shall amend the*  
13 *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 allow*  
24 *for the assistance of health professionals, State or*

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

3            “(3) *NONDELEGATION.*—*An amended order*  
4        *under this subsection shall be ordered by the Secretary*  
5        *or an official designated by the Secretary. An official*  
6        *may not be so designated unless the official is the di-*  
7        *rector of the district under this Act in which the arti-*  
8        *cle involved is located, or is an official senior to such*  
9        *director.*

10        “(f) *EMERGENCY RECALL ORDER.*—

11            “(1) *IN GENERAL.*—*If the Secretary has a rea-*  
12        *sonable belief that an article of food subject to an*  
13        *order under subsection (c) presents an imminent*  
14        *threat of serious adverse health consequences or death*  
15        *to humans or animals, the Secretary may issue an*  
16        *order requiring any person who distributes such arti-*  
17        *cle—*

18            “(A) *to immediately recall such article; and*

19            “(B) *to provide for notice, including to in-*  
20        *dividuals as appropriate, to persons who may be*  
21        *affected by the recall.*

22            “(2) *ACTION FOLLOWING ORDER.*—*Any person*  
23        *who is subject to an emergency recall order under this*  
24        *subsection shall immediately recall such article and*  
25        *provide notification as required by such order, and*

1        *may appeal within 24 hours after issuance such order*  
2        *to the Secretary. An informal hearing shall be held*  
3        *within as soon as practicable but not later than 5 cal-*  
4        *endar days, or less as determined by the Secretary,*  
5        *after such an appeal is filed, unless the parties jointly*  
6        *agree to an extension. After affording an opportunity*  
7        *for an informal hearing, the Secretary shall deter-*  
8        *mine whether the order should be amended pursuant*  
9        *to subsection (e)(1). If, after providing an oppor-*  
10       *tunity for such a hearing, the Secretary determines*  
11       *that inadequate grounds exist to support the actions*  
12       *required by the order, the Secretary shall vacate the*  
13       *order.*

14                *“(3) NONDELEGATION.—An order under this*  
15        *subsection shall be issued by the Commissioner of*  
16        *Food and Drugs, the Principal Deputy Commis-*  
17        *sioner, or the Associate Commissioner for Regulatory*  
18        *Affairs of the Food and Drug Administration.*

19                *“(g) NOTICE TO CONSUMERS AND HEALTH OFFI-*  
20        *CIALS.—The Secretary shall, as the Secretary determines to*  
21        *be necessary, provide notice of a recall order under this sec-*  
22        *tion to consumers to whom the article was, or may have*  
23        *been, distributed and to appropriate State and local health*  
24        *officials.*

1           “(h) *SAVINGS CLAUSE.*—Nothing contained in this sec-  
2   tion shall be construed as limiting—

3           “(1) the authority of the Secretary to issue an  
4   order to cease distribution of, or to recall, an article  
5   under any other provision of this Act or the Public  
6   Health Service Act; or

7           “(2) the ability of the Secretary to request any  
8   person to perform a voluntary activity related to any  
9   article subject to this Act or the Public Health Service  
10   Act.”.

11          (c) *ARTICLES SUBJECT TO REFUSAL.*—The third sen-  
12   tence of subsection (a) of section 801 (21 U.S.C. 381), as  
13   amended by section 107(b), is amended by inserting “or (5)  
14   such article is subject to an order under section 420 to cease  
15   distribution of or recall the article,” before “then such arti-  
16   cle shall be refused admission”.

17          (d) *EFFECTIVE DATE.*—Sections 301(pp)(1) and 420  
18   of the Federal Food, Drug, and Cosmetic Act, as added by  
19   subsections (a) and (b), shall apply with respect to articles  
20   of food as of such date, not later than 1 year after the date  
21   of the enactment of this Act, as the Secretary of Health and  
22   Human Services shall specify.

1 **SEC. 112. REPORTABLE FOOD REGISTRY; EXCHANGE OF IN-**  
2 **FORMATION.**

3 (a) *REPORTABLE FOOD REGISTRY.*—Section 417 (21  
4 *U.S.C. 350f)* is amended—

5 (1) in subsection (a)(1), by striking “means a  
6 person” and all that follows through the end of para-  
7 graph (1) and inserting the following: “means—

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

13 “(B) a person who owns, operates, is an  
14 agent of, or is otherwise responsible for such food  
15 on a farm (as such term is defined in section  
16 1.227(b)(3) of title 21, Code of Federal Regula-  
17 tions, or successor regulations) at which such  
18 food is produced for sale or distribution in inter-  
19 state commerce;

20 “(C) a person who owns, operates, or is an  
21 agent of a restaurant or other retail food estab-  
22 lishment (as such terms are defined in section  
23 1.227(b)(11) and (12), respectively, of title 21,  
24 Code of Federal Regulations, or successor regula-  
25 tions) at which such food is offered for sale; or



1           “(D) a person that is required to register  
2           pursuant to section 801(r) with respect to impor-  
3           tation of such food.”;

4           (2) in subsection (b), by adding at the end the  
5           following:

6           “(3) *REPORTING BY RESTAURANTS AND RETAIL*  
7           *FOOD ESTABLISHMENTS.*—In addition to the elec-  
8           tronic portal described in paragraph (1), the Sec-  
9           retary shall make available alternative means of re-  
10          porting under this section with respect to restaurants  
11          and other retail food establishments with limited abil-  
12          ity for such reporting.”;

13          (3) in subsection (d)(1)—

14                (A) in the matter preceding subparagraph  
15                (A), by inserting “following a timely review of  
16                any reasonably available data and information,”  
17                after “reportable food.”;

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

20                (C) by redesignating subparagraph (B) as  
21                subparagraph (C); and

22                (D) by inserting after subparagraph (A) the  
23                following:

24                        “(B) submit, with such report, through the  
25                        electronic portal, documentation of results from

1           *any sampling and testing of such article, includ-*  
2           *ing—*

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

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

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

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

25           (4) *in subsection (e)—*

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

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

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

7                   (b) *EXCHANGE OF INFORMATION*.—Section 708 (21  
8                   U.S.C. 379) is amended—

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

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

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

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

23                  “(2)(A) In carrying out this Act, the Secretary may  
24                  provide to a State or local government agency any informa-  
25                  tion relating to food that is exempt from disclosure pursu-

1 *ant to section 552(a) of title 5, United States Code, by rea-*  
2 *son of subsection (b)(4) of such section, or that is referred*  
3 *to in section 301(j) or 415(a)(4).*

4       *“(B) Any such information provided to a State or local*  
5 *government agency shall not be disclosed by such agency.*

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

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

20               *“(A) to any foreign government agency; or*

21               *“(B) any international organization established*  
22 *by law, treaty, or other governmental action and hav-*  
23 *ing responsibility—*

24                       *“(i) to facilitate global or regional harmoni-*  
25 *zation of standards and requirements in an area*

1           *of responsibility of the Food and Drug Adminis-*  
2           *tration; or*

3           *“(i) to promote and coordinate public*  
4           *health efforts,*

5           *if the agency or organization provides adequate assur-*  
6           *ances to the Secretary that the agency or organization*  
7           *will preserve the confidentiality of the information.*

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

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

24          *“(e) Nothing in subsection (d) authorizes the Secretary*  
25          *to withhold information from the Congress or prevents the*

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

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

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

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

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

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

17 “(a) *IN GENERAL.—The Secretary may establish by*  
18 *regulation or guidance a program that facilitates the move-*  
19 *ment of food through the importation process under this Act*  
20 *if the importer of such food—*

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

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

4           “(3) provides supporting information to the Sec-  
5 retary.

6           “(b) *GUIDELINES.*—

7           “(1) *DEVELOPMENT.*—For purposes of the pro-  
8 gram established under subsection (a), the Secretary  
9 shall develop safety and security guidelines applicable  
10 to the importation of food.

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

13           “(A) The personnel of the person importing  
14 the food.

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

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

20           “(D) Vendor and supplier information.

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

24           “(F) Such other factors as the Secretary de-  
25 termines necessary.”.

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

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

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

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

11 (1) in subsection (b)(1), by adding at the end the  
12 following: “The quality factor requirements estab-  
13 lished under this paragraph may include require-  
14 ments for one or more clinical studies to demonstrate  
15 that the new infant formula supports normal physical  
16 growth of infants.”;

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

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

25 (3) in subsection (c)(1)—



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

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

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

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

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

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

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

1                   ***Subtitle B—Intervention***

2   ***SEC. 121. SURVEILLANCE.***

3           (a) *DEFINITION OF FOOD-BORNE ILLNESS OUT-*  
4 *BREAK.*—*In this section, the term “food-borne illness out-*  
5 *break” means the occurrence of 2 or more cases of a similar*  
6 *illness resulting from the ingestion of a food.*

7           (b) *FOOD-BORNE ILLNESS SURVEILLANCE SYS-*  
8 *TEMS.*—*The Secretary, acting through the Director of the*  
9 *Centers for Disease Control and Prevention, shall enhance*  
10 *food-borne illness surveillance systems to improve the collec-*  
11 *tion, analysis, reporting, and usefulness of data on food-*  
12 *borne illnesses by—*

13                   (1) *coordinating Federal, State, and local food-*  
14 *borne illness surveillance systems, including com-*  
15 *plaint systems, and increasing participation in na-*  
16 *tional networks of public health and food regulatory*  
17 *agencies and laboratories;*

18                   (2) *facilitating sharing of findings on a more*  
19 *timely basis among governmental agencies, including*  
20 *the Food and Drug Administration, the Department*  
21 *of Agriculture, and State and local agencies, and with*  
22 *the public;*

23                   (3) *developing improved epidemiological tools for*  
24 *obtaining quality exposure data, and microbiological*  
25 *methods for classifying cases;*

1           (4) *augmenting such systems to improve attribu-*  
2           *tion of a food-borne illness outbreak to a specific food;*

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

7           (6) *allowing timely public access to aggregated,*  
8           *de-identified surveillance data;*

9           (7) *at least annually, publishing current reports*  
10          *on findings from such systems;*

11          (8) *establishing a flexible mechanism for rapidly*  
12          *initiating scientific research by academic institutions;*

13          (9) *integrating food-borne illness surveillance*  
14          *systems and data with other biosurveillance and pub-*  
15          *lic health situational awareness capabilities at the*  
16          *Federal, State, and local levels; and*

17          (10) *other activities as determined appropriate*  
18          *by the Secretary.*

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

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

1           (A) *Improve food-borne illness outbreak re-*  
2           *sponse and containment.*

3           (B) *Accelerate food-borne illness surveillance*  
4           *and outbreak investigation, including rapid*  
5           *shipment of clinical isolates from clinical labora-*  
6           *tories to appropriate State laboratories, and con-*  
7           *ducting more standardized illness outbreak inter-*  
8           *views.*

9           (C) *Strengthen the capacity of State and*  
10          *local agencies to carry out inspections and en-*  
11          *force safety standards.*

12          (D) *Improve the effectiveness of Federal,*  
13          *State, and local partnerships to coordinate food*  
14          *safety and defense resources and reduce the inci-*  
15          *dence of food-borne illness.*

16          (E) *Share information on a timely basis*  
17          *among public health and food regulatory agen-*  
18          *cies, with the food industry, with health care*  
19          *providers, and with the public.*

20          (2) *REVIEW.*—*In developing of the strategies re-*  
21          *quired by paragraph (1), the Secretary shall, not*  
22          *later than 1 year after the date of enactment of this*  
23          *Act, complete a review of State and local capacities,*  
24          *and needs for enhancement, which may include a sur-*  
25          *vey with respect to—*

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

3                   (B) *laboratory capacity to support surveil-*  
4                   *lance, outbreak response, inspection, and enforce-*  
5                   *ment activities;*

6                   (C) *information systems to support data*  
7                   *management and sharing of food safety and de-*  
8                   *fense information among State and local agen-*  
9                   *cies and with counterparts at the Federal level;*  
10                  *and*

11                  (D) *other State and local activities and*  
12                  *needs as determined appropriate by the Sec-*  
13                  *retary.*

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

15                  (a) *PUBLIC EDUCATION.*—*The Secretary, in coopera-*  
16                  *tion with private and public organizations, including the*  
17                  *appropriate State entities, shall design and implement a*  
18                  *national public education program on food safety. The pro-*  
19                  *gram shall provide—*

20                         (1) *information to the public so that individuals*  
21                         *can understand the potential impact and risk of food-*  
22                         *borne illness, take action to reduce their risk of food-*  
23                         *borne illness and injury, and make healthy dietary*  
24                         *choices;*

1           (2) *information to health professionals so that*  
2           *they may improve diagnosis and treatment of food-re-*  
3           *lated illness and advise individuals whose health con-*  
4           *ditions place them in particular risk; and*

5           (3) *such other information or advice to con-*  
6           *sumers and other persons as the Secretary determines*  
7           *will promote the purposes of this Act.*

8           (b) *HEALTH ADVISORIES.*—*The Secretary shall work*  
9           *with the States and other appropriate entities to—*

10           (1) *develop and distribute regional and national*  
11           *advisories concerning food safety;*

12           (2) *develop standardized formats for written and*  
13           *broadcast advisories; and*

14           (3) *incorporate State and local advisories into*  
15           *the national public education program required under*  
16           *subsection (a).*

17   **SEC. 123. RESEARCH.**

18           *The Secretary shall conduct research to assist in the*  
19           *implementation of this Act, including studies to—*

20           (1) *improve sanitation and food safety practices*  
21           *in the production, harvesting, and processing of food*  
22           *products;*

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

1           (3) *develop efficient, rapid, and sensitive meth-*  
2           *ods for determining and detecting the presence of con-*  
3           *taminants in food products;*

4           (4) *determine the sources of contamination of*  
5           *food and food products, including critical points of*  
6           *risk for fresh produce and other raw agricultural*  
7           *commodities;*

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 evaluate*  
20          *methods to reduce the transfer of antibiotic resistance*  
21          *to humans; and*

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

1                                    ***Subtitle C—Response***

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

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

12    **SEC. 132. ADMINISTRATIVE DETENTION.**

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

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

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

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

24                    *(4) in paragraph (3), by striking the third sen-*  
25 *tence; and*



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

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

7           (c) *EFFECTIVE DATE.*—The amendments made by this  
8           section shall take effect 180 days after the date of the enact-  
9           ment of this Act.

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

11           (a) *PROHIBITED ACT.*—Section 301 (21 U.S.C. 331),  
12           as amended by sections 110 and 111, is amended by adding  
13           at the end by adding the following:

14           “(qq) The violation of a quarantine under section  
15           304(i).”.

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

18           “(i) *QUARANTINE OF GEOGRAPHIC LOCATION.*—

19           “(1) *AUTHORITY TO QUARANTINE.*—If the Sec-  
20           retary determines that there is credible evidence or in-  
21           formation that an article of food presents an immi-  
22           nent threat of serious adverse health consequences or  
23           death to humans or animals, the Secretary may quar-  
24           antine any geographic area within the United States  
25           where the Secretary reasonably believes such food is

1        *located or from which such food originated. The au-*  
2        *thority to quarantine includes prohibiting or restrict-*  
3        *ing the movement of food or of any vehicle being used*  
4        *or that has been used to transport or hold such food*  
5        *within the geographic area. Any quarantine under*  
6        *this paragraph shall be no greater than is appro-*  
7        *priate, as determined by the Secretary, to protect the*  
8        *public health.*

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

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

16            *“(B) the area affected by the intended quar-*  
17        *antine action;*

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

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

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

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

7   **SEC. 134. CRIMINAL PENALTIES.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22           “(rr) The submission of information relating to food  
23 that is required by or under section 801 that is inaccurate  
24 or incomplete.

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

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

6           “(q) *DOCUMENTATION.*—

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

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

## 15           **TITLE II—MISCELLANEOUS**

### 16           **SEC. 201. FOOD SUBSTANCES GENERALLY RECOGNIZED AS** 17                   **SAFE.**

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

20                   “*Substances Generally Recognized as Safe*

21                   “(k)(1) *Not later than 60 days after the date of receipt*  
22 *by the Secretary, after the date of the enactment of this sub-*  
23 *section, of a determination that a substance is a GRAS food*  
24 *substance, the Secretary shall post notice of such determina-*

1 *tion and the supporting scientific justifications on the Food*  
2 *and Drug Administration’s public Web site.*

3 “(2) *Not later than 60 days after the date of receipt*  
4 *of a request under paragraph (1), the Secretary shall ac-*  
5 *knowledge receipt of such request by informing the requester*  
6 *in writing of the date on which the request was received.*

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

17 **SEC. 202. COUNTRY OF ORIGIN LABELING; DISCLOSURE OF**  
18 **SOURCE OF INGREDIENTS.**

19 (a) *MISBRANDING.—Section 403 (21 U.S.C. 343), as*  
20 *amended by sections 101(a), 109(a), and 114(a), is amend-*  
21 *ed by adding at the end the following:*

22 “(cc) *In the case of a processed food, if the labeling*  
23 *of the food fails to identify the country in which the final*  
24 *processing of the food occurs.*

1       “(dd) *In the case of nonprocessed food, if the labeling*  
2 *of the food fails to identify the country of origin of the*  
3 *food.*”.

4       **(b) REGULATIONS.—**

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

11           **(2) RELATION TO OTHER REQUIREMENTS.—***Reg-*  
12 *ulations promulgated under paragraph (1) shall pro-*  
13 *vide that labeling meets the requirements of para-*  
14 *graphs (cc) and (dd) of section 403 of the Federal*  
15 *Food, Drug, and Cosmetic Act, as added by subsection*  
16 *(a), if—*

17                   **(A)** *in the case of a processed food, the label*  
18 *of the food informs the consumer of the country*  
19 *where the final processing of the food occurred in*  
20 *accordance with labeling requirements of the*  
21 *United States Customs and Border Protection; or*

22                   **(B)** *in the case of a nonprocessed food, the*  
23 *label of the food informs the consumer of the*  
24 *country of origin of the food in accordance with*

1           *labeling requirements of the Department of Agri-*  
2           *culture.*

3           (c) *EFFECTIVE DATE.*—*The requirements of para-*  
4           *graphs (cc) and (dd) 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 enact-*  
7           *ment of this Act.*

8           **SEC. 203. 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 in-  
5           serting “the food, drug, or device”;

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

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

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

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

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

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

13 **SEC. 204. REGISTRATION FOR COMMERCIAL IMPORTERS OF**  
14 **FOOD; FEE.**

15 (a) *REGISTRATION.—*

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

19 “(tt) *The failure to register in accordance with section*  
20 *801(r).”.*

21 (2) *MISBRANDING.—Section 403 (21 U.S.C. 343)*  
22 *as amended by sections 101(a), 109(a), 114(a), and*  
23 *202(a), is amended by adding at the end the fol-*  
24 *lowing:*

1       “(ee) *If it is imported or offered for import by an im-*  
2 *porter not duly registered under section 801(r).*”.

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

6       “(r) *REGISTRATION OF IMPORTERS.*—

7           “(1) *REGISTRATION.*—*The Secretary shall re-*  
8 *quire an importer of food—*

9               “(A) *to be registered with the Secretary in*  
10 *a form and manner specified by the Secretary;*  
11 *and*

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

15           “(2) *GOOD IMPORTER PRACTICES.*—*The mainte-*  
16 *nance of registration under this subsection is condi-*  
17 *tioned on compliance with good importer practices.*  
18 *Good importer practices shall include the verification*  
19 *of good manufacturing practices and preventive con-*  
20 *trols of the importer’s foreign suppliers, as applicable.*

21       “(3) *SUSPENSION OF REGISTRATION.*—

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

1                   “(i) a violation of this Act; or

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

6                   “(B) *REQUEST*.—The importer whose reg-  
7                   istration is suspended may request that the Sec-  
8                   retary vacate the suspension of registration when  
9                   such importer has corrected the violation that is  
10                  the basis for such suspension.

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

15                  “(4) *CANCELLATION OF REGISTRATION*.—

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

23                  “(B) *NOTICE OF CANCELLATION*.—Cancell-  
24                  ation shall be preceded by notice to the importer

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

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

8           “(5) *EXEMPTIONS.*—*The Secretary, by notice*  
9           *published in the Federal Register—*

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

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

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

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

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

4                   **“PART 7—IMPORTERS OF FOOD**

5           **“SEC. 744. IMPORTERS OF FOOD.**

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

9           “(b) *AMOUNT OF FEE.*—

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

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

13                           “(B) for fiscal year 2011 and each subse-  
14 quent fiscal year, the fee for fiscal year 2010 as  
15 adjusted under paragraph (2).

16                   “(2) *ADJUSTMENT.*—For fiscal year 2011 and  
17 subsequent fiscal years, the fees established pursuant  
18 to paragraph (1) shall be adjusted by the Secretary  
19 by notice, published in the Federal Register, for a fis-  
20 cal year to reflect the greater of—

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

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

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

10          “(C) the average annual change in the cost,  
11          per full-time equivalent position of the Food and  
12          Drug Administration, of all personnel compensa-  
13          tion and benefits paid with respect to such posi-  
14          tions for the first 5 years of the preceding 6 fis-  
15          cal years.

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

21          “(4) WAIVER FOR IMPORTERS REQUIRED TO PAY  
22          REGISTRATION FEE.—In the case of a person who is  
23          required to pay both a fee under section 743 for reg-  
24          istration of one or more facilities under section 415  
25          and a fee under this section for registration as an im-

1        *porter of food under section 801(r), the Secretary*  
2        *shall waive the fees applicable to such person under*  
3        *section 743 or the fee applicable to such person under*  
4        *this section.*

5        *“(c) CREDITING AND AVAILABILITY OF FEES.—*

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

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

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

22                *“(B) shall only be collected and available to*  
23        *cover the costs associated with registering im-*  
24        *porters under section 801(r) and with ensuring*



1           *compliance with good importer practices respect-*  
2           *ing food.*

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

7           *(c) INSPECTION.*—*Section 704 (21 U.S.C. 374), as*  
8           *amended by section 105, is amended by adding at the end*  
9           *the following:*

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

16        ***SEC. 205. REGISTRATION FOR CUSTOMS BROKERS AND FIL-***  
17                                ***ERS; FEE.***

18          *(a) REGISTRATION.*—

19                (1) *PROHIBITIONS.*—*Section 301(tt) (21 U.S.C.*  
20                *331), as added by section 204, is amended by insert-*  
21                *ing “or 801(s)” after “801(r)”.*

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

24                        (A) *by inserting “or a customs broker or*  
25                        *filer” after “by an importer”; and*

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

2                   (3) *REGISTRATION.*—Section 801, as amended by  
3 sections 109, 136, and 204, is amended by adding at  
4 the end the following:

5                   “(s) *REGISTRATION OF CUSTOMS BROKERS AND FIL-*  
6 *ERS.*—

7                   “(1) *REGISTRATION.*—The Secretary shall re-  
8 quire a customs broker or filer, with respect to the im-  
9 portation of food—

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

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

16                   “(2) *SUSPENSION OF REGISTRATION.*—

17                   “(A) *IN GENERAL.*—Registration under this  
18 subsection is subject to suspension upon a find-  
19 ing by the Secretary, after notice and an oppor-  
20 tunity for an informal hearing, of—

21                   “(i) a violation of this Act; or

22                   “(ii) the knowing or repeated making  
23 of an inaccurate or incomplete statement or  
24 submission of information relating to the  
25 importation of food.

1           “(B) *REQUEST.*—*The customs broker or*  
2           *filer whose registration is suspended may request*  
3           *that the Secretary vacate the suspension of reg-*  
4           *istration when such customs broker or filer has*  
5           *corrected the violation that is the basis for such*  
6           *suspension.*

7           “(C) *VACATING OF SUSPENSION.*—*If the*  
8           *Secretary determines that adequate reasons do*  
9           *not exist to continue the suspension of a registra-*  
10           *tion, the Secretary shall vacate such suspension.*

11           “(3) *CANCELLATION OF REGISTRATION.*—

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

19           “(B) *NOTICE OF CANCELLATION.*—*Cancell-*  
20           *ation shall be preceded by notice to the customs*  
21           *broker or filer of the intent to cancel the registra-*  
22           *tion and the basis for such cancellation.*

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

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

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

5                     “(A) *shall establish an exemption from the*  
6                     *requirements of this subsection for importations*  
7                     *for personal use; and*

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

10           (4) *REGULATIONS.*—*Not later than 24 months*  
11           *after the date of the enactment of this Act, the Sec-*  
12           *retary of Health and Human Services shall promul-*  
13           *gate the regulations required to carry out section*  
14           *801(s) of the Federal Food, Drug, and Cosmetic Act,*  
15           *as added by paragraph (3).*

16           (5) *EFFECTIVE DATE.*—*The amendments made*  
17           *by this subsection shall take effect on the date that is*  
18           *24 months after the date of enactment of this Act.*

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

22                     “(j) *BROKERS AND FILERS.*—*Every person engaged in*  
23                     *the brokering for import or filing for import of any food*  
24                     *shall, upon request of an officer or employee designated by*  
25                     *the Secretary, permit such officer or employee at all reason-*

1 *able times to inspect the facilities of such person and have*  
2 *access to, and to copy and verify, any related records.”.*

3 **SEC. 206. UNIQUE IDENTIFICATION NUMBER FOR FOOD FA-**  
4 **CILITIES, IMPORTERS, CUSTOM BROKERS,**  
5 **AND FILERS.**

6 *Chapter IX (21 U.S.C. 391 et seq) is amended by add-*  
7 *ing at the end the following:*

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

9 *“(a) REGISTRATION OF FACILITY OR ESTABLISH-*  
10 *MENT.—A person required to register a facility pursuant*  
11 *to section 415 shall submit, at the time of registration, a*  
12 *unique facility identifier for the facility or establishment.*

13 *“(b) REGISTRATION OF IMPORTERS, CUSTOM BRO-*  
14 *KERS, AND FILERS.—A person required to register pursu-*  
15 *ant to section 801(r) or 801(s) shall submit, at the time*  
16 *of registration, a unique facility identifier for the principal*  
17 *place of business for which such person is required to reg-*  
18 *ister under section 801(r) or 801(s).*

19 *“(c) GUIDANCE.—The Secretary may, by guidance,*  
20 *specify the unique numerical identifier system to be used*  
21 *to meet the requirements of subsections (a) and (b) and the*  
22 *form, manner, and timing of a submission under such sub-*  
23 *sections.*

24 *“(d) IMPORTATION.—An article of food imported or of-*  
25 *fered for import shall be refused admission unless the appro-*

1 *priate unique facility identifiers, as specified by the Sec-*  
2 *retary, are provided for such article.”.*

3 **SEC. 207. PROHIBITION AGAINST DELAYING, LIMITING, OR**  
4 **REFUSING INSPECTION.**

5 *(a) ADULTERATION.—Section 402 (21 U.S.C. 342), as*  
6 *amended by sections 102, 103(a), and 104(a), is amended*  
7 *by adding at the end the following:*

8 *“(n) If it has been produced, manufactured, processed,*  
9 *packed, or held in any farm, factory, warehouse, or estab-*  
10 *lishment and the owner, operator, or agent of such farm,*  
11 *factory, warehouse, or establishment, or any agent of a gov-*  
12 *ernmental authority in the foreign country within which*  
13 *such farm, factory, warehouse, or establishment is located,*  
14 *delays or limits an inspection, or refuses to permit entry*  
15 *or inspection, under section 414 or 704.”.*

16 *(b) FOREIGN INSPECTIONS.—Section 704(a)(1) (21*  
17 *U.S.C. 374(a)(1)), as amended by section 106(c), is amend-*  
18 *ed—*

19 *(1) in the first sentence, by inserting “, includ-*  
20 *ing any such food factory, warehouse, or establish-*  
21 *ment whether foreign or domestic,” after “factory,*  
22 *warehouse, or establishment”;* and

23 *(2) in the third sentence, by inserting “, includ-*  
24 *ing any food factory, warehouse, establishment, or*  
25 *consulting laboratory whether foreign or domestic,”*

1       *after “factory, warehouse, establishment, or consulting*  
2       *laboratory”.*

3       **SEC. 208. DEDICATED FOREIGN INSPECTORATE.**

4       *Section 704 (21 U.S.C. 374), as amended by sections*  
5       *105, 204, and 205, is amended by adding at the end the*  
6       *following:*

7       “(k) *DEDICATED FOREIGN INSPECTORATE.—The Sec-*  
8       *retary shall establish and maintain a corps of inspectors*  
9       *dedicated to inspections of foreign food facilities. This corps*  
10       *shall be staffed and funded by the Secretary at a level suffi-*  
11       *cient to enable it to assist the Secretary in achieving the*  
12       *frequency of inspections for food facilities as described in*  
13       *this Act.”.*

14       **SEC. 209. PLAN AND REVIEW OF CONTINUED OPERATION**  
15               **OF FIELD LABORATORIES.**

16       (i) *SUBMISSION OF PLAN.—Not later than 90 days be-*  
17       *fore the Secretary terminates or consolidates any labora-*  
18       *tory, district office, or the functions (including the inspec-*  
19       *tion and compliance functions) of any such laboratory or*  
20       *district office, specified in subsection (b), the Secretary shall*  
21       *submit a reorganization plan to the Comptroller General*  
22       *of the United States, the Committee on Energy and Com-*  
23       *merce of the House of Representatives, and the Committee*  
24       *on Health, Education, Labor, and Pensions of the Senate.*

1       (b) *SPECIFIED LABORATORIES AND OFFICES.*—The  
2 laboratories and offices specified in this subsection are the  
3 following:

4           (1) *Any of the 13 field laboratories responsible*  
5 *for analyzing food that were operated by the Office of*  
6 *Regulatory Affairs of the Food and Drug Administra-*  
7 *tion as of January 1, 2007.*

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

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

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

16       (a) *IN GENERAL.*—Section 301(q)(2) (21 U.S.C.  
17 331(q)(2)) is amended by inserting after “device” the fol-  
18 lowing: “or food”.

19       (b) *EFFECTIVE DATE.*—The amendment made by sub-  
20 section (a) shall apply to submissions made on or after the  
21 date of the enactment of this Act.

22 **SEC. 211. SUBPOENA AUTHORITY.**

23       (a) *PROHIBITED ACT.*—Section 301(f) is amended by  
24 inserting before the period the following: “or the failure or  
25 refusal to obey a subpoena issued pursuant to section 311”.



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

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

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

5                   “(1) *any hearing, investigation, or other pro-*  
6 *ceeding respecting a violation of a provision of this*  
7 *Act, the Public Health Service Act, or the Federal*  
8 *Anti-Tampering Act, relating to food; or*

9                   “(2) *any hearing, investigation, or other pro-*  
10 *ceeding to determine if a person is in violation of a*  
11 *specific provision of this Act, the Public Health Serv-*  
12 *ice Act, or the Federal Anti-Tampering Act, relating*  
13 *to food,*

14 *the Commissioner may issue subpoenas requiring the at-*  
15 *tendance and testimony of witnesses and the production of*  
16 *records and other things.*

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

22           “(c) *SERVICE OF SUBPOENA.—*

23                   “(1) *IN GENERAL.—Subpoenas of the Commis-*  
24 *sioner shall be served by a person authorized by the*  
25 *Commissioner by delivering a copy thereof to the per-*

1        *son named therein or by certified mail addressed to*  
2        *such person at such person's last known dwelling*  
3        *place or principal place of business.*

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

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

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

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

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

19           “(f) *NONDISCLOSURE.*—*A United States district court*  
20 *for the district in which the subpoena is or will be served,*  
21 *upon application of the Commissioner, may issue an ex*  
22 *parte order that no person or entity disclose to any other*  
23 *person or entity (other than to an attorney to obtain legal*  
24 *advice) the existence of such subpoena for a period of up*  
25 *to 90 days. Such order may be issued on a showing that*

1 *the records or things being sought may be relevant to the*  
2 *hearing, investigation, proceeding, or other matter and that*  
3 *there is reason to believe that such disclosure may result*  
4 *in—*

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

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

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

11           “(4) *destruction of or tampering with evidence;*

12           *or*

13           “(5) *intimidation of potential witnesses.*

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

18           “(g) *RELATION TO OTHER PROVISIONS.—The sub-*  
19 *poena authority vested in the Commissioner and the district*  
20 *courts of the United States by this section is in addition*  
21 *to any such authority vested in the Commissioner or such*  
22 *courts by other provisions of law.*

23           “(h) *NONDELEGATION.—The authority to issue a sub-*  
24 *poena under this section is limited to the Secretary or an*  
25 *official designated by the Secretary. An official may not*

1 *be so designated unless the official is the director of the dis-*  
2 *trict under this Act in which the article involved is located,*  
3 *or is an official senior to such director.”.*

4 **SEC. 212. WHISTLEBLOWER PROTECTIONS.**

5 *Chapter IX (21 U.S.C. 391 et seq.), as amended by*  
6 *section 206, is amended by adding at the end the following:*

7 **“SEC. 912. PROTECTIONS FOR EMPLOYEES WHO REFUSE TO**  
8 **VIOLATE, OR WHO DISCLOSE VIOLATIONS OF,**  
9 **THIS ACT OR SECTION 351 OF THE PUBLIC**  
10 **HEALTH SERVICE ACT.**

11 *“(a) IN GENERAL.—No person who submits or is re-*  
12 *quired under this Act or the Public Health Service Act to*  
13 *submit any information related to a food, or any officer,*  
14 *employee, contractor, subcontractor, or agent of such person*  
15 *may discharge, demote, suspend, threaten, harass, or in any*  
16 *other manner discriminate against an employee in the*  
17 *terms and conditions of employment because of any lawful*  
18 *act done by the employee, including within the ordinary*  
19 *course of the job duties of such employee—*

20 *“(1) to provide information, cause information*  
21 *to be provided, or otherwise assist in any investiga-*  
22 *tion regarding any conduct which the employee rea-*  
23 *sonably believes constitutes a violation of this Act, or*  
24 *any other provision of Federal law relating to the*  
25 *safety of a food, if the information or assistance is*

1       *provided to, or an investigation stemming from the*  
2       *provided information is conducted by—*

3               “(A) a *Federal regulatory or law enforce-*  
4               *ment agency;*

5               “(B) *any Member of Congress or any com-*  
6               *mittee of Congress; or*

7               “(C) *a person with supervisory authority*  
8               *over the employee (or such other person working*  
9               *for the employer who has the authority to inves-*  
10              *tigate, discover, or terminate the misconduct);*

11              “(2) *to file, cause to be filed, testify, participate*  
12              *in, or otherwise assist in a proceeding filed, or about*  
13              *to be filed (with any knowledge of the employer), in*  
14              *any court or administrative forum relating to any*  
15              *such alleged violation; or*

16              “(3) *to refuse to commit or assist in any such*  
17              *violation.*

18              “(b) *ENFORCEMENT ACTION.—*

19              “(1) *IN GENERAL.—An employee who alleges dis-*  
20              *charge or other discrimination in violation of sub-*  
21              *section (a) may seek relief in accordance with the pro-*  
22              *visions of subsection (c) by—*

23              “(A) *filing a complaint with the Secretary*  
24              *of Labor; or*

1           “(B) *if the Secretary of Labor has not*  
2           *issued a final decision within 210 days of the fil-*  
3           *ing of the complaint and there is no showing*  
4           *that such delay is due to the bad faith of the*  
5           *claimant, or within 90 days after receiving a*  
6           *final decision or order from the Secretary, bring-*  
7           *ing an action at law or equity for de novo re-*  
8           *view in the appropriate district court of the*  
9           *United States, which court shall have jurisdic-*  
10           *tion over such action without regard to the*  
11           *amount in controversy, and which action shall,*  
12           *at the request of either party to such action, be*  
13           *tried by the court with a jury.*

14           “(2) *PROCEDURE.—*

15           “(A) *IN GENERAL.—Any action under*  
16           *paragraph (1) shall be governed under the rules*  
17           *and procedures set forth in section 42121(b) of*  
18           *title 49, United States Code.*

19           “(B) *EXCEPTION.—Notification in an ac-*  
20           *tion under paragraph (1) shall be made in ac-*  
21           *cordance with section 42121(b)(1) of title 49,*  
22           *United States Code, except that such notification*  
23           *shall be made to the person named in the com-*  
24           *plaint and to the employer.*

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

5           “(D) *STATUTE OF LIMITATIONS.*—*An action*  
6           *under paragraph (1) shall be commenced not*  
7           *later than 180 days after the date on which the*  
8           *violation occurs.*

9           “(c) *REMEDIES.*—

10           “(1) *IN GENERAL.*—*An employee prevailing in*  
11           *any action under subsection (b)(1) shall be entitled to*  
12           *all relief necessary to make the employee whole.*

13           “(2) *ISSUANCE OF ORDER.*—*If, in response to a*  
14           *complaint filed under subsection (b)(1), the Secretary*  
15           *of Labor or the district court, as applicable, deter-*  
16           *mines that a violation of subsection (a) has occurred,*  
17           *the Secretary or the court shall order the person who*  
18           *committed such violation—*

19           “(A) *to take affirmative action to abate the*  
20           *violation;*

21           “(B) *to—*

22           “(i) *reinstate the complainant to his or*  
23           *her former position together with compensa-*  
24           *tion (including backpay); and*



1                   “(ii) restore the terms, conditions, and  
2                   privileges associated with his or her employ-  
3                   ment; and

4                   “(C) to provide compensatory damages to  
5                   the complainant.

6                   If such an order is issued under this paragraph, the  
7                   Secretary or the court, at the request of the complain-  
8                   ant, shall assess against the person against whom the  
9                   order is issued a sum equal to the aggregate amount  
10                  of all costs and expenses (including attorney and ex-  
11                  pert witness fees) reasonably incurred, as determined  
12                  by the Secretary, by the complainant for, or in con-  
13                  nection with, the bringing of the complaint upon  
14                  which the order was issued.

15                  “(d) *RIGHTS RETAINED BY EMPLOYEE.*—Nothing in  
16                  this section shall be deemed to diminish the rights, privi-  
17                  leges, or remedies of any employee under any Federal or  
18                  State law or under any collective bargaining agreement.  
19                  The rights and remedies in this section may not be waived  
20                  by any agreement, policy, form, or condition of employ-  
21                  ment.”.

22                  **SEC. 213. EXTRATERRITORIAL JURISDICTION.**

23                  (a) *PROHIBITED ACT.*—Section 301 (21 U.S.C. 331),  
24                  as amended by sections 110, 111, 133, 136, and 204, is  
25                  amended by adding at the end the following:

1           “(uu) *The production, manufacture, processing, prepa-*  
2 *ration, packing, holding, or distribution of an adulterated*  
3 *or misbranded food with the knowledge or intent that such*  
4 *article will be imported into the United States.”.*

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

8           **“SEC. 312. EXTRATERRITORIAL JURISDICTION.**

9           *“There is extraterritorial Federal jurisdiction over any*  
10 *violation of this Act relating to any article of food if such*  
11 *article was intended for import into the United States or*  
12 *if any act in furtherance of the violation was committed*  
13 *in the United States.”.*

14           **SEC. 214. SUPPORT FOR TRAINING INSTITUTES.**

15           *The Secretary of Health and Human Services, acting*  
16 *through the Commissioner of Food and Drugs, shall provide*  
17 *financial and other assistance to appropriate entities to es-*  
18 *tablish and maintain one or more university-affiliated food*  
19 *protection training institutes that—*

20                   (1) *conduct training related to food protection*  
21 *activities for Federal, State, local, territorial, and*  
22 *tribal officials; and*

23                   (2) *meet standards developed by the Secretary.*

1 **SEC. 215. BISPHENOL A IN FOOD AND BEVERAGE CON-**  
2 **TAINERS.**

3 (a) *NOTICE OF DETERMINATION.*—No later than De-  
4 cember 31, 2009, the Secretary of Health and Human Serv-  
5 ices shall notify the Congress whether the available scientific  
6 data support a determination that there is a reasonable cer-  
7 tainty of no harm, for infants, young children, pregnant  
8 women, and adults, for approved uses of polycarbonate  
9 plastic and epoxy resin made with bisphenol A in food and  
10 beverage containers, including reusable food and beverage  
11 containers, under the conditions of use prescribed in current  
12 Food and Drug Administration regulations.

13 (b) *NOTICE OF ACTIONS TO BE TAKEN.*—If the Sec-  
14 retary concludes that such a determination cannot be made  
15 for any approved use, the Secretary shall notify the Con-  
16 gress of the actions the Secretary intends to take under the  
17 Secretary's authority to regulate food additives to protect  
18 the public health, which may include—

19 (1) *revoking or modifying any of the approved*  
20 *uses of bisphenol A in food and beverage containers,*  
21 *including reusable food and beverage containers; and*

22 (2) *ensuring that the public is sufficiently in-*  
23 *formed of such determination and the steps the public*  
24 *may take in response to such determination.*

25 (c) *RULE OF CONSTRUCTION.*—Nothing herein is in-  
26 tended or shall be construed to modify existing Food and

- 1 *Drug Administration authority, procedures, or policies for*
- 2 *assessing scientific data, making safety determinations, or*
- 3 *regulating the safe use of food additives.*