

111TH CONGRESS
1ST SESSION

H. R. 875

To establish the Food Safety Administration within the Department of Health and Human Services to protect the public health by preventing food-borne illness, ensuring the safety of food, improving research on contaminants leading to food-borne illness, and improving security of food from intentional contamination, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 4, 2009

Ms. DELAURO (for herself, Ms. ESHOO, Ms. DEGETTE, Ms. SCHAKOWSKY, Mr. ENGEL, Ms. CASTOR of Florida, Mr. MURPHY of Connecticut, Ms. SUTTON, Mrs. LOWEY, Ms. SLAUGHTER, Mr. HINCHEY, Mr. MCGOVERN, Ms. WASSERMAN SCHULTZ, Ms. HIRONO, Mr. GRIJALVA, Mr. SCHAUER, Mr. NADLER of New York, Mr. BISHOP of New York, Ms. LINDA T. SÁNCHEZ of California, Mr. MCDERMOTT, Mr. RYAN of Ohio, Ms. GIFFORDS, Mr. FILNER, Mr. HALL of New York, Ms. LEE of California, Ms. PINGREE of Maine, Ms. KAPTUR, Mr. BISHOP of Georgia, Ms. MOORE of Wisconsin, and Mr. DEFazio) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Agriculture, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To establish the Food Safety Administration within the Department of Health and Human Services to protect the public health by preventing food-borne illness, ensuring the safety of food, improving research on contaminants leading to food-borne illness, and improving security of food from intentional contamination, 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; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
 5 “Food Safety Modernization Act of 2009”.

6 (b) **TABLE OF CONTENTS.**—The table of contents of
 7 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings; purposes.
- Sec. 3. Definitions.

TITLE I—ESTABLISHMENT OF THE FOOD SAFETY
ADMINISTRATION

- Sec. 101. Establishment of the food safety administration.
- Sec. 102. Consolidation of food safety functions.
- Sec. 103. Additional duties of the administration.

TITLE II—ADMINISTRATION OF FOOD SAFETY PROGRAM

- Sec. 201. Administration of national program.
- Sec. 202. Registration of food establishments and foreign food establishments.
- Sec. 203. Preventive process controls to reduce adulteration of food.
- Sec. 204. Performance standards for contaminants in food.
- Sec. 205. Inspections of food establishments.
- Sec. 206. Food production facilities.
- Sec. 207. Federal and State cooperation.
- Sec. 208. Imports.
- Sec. 209. Resource plan.
- Sec. 210. Traceback requirements.
- Sec. 211. Accredited laboratories.

TITLE III—RESEARCH AND EDUCATION

- Sec. 301. Public health assessment system.
- Sec. 302. Public education and advisory system.
- Sec. 303. Research.
- Sec. 304. Working group on improving foodborne illness surveillance.
- Sec. 305. Career-spanning training for food inspectors.
- Sec. 306. Food-Borne Illness Health Registry.
- Sec. 307. Study on Federal resources.

TITLE IV—ENFORCEMENT

- Sec. 401. Prohibited acts.
- Sec. 402. Food detention, seizure, and condemnation.
- Sec. 403. Notification and recall.
- Sec. 404. Injunction proceedings.
- Sec. 405. Civil and criminal penalties.

Sec. 406. Presumption.
Sec. 407. Whistleblower protection.
Sec. 408. Administration and enforcement.
Sec. 409. Citizen civil actions.

TITLE V—IMPLEMENTATION

Sec. 501. Reorganization plan.
Sec. 502. Transitional authorities.
Sec. 503. Savings provisions.
Sec. 504. Conforming amendments.
Sec. 505. Additional technical and conforming amendments.
Sec. 506. Regulations.
Sec. 507. Authorization of appropriations.
Sec. 508. Limitation on authorization of appropriations.

1 **SEC. 2. FINDINGS; PURPOSES.**

2 (a) FINDINGS.—Congress finds that—

3 (1) the safety of the food supply of the United
4 States is vital to the public health, to public con-
5 fidence in the food supply, and to the success of the
6 food sector of the Nation’s economy;

7 (2) lapses in the protection of the food supply
8 and loss of public confidence in food safety are dam-
9 aging to consumers and the food industry, and place
10 a burden on interstate commerce and international
11 trade;

12 (3) recent ongoing events demonstrate that the
13 food safety program at the Food and Drug Adminis-
14 tration is not effective in controlling hazards in food
15 coming from farms and factories in the United
16 States and food and food ingredients coming from
17 foreign countries, and these events have adversely
18 affected consumer confidence;

1 (4) the safety and security of the food supply
2 require a systemwide approach to prevent food-borne
3 illness involving the integrated efforts of Federal,
4 State and local agencies; a thorough, broad-based,
5 and coordinated approach to basic and applied
6 science; and intensive, effective, and efficient man-
7 agement of the Nation’s food safety program;

8 (5) the task of preserving the safety of the food
9 supply of the United States faces tremendous pres-
10 sures with regard to—

11 (A) emerging pathogens and other con-
12 taminants and the ability to detect all forms of
13 contamination;

14 (B) the threat of intentional contamination
15 of the food supply;

16 (C) a growing number of people at high
17 risk for food-borne illnesses, including an in-
18 creasing population of aging and immune-com-
19 promised consumers, together with infants and
20 children;

21 (D) an increasing volume of imported food,
22 without adequate monitoring, inspection, and
23 systems for prevention of food safety problems;
24 and

1 (E) maintenance of rigorous inspection of
2 the domestic food processing and food service
3 industries;

4 (6) Federal food safety standard setting, in-
5 spection, enforcement, and research efforts should be
6 based on the best available science and public health
7 considerations, and food safety resources should be
8 systematically deployed in ways that most effectively
9 prevent food-borne illness;

10 (7) the Food and Drug Administration, an
11 agency within the Department of Health and
12 Human Services, has regulatory jurisdiction over the
13 safety and labeling of 80 percent of the American
14 food supply, encompassing all foods except meat,
15 poultry, and egg products, as well as drugs, medical
16 devices, and biologics;

17 (8) rapid technological advance and the expan-
18 sion and globalization of industries in all areas of
19 Food and Drug Administration jurisdiction present
20 challenges and require leadership beyond the capac-
21 ity of any one agency or agency head to provide;

22 (9) in the food safety area, the Food and Drug
23 Administration implements provisions of the Federal
24 Food, Drug, and Cosmetic Act that are 70 years old
25 and that antiquated law limits the Food and Drug

1 Administration's role largely to reacting to and cor-
2 recting food safety problems after they occur, rather
3 than working with the food industry to systemati-
4 cally prevent problems;

5 (10) the Food and Drug Administration's effec-
6 tiveness is further impaired by fragmentation of
7 leadership and management within the Administra-
8 tion, as major food safety responsibilities are dis-
9 persed across the Administration's Center for Food
10 Safety and Applied Nutrition, Center for Veterinary
11 Medicine, and Office of Regulatory Affairs;

12 (11) there is no official with the full-time re-
13 sponsibility and budget authority for food safety at
14 the Food and Drug Administration and food safety
15 competes unsuccessfully with the drug and medical
16 device programs for senior agency management at-
17 tention and resources; and

18 (12) improving Federal oversight of food safety
19 requires a modern food safety mandate, clear au-
20 thorities, and a dedicated official within the Depart-
21 ment of Health and Human Services with budget
22 authority to manage an integrated organizational
23 structure and report directly to the Secretary.

24 (b) PURPOSES.—The purposes of this Act are—

1 (1) to establish an agency within the Depart-
2 ment of Health and Human Services to be known as
3 the “Food Safety Administration” to—

4 (A) regulate food safety and labeling to
5 strengthen the protection of the public health;

6 (B) ensure that food establishments fulfill
7 their responsibility to process, store, hold, and
8 transport food in a manner that protects the
9 public health of all people in the United States;

10 (C) lead an integrated, systemwide ap-
11 proach to food safety and to make more effec-
12 tive and efficient use of resources to prevent
13 food-borne illness;

14 (D) provide a single focal point within the
15 Department of Health and Human Services for
16 food safety leadership, both nationally and
17 internationally; and

18 (E) provide an integrated food safety re-
19 search capability, including internally gen-
20 erated, scientifically and statistically valid stud-
21 ies, in cooperation with academic institutions
22 and other scientific entities of the Federal and
23 State governments;

24 (2) to transfer to the Food Safety Administra-
25 tion the food safety, labeling, inspection, and en-

1 enforcement functions that, as of the day before the
2 date of the enactment of this Act, are performed by
3 various components of the Food and Drug Adminis-
4 tration and the National Oceanic and Atmospheric
5 Administration;

6 (3) to modernize and strengthen the Federal
7 food safety law to ensure more effective application
8 and efficient management of the laws for the protec-
9 tion and improvement of public health; and

10 (4) to establish that food establishments have
11 responsibility to ensure that all stages of production,
12 processing, and distribution of their products or
13 products under their control satisfy the requirements
14 of this law.

15 **SEC. 3. DEFINITIONS.**

16 In this Act:

17 (1) ADMINISTRATION.—The term “Administra-
18 tion” means the Food Safety Administration estab-
19 lished under section 101(a)(1).

20 (2) ADMINISTRATOR.—The term “Adminis-
21 trator” means the Administrator of Food Safety ap-
22 pointed under section 101(a)(2).

23 (3) ADULTERATED.—

24 (A) IN GENERAL.—The term “adulter-
25 ated” has the meaning given that term in sec-

1 tion 402 of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 342).

3 (B) INCLUSION.—The term “adulterated”
4 includes bearing or containing a contaminant
5 that causes illness or death among sensitive
6 populations.

7 (4) AGENCY.—The term “agency” has the
8 meaning given that term in section 551 of title 5,
9 United States Code.

10 (5) CATEGORY 1 FOOD ESTABLISHMENT.—The
11 term “category 1 food establishment” means a food
12 establishment (other than a seafood processing es-
13 tablishment) that slaughters, for the purpose of pro-
14 ducing food, animals that are not subject to inspec-
15 tion under the Federal Meat Inspection Act or poul-
16 try that are not subject to inspection under the
17 Poultry Products Inspection Act.

18 (6) CATEGORY 2 FOOD ESTABLISHMENT.—The
19 term “category 2 food establishment” means a sea-
20 food processing establishment or other food estab-
21 lishment (other than a category 1 establishment) not
22 subject to inspection under the Federal Meat Inspec-
23 tion Act, the Poultry Products Inspection Act, or the
24 Egg Products Inspection Act, that processes raw
25 seafood or other raw animal products, whether fresh

1 or frozen, or other products that the Administrator
2 determines by regulation to pose a significant risk of
3 hazardous contamination.

4 (7) CATEGORY 3 FOOD ESTABLISHMENT.—The
5 term “category 3 food establishment” means a food
6 establishment (other than a category 1 or category
7 2 establishment) that processes cooked, pasteurized,
8 or otherwise ready-to-eat seafood or other animal
9 products, fresh produce in ready-to-eat raw form, or
10 other products that pose a risk of hazardous con-
11 tamination.

12 (8) CATEGORY 4 FOOD ESTABLISHMENT.—The
13 term “category 4 food establishment” means a food
14 establishment that processes all other categories of
15 food products not described in paragraphs (5)
16 through (7).

17 (9) CATEGORY 5 FOOD ESTABLISHMENT.—The
18 term “category 5 food establishment” means a food
19 establishment that stores, holds, or transports food
20 products prior to delivery for retail sale.

21 (10) CONTAMINANT.—The term “contaminant”
22 includes a bacterium, chemical, natural toxin or
23 manufactured toxicant, virus, parasite, prion, phys-
24 ical hazard, or other human pathogen that when

1 found on or in food can cause human illness, injury,
2 or death.

3 (11) HAZARDOUS CONTAMINATION.—The term
4 “hazardous contamination” refers to the presence of
5 a contaminant in food at levels that pose a risk of
6 human illness, injury, or death or are capable of
7 reaching levels that pose such risk during the shelf
8 life of the product.

9 (12) FOOD.—The term “food” means a product
10 intended to be used for food or drink for a human
11 or an animal and components thereof.

12 (13) FOOD ESTABLISHMENT.—

13 (A) IN GENERAL.—The term “food estab-
14 lishment” means a slaughterhouse (except those
15 regulated under the Federal Meat Inspection
16 Act or the Poultry Products Inspection Act),
17 factory, warehouse, or facility owned or oper-
18 ated by a person located in any State that proc-
19 esses food or a facility that holds, stores, or
20 transports food or food ingredients.

21 (B) EXCLUSIONS.—For the purposes of
22 registration, the term “food establishment”
23 does not include a food production facility as
24 defined in paragraph (14), restaurant, other re-
25 tail food establishment, nonprofit food estab-

1 lishment in which food is prepared for or served
2 directly to the consumer, or fishing vessel
3 (other than a fishing vessel engaged in proc-
4 essing, as that term is defined in section 123.3
5 of title 21, Code of Federal Regulations).

6 (14) FOOD PRODUCTION FACILITY.—The term
7 “food production facility” means any farm, ranch,
8 orchard, vineyard, aquaculture facility, or confined
9 animal-feeding operation.

10 (15) FOOD SAFETY LAW.—The term “food safe-
11 ty law” means—

12 (A) the provisions of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 301 et
14 seq.) related to and requiring the safety, qual-
15 ity, nutritional composition, labeling, and in-
16 spection of food, infant formulas, food addi-
17 tives, pesticide residues, and other substances
18 present in food;

19 (B) the provisions of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 301 et 11
21 seq.) and of any other Acts that are adminis-
22 tered by the Center for Veterinary Medicine of
23 the Food and Drug Administration;

24 (C) the provisions of the Public Health
25 Service Act that relate in any way to studying,

1 surveying, containing, or preventing food-borne
2 illness; and

3 (D) the provisions of this Act.

4 (16) FOREIGN FOOD ESTABLISHMENT.—The
5 term “foreign food establishment” means any cat-
6 egory 1 through 5 food establishment or food pro-
7 duction facility located outside the United States
8 that processes or produces food or food ingredients
9 for consumption in the United States.

10 (17) INTERSTATE COMMERCE.—The term
11 “interstate commerce” has the meaning given that
12 term in section 201(b) of the Federal Food, Drug,
13 and Cosmetic Act (21 U.S.C. 321(b)).

14 (18) MISBRANDED.—The term “misbranded”
15 has the meaning given that term in section 403 of
16 the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 343).

18 (19) PROCESS.—The term “process” or “proc-
19 essing” means the commercial slaughter, packing,
20 preparation, or manufacture of food.

21 (20) STATE.—The term “State” means—

22 (A) a State;

23 (B) the District of Columbia;

24 (C) the Commonwealth of Puerto Rico;

25 and

1 (D) any other territory or possession of the
2 United States.

3 **TITLE I—ESTABLISHMENT OF**
4 **THE FOOD SAFETY ADMINIS-**
5 **TRATION**

6 **SEC. 101. ESTABLISHMENT OF THE FOOD SAFETY ADMINIS-**
7 **TRATION.**

8 (a) ESTABLISHMENT.—

9 (1) IN GENERAL.—There is established in the
10 Department of Health and Human Services an agen-
11 cy to be known as the “Food Safety Administra-
12 tion”.

13 (2) HEAD OF THE ADMINISTRATION.—The Ad-
14 ministration shall be headed by the Administrator of
15 Food Safety, who shall be appointed by the Presi-
16 dent, by and with the advice and consent of the Sen-
17 ate, for a term of 5 years, and who may be re-
18 appointed.

19 (3) DELEGATION.—All the authorities and re-
20 sponsibilities assigned to the Secretary of Health
21 and Human Services in the food safety law are here-
22 by assigned to the Administrator.

23 (b) DUTIES OF ADMINISTRATOR.—The Adminis-
24 trator shall—

25 (1) administer and enforce the food safety law;

1 (2) serve as the food safety leader within the
2 Department of Health and Human Services and co-
3 ordinator of all Department activities related to en-
4 suring the safety, quality, and proper labeling of the
5 food supply;

6 (3) represent the United States in relevant
7 international food safety bodies and discussions;

8 (4) promulgate regulations to ensure the safety
9 and security of the food supply from all forms of
10 contamination, including intentional contamination;
11 and

12 (5) oversee within the Department of Health
13 and Human Services—

14 (A) in consultation with the Director of the
15 Centers for Disease Control and Prevention, all
16 activities related to foodborne illness surveil-
17 lance and investigation of foodborne illness out-
18 breaks;

19 (B) implementation of food safety inspec-
20 tion, enforcement, and research efforts to pro-
21 tect the public health;

22 (C) development of consistent and science-
23 based standards for safe food;

1 (D) coordination and prioritization of food
2 safety research and education programs with
3 other Federal agencies;

4 (E) prioritization of food safety efforts and
5 deployment of food safety resources to achieve
6 the greatest possible benefit in reducing food-
7 borne illness;

8 (F) coordination of the response to food-
9 borne illness outbreaks with other Federal and
10 State agencies; and

11 (G) integration of food safety activities
12 with State and local agencies.

13 **SEC. 102. CONSOLIDATION OF FOOD SAFETY FUNCTIONS.**

14 (a) **TRANSFER OF FUNCTIONS AND RESOURCES.—**

15 For each component of the Department of Health and
16 Human Services or the Department of Commerce specified
17 in subsection (b), there are transferred to the Administra-
18 tion all functions, personnel, and assets (including facili-
19 ties and financial resources) of those components as of the
20 day before the date of the enactment of this Act (including
21 all related functions of any officer or employee of the com-
22 ponent) that relate to administration or enforcement of
23 the food safety law, as determined by the President.

24 (b) **TRANSFERRED FUNCTIONS AND RESOURCES.—**

25 The components referred to in subsection (a) are—

1 (1) the Center for Food Safety and Applied Nu-
2 trition of the Food and Drug Administration;

3 (2) the Center for Veterinary Medicine of the
4 Food and Drug Administration;

5 (3) the National Center for Toxicological Re-
6 search of the Food and Drug Administration;

7 (4) the personnel and assets of the Office of
8 Regulatory Affairs of the Food and Drug Adminis-
9 tration used to administer and conduct inspections
10 of food establishments and imports and conduct lab-
11 oratory analyses and other investigations relating to
12 food safety and enforcement of the food safety law;

13 (5) the personnel and assets of the Office of the
14 Commissioner of Food and Drugs used to support—

15 (A) the Center for Food Safety and Ap-
16 plied Nutrition;

17 (B) the Center for Veterinary Medicine;

18 (C) the National Center for Toxicological
19 Research; and

20 (D) the personnel and assets of the Office
21 of Regulatory Affairs described in paragraph
22 (4); and

23 (6) the personnel and assets of the National
24 Marine Fisheries Service of the National Oceanic
25 and Atmospheric Administration of the Department

1 of Commerce used to administer the seafood inspec-
2 tion program.

3 (c) RENAMING AND RESERVATION OF AGENCY IDEN-
4 TITY.—The Food and Drug Administration in the Depart-
5 ment of Health and Human Services is hereby renamed
6 the Federal Drug and Device Administration and may be
7 referred to as “FDA”.

8 (d) SHARING OF FACILITIES AND RESOURCES.—The
9 Food Safety Administration and the Federal Drug and
10 Device Administration shall enter into such agreements
11 concerning the sharing of facilities and other resources as
12 may be appropriate to make efficient use of such facilities
13 and resources and achieve their respective missions.

14 **SEC. 103. ADDITIONAL DUTIES OF THE ADMINISTRATION.**

15 (a) OFFICERS AND EMPLOYEES.—The Administrator
16 may—

17 (1) appoint officers and employees for the Ad-
18 ministration in accordance with the provisions of
19 title 5, United States Code, relating to appointment
20 in the competitive service; and

21 (2) fix the compensation of those officers and
22 employees in accordance with chapter 51 and with
23 subchapter III of chapter 53 of that title, relating to
24 classification and General Schedule pay rates.

1 (b) EXPERTS AND CONSULTANTS.—The Adminis-
2 trator may—

3 (1) procure the services of temporary or inter-
4 mittent experts and consultants as authorized by
5 section 3109 of title 5, United States Code; and

6 (2) pay in connection with those services the
7 travel expenses of the experts and consultants, in-
8 cluding transportation and per diem in lieu of sub-
9 sistence while away from the homes or regular
10 places of business of the individuals, as authorized
11 by section 5703 of that title.

12 (c) BUREAUS, OFFICES, AND DIVISIONS.—The Ad-
13 ministrator may establish within the Administration such
14 bureaus, offices, and divisions as the Administrator deter-
15 mines are necessary to perform the duties of the Adminis-
16 trator.

17 (d) ADVISORY COMMITTEES.—

18 (1) IN GENERAL.—The Administrator shall es-
19 tablish advisory committees that consist of rep-
20 resentatives of scientific expert bodies, academics,
21 industry specialists, and consumers.

22 (2) DUTIES.—The duties of an advisory com-
23 mittee established under paragraph (1) may include
24 developing recommendations with respect to the de-

1 velopment of new processes, research, communica-
2 tions, performance standards, and inspection.

3 **TITLE II—ADMINISTRATION OF**
4 **FOOD SAFETY PROGRAM**

5 **SEC. 201. ADMINISTRATION OF NATIONAL PROGRAM.**

6 (a) IN GENERAL.—The Administrator shall—

7 (1) develop, administer, and annually update a
8 national food safety program (referred to in this sec-
9 tion as the “program”) to protect public health; and

10 (2) ensure that persons who produce, process,
11 or distribute food meet their responsibility to pre-
12 vent or minimize food safety hazards related to their
13 products.

14 (b) COMPREHENSIVE ANALYSIS.—The program shall
15 be based on a comprehensive analysis of the hazards asso-
16 ciated with different food and with the processing of dif-
17 ferent food, including the identification and evaluation
18 of—

19 (1) the severity of the potential health risks;

20 (2) the sources of potentially hazardous con-
21 tamination or practices extending from the farm or
22 ranch to the consumer that may increase the risk of
23 food-borne illness;

1 (3) the potential for persistence, multiplication,
2 or concentration of naturally occurring or added
3 contaminants in food;

4 (4) the potential for hazardous contamination
5 to have cumulative toxic effects, multigenerational
6 effects, or effects on specific categories of con-
7 sumers;

8 (5) opportunities across the food production,
9 processing, distribution, and retail system to reduce
10 potential health risks; and

11 (6) opportunities for intentional contamination
12 of food or food ingredients.

13 (c) PROGRAM ELEMENTS.—In carrying out the pro-
14 gram, the Administrator shall—

15 (1) adopt and implement a national system for
16 the registration of food establishments and foreign
17 food establishments, as provided in section 202 of
18 this Act;

19 (2) adopt and implement a national system for
20 regular unannounced inspection of food establish-
21 ments;

22 (3) require and enforce the adoption of preven-
23 tive process controls in food establishments, based
24 on the best available scientific and public health con-
25 siderations and best available technologies;

1 (4) establish and enforce science-based stand-
2 ards for—

3 (A) potentially hazardous substances that
4 may contaminate food; and

5 (B) safety and sanitation in the processing
6 and handling of food;

7 (5) implement a statistically valid sampling pro-
8 gram with the stringency and frequency to independ-
9 ently monitor that industry programs and proce-
10 dures that prevent food contamination are effective
11 on an ongoing basis and that food meets the stand-
12 ards established under this Act;

13 (6) implement appropriate surveillance proce-
14 dures and requirements to ensure the safety and se-
15 curity of imported food;

16 (7) coordinate and collaborate with other agen-
17 cies and State or local governments in carrying out
18 inspection, enforcement, research, and monitoring;

19 (8) implement a national system to identify the
20 food products posing the greatest public health risk
21 and to analyze the effectiveness of existing food safe-
22 ty programs, in conjunction with the Centers for
23 Disease Control and Prevention and other Federal
24 agencies;

1 (9) develop public education, risk communica-
2 tion, and advisory programs;

3 (10) implement an applied research program to
4 further the purposes of this Act;

5 (11) coordinate and prioritize food safety re-
6 search and educational programs with other Federal
7 agencies and with State and local governments; and

8 (12) provide technical assistance to farmers and
9 food establishments that are small business concerns
10 (meeting the requirements of section 3(a) of the
11 Small Business Act and the regulations promulgated
12 thereunder) to assist with compliance with the re-
13 quirements of this Act.

14 **SEC. 202. REGISTRATION OF FOOD ESTABLISHMENTS AND**
15 **FOREIGN FOOD ESTABLISHMENTS.**

16 (a) **IN GENERAL.**—Any food establishment or foreign
17 food establishment engaged in manufacturing, processing,
18 packing, or holding food for consumption in the United
19 States shall register annually with the Administrator.

20 (b) **REGISTRATION REQUIREMENTS.**—

21 (1) **IN GENERAL.**—To be registered under sub-
22 section (a), a food establishment shall submit a reg-
23 istration or reregistration to the Administrator.

24 (2) **REGISTRATION.**—Registration under this
25 section shall begin within 90 days of the enactment

1 of this Act. Each such registration shall be sub-
2 mitted to the Secretary through an electronic portal
3 and shall contain such information as the Secretary,
4 by guidance, determines to be appropriate. Such reg-
5 istration shall contain the following information:

6 (A) The name, address, and emergency
7 contact information of each domestic food es-
8 tablishment or foreign food establishment that
9 the registrant owns or operates under this Act
10 and all trade names under which the registrant
11 conducts business in the United States relating
12 to food.

13 (B) The primary purpose and business ac-
14 tivity of each domestic food establishment or
15 foreign food establishment, including the dates
16 of operation if the domestic food establishment
17 or foreign food establishment is seasonal.

18 (C) The types of food processed or sold at
19 each domestic food establishment or, for foreign
20 food establishments selling food for consump-
21 tion in the United States, the specific food cat-
22 egories of that food as listed under section
23 170.3(n) of title 21, Code of Federal Regula-
24 tions, or such other categories as the Adminis-
25 trator may designate in guidance, action level,

1 or regulations for evaluating potential threats
2 to food protection.

3 (D) The name, address, and 24-hour emer-
4 gency contact information of the United States
5 distribution agent for each domestic food estab-
6 lishment or foreign food establishment, who
7 shall maintain information on the distribution
8 of food, including lot information, and whole-
9 saler and retailer distribution.

10 (E) An assurance that the registrant will
11 notify the Administrator of any change in the
12 products, function, or legal status of the domes-
13 tic food establishment or foreign food establish-
14 ment (including cessation of business activities)
15 not later than 30 days after such change.

16 (3) PROCEDURE.—Upon receipt of a completed
17 registration described in paragraph (1), the Admin-
18 istrator shall notify the registrant of the receipt of
19 the registration, designate each establishment as a
20 category 1, 2, 3, 4, or 5 food establishment, and as-
21 sign a registration number to each domestic food es-
22 tablishment and foreign food establishment.

23 (4) LIST.—The Administrator shall annually
24 compile a list of domestic food establishments and a
25 list of foreign food establishments that are registered

1 under this section. The Administrator may establish
2 the manner of and any fees required for reregistra-
3 tion and any circumstances by which either such list
4 may be shared with other governmental authorities.
5 The Administrator may remove from either list the
6 name of any establishment that fails to reregister,
7 and such delisting shall be treated as a suspension.

8 (5) DISCLOSURE EXEMPTION.—The disclosure
9 requirements under section 552 of title 5, United
10 States Code, shall not apply to—

11 (A) the list compiled under paragraph (4);

12 and

13 (B) information derived from the list under
14 paragraph (4), to the extent that it discloses
15 the identity or location of a specific person.

16 (6) SUSPENSION OF REGISTRATION.—

17 (A) IN GENERAL.—The Administrator may
18 suspend the registration of a domestic food es-
19 tablishment or foreign food establishment, in-
20 cluding the facility of an importer, for violation
21 of a food safety law that is either repeated or
22 could result in serious adverse health con-
23 sequences or death to humans or animals.

24 (B) NOTICE AND OPPORTUNITY FOR
25 HEARING.—The Administrator shall provide no-

1 tice of an intent to suspend the registration of
2 an establishment under this paragraph to a reg-
3 istrant and provide the registrant with an op-
4 portunity for an administrative hearing within 3
5 days. The Administrator may issue a written
6 order of suspension following the hearing, if the
7 Administrator finds that a violation described
8 in subparagraph (A) has occurred.

9 (C) JUDICIAL REVIEW.—The issuance of
10 an order of suspension under subparagraph (B)
11 shall be considered to be a final agency action
12 subject to judicial review in accordance with the
13 provisions of chapter 7 of title 5, United States
14 Code.

15 (7) REINSTATEMENT.—A registration that is
16 suspended under this section may be reinstated
17 based on a showing that adequate process controls
18 have been instituted that would prevent future viola-
19 tions and there are assurances from the registrant
20 that the violations will not be repeated.

21 (c) TRANSITIONAL PROVISION.—During the 6-month
22 period following the date of the enactment of this Act, a
23 food establishment is deemed to be registered in accord-
24 ance with this section if the establishment is registered

1 under section 415 of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 350d).

3 (d) REPEAL.—Effective at the end of the 6-month
4 period following the date of the enactment of this Act, sec-
5 tion 415 of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 350d) is repealed.

7 **SEC. 203. PREVENTIVE PROCESS CONTROLS TO REDUCE**
8 **ADULTERATION OF FOOD.**

9 (a) IN GENERAL.—The Administrator shall, upon the
10 basis of best available public health, scientific, and techno-
11 logical data, promulgate regulations to ensure that food
12 establishments carry out their responsibilities under the
13 food safety law.

14 (b) REGULATIONS.—Not later than 1 year after the
15 date of the enactment of this Act, the Administrator shall
16 promulgate regulations that require all food establish-
17 ments, within time frames determined by the Adminis-
18 trator—

19 (1) to adopt preventive process controls that—

20 (A) reflect the standards and procedures
21 recognized by relevant authoritative bodies;

22 (B) are adequate to protect the public
23 health;

24 (C) meet relevant regulatory and food safe-
25 ty standards;

1 (D) limit the presence and growth of con-
2 taminants in food prepared in a food establish-
3 ment using the best reasonably available tech-
4 niques and technologies; and

5 (E) are tailored to the hazards and proc-
6 esses in particular establishments or environ-
7 ments;

8 (2) to establish a sanitation plan and program
9 that meets standards set by the Administrator;

10 (3) to meet performance standards for haz-
11 ardous contamination established under section 204;

12 (4) to implement recordkeeping to monitor com-
13 pliance with regulatory requirements;

14 (5) to implement recordkeeping and labeling of
15 all food and food ingredients to facilitate their iden-
16 tification and traceability in the event of a recall or
17 market removal;

18 (6) to implement product and environmental
19 sampling at a frequency and in a manner sufficient
20 to ensure that process controls are effective on an
21 ongoing basis and that regulatory standards are
22 being met;

23 (7) to label food intended for final processing
24 outside commercial food establishments with instruc-

1 tions for handling and preparation for consumption
2 that will destroy microbial contaminants; and

3 (8) to provide for agency access to records kept
4 by the food establishments and submission of copies
5 of records to the Administrator, as the Adminis-
6 trator determines appropriate.

7 (c) SPECIFIC HAZARD CONTROLS.—The Adminis-
8 trator may require any person with responsibility for or
9 control over food or food ingredients to adopt specific haz-
10 ard controls, if such controls are needed to ensure the pro-
11 tection of the public health.

12 **SEC. 204. PERFORMANCE STANDARDS FOR CONTAMINANTS**
13 **IN FOOD.**

14 (a) IN GENERAL.—To protect the public health, the
15 Administrator shall establish by guidance document, ac-
16 tion level, or regulation and enforce performance stand-
17 ards that define, with respect to specific foods and con-
18 taminants in food, the level of food safety performance
19 that a person responsible for producing, processing, or
20 selling food shall meet.

21 (b) IDENTIFICATION OF CONTAMINANTS; PERFORM-
22 ANCE STANDARDS.—

23 (1) LIST OF CONTAMINANTS.—Not later than 6
24 months after the date of the enactment of this Act,
25 the Administrator shall publish in the Federal Reg-

1 ister a list of the contaminants in foods that have
2 the greatest adverse impact on public health in
3 terms of the number and severity of illnesses and
4 number of deaths associated with foods regulated
5 under this Act. Where appropriate, the Adminis-
6 trator shall indicate whether the risk posed by a con-
7 taminant is generalized or specific to particular
8 foods or ingredients.

9 (2) PERFORMANCE STANDARDS.—

10 (A) ESTABLISHMENT.—The Administrator
11 shall establish by guidance document, action
12 level, or regulation a performance standard for
13 each contaminant in the list under paragraph
14 (1) at levels appropriate to protect against the
15 potential adverse health effects of the contami-
16 nant.

17 (B) TIMING.—The Administrator shall es-
18 tablish a performance standard under subpara-
19 graph (A) for each contaminant in the list
20 under paragraph (1)—

21 (i) as soon as practicable; or

22 (ii) in the case of a contaminant de-
23 scribed in subparagraph (C), by the date
24 described in such subparagraph.

1 (C) SIGNIFICANT CONTAMINANTS.—The
2 list under paragraph (1) (and any revision
3 thereto) shall identify the 5 most significant
4 contaminants in the list (in terms of the num-
5 ber and severity of illnesses and number of
6 deaths associated with foods regulated under
7 this Act). Not later than 3 years after a con-
8 taminant is so identified, the Administrator
9 shall promulgate a performance standard under
10 subparagraph (A) for the contaminant.

11 (3) REVIEW; REVISION.—Not less than every 3
12 years, the Administrator shall review and, if nec-
13 essary, revise—

14 (A) the list of contaminants under para-
15 graph (1); and

16 (B) each performance standard established
17 under paragraph (2).

18 (c) PERFORMANCE STANDARDS.—

19 (1) IN GENERAL.—The performance standards
20 established under this section may include—

21 (A) health-based standards that set the
22 level of a contaminant that can safely and law-
23 fully be present in food;

24 (B) zero tolerances, including any zero tol-
25 erance performance standards in effect on the

1 day before the date of the enactment of this
2 Act, when necessary to protect against signifi-
3 cant adverse health outcomes;

4 (C) process standards, such as log reduc-
5 tion criteria for cooked products, when suffi-
6 cient to ensure the safety of processed food; and

7 (D) in the absence of data to support a
8 performance standard described in subpara-
9 graph (A), (B), or (C), standards that define
10 required performance on the basis of reliable in-
11 formation on the best reasonably achievable
12 performance, using best available technologies,
13 interventions, and practices.

14 (2) BEST REASONABLY ACHIEVABLE PERFORM-
15 ANCE STANDARDS.—In developing best reasonably
16 achievable performance standards under paragraph
17 (1)(D), the Administrator shall collect, or contract
18 for the collection of, data on current best practices
19 and food safety outcomes related to the contami-
20 nants and foods in question, as the Administrator
21 determines necessary.

22 (3) REVOCATION BY ADMINISTRATOR.—All per-
23 formance standards, tolerances, action levels, or
24 other similar standards in effect on the date of the

1 enactment of this Act shall remain in effect until re-
2 vised or revoked by the Administrator.

3 (d) ENFORCEMENT.—

4 (1) IN GENERAL.—In conjunction with the es-
5 tablishment of a performance standard under this
6 section, the Administrator shall develop a statis-
7 tically valid sampling program with the stringency
8 and frequency sufficient to independently monitor
9 whether food establishments are complying with the
10 performance standard and implement the program
11 within 1 year of the promulgation of the standard.

12 (2) INSPECTIONS.—If the Administrator deter-
13 mines that a food establishment fails to meet a
14 standard promulgated under this section, the Ad-
15 ministrator shall, as appropriate—

16 (A) detain, seize, or condemn food from
17 the food establishment under section 402;

18 (B) order a recall of food from the food es-
19 tablishment under section 403;

20 (C) increase the inspection frequency for
21 the food establishment;

22 (D) withdraw the mark of inspection from
23 the food establishment, if in use; or

1 (E) take other appropriate enforcement ac-
2 tion concerning the food establishment, includ-
3 ing withdrawal of registration.

4 (e) NEWLY IDENTIFIED CONTAMINANTS.—Notwith-
5 standing any other provision of this section, the Adminis-
6 trator shall establish interim performance standards for
7 newly identified contaminants as necessary to protect the
8 public health.

9 **SEC. 205. INSPECTIONS OF FOOD ESTABLISHMENTS.**

10 (a) IN GENERAL.—The Administrator shall establish
11 an inspection program, which shall include statistically
12 valid sampling of food and facilities to enforce perform-
13 ance standards. The inspection program shall be designed
14 to determine if each food establishment—

15 (1) is operated in a sanitary manner;

16 (2) has continuous preventive control systems,
17 interventions, and processes in place to minimize or
18 eliminate contaminants in food;

19 (3) is in compliance with applicable perform-
20 ance standards established under section 204, and
21 other regulatory requirements;

22 (4) is processing food that is not adulterated or
23 misbranded;

1 (5) maintains records of process control plans
2 under section 203, and other records related to the
3 processing, sampling, and handling of food; and

4 (6) is otherwise in compliance with the require-
5 ments of the food safety law.

6 (b) ESTABLISHMENT CATEGORIES AND INSPECTION
7 FREQUENCIES.—The resource plan required under section
8 209, including the description of resources required to
9 carry out inspections of food establishments, shall be
10 based on the following categories and inspection fre-
11 quencies, subject to subsections (c), (d), and (e):

12 (1) CATEGORY 1 FOOD ESTABLISHMENTS.—A
13 category 1 food establishment shall be subject to
14 antemortem, postmortem, and continuous inspection
15 of each slaughter line during all operating hours,
16 and other inspection on a daily basis, sufficient to
17 verify that—

18 (A) diseased animals are not offered for
19 slaughter;

20 (B) the food establishment has successfully
21 identified and removed from the slaughter line
22 visibly defective or contaminated carcasses, has
23 avoided cross-contamination, and has destroyed
24 or reprocessed such carcasses in a manner ac-
25 ceptable to the Administrator; and

1 (C) applicable performance standards and
2 other provisions of the food safety law, includ-
3 ing those intended to eliminate or reduce patho-
4 gens, have been satisfied.

5 (2) CATEGORY 2 FOOD ESTABLISHMENTS.—A
6 category 2 food establishment shall—

7 (A) have ongoing verification that its proc-
8 esses are controlled; and

9 (B) be randomly inspected at least weekly.

10 (3) CATEGORY 3 FOOD ESTABLISHMENTS.—A
11 category 3 food establishment shall—

12 (A) have ongoing verification that its proc-
13 esses are controlled; and

14 (B) be randomly inspected at least month-
15 ly.

16 (4) CATEGORY 4 FOOD ESTABLISHMENTS.—A
17 category 4 food establishment shall—

18 (A) have ongoing verification that its proc-
19 esses are controlled; and

20 (B) be randomly inspected at least quar-
21 terly.

22 (5) CATEGORY 5 FOOD ESTABLISHMENTS.—A
23 category 5 food establishment shall—

24 (A) have ongoing verification that its proc-
25 esses are controlled; and

1 (B) be randomly inspected at least annu-
2 ally.

3 (c) ESTABLISHMENT OF INSPECTION PROCE-
4 DURES.—The Administrator shall establish procedures
5 under which inspectors shall take random samples, photo-
6 graphs, and copies of records in food establishments.

7 (d) ALTERNATIVE INSPECTION FREQUENCIES.—
8 With respect to a subcategory of food establishment under
9 category 2, 3, 4, or 5, the Administrator may establish
10 alternative increasing or decreasing inspection frequencies
11 for subcategories of food establishments or individual es-
12 tablishments, to foster risk-based allocation of resources.
13 Before establishing an alternative inspection frequency for
14 a subcategory of food establishments or individual estab-
15 lishments, the Administrator shall take into consideration
16 the evidence described in paragraph (2)(D) and the overall
17 record of compliance described in paragraph (2)(E) for
18 such subcategory. In establishing alternative inspection
19 frequencies under this subsection, the Administrator shall
20 comply with the following criteria and procedures:

21 (1) Subcategories of food establishments and
22 their alternative inspection frequencies shall be de-
23 fined by regulation, subject to paragraphs (2) and
24 (3).

1 (2) In defining subcategories of food establish-
2 ments and their alternative inspection frequencies
3 under paragraphs (1) and (2), the Administrator
4 shall consider—

5 (A) the nature of the food products being
6 processed, stored, or transported;

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

9 (C) the inherent likelihood that the prod-
10 ucts will contribute to the risk of food-borne ill-
11 ness;

12 (D) the best available evidence concerning
13 reported illnesses associated with the foods
14 processed, stored, held, or transported in the
15 proposed subcategory of establishments; and

16 (E) the overall record of compliance with
17 food safety law among establishments in the
18 proposed subcategory, including compliance
19 with applicable performance standards and the
20 frequency of recalls.

21 (3) The Administrator may adopt alternative
22 inspection frequencies for increased or decreased in-
23 spection for a specific establishment and shall annu-
24 ally publish a list of establishments subject to alter-
25 native inspections.

1 (4) In adopting alternative inspection fre-
2 quencies for a specific establishment, the Adminis-
3 trator shall consider—

4 (A) the criteria in paragraph (2), together
5 with any evidence submitted from the individual
6 food establishment supporting a request for an
7 alternative inspection frequency, including the
8 establishment's record for implementing effec-
9 tive preventive process control systems;

10 (B) whether products from the specific es-
11 tablishment have been associated with a case or
12 an outbreak of food-borne illness; and

13 (C) the establishment's record of compli-
14 ance with food safety law, including compliance
15 with applicable performance standards and the
16 frequency of recalls.

17 (e) EFFECTIVE DATE.—The inspection mandates
18 shall go into effect 2 years after the date of the enactment
19 of this Act.

20 (f) MAINTENANCE AND INSPECTION OF RECORDS.—

21 (1) IN GENERAL.—

22 (A) RECORDS.—A food establishment
23 shall—

24 (i) maintain such records as the Ad-
25 ministrators shall require by regulation, in-

1 including all records relating to the proc-
2 essing, distributing, receipt, or importation
3 of any food; and

4 (ii) permit the Administrator, in addi-
5 tion to any authority transferred to the
6 Administrator pursuant to section 102,
7 upon presentation of appropriate creden-
8 tials and at reasonable times and in a rea-
9 sonable manner, to have access to and
10 copy all records maintained by or on behalf
11 of such food establishment representative
12 in any format (including paper or elec-
13 tronic) and at any location, that are nec-
14 essary to assist the Administrator—

15 (I) to determine whether the food
16 is contaminated or not in compliance
17 with the food safety law; or

18 (II) to track the food in com-
19 merce.

20 (B) REQUIRED DISCLOSURE.—A food es-
21 tablishment shall have an affirmative obligation
22 to disclose to the Administrator the results of
23 testing or sampling of food, equipment, or ma-
24 terial in contact with food, that is positive for
25 any contaminant.

1 (2) MAINTENANCE OF RECORDS.—The records
2 in paragraph (1) shall be maintained for a reason-
3 able period of time, as determined by the Adminis-
4 trator.

5 (3) REQUIREMENTS.—The records in para-
6 graph (1) shall include records describing—

7 (A) the origin, receipt, delivery, sale, move-
8 ment, holding, and disposition of food or ingre-
9 dients;

10 (B) the identity and quantity of ingredi-
11 ents used in the food;

12 (C) the processing of the food;

13 (D) the results of laboratory, sanitation, or
14 other tests performed on the food or in the food
15 establishment;

16 (E) consumer complaints concerning the
17 food or packaging of the food;

18 (F) the production codes, open date codes,
19 and locations of food production; and

20 (G) other matters reasonably related to
21 whether food is adulterated or misbranded, or
22 otherwise fails to meet the requirements of this
23 Act.

24 (g) PROTECTION OF SENSITIVE INFORMATION.—

1 (1) IN GENERAL.—The Administrator shall de-
2 velop and maintain procedures to prevent the unau-
3 thorized disclosure of any trade secret or commer-
4 cially valuable confidential information obtained by
5 the Administrator.

6 (2) LIMITATION.—The requirements under this
7 subsection and subsection (f) do not—

8 (A) limit the authority of the Adminis-
9 trator to inspect or copy records or to require
10 the establishment or maintenance of records
11 under this Act;

12 (B) have any legal effect on section 1905
13 of title 18, United States Code;

14 (C) extend to any food recipe, financial
15 data, pricing data, or personnel data;

16 (D) limit the public disclosure of distribu-
17 tion records or other records related to food
18 subject to a voluntary or mandatory recall
19 under section 403; or

20 (E) limit the authority of the Adminis-
21 trator to promulgate regulations to permit the
22 sharing of data with other governmental au-
23 thorities.

24 (h) BRIBERY OF OR GIFTS TO INSPECTOR OR OTHER
25 OFFICERS AND ACCEPTANCE OF GIFTS.—Any person or

1 agent or employee thereof that gives, pays, or offers, di-
2 rectly or indirectly, to the Administrator or any employee
3 or other designee thereof authorized to perform any duty
4 under the food safety law any money or other thing of
5 value, with intent to influence the discharge of any duty
6 under such law, shall be imprisoned for not more than 5
7 years, fined in accordance with title 18, United States
8 Code, or both. Any Administrator, employee, or other des-
9 ignee that solicits or accepts any money or other thing
10 of value from any person, with intent to influence the dis-
11 charge of any duty under the food safety law, shall be
12 summarily discharged from office and imprisoned for not
13 more than 5 years, fined in accordance with title 18,
14 United States Code, or both.

15 **SEC. 206. FOOD PRODUCTION FACILITIES.**

16 (a) **AUTHORITIES.**—In carrying out the duties of the
17 Administrator and the purposes of this Act, the Adminis-
18 trator shall have the authority, with respect to food pro-
19 duction facilities, to—

20 (1) visit and inspect food production facilities in
21 the United States and in foreign countries to deter-
22 mine if they are operating in compliance with the re-
23 quirements of the food safety law;

1 (2) review food safety records as required to be
2 kept by the Administrator under section 210 and for
3 other food safety purposes;

4 (3) set good practice standards to protect the
5 public and animal health and promote food safety;

6 (4) conduct monitoring and surveillance of ani-
7 mals, plants, products, or the environment, as ap-
8 propriate; and

9 (5) collect and maintain information relevant to
10 public health and farm practices.

11 (b) INSPECTION OF RECORDS.—A food production
12 facility shall permit the Administrator upon presentation
13 of appropriate credentials and at reasonable times and in
14 a reasonable manner, to have access to and ability to copy
15 all records maintained by or on behalf of such food pro-
16 duction establishment in any format (including paper or
17 electronic) and at any location, that are necessary to assist
18 the Administrator—

19 (1) to determine whether the food is contami-
20 nated, adulterated, or otherwise not in compliance
21 with the food safety law; or

22 (2) to track the food in commerce.

23 (c) REGULATIONS.—Not later than 1 year after the
24 date of the enactment of this Act, the Administrator, in
25 consultation with the Secretary of Agriculture and rep-

1 representatives of State departments of agriculture, shall pro-
2 mulgate regulations to establish science-based minimum
3 standards for the safe production of food by food produc-
4 tion facilities. Such regulations shall—

5 (1) consider all relevant hazards, including
6 those occurring naturally, and those that may be un-
7 intentionally or intentionally introduced;

8 (2) require each food production facility to have
9 a written food safety plan that describes the likely
10 hazards and preventive controls implemented to ad-
11 dress those hazards;

12 (3) include, with respect to growing, harvesting,
13 sorting, and storage operations, minimum standards
14 related to fertilizer use, nutrients, hygiene, pack-
15 aging, temperature controls, animal encroachment,
16 and water;

17 (4) include, with respect to animals raised for
18 food, minimum standards related to the animal's
19 health, feed, and environment which bear on the
20 safety of food for human consumption;

21 (5) provide a reasonable period of time for com-
22 pliance, taking into account the needs of small busi-
23 nesses for additional time to comply;

24 (6) provide for coordination of education and
25 enforcement activities by State and local officials, as

1 designated by the Governors of the respective States;
2 and

3 (7) include a description of the variance process
4 under subsection (d) and the types of permissible
5 variances which the Administrator may grant under
6 such process.

7 (d) VARIANCES.—States and foreign countries that
8 export produce intended for consumption in the United
9 States may request from the Administrator variances from
10 the requirements of the regulations under subsection (c).

11 A request shall—

12 (1) be in writing;

13 (2) describe the reasons the variance is nec-
14 essary;

15 (3) describe the procedures, processes, and
16 practices that will be followed under the variance to
17 ensure produce is not adulterated; and

18 (4) contain any other information required by
19 the Administrator.

20 (e) APPROVAL OR DISAPPROVAL OF VARIANCES.—If
21 the Administrator determines after review of a request
22 under subsection (d) that the requested variance provides
23 equivalent protections to those promulgated under sub-
24 section (c), the Administrator may approve the request.
25 The Administrator shall deny a request if it is—

1 (1) not sufficiently detailed to permit a deter-
2 mination;

3 (2) fails to cite sufficient grounds for allowing
4 a variance; or

5 (3) does not provide reasonable assurances that
6 the produce will not be adulterated.

7 (f) ENFORCEMENT.—The Administrator may coordi-
8 nate with the agency or department designated by the
9 Governor of each State to perform activities to ensure
10 compliance with this section.

11 (g) IMPORTED PRODUCE.—Not later than 1 year
12 after the date of the enactment of this Act, the Adminis-
13 trator shall promulgate regulations to ensure that raw ag-
14 ricultural commodities and minimally processed produce
15 imported into the United States can meet standards for
16 food safety, inspection, labeling, and consumer protection
17 that are at least equal to standards applicable to such
18 commodities and produce produced in the United States.

19 **SEC. 207. FEDERAL AND STATE COOPERATION.**

20 (a) IN GENERAL.—

21 (1) AUTHORITY.—The Administrator shall
22 strengthen and expand food-borne illness surveil-
23 lance systems to—

24 (A) inform and evaluate efforts to prevent
25 food-borne illness; and

1 (B) enhance the identification and inves-
2 tigation of, and response to, food-borne illness
3 outbreaks.

4 (2) FOOD-BORNE ILLNESS OUTBREAK.—For
5 purposes of this section, the term “foodborne illness
6 outbreak” means the occurrence of 2 or more cases
7 of a similar illness resulting from the ingestion of a
8 common food.

9 (b) FOOD-BORNE ILLNESS SURVEILLANCE SYS-
10 TEMS.—The Administrator, in collaboration with the Cen-
11 ters for Disease Control and Prevention, shall enhance
12 food-borne illness surveillance systems to improve the col-
13 lection, analysis, reporting, and usefulness of data on food-
14 borne illnesses by—

15 (1) coordinating food-borne illness surveillance
16 systems, including complaint systems, in order to—

17 (A) produce better information on illnesses
18 associated with foods, including sources and
19 risk factors for infections by emerging patho-
20 gens; and

21 (B) facilitate sharing of data acquisition
22 and findings on a more timely basis among gov-
23 ernmental agencies, including the Food Safety
24 Administration, the Food Safety and Inspection

1 Service, and State and local agencies, and with
2 the public;

3 (2) augmenting such systems to improve attri-
4 bution of a food-borne illness outbreak to a specific
5 food;

6 (3) developing improved epidemiological tools
7 for obtaining quality exposure data, microbiological
8 methods for classifying cases and detecting clusters,
9 and improved tracebacks to rapidly and specifically
10 identify contaminated food products;

11 (4) expanding capacity of such systems for im-
12 plementation of fingerprinting strategies for food-
13 borne infectious agents, including parasites and hep-
14 atitis A, in order to increase pathogen discovery ef-
15 forts to identify new or rarely documented causes of
16 food-borne illness;

17 (5) allowing timely public access to de-identi-
18 fied, aggregate surveillance data;

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

21 (7) exploring establishment of registries for
22 long-term case follow-up to better characterize late
23 complications of food-borne illness;

1 (8) increasing participation in national net-
2 works of public health and food regulatory agencies
3 and laboratories to—

4 (A) allow public health officials at the Fed-
5 eral, State, and local levels to share and accept
6 laboratory analytic findings; and

7 (B) identify food-borne illness outbreaks
8 and attribute such outbreaks to specific foods
9 through submission of standardized molecular
10 subtypes (also known as “fingerprints”) of
11 food-borne illness pathogens to a centralized
12 database; and

13 (9) establishing a flexible mechanism for rapidly
14 supporting scientific research by academic centers of
15 excellence, which may include staff representing aca-
16 demic clinical researchers, food microbiologists, ani-
17 mal and plant disease specialists, ecologists, and
18 other allied disciplines.

19 (c) IMPROVING STATE SURVEILLANCE CAPACITY.—

20 The Administrator, in collaboration with the Director of
21 the Centers for Disease Control and Prevention, shall im-
22 prove capacity for surveillance in the States by—

23 (1) supporting outbreak investigations with
24 needed specialty expertise, including epidemiological,
25 microbiological, and environmental expertise, to as-

1 sist identification of underlying common sources and
2 contributing factors;

3 (2) identifying, disseminating, and supporting
4 implementation of model practices at the State and
5 local level for—

6 (A) facilitating rapid shipment of clinical
7 isolates from clinical laboratories to State pub-
8 lic health laboratories to avoid delays in testing;

9 (B) conducting rapid and more standard-
10 ized interviewing of cases associated with major
11 enteric pathogens, including prior to designa-
12 tion of clusters as food-borne illness outbreaks;

13 (C) conducting and evaluating rapid and
14 standardized interviews of healthy control per-
15 sons;

16 (D) sharing information on a timely
17 basis—

18 (i) within public health and food regu-
19 latory agencies;

20 (ii) among such agencies;

21 (iii) with the food industry;

22 (iv) with healthcare providers; and

23 (v) with the public;

24 (3) developing, regularly updating, and dissemi-
25 nating training curricula on food-borne illness sur-

1 veillance investigations, including standard sampling
2 methods and laboratory procedures;

3 (4) integrating new molecular diagnostic tools
4 for parasites into web-based consultation services for
5 parasitic infections to accelerate the identification of
6 these food-borne infectious agents;

7 (5) supporting research to develop and deploy
8 new subtyping methods for salmonella, E. coli,
9 campylobacter, and other pathogens, to increase the
10 speed and accuracy of diagnoses;

11 (6) determining minimum core competencies for
12 public health laboratories, and developing self-eval-
13 uation and proficiency-testing tools for such labora-
14 tories;

15 (7) facilitating regional public health laboratory
16 partnerships to leverage resources, including equip-
17 ment and physical space, and increase surge capac-
18 ity;

19 (8) providing technical assistance, which may
20 include the detailing of officers and employees of the
21 Administrator, to State and local public health and
22 food regulatory agencies;

23 (9) partnering with the Food Safety Adminis-
24 tration to increase communication, coordination, and

1 integration of food-borne illness surveillance and
2 outbreak investigation activities; and

3 (10) developing and periodically updating re-
4 sponse and interview procedures so that such proce-
5 dures are standardized and tested.

6 (d) PROGRAM ACTIVITIES.—The Administrator shall
7 carry out activities to support core food safety functions
8 of State and local public health laboratories, including—

9 (1) establishing fellowships, stipends, and schol-
10 arships to address critical workforce shortages;

11 (2) training and coordination of State and local
12 personnel;

13 (3) establishing partnerships between private
14 and public laboratories to facilitate sharing of posi-
15 tive enteric specimens and improve surge capacity;

16 (4) strengthening capacity to participate in ex-
17 isting or new food-borne illness surveillance systems;
18 and

19 (5) purchasing and maintaining data systems
20 hardware and software and laboratory equipment.

21 (e) PLAN TO IMPROVE FOOD SAFETY CAPACITY AT
22 THE STATE AND LOCAL LEVEL.—

23 (1) GOALS.—The Administrator shall leverage
24 and enhance the food safety capacity and roles of
25 State and local agencies and integrate State and

1 local agencies as fully as possible into national food
2 safety efforts, in order to achieve the following goals:

3 (A) Improve food-borne illness outbreak re-
4 sponse and containment.

5 (B) Improve the contribution of food-borne
6 illness surveillance and investigation to the pre-
7 vention of food-borne illness.

8 (C) Strengthen oversight of food safety at
9 the retail level.

10 (D) Strengthen the capacity of State and
11 local agencies to carry out inspections and en-
12 force safety standards in food processing estab-
13 lishments, as part of a national strategy and
14 plan to provide an adequate level of inspection
15 and achieve compliance with safety standards in
16 such establishments.

17 (E) Make more effective use of the Na-
18 tion's combined food safety resources to reduce
19 the burden of food-borne illness.

20 (2) SURVEY.—In preparation for development
21 of the plan required by paragraph (3), the Adminis-
22 trator shall, not later than 1 year after the date of
23 enactment of this part, complete a survey of State
24 and local capacities, and needs for enhancement,
25 with respect to—

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

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

6 (C) information systems to support data
7 management and sharing of food safety infor-
8 mation among State and local agencies and
9 with counterparts at the Federal level;

10 (D) legal authorities of State and local
11 agencies to support the roles of such agencies
12 in a national food safety system; and

13 (E) organizational arrangements for man-
14 aging and coordinating food safety activities.

15 (3) PLAN.—Taking into account the goals es-
16 tablished in paragraph (1), results from the survey
17 required in paragraph (2), and consultations with
18 State and local agencies and other food safety stake-
19 holders, the Administrator shall, not later than 2
20 years after the date of enactment of this part, de-
21 velop, publish, and begin implementation of a plan
22 that includes the following elements:

23 (A) Criteria for assessing the adequacy of
24 State and local capacity to perform food safety

1 functions as part of a national food safety sys-
2 tem.

3 (B) Priorities for enhancing the capacity of
4 State and local agencies.

5 (C) Action plans for meeting the highest
6 priority capacity needs, including budget re-
7 quirements and financing plans that take into
8 account Federal, State, and local resources.

9 (D) Improved coordination and informa-
10 tion flow among Federal, State, and local agen-
11 cies to strengthen food-borne illness surveil-
12 lance, outbreak response, and investigation and
13 to ensure that agencies at all levels have the in-
14 formation on origins and causes of food-borne
15 illness that such agencies need to plan preven-
16 tive measures.

17 (E) Integration of the inspection and com-
18 pliance programs in food processing establish-
19 ments of the Food Safety Administration and
20 State and local agencies, including—

21 (i) joint planning and priority setting
22 to ensure that the collective effort has the
23 greatest possible impact on achieving com-
24 pliance with food safety standards and re-
25 ducing food-borne illness;

1 (ii) elimination of barriers to the free
2 flow of information among the Food Safety
3 Administration and State and local agen-
4 cies with respect to inspection and compli-
5 ance programs and integration of State
6 and Federal inspection and laboratory data
7 systems;

8 (iii) steps to expand, and ensure the
9 vigor and consistency of, State inspection
10 of processing establishments under con-
11 tract to the Food Safety Administration;
12 and

13 (iv) reliance by the Food Safety Ad-
14 ministration on State inspection and food
15 sample analyses in Federal enforcement
16 activities.

17 (4) FOOD SAFETY CAPACITY BUILDING
18 GRANTS.—The Administrator shall make grants to
19 State and local agencies to enhance State and local
20 food safety capacity and programs and support
21 achievement of the goals established in paragraph
22 (1). In awarding such grants, the Administrator
23 shall take into account the criteria and priorities es-
24 tablished by the Administrator under paragraph (3).

1 (5) REPORT TO CONGRESS.—Not later than 1
2 year after the date of enactment of this part, and
3 on an annual basis thereafter, the Administrator
4 shall submit to Congress a report that describes—

5 (A) progress made in implementing this
6 section, including any obstacles to such imple-
7 mentation; and

8 (B) any legislative recommendations or ad-
9 ditional resources needed for full implementa-
10 tion.

11 (f) SERVICE AGREEMENTS.—

12 (1) IN GENERAL.—The Administrator may,
13 under agreements entered into with Federal, State,
14 or local agencies, use on a reimbursable basis or oth-
15 erwise the qualified personnel and services of those
16 agencies in carrying out this Act.

17 (2) TRAINING.—Agreements with a State under
18 this subsection shall provide for training of State
19 employees.

20 (3) MAINTENANCE OF AGREEMENTS.—The Ad-
21 ministrator shall maintain any agreement described
22 in paragraph (1) that is in effect on the day before
23 the date of the enactment of this Act until the Ad-
24 ministrator evaluates such agreement and deter-

1 mines whether to maintain or substitute such agree-
2 ment.

3 (4) COMMISSIONING.—Where necessary and ap-
4 propriate to fulfill the provisions of this Act or other
5 food safety law, the Administrator shall, as part of
6 any service agreement, commission qualified State
7 and local regulatory officials and inspectors to assist
8 the Administrator in carrying out the food safety
9 law and accord such commissioned officials and in-
10 spectors access to information in possession of the
11 Administrator as if they were Federal employees.

12 **SEC. 208. IMPORTS.**

13 (a) IN GENERAL.—All imported food under this Act
14 shall meet requirements for food safety, inspection, label-
15 ing, and consumer protection that are at least equal to
16 those applicable to food grown, manufactured, processed,
17 packed, or held for consumption in the United States.

18 (b) CERTIFICATION SYSTEM.—Not later than 2 years
19 after the date of the enactment of this Act, the Adminis-
20 trator shall establish a system under which food products
21 offered for importation into the United States shall be cer-
22 tified by the accredited foreign government in the country
23 of export or by an accredited certifying agent meeting all
24 applicable standards under this section.

1 (1) Category 1, 2, and 3 food establishments
2 shall secure certification of products from the ac-
3 credited foreign government in the country where
4 the products are produced and must enter the
5 United States through ports designated by the Ad-
6 ministrator.

7 (2) Category 4 and 5 food establishments shall
8 be certified either by—

9 (A) the accredited foreign government in
10 the country where the products are produced;
11 or

12 (B) a certifying agent that has been ac-
13 credited under subsection (c).

14 (3) Beginning not later than 5 years after the
15 date of the enactment of this Act, food from cat-
16 egory 4 and 5 food establishments that is not cer-
17 tified by an accredited entity described in subsection
18 (c) shall not enter the United States except through
19 ports of entry that are located in a metropolitan
20 area with an accredited food testing laboratory.

21 (c) CERTIFICATION STANDARD.—

22 (1) IN GENERAL.—A foreign government or
23 third party agent requesting accreditation to certify
24 food for entry into the United States shall dem-
25 onstrate, in a manner determined appropriate by the

1 Administrator, that food produced under the super-
2 vision of the foreign government or third party
3 agent, respectively, can meet standards for food
4 safety, inspection, labeling, and consumer protection
5 that are at least equal to standards applicable to
6 food produced in the United States.

7 (2) REQUEST BY FOREIGN GOVERNMENT.—

8 Prior to accrediting a foreign government, the Ad-
9 ministrator shall—

10 (A) review and audit the food safety pro-
11 gram of the requesting foreign government (in-
12 cluding all statutes, regulations, and inspection
13 authority); and

14 (B) determine that the exporting coun-
15 try—

16 (i) administers a food control program
17 that requires food exporters to implement
18 hazard control measures for physical,
19 chemical, and biological contaminants;

20 (ii) ensures sanitary operations of fa-
21 cilities;

22 (iii) utilizes testing and verification
23 programs; and

24 (iv) administers an effective enforce-
25 ment program.

1 (3) REQUEST BY A CERTIFYING AGENT.—Prior
2 to accrediting a certifying agent, the Administrator
3 shall—

4 (A) review the training and qualifications
5 of auditors and other employees used by the
6 agent;

7 (B) ensure that any such auditors have
8 completed such training as may be required by
9 the Administrator for the conduct of food safety
10 inspections; and

11 (C) conduct reviews of internal systems
12 and such other investigation as the Adminis-
13 trator deems necessary to determine that the
14 certifying agent is capable of auditing food es-
15 tablishments—

16 (i) to assess the adequacy of systems
17 and standards in use; and

18 (ii) to ensure that food approved by
19 the agent for import to the United States
20 meets the requirements of this Act.

21 (4) CERTIFICATION TO ACCOMPANY EACH SHIP-
22 MENT.—As a condition of accrediting any foreign
23 government or certifying agent, such government or
24 agent shall agree to issue a written and electronic
25 certification to accompany each shipment intended

1 for import to the United States from any food estab-
2 lishment which the government or agent certifies,
3 subject to requirements set forth by the Adminis-
4 trator.

5 (d) AUDITS; INSPECTIONS.—Following any accredita-
6 tion under subsection (c), the Administrator may at any
7 time—

8 (1) conduct an on-site audit of any food estab-
9 lishment registered under section 202, with or with-
10 out the certifying agent; or

11 (2) require a certifying agent to submit an on-
12 site audit report and any other reports or documents
13 which the agent requires as part of the audit proc-
14 ess, including documentation that the food establish-
15 ment is in compliance with registration requirements
16 and prior notice requirements for food imported to
17 the United States.

18 (e) LIMITATION.—A foreign government or other cer-
19 tifying agent accredited by the Administrator to certify
20 food for import to the United States under this section
21 may certify only the food products or food categories for
22 importation to the United States that are specified in the
23 grant of accreditation.

1 (f) WITHDRAWAL OF ACCREDITATION.—The Admin-
2 istrator may withdraw accreditation from a foreign gov-
3 ernment or certifying agent—

4 (1) if food approved by the foreign government
5 or certifying agent is linked to an outbreak of
6 human illness;

7 (2) following an investigation and finding by
8 the Administrator that the programs of the foreign
9 government, or a foreign food establishment certified
10 by the certifying agent, are no longer equal to those
11 applied to food grown, manufactured, processed,
12 packed, or held in the United States; or

13 (3) following a refusal to allow United States
14 officials to conduct such audits and investigations as
15 may be necessary to ensure continued compliance
16 with the requirements of this section.

17 (g) RENEWAL OF ACCREDITATION.—The Adminis-
18 trator shall audit foreign governments and certifying
19 agents whenever needed, but no less than once every 3
20 years, to ensure the continued compliance with the re-
21 quirements set forth in this section. Renewal of accredita-
22 tion shall occur following each satisfactory audit.

23 (h) REQUIRED ROUTINE INSPECTION.—The Admin-
24 istrator shall routinely inspect food before or at entry into
25 the United States to ensure ongoing compliance with food

1 safety law and where appropriate, as part of the audit of
2 any certifying entity.

3 (i) ENFORCEMENT.—The Administrator may—

4 (1) deny importation of food from any foreign
5 country if the government of such country does not
6 permit United States officials to enter the foreign
7 country to conduct such audits and inspections as
8 may be necessary to fulfill requirements under this
9 section;

10 (2) deny importation of food from any foreign
11 country or foreign food establishment that does not
12 consent to a timely investigation by the Administra-
13 tion when food from that foreign country or foreign
14 food establishment is linked to a food-borne illness
15 outbreak or is otherwise found to be adulterated or
16 misbranded;

17 (3) promulgate regulations to carry out the pur-
18 poses of this section, including setting terms and
19 conditions for the destruction of products that fail to
20 meet the requirements of this Act; and

21 (4) establish such fees as are necessary to carry
22 out the implementation of the accreditation and in-
23 spection programs required under this section.

24 (j) DETENTION AND SEIZURE.—Any food imported
25 for consumption in the United States may be detained,

1 seized, or condemned pursuant to section 402 or recalled
2 pursuant to section 403.

3 (k) CERTIFYING AGENTS.—Entities eligible for ac-
4 creditation as a certifying agent under subsection (c) may
5 include—

6 (1) a State or regional food authority; or

7 (2) a foreign or domestic cooperative that ag-
8 gregates the products of growers or processors for
9 importation.

10 (l) AVOIDING CONFLICTS OF INTEREST WITH CERTI-
11 FYING AGENTS.—

12 (1) IN GENERAL.—To be eligible for accredita-
13 tion under subsection (c), a certifying agent shall—

14 (A) not be owned, managed, or controlled
15 by any person that owns or operates an estab-
16 lishment whose products are to be certified by
17 such agent;

18 (B) have procedures to ensure against the
19 use, in carrying out audits of food establish-
20 ments under this section, of any officer or em-
21 ployee of such agent that has a financial con-
22 flict of interest regarding an establishment
23 whose products are to be certified by such
24 agent; and

1 (C) annually make available to the Sec-
2 retary, disclosures of the extent to which such
3 agent, and the officers and employees of such
4 agent, have maintained compliance with sub-
5 paragraphs (A) and (B) relating to financial
6 conflicts of interest.

7 (2) REGULATIONS.—The Secretary shall pro-
8 mulgate regulations not later than 18 months after
9 the date of the enactment of this Act to ensure that
10 there are protections against conflicts of interest be-
11 tween a certifying agent and the establishments
12 whose products are to be certified by such agent.
13 Such regulations shall include—

14 (A) requiring that domestic audits per-
15 formed under this section be unannounced;

16 (B) a structure, including timing and pub-
17 lic disclosure, for fees paid by food establish-
18 ments to certifying agents to decrease the po-
19 tential for conflicts of interest; and

20 (C) appropriate limits on financial affili-
21 ations between a certifying agent and any per-
22 son that owns or operates an establishment
23 whose products are to be certified by such
24 agent.

1 **SEC. 209. RESOURCE PLAN.**

2 (a) IN GENERAL.—The Administrator shall prepare
3 and update annually a resource plan describing the re-
4 sources required, in the best professional judgment of the
5 Administrator, to develop and fully implement the national
6 food safety program established under this Act.

7 (b) CONTENTS OF PLAN.—The resource plan shall—

8 (1) describe quantitatively the personnel, finan-
9 cial, and other resources required to carry out the
10 inspection of food establishments under section 205
11 and other requirements of this Act;

12 (2) allocate inspection resources in a manner
13 reflecting the distribution of risk and opportunities
14 to reduce risk across the food supply to the extent
15 feasible based on the best available information, and
16 subject to section 205; and

17 (3) describe the personnel, facilities, equipment,
18 and other resources needed to carry out inspection
19 and other oversight activities, at a total resource
20 level equal to at least 50 percent of the resources re-
21 quired to carry out inspections in food establish-
22 ments under section 205 and food production facili-
23 ties under section 206—

24 (A) in foreign establishments and produc-
25 tion facilities; and

26 (B) at the point of importation.

1 (c) GRANTS.—The resource plan shall include rec-
2 ommendations for funding to provide grants to States and
3 local governments to carry out food safety activities and
4 inspections of food establishments and food production fa-
5 cilities and include resources to audit such programs.

6 (d) SUBMISSION OF PLAN.—The Administrator shall
7 submit annually to the Committee on Appropriations of
8 the Senate, the Committee on Appropriations of the House
9 of Representatives, and other relevant committees of Con-
10 gress, the resource plan required under this section.

11 **SEC. 210. TRACEBACK REQUIREMENTS.**

12 (a) IN GENERAL.—The Administrator, in order to
13 protect the public health, shall establish a national
14 traceability system that enables the Administrator to re-
15 trieve the history, use, and location of an article of food
16 through all stages of its production, processing, and dis-
17 tribution.

18 (b) APPLICABILITY.—Traceability requirements
19 under this section shall apply to food from food production
20 facilities, food establishments, and foreign food establish-
21 ments.

22 (c) REQUIREMENTS.—

23 (1) STANDARDS.—The Administrator shall es-
24 tablish standards for the type of information, for-
25 mat, and timeframe for food production facilities

1 and food establishments to submit records to aid the
2 Administrator in effectively retrieving the history,
3 use, and location of an item of food.

4 (2) RULE OF CONSTRUCTION.—Nothing in this
5 section shall be construed as requiring the Adminis-
6 trator to prescribe a specific technology for the
7 maintenance of records or labeling of food to carry
8 out the requirements of this section.

9 (3) AVAILABILITY OF RECORDS FOR INSPEC-
10 TION.—Any records that are required by the Admin-
11 istrator under this section shall be available for in-
12 spection by the Administrator upon oral or written
13 request.

14 (4) DEMONSTRATION OF ABILITY.—The Ad-
15 ministrator, during any inspection, may require a
16 food establishment to demonstrate its ability to trace
17 an item of food and submit the information in the
18 format and timeframe required under paragraph (1).

19 (d) RELATIONSHIP TO OTHER REQUIREMENTS.—

20 (1) CONSISTENCY WITH EXISTING STATUTES
21 AND REGULATIONS.—To the extent possible, the Ad-
22 ministrator should establish the national traceability
23 system under this section to be consistent with exist-
24 ing statutes and regulations that require record-

1 keeping or labeling for identifying the origin or his-
2 tory of food or food animals.

3 (2) EXISTING LAWS.—For purposes of this sub-
4 section, the Administrator should review the fol-
5 lowing:

6 (A) Country of origin labeling require-
7 ments of subtitle D of the Agricultural Mar-
8 keting Act of 1946 (7 U.S.C. 1638 et seq.).

9 (B) The Perishable Agricultural Commod-
10 ities Act of 1930 (7 U.S.C. 499a–t).

11 (C) Country of origin labeling require-
12 ments of section 304 of the Tariff Act of 1930
13 (19 U.S.C. § 1340).

14 (D) The National Animal Identification
15 System as authorized by the Animal Health
16 Protection Act of 2002 (7 U.S.C. 8301 et seq.).

17 (3) CERTAIN REQUIREMENTS.—Nothing con-
18 tained in this section prevents or interferes with im-
19 plementation of the country of origin labeling re-
20 quirements of subtitle D of the Agricultural Mar-
21 keting Act of 1946 (7 U.S.C. 1638 et seq.).

22 **SEC. 211. ACCREDITED LABORATORIES.**

23 (a) ESTABLISHMENT OF PROGRAM.—The Adminis-
24 trator shall establish a program for accrediting labora-

1 tories to perform sampling and testing for purposes of this
2 Act. Such program shall include—

3 (1) standards for appropriate sampling and an-
4 alytical procedures;

5 (2) training and experience qualification levels
6 for individuals who conduct sampling and analysis;

7 (3) annual onsite visits to audit the perform-
8 ance of an accredited laboratory; and

9 (4) such additional requirements as the Admin-
10 istrator determines to be appropriate.

11 (b) REQUIREMENTS.—To be accredited under this
12 section, a laboratory shall—

13 (1) prepare and submit an application for ac-
14 creditation to the Administrator;

15 (2) meet required tests and standards estab-
16 lished by the Administrator; and

17 (3) comply with such terms and conditions as
18 are determined necessary by the Administrator.

19 (c) ACCREDITING BODIES.—The Administrator may
20 approve State agencies or private, nonprofit entities as ac-
21 crediting bodies to act on behalf of the Administrator in
22 accrediting laboratories under this section. The Adminis-
23 trator shall—

24 (1) in making such approvals—

1 (A) oversee and review the performance of
2 any accrediting body acting on behalf of the
3 Administrator to ensure that such accrediting
4 body is in compliance with the requirements of
5 this section; and

6 (B) have the right to obtain from an ac-
7 crediting body acting on behalf of the Adminis-
8 trator and from any laboratory that may be cer-
9 tified by such a body all records and materials
10 that may be necessary for the oversight and re-
11 view required by subparagraph (A);

12 (2) reevaluate accreditation bodies approved
13 under paragraph (1) whenever—

14 (A) the Administrator determines a labora-
15 tory accredited by the accrediting body is no
16 longer in compliance with this section;

17 (B) the Administrator determines the ac-
18 crediting body is no longer in compliance with
19 the requirements of this section; or

20 (C) no less than once every 5 years; and

21 (3) promptly revoke the approval of any accred-
22 itation body found not to be in compliance with the
23 requirements of this section.

1 (d) REVOCATION OF ACCREDITATION.—The Admin-
2 istrator shall revoke the accreditation of any laboratory
3 that fails to meet the requirements this section.

4 **TITLE III—RESEARCH AND**
5 **EDUCATION**

6 **SEC. 301. PUBLIC HEALTH ASSESSMENT SYSTEM.**

7 (a) IN GENERAL.—The Administrator, acting in co-
8 ordination with the Director of the Centers for Disease
9 Control and Prevention and with food safety and research
10 programs of the Department of Agriculture, shall—

11 (1) identify on an ongoing basis the priorities
12 for collection of epidemiological data and for other
13 food safety research and data collection that are
14 most important to implementing the food safety law
15 and reducing the public health burden of food-borne
16 illness;

17 (2) have full access for purposes of imple-
18 menting the food safety law to the applicable data
19 and data systems of the Centers for Disease Control
20 and Prevention, including data made available to the
21 Centers by a State;

22 (3) provide appropriate support and input on
23 the design and implementation by the Centers for
24 Disease Control and Prevention and the States of an
25 active surveillance system that provides information

1 on the incidence and causes of food-borne illness
2 which is timely, detailed, and representative of the
3 population of the United States;

4 (4) based on data and information obtained
5 from the Centers for Disease Control and Preven-
6 tion, the States, and other sources, assess the inci-
7 dence, distribution, public health impact, and causes
8 of human illness in the United States associated
9 with the consumption of food, and conduct research
10 and analysis to devise effective and feasible interven-
11 tions to reduce food-borne illness;

12 (5) maintain a state-of-the-art DNA matching
13 system and epidemiological system dedicated to food-
14 borne illness identification, outbreaks, and contain-
15 ment; and

16 (6) utilize surveillance data created by means of
17 monitoring and statistical studies conducted as part
18 of its own inspection.

19 (b) PUBLIC HEALTH SAMPLING.—

20 (1) IN GENERAL.—Not later than 1 year after
21 the enactment of this Act, the Administrator shall
22 establish guidelines for a sampling system under
23 which the Administrator shall take and analyze sam-
24 ples of food—

1 (A) to assist the Administrator in carrying
2 out this Act; and

3 (B) to assess the nature, frequency of oc-
4 currence, and quantities of contaminants in
5 food.

6 (2) REQUIREMENTS.—The sampling system de-
7 scribed in paragraph (1) shall provide—

8 (A) statistically valid monitoring, including
9 market-based studies, on the nature, frequency
10 of occurrence, and quantities of contaminants
11 in food available to consumers; and

12 (B) at the request of the Administrator,
13 such other information, including analysis of
14 monitoring and verification samples, as the Ad-
15 ministrator determines may be useful in assess-
16 ing the occurrence of contaminants in food.

17 (c) ASSESSMENT OF HEALTH HAZARDS.—

18 (1) IN GENERAL.—Through the surveillance
19 system and analyses referred to in subsection (a)
20 and the sampling system described in subsection (b),
21 the Administrator shall—

22 (A) rank food categories based on the haz-
23 ard to human health presented by the food cat-
24 egory and specific chemical and microbiological

1 hazards associated with foods in those cat-
2 egories;

3 (B) identify appropriate industry and regu-
4 latory approaches to minimize hazards in the
5 food supply; and

6 (C) assess the conditions affecting the like-
7 lihood that emerging pathogens and diseases,
8 including zoonosis, will affect the safety of the
9 food supply and possible strategies for mini-
10 mizing the potential risk to public health associ-
11 ated with emerging pathogens and diseases.

12 (2) COMPONENTS OF ANALYSIS.—The analysis
13 under subsection (b)(1) may include—

14 (A) a comparison of the safety of commer-
15 cial processing with the health hazards associ-
16 ated with food that is harvested for recreational
17 or subsistence purposes and prepared non-
18 commercially;

19 (B) a comparison of the safety of food that
20 is domestically processed with the health haz-
21 ards associated with food that is processed out-
22 side the United States;

23 (C) a description of contamination origi-
24 nating from handling practices that occur prior
25 to or after the sale of food to consumers; and

1 (D) use of comparative risk assessments.

2 **SEC. 302. PUBLIC EDUCATION AND ADVISORY SYSTEM.**

3 (a) PUBLIC EDUCATION.—

4 (1) IN GENERAL.—The Administrator, in co-
5 operation with private and public organizations, in-
6 cluding the cooperative extension services and build-
7 ing on the efforts of appropriate State and local en-
8 tities, shall establish a national public education pro-
9 gram on food safety.

10 (2) REQUIREMENTS.—The program shall pro-
11 vide—

12 (A) information to the public regarding
13 Federal standards and best practices, and pro-
14 motion of public awareness and understanding
15 of those standards and practices;

16 (B) information for health professionals—

17 (i) to improve diagnosis and treatment
18 of food-related illness; and

19 (ii) to advise individuals at special
20 risk for food-related illnesses; and

21 (C) such other information or advice, in-
22 cluding on safe food handling practices, to con-
23 sumers and other persons as the Administrator
24 determines will promote the purposes of this
25 Act.

1 (b) HEALTH ADVISORIES.—The Administrator, in
2 consultation with other Federal departments and agencies
3 as the Administrator determines necessary, shall work
4 with the States and other appropriate entities—

5 (1) to develop and distribute regional and na-
6 tional advisories concerning food safety;

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

9 (3) to incorporate State and local advisories
10 into the national public education program estab-
11 lished under subsection (a); and

12 (4) to present prompt, specific information re-
13 garding food found to pose a threat to the public
14 health, including by identifying the retailers and
15 food establishments where such food has been sold.

16 **SEC. 303. RESEARCH.**

17 (a) IN GENERAL.—The Administrator shall conduct
18 research to carry out this Act, including studies to—

19 (1) improve sanitation and food safety practices
20 in the processing of food;

21 (2) develop improved techniques to monitor and
22 inspect food;

23 (3) develop efficient, rapid, and sensitive meth-
24 ods to detect contaminants in food;

1 (4) determine the sources of contamination of
2 contaminated food;

3 (5) develop food consumption data;

4 (6) identify ways that animal production tech-
5 niques could improve the safety of the food supply;

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

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

10 (9) address common and emerging zoonotic dis-
11 eases;

12 (10) develop methods to reduce or destroy
13 harmful pathogens before, during, and after proc-
14 essing;

15 (11) analyze the incidence of antibiotic
16 resistance as it pertains to the food supply and de-
17 velop new methods to reduce the transfer of anti-
18 biotic resistance to humans; and

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

21 (b) CONTRACT AUTHORITY.—The Administrator may
22 enter into contracts and agreements with any State, uni-
23 versity, Federal Government agency, or person to carry
24 out this section.

1 **SEC. 304. WORKING GROUP ON IMPROVING FOODBORNE**
2 **ILLNESS SURVEILLANCE.**

3 Not later than 180 days after the date of enactment
4 of this Act, the Administrator shall establish a diverse
5 working group of experts and stakeholders from Federal,
6 State, and local food safety and health agencies, the food
7 industry, consumer organizations, and academia. Such
8 working group shall provide the Administrator, through
9 at least annual meetings of the working group and an an-
10 nual public report, advice and recommendations on an on-
11 going and regular basis regarding the improvement of
12 food-borne illness surveillance, including advice and rec-
13 ommendations on—

14 (1) the priority needs of regulatory agencies,
15 the food industry, and consumers for information
16 and analysis on food-borne illness and its causes
17 that can be used to prevent food-borne illness;

18 (2) opportunities to improve the effectiveness of
19 initiatives at the Federal, State, and local levels, in-
20 cluding coordination and integration of activities
21 among Federal agencies, and between the Federal,
22 State, and local levels of government;

23 (3) improvement in the timeliness and depth of
24 access by regulatory and health agencies, the food
25 industry, academic researchers, and consumers to
26 food-borne illness surveillance data collected by gov-

1 ernment agencies at all levels, including data com-
2 piled by the Centers for Disease Control and Preven-
3 tion;

4 (4) key barriers to improvement in food-borne
5 illness surveillance and its utility for preventing
6 food-borne illness at Federal, State, and local levels;
7 and

8 (5) specific actions to reduce barriers to such
9 improvement, implement the working group's rec-
10 ommendations, with measurable objectives and
11 timelines, and identification of resource and staffing
12 needs.

13 **SEC. 305. CAREER-SPANNING TRAINING FOR FOOD INSPEC-**
14 **TORS.**

15 (a) **IN GENERAL.**—The Administrator shall make a
16 grant to an entity described in subsection (c) to provide
17 training to Federal, State, and local food inspectors.

18 (b) **USE OF FUNDS.**—The Administrator may make
19 a grant under this section to an applicant only if the appli-
20 cant agrees to use the grant to provide regular, standard-
21 ized, graduated, career-spanning training, based on a cur-
22 riculum developed by the Association of Food and Drug
23 Officials, to Federal, State, and local food inspectors.

24 (c) **ELIGIBLE ENTITY.**—An entity described in this
25 subsection is an entity that—

1 (1) is described in section 501(c)(3) of the In-
2 ternal Revenue Code of 1986 (26 U.S.C. 501(c)(3));

3 (2) has the capability to train not less than
4 1,000 food inspectors per year; and

5 (3) offers both on-site and off-site training for
6 food inspectors.

7 **SEC. 306. FOOD-BORNE ILLNESS HEALTH REGISTRY.**

8 (a) PURPOSE.—The purpose of the registry under
9 subsection (b) is to stimulate research on the trends,
10 sources, health outcomes, and preventive strategies related
11 to food-borne disease.

12 (b) REGISTRY.—For the purpose described in sub-
13 section (a), the Secretary of Health and Human Services,
14 acting through the Director of the Centers for Disease
15 Control and Prevention, shall develop and maintain a reg-
16 istry, to be known as the Food-Borne Illness Health Reg-
17 istry, consisting of data on the trends, sources, health out-
18 comes, and preventive strategies related to food-borne dis-
19 ease.

20 **SEC. 307. STUDY ON FEDERAL RESOURCES.**

21 Not later than one year after the date of the enact-
22 ment of this Act, the Comptroller General of the United
23 States shall complete a study on the Federal resources
24 being dedicated to food-borne illness and food safety re-

1 search and submit a report on the results of such study
2 to the Congress.

3 **TITLE IV—ENFORCEMENT**

4 **SEC. 401. PROHIBITED ACTS.**

5 It is prohibited—

6 (1) to manufacture, introduce, deliver for intro-
7 duction, or receive in interstate commerce any food
8 that is adulterated, misbranded, or otherwise unsafe;

9 (2) to adulterate or misbrand any food in inter-
10 state commerce;

11 (3) for a food establishment or foreign food es-
12 tablishment to fail to register under section 202, or
13 to operate without a valid registration;

14 (4) to refuse to permit access to a food estab-
15 lishment or food production facility for the inspec-
16 tion and copying of a record as required under sec-
17 tions 205(f) and 206(a);

18 (5) to fail to establish or maintain any record
19 or to make any report as required under sections
20 205(f) and 206(b);

21 (6) to refuse to permit entry to or inspection of
22 a food establishment as required under section 205;

23 (7) to fail to provide to the Administrator the
24 results of testing or sampling of food, equipment, or

1 material in contact with food, that is positive for any
2 contaminant under section 205(f)(1)(B);

3 (8) to fail to comply with a provision, regula-
4 tion, or order of the Administrator under section
5 202, 203, 204, 206, or 208;

6 (9) to slaughter an animal that is capable for
7 use in whole or in part as human food at a food es-
8 tablishment processing any food for commerce, ex-
9 cept in compliance with the food safety law;

10 (10) to transfer food in violation of an adminis-
11 trative detention order under section 402 or to re-
12 move or alter a required mark or label identifying
13 the food as detained;

14 (11) to fail to comply with a recall or other
15 order under section 403; or

16 (12) to otherwise violate the food safety law.

17 **SEC. 402. FOOD DETENTION, SEIZURE, AND CONDEMNATION.**
18 **TION.**

19 (a) ADMINISTRATIVE DETENTION OF FOOD.—

20 (1) EXPANDED AUTHORITY.—The Adminis-
21 trator shall have authority under section 304 of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 334) to administratively detain and seize any food
24 regulated under this Act that the Administrator has
25 reason to believe is unsafe, is adulterated or mis-

1 branded, or otherwise fails to meet the requirements
2 of the food safety law.

3 (2) DETENTION AUTHORITY.—If, during an in-
4 spection conducted in accordance with section 205 or
5 208, an officer, employee, or agent of the Adminis-
6 tration making the inspection has reason to believe
7 that a domestic food, imported food, or food offered
8 for import is unsafe, is adulterated or misbranded,
9 or otherwise fails to meet the requirements of this
10 the food safety law, the officer, employee, or agent
11 may order the food detained.

12 (3) PERIOD OF DETENTION.—

13 (A) IN GENERAL.—A food may be detained
14 under paragraph (1) or (2) for a reasonable pe-
15 riod, not to exceed 20 days, unless a longer pe-
16 riod, not to exceed 30 days, is necessary for the
17 Administrator to institute a seizure action.

18 (B) PERISHABLE FOOD.—The Adminis-
19 trator shall provide by regulation for procedures
20 to institute a seizure action on an expedited
21 basis with respect to perishable food.

22 (4) SECURITY OF DETAINED FOOD.—

23 (A) IN GENERAL.—A detention order
24 under this subsection—

1 (i) may require that the food be la-
2 beled or marked as detained; and

3 (ii) shall require that the food be re-
4 moved to a secure facility, if appropriate.

5 (B) FOOD SUBJECT TO AN ORDER.—A
6 food subject to a detention order under this
7 subsection shall not be transferred by any per-
8 son from the place at which the food is re-
9 moved, until released by the Administrator or
10 until the expiration of the detention period ap-
11 plicable under the order, whichever occurs first.

12 (C) DELIVERY OF FOOD.—This subsection
13 does not authorize the delivery of a food in ac-
14 cordance with execution of a bond while the ar-
15 ticle is subject to the order.

16 (b) APPEAL OF DETENTION ORDER.—

17 (1) IN GENERAL.—A person who would be enti-
18 tled to be a claimant for a food subject to a deten-
19 tion order under subsection (a) if the food were
20 seized under section 304 of the Federal Food, Drug,
21 and Cosmetic Act (21 U.S.C. 334), may appeal the
22 order to the Administrator.

23 (2) ACTION BY THE ADMINISTRATOR.—Not
24 later than 5 days after an appeal is filed under para-
25 graph (1), the Administrator, after providing an op-

1 portunity for an informal hearing, shall confirm,
2 modify, or terminate the order involved.

3 (3) FINAL AGENCY ACTION.—Confirmation,
4 modification, or termination by the Administrator
5 under paragraph (2) shall be considered a final
6 agency action for purposes of section 702 of title 5,
7 United States Code.

8 (4) TERMINATION.—A detention order under
9 subsection (a) shall be considered to be terminated
10 if, after 5 days, the Administrator has failed—

11 (A) to provide an opportunity for an infor-
12 mal hearing; or

13 (B) to confirm, modify, or terminate the
14 order.

15 (5) EFFECT OF INSTITUTING COURT ACTION.—
16 If the Administrator initiates an action under sec-
17 tion 302 of the Federal Food, Drug, and Cosmetic
18 Act (21 U.S.C. 332) or section 304(a) of that Act
19 (21 U.S.C. 334(a)) for a food subject to a detention
20 order under subsection (a), the process for the ap-
21 peal of the detention order with respect to such food
22 shall terminate.

23 (c) CONDEMNATION OF FOOD.—

1 (1) IN GENERAL.—After confirming a detention
2 order, the Administrator may order the food con-
3 demned.

4 (2) DESTRUCTION OF FOOD.—Any food con-
5 demned shall be destroyed under the supervision of
6 the Administrator.

7 (3) RELEASE OF FOOD.—If the Administrator
8 determines that, through reprocessing, relabeling, or
9 other action, a detained food can be brought into
10 compliance with this Act, the food may be released
11 following a determination by the Administrator that
12 the relabeling or other action as specified by the Ad-
13 ministrator has been performed.

14 (d) TEMPORARY HOLDS AT PORTS OF ENTRY.—

15 (1) IN GENERAL.—If an officer or qualified em-
16 ployee of the Administration has reason to believe
17 that a food is unsafe, is adulterated or misbranded,
18 or otherwise fails to meet the requirements of this
19 Act, and the officer or qualified employee is unable
20 to inspect, examine, or investigate the food when the
21 food is offered for import at a port of entry into the
22 United States, the officer or qualified employee shall
23 request the Secretary of Homeland Security to hold
24 the food at the port of entry for a reasonable period
25 of time, not to exceed 24 hours, to enable the Ad-

1 administrator to inspect or investigate the food as ap-
2 propriate.

3 (2) REMOVAL TO SECURE FACILITY.—The Ad-
4 ministrator shall work in coordination with the Sec-
5 retary of Homeland Security to remove a food held
6 in accordance with paragraph (1) to a secure facility
7 as appropriate.

8 (3) PROHIBITION ON TRANSFER.—During the
9 period in which food is held, the food shall not be
10 transferred by any person from the port of entry
11 into the United States, or from the secure facility to
12 which the food has been removed.

13 (4) DELIVERY IN ACCORDANCE WITH A
14 BOND.—The delivery of the food in accordance with
15 the execution of a bond while the food is held is not
16 authorized.

17 (5) PROHIBITION ON REEXPORT.—A food found
18 unfit for human or animal consumption shall be pro-
19 hibited from reexport without further processing to
20 remove the contamination and reinspection by the
21 Administration.

22 **SEC. 403. NOTIFICATION AND RECALL.**

23 (a) NOTICE TO ADMINISTRATOR OF VIOLATION.—

24 (1) IN GENERAL.—A person that has reason to
25 believe that any food introduced into or in interstate

1 commerce, or held for sale (whether or not the first
2 sale) after shipment in interstate commerce, may be
3 in violation of the food safety law shall immediately
4 notify the Administrator of the identity and location
5 of the food.

6 (2) MANNER OF NOTIFICATION.—Notification
7 under paragraph (1) shall be made in such manner
8 and by such means as the Administrator may re-
9 quire by regulation.

10 (b) RECALL AND CONSUMER NOTIFICATION.—

11 (1) VOLUNTARY ACTIONS.—If the Adminis-
12 trator determines that food is in violation of the food
13 safety law when introduced into or while in inter-
14 state commerce or while held for sale (whether or
15 not the first sale) after shipment in interstate com-
16 merce and that there is a reasonable probability that
17 the food, if consumed, would present a threat to
18 public health, as determined by the Administrator,
19 the Administrator shall give the appropriate persons
20 (including the manufacturers, importers, distribu-
21 tors, or retailers of the food) an opportunity to—

22 (A) cease distribution of the food;

23 (B) notify all persons—

24 (i) processing, distributing, or other-
25 wise handling the food to immediately

1 cease such activities with respect to the
2 food; or

3 (ii) to which the food has been distrib-
4 uted, transported, or sold, to immediately
5 cease distribution of the food;

6 (C) recall the food;

7 (D) in conjunction with the Administrator,
8 provide notice of the finding of the Adminis-
9 trator—

10 (i) to consumers to whom the food
11 was, or may have been, distributed; and

12 (ii) to State and local public health of-
13 ficials; or

14 (E) take any combination of the measures
15 described in this paragraph, as determined by
16 the Administrator to be appropriate in the cir-
17 cumstances.

18 (2) MANDATORY ACTIONS.—If a person re-
19 ferred to in paragraph (1) refuses to or does not
20 adequately carry out the actions described in that
21 paragraph within the time period and in the manner
22 prescribed by the Administrator, the Administrator
23 shall—

24 (A) have authority to control and possess
25 the food, including ordering the shipment of the

1 food from the food establishment to the Admin-
2 istrator—

3 (i) at the expense of the food estab-
4 lishment; or

5 (ii) in an emergency (as determined
6 by the Administrator), at the expense of
7 the Administration; and

8 (B) by order, require, as the Administrator
9 determines to be necessary, the person to imme-
10 diately—

11 (i) cease distribution of the food; and

12 (ii) notify all persons—

13 (I) processing, distributing, or
14 otherwise handling the food to imme-
15 diately cease such activities with re-
16 spect to the food; or

17 (II) if the food has been distrib-
18 uted, transported, or sold, to imme-
19 diately cease distribution of the food.

20 (3) NOTIFICATION TO CONSUMERS BY ADMINIS-
21 TRATOR.—The Administrator shall, as the Adminis-
22 trator determines to be necessary—

23 (A) provide notice of the finding of the Ad-
24 ministrator under paragraph (1)—

1 (i) to consumers to whom the food
2 was, or may have been, distributed; and

3 (ii) to State and local public health of-
4 ficials; and

5 (B) provide notice to the public of the
6 names and addresses of retail locations at
7 which recalled food products were available for
8 sale.

9 (4) NONDISTRIBUTION BY NOTIFIED PER-
10 SONS.—A person that processes, distributes, or oth-
11 erwise handles the food, or to which the food has
12 been distributed, transported, or sold, and that is
13 notified under paragraph (1)(B) or (2)(B) shall im-
14 mediately cease distribution of the food.

15 (5) AVAILABILITY OF RECORDS TO ADMINIS-
16 TRATOR.—Each person referred to in paragraph (1)
17 that processed, distributed, or otherwise handled
18 food shall make available to the Administrator infor-
19 mation necessary to carry out this subsection, as de-
20 termined by the Administrator, regarding—

21 (A) persons that processed, distributed, or
22 otherwise handled the food; and

23 (B) persons to which the food has been
24 transported, sold, distributed, or otherwise han-
25 dled.

1 (c) INFORMAL HEARINGS ON ORDERS.—

2 (1) IN GENERAL.—The Administrator shall pro-
3 vide any person subject to an order under subsection
4 (b) with an opportunity for an informal hearing, to
5 be held as soon as practicable but not later than 2
6 business days after the issuance of the order.

7 (2) SCOPE OF THE HEARING.—In a hearing
8 under paragraph (1), the Administrator shall con-
9 sider the actions required by the order and any rea-
10 sons why the food that is the subject of the order
11 should not be recalled.

12 (d) POST-HEARING RECALL ORDERS.—

13 (1) AMENDMENT OF ORDER.—If, after pro-
14 viding an opportunity for an informal hearing under
15 subsection (c), the Administrator determines that
16 there is a reasonable probability that the food that
17 is the subject of an order under subsection (b), if
18 consumed, would present a threat to the public
19 health, the Administrator, as the Administrator de-
20 termines to be necessary, may—

21 (A) amend the order to require recall of
22 the food or other appropriate action;

23 (B) specify a timetable in which the recall
24 shall occur;

1 (C) require periodic reports to the Admin-
2 istrator describing the progress of the recall;
3 and

4 (D) provide notice of the recall to con-
5 sumers to whom the food was, or may have
6 been, distributed.

7 (2) VACATION OF ORDERS.—If, after providing
8 an opportunity for an informal hearing under sub-
9 section (c), the Administrator determines that ade-
10 quate grounds do not exist to continue the actions
11 required by the order, the Administrator shall vacate
12 the order.

13 (e) REMEDIES NOT EXCLUSIVE.—The remedies pro-
14 vided in this section shall be in addition to, and not exclu-
15 sive of, other remedies that may be available.

16 **SEC. 404. INJUNCTION PROCEEDINGS.**

17 (a) JURISDICTION.—The district courts of the United
18 States, and the United States courts of the territories and
19 possessions of the United States, shall have jurisdiction,
20 for cause shown, to restrain a violation of section 202,
21 203, 204, 208, or 401 (or a regulation promulgated there-
22 under).

23 (b) TRIAL.—In a case in which violation of an injunc-
24 tion or restraining order issued under this section also

1 constitutes a violation of the food safety law, trial shall
2 be by the court or, upon demand of the accused, by a jury.

3 **SEC. 405. CIVIL AND CRIMINAL PENALTIES.**

4 (a) CIVIL SANCTIONS.—

5 (1) CIVIL PENALTY.—

6 (A) IN GENERAL.—Any person that com-
7 mits an act that violates the food safety law (in-
8 cluding a regulation promulgated or order
9 issued under the food safety law) may be as-
10 sessed a civil penalty by the Administrator of
11 not more than \$1,000,000 for each such act.

12 (B) SEPARATE OFFENSE.—Each act de-
13 scribed in subparagraph (A) and each day dur-
14 ing which that act continues shall be considered
15 a separate offense.

16 (2) OTHER REQUIREMENTS.—

17 (A) WRITTEN ORDER.—The civil penalty
18 described in paragraph (1) shall be assessed by
19 the Administrator by a written order, which
20 shall specify the amount of the penalty and the
21 basis for the penalty under subparagraph (B)
22 considered by the Administrator.

23 (B) AMOUNT OF PENALTY.—Subject to
24 paragraph (1)(A), the amount of the civil pen-

1 alty shall be determined by the Administrator,
2 after considering—

3 (i) the gravity of the violation;

4 (ii) the degree of culpability of the
5 person;

6 (iii) the size and type of the business
7 of the person; and

8 (iv) any history of prior offenses by
9 the person under the food safety law.

10 (C) REVIEW OF ORDER.—The order may
11 be reviewed only in accordance with subsection
12 (c).

13 (b) CRIMINAL SANCTIONS.—

14 (1) OFFENSE RESULTING IN SERIOUS ILL-
15 NESS.—Notwithstanding section 303(a) of the Fed-
16 eral Food, Drug, and Cosmetic Act (21 U.S.C.
17 333(a)), if a violation of any provision of section 301
18 of such Act (21 U.S.C. 301) with respect to an adul-
19 terated or misbranded food results in serious illness,
20 the person committing the violation shall be impris-
21 oned for not more than 5 years, fined in accordance
22 with title 18, United States Code, or both.

23 (2) OFFENSE RESULTING IN DEATH.—Notwith-
24 standing section 303(a) of the Federal Food, Drug,
25 and Cosmetic Act (21 U.S.C. 333(a)), if a violation

1 of any provision of section 301 of such Act (21
2 U.S.C. 331) with respect to an adulterated or mis-
3 branded food results in death, the person commit-
4 ting the violation shall be imprisoned for not more
5 than 10 years, fined in accordance with title 18,
6 United States Code, or both.

7 (c) JUDICIAL REVIEW.—

8 (1) IN GENERAL.—An order assessing a civil
9 penalty against a person under subsection (a) shall
10 be a final order unless the person—

11 (A) not later than 30 days after the effec-
12 tive date of the order, files a petition for judi-
13 cial review of the order in the United States
14 court of appeals for the circuit in which that
15 person resides or has its principal place of busi-
16 ness or the United States Court of Appeals for
17 the District of Columbia; and

18 (B) simultaneously serves a copy of the pe-
19 tition by certified mail to the Administrator.

20 (2) FILING OF RECORD.—Not later than 45
21 days after the service of a copy of the petition under
22 paragraph (1)(B), the Administrator shall file in the
23 court a certified copy of the administrative record
24 upon which the order was issued.

1 (3) STANDARD OF REVIEW.—The findings of
2 the Administrator relating to the order shall be set
3 aside only if found to be unsupported by substantial
4 evidence on the record as a whole.

5 (d) COLLECTION ACTIONS FOR FAILURE TO PAY.—

6 (1) IN GENERAL.—If any person fails to pay a
7 civil penalty assessed under subsection (a) after the
8 order assessing the penalty has become a final order,
9 or after the court of appeals described in subsection
10 (b) has entered final judgment in favor of the Ad-
11 ministrator, the Administrator shall refer the matter
12 to the Attorney General, who shall institute in a
13 United States district court of competent jurisdic-
14 tion a civil action to recover the amount assessed.

15 (2) LIMITATION ON REVIEW.—In a civil action
16 under paragraph (1), the validity and appropriate-
17 ness of the order of the Administrator assessing the
18 civil penalty shall not be subject to judicial review.

19 (e) PENALTIES PAID INTO ACCOUNT.—The Adminis-
20 trator—

21 (1) shall deposit penalties collected under this
22 section in an account in the Treasury; and

23 (2) may use the funds in the account, without
24 further appropriation or fiscal year limitation—

1 (A) to carry out enforcement activities
2 under the food safety law; or

3 (B) to provide assistance to States to in-
4 spect retail commercial food establishments or
5 other food or firms under the jurisdiction of
6 State food safety programs.

7 (f) DISCRETION OF THE ADMINISTRATOR TO PROS-
8 ECUTE.—Nothing in this Act requires the Administrator
9 to report for prosecution, or for the commencement of an
10 action, the violation of the food safety law in a case in
11 which the Administrator finds that the public interest will
12 be adequately served by the assessment of a civil penalty
13 under this section.

14 (g) REMEDIES NOT EXCLUSIVE.—The remedies pro-
15 vided in this section are in addition to, and not exclusive
16 of, other remedies that may be available.

17 **SEC. 406. PRESUMPTION.**

18 In any action to enforce the requirements of the food
19 safety law, the connection with interstate commerce re-
20 quired for jurisdiction shall be presumed to exist.

21 **SEC. 407. WHISTLEBLOWER PROTECTION.**

22 (a) IN GENERAL.—

23 (1) PROHIBITION.—No Federal employee, em-
24 ployee of a Federal contractor or subcontractor, or
25 covered individual may be discharged, demoted, sus-

1 pended, threatened, harassed, or in any other man-
2 ner discriminated against, because of any lawful act
3 done by the employee or covered individual to—

4 (A) provide information, cause information
5 to be provided, or otherwise assist in an inves-
6 tigation regarding any conduct that the covered
7 individual reasonably believes constitutes a vio-
8 lation of any law, rule, or regulation, or that
9 the covered individual reasonably believes con-
10 stitutes a threat to the public health, when the
11 information or assistance is provided to, or the
12 investigation is conducted by—

13 (i) a Federal regulatory or law en-
14 forcement agency;

15 (ii) a Member or committee of Con-
16 gress; or

17 (iii) a person with supervisory author-
18 ity over the covered individual (or such
19 other individual who has the authority to
20 investigate, discover, or terminate mis-
21 conduct);

22 (B) file, cause to be filed, testify, partici-
23 pate in, or otherwise assist in a proceeding or
24 action filed or about to be filed relating to a
25 violation of any law, rule, or regulation; or

1 (C) refused to violate or assist in the viola-
2 tion of any law, rule, or regulation.

3 (2) DEFINITION.—For the purposes of this sec-
4 tion, the term “covered individual” means an indi-
5 vidual who is an employee of—

6 (A) a food establishment;

7 (B) a food production facility;

8 (C) a restaurant;

9 (D) a retail food establishment other than
10 a restaurant;

11 (E) a nonprofit food establishment in
12 which food is prepared for or served directly to
13 the consumer;

14 (F) a fishing vessel; or

15 (G) an agent of any of the above.

16 (b) ENFORCEMENT ACTION.—

17 (1) IN GENERAL.—A covered individual who al-
18 leges discharge or other discrimination by any per-
19 son in violation of subsection (a) may seek relief
20 under subsection (c) by filing a complaint with the
21 Secretary of Labor. If the Secretary of Labor has
22 not issued a final decision within 180 days after the
23 date on which the complaint is filed and there is no
24 showing that such delay is due to the bad faith of
25 the claimant, the claimant may bring an action at

1 law or equity for de novo review in the appropriate
2 district court of the United States, which shall have
3 jurisdiction over such an action without regard to
4 the amount in controversy.

5 (2) PROCEDURE.—

6 (A) IN GENERAL.—An action under para-
7 graph (1) shall be governed under the rules and
8 procedures set forth in section 42121(b) of title
9 49, United States Code.

10 (B) EXCEPTION.—Notification under sec-
11 tion 42121(b)(1) of title 49, United States
12 Code, shall be made to the person named in the
13 complaint and to the person’s employer.

14 (C) BURDENS OF PROOF.—An action
15 brought under paragraph (1) shall be governed
16 by the legal burdens of proof set forth in sec-
17 tion 42121(b) of title 49, United States Code.

18 (D) STATUTE OF LIMITATIONS.—An action
19 under paragraph (1) shall be commenced not
20 later than 90 days after the date on which the
21 violation occurs.

22 (c) REMEDIES.—

23 (1) IN GENERAL.—A covered individual pre-
24 vailing in any action under subsection (b)(1) shall be

1 entitled to all relief necessary to make the covered
2 individual whole.

3 (2) COMPENSATORY DAMAGES.—Relief for any
4 action described in paragraph (1) shall include—

5 (A) reinstatement with the same seniority
6 status that the covered individual would have
7 had, but for the discrimination;

8 (B) the amount of any back pay, with in-
9 terest; and

10 (C) compensation for any special damages
11 sustained as a result of the discrimination, in-
12 cluding litigation costs, expert witness fees, and
13 reasonable attorney’s fees.

14 (d) RIGHTS RETAINED BY THE COVERED INDI-
15 VIDUAL.—Nothing in this section shall be construed to di-
16 minish the rights, privileges, or remedies of any covered
17 individual under any Federal or State law, or under any
18 collective bargaining agreement.

19 **SEC. 408. ADMINISTRATION AND ENFORCEMENT.**

20 (a) IN GENERAL.—For the efficient administration
21 and enforcement of the food safety law, the provisions (in-
22 cluding provisions relating to penalties) of sections 6, 8,
23 9, and 10 of the Federal Trade Commission Act (15
24 U.S.C. 46, 48, 49, and 50) (except subsections (c) through
25 (h) of section 6 of that Act), relating to the jurisdiction,

1 powers, and duties of the Federal Trade Commission and
2 the Attorney General to administer and enforce that Act,
3 and to the rights and duties of persons with respect to
4 whom the powers are exercised, shall apply to the jurisdic-
5 tion, powers, and duties of the Administrator and the At-
6 torney General in administering and enforcing the provi-
7 sions of the food safety law and to the rights and duties
8 of persons with respect to whom the powers are exercised,
9 respectively.

10 (b) INQUIRIES AND ACTIONS.—

11 (1) IN GENERAL.—The Administrator, in per-
12 son or by such agents as the Administrator may des-
13 ignate, may prosecute any inquiry necessary to carry
14 out the duties of the Administrator under the food
15 safety law in any part of the United States.

16 (2) POWERS.—The powers conferred by sec-
17 tions 9 and 10 of the Federal Trade Commission
18 Act (15 U.S.C. 49 and 50) on the United States dis-
19 trict courts may be exercised for the purposes of this
20 chapter by any United States district court of com-
21 petent jurisdiction.

22 **SEC. 409. CITIZEN CIVIL ACTIONS.**

23 (a) CIVIL ACTIONS.—A person may commence a civil
24 action against—

1 (1) a person that violates a regulation (includ-
2 ing a regulation establishing a performance stand-
3 ard), order, or other action of the Administrator to
4 ensure the safety of food; or

5 (2) the Administrator (in his or her capacity as
6 the Administrator), if the Administrator fails to per-
7 form an act or duty to ensure the safety of food that
8 is not discretionary under the food safety law.

9 (b) COURT.—In an action commenced under this sec-
10 tion:

11 (1) IN GENERAL.—The action shall be com-
12 menced—

13 (A) in the case of a civil action against a
14 person, the United States district court for the
15 district in which the defendant resides, is
16 found, or has an agent; and

17 (B) in the case of a civil action against the
18 Administrator, any United States district court.

19 (2) JURISDICTION.—The court shall have juris-
20 diction, without regard to the amount in con-
21 troversy, or the citizenship of the parties, to enforce
22 a regulation (including a regulation establishing a
23 performance standard), order, or other action of the
24 Administrator, or to order the Administrator to per-
25 form the act or duty.

1 (3) DAMAGES.—The court may—

2 (A) award damages, in the amount of dam-
3 ages actually sustained; and

4 (B) if the court determines it to be in the
5 interest of justice, award the plaintiff the costs
6 of suit, including reasonable attorney’s fees,
7 reasonable expert witness fees, and penalties.

8 (c) REMEDIES NOT EXCLUSIVE.—The remedies pro-
9 vided for in this section shall be in addition to, and not
10 exclusive of, other remedies that may be available.

11 **TITLE V—IMPLEMENTATION**

12 **SEC. 501. REORGANIZATION PLAN.**

13 (a) SUBMISSION OF PLAN.—Not later than 180 days
14 after the enactment of this Act, the President shall trans-
15 mit to the appropriate congressional committees a reorga-
16 nization plan regarding the following:

17 (1) The transfer of agencies, personnel, assets,
18 and obligations to the Administration pursuant to
19 this Act.

20 (2) Any consolidation, reorganization, or
21 streamlining of agencies transferred to the Adminis-
22 tration pursuant to this Act.

23 (b) PLAN ELEMENTS.—The plan transmitted under
24 subsection (a) shall contain, consistent with this Act, such

1 elements as the President determines appropriate, includ-
2 ing the following:

3 (1) The timetable for transfer and identification
4 of any functions of agencies designated to be trans-
5 ferred to the Administration pursuant to this Act
6 that will not be transferred promptly to the Admin-
7 istration under the plan.

8 (2) Specification of the steps to be taken by the
9 Administrator to organize the Administration, in-
10 cluding the delegation or assignment of functions
11 transferred to the Administration among the officers
12 of the Administration in order to permit the Admin-
13 istration to carry out the functions transferred
14 under the plan.

15 (3) Specification of the funds available to each
16 agency that will be transferred to the Administration
17 as a result of transfers under the plan.

18 (4) Specification of the proposed allocations
19 within the Administration of unexpended funds
20 transferred in connection with transfers under the
21 plan.

22 (5) Specification of any proposed disposition of
23 property, facilities, contracts, records, and other as-
24 sets and obligations of agencies transferred under
25 the plan.

1 (6) Specification of the proposed allocations
2 within the Administration of the functions of the
3 agencies and subdivisions that are not related di-
4 rectly to ensuring the safety of food.

5 (c) MODIFICATION OF PLAN.—The President may,
6 on the basis of consultations with the appropriate congres-
7 sional committees, modify or revise any part of the plan
8 until that part of the plan becomes effective in accordance
9 with subsection (d).

10 (d) EFFECTIVE DATE.—

11 (1) IN GENERAL.—The reorganization plan de-
12 scribed in this section, including any modifications
13 or revisions of the plan under subsection (c), shall
14 become effective for an agency on the earlier of—

15 (A) the date specified in the plan (or the
16 plan as modified pursuant to subsection (c)),
17 except that such date may not be earlier than
18 90 days after the date the President has trans-
19 mitted the reorganization plan to the appro-
20 priate congressional committees pursuant to
21 subsection (a); or

22 (B) the end of the 12-month period begin-
23 ning on the date of the enactment of this Act.

24 (2) STATUTORY CONSTRUCTION.—Nothing in
25 this subsection may be construed to require the

1 transfer of functions, personnel, records, balances of
2 appropriations, or other assets of an agency on a
3 single date.

4 (3) SUPERSEDES EXISTING LAW.—Paragraph
5 (1) shall apply notwithstanding section 905(b) of
6 title 5, United States Code.

7 **SEC. 502. TRANSITIONAL AUTHORITIES.**

8 (a) PROVISION OF ASSISTANCE BY OFFICIALS.—
9 Until the transfer of an agency to the Administration, any
10 official having authority over or function relating to the
11 agency immediately before the date of the enactment of
12 this Act shall provide the Administrator such assistance,
13 including the use of personnel and assets, as the Adminis-
14 trator may request in preparing for the transfer and inte-
15 gration of the agency to the Administration.

16 (b) SERVICES AND PERSONNEL.—During the transi-
17 tion period, upon the request of the Administrator, the
18 head of any executive agency may provide services or de-
19 tail personnel to assist with the transition.

20 (c) ACTING OFFICIALS.—

21 (1) IN GENERAL.—During the transition pe-
22 riod, pending the advice and consent of the Senate
23 to the appointment of an officer required by this Act
24 to be appointed by and with such advice and con-
25 sent, the President may designate any officer whose

1 appointment was required to be made by and with
2 such advice and consent and who was such an officer
3 immediately before the date of the enactment of this
4 Act (and who continues to be in office) or imme-
5 diately before such designation, to act in such office
6 until the same is filled as provided in this Act.

7 (2) COMPENSATION.—While acting pursuant to
8 paragraph (1), such officers shall receive compensa-
9 tion at the higher of—

10 (A) the rates provided by this Act for the
11 respective offices in which they act; or

12 (B) the rates provided for the offices held
13 at the time of designation.

14 (3) LIMITATION.—Nothing in this Act shall be
15 construed to require the advice and consent of the
16 Senate to the appointment by the President to a po-
17 sition in the Administration of any officer whose
18 agency is transferred to the Administration pursuant
19 to this Act and whose duties following such transfer
20 are germane to those performed before such trans-
21 fer.

22 (d) TRANSFER OF PERSONNEL, ASSETS, OBLIGA-
23 TIONS, AND FUNCTION.—

24 (1) IN GENERAL.—Consistent with section 1531
25 of title 31, United States Code, the personnel, as-

1 sets, liabilities, contracts, property, records, and un-
2 expended balances of appropriations, authorizations,
3 allocations, and other funds that relate to the func-
4 tions transferred under subsection (a) from a Fed-
5 eral agency shall be transferred to the Administra-
6 tion.

7 (2) UNEXPENDED FUNDS.—Unexpended funds
8 transferred under this subsection shall be used by
9 the Administration only for the purposes for which
10 the funds were originally authorized and appro-
11 priated.

12 **SEC. 503. SAVINGS PROVISIONS.**

13 (a) COMPLETED ADMINISTRATIVE ACTIONS.—The
14 enactment of this Act or the transfer of functions under
15 this Act shall not affect any order, determination, rule,
16 regulation, tolerance, guidance, permit, personnel action,
17 agreement, grant, contract, certificate, license, registra-
18 tion, user fees, privilege, or other administrative action
19 issued, made, granted, or otherwise in effect or final with
20 respect to that agency on the day before the transfer date
21 with respect to the transferred functions.

22 (b) PENDING PROCEEDINGS.—Subject to the author-
23 ity of the Administrator under this Act—

24 (1) pending proceedings in an agency, including
25 notices of proposed rulemaking, and applications for

1 licenses, permits, certificates, grants, and financial
2 assistance, shall continue notwithstanding the enact-
3 ment of this Act or the transfer of the agency to the
4 Administration, unless discontinued or modified
5 under the same terms and conditions and to the
6 same extent that such discontinuance or modifica-
7 tion could have occurred if such enactment or trans-
8 fer had not occurred; and

9 (2) orders issued in such proceedings, and ap-
10 peals therefrom, and payments made pursuant to
11 such orders, shall issue in the same manner on the
12 same terms as if this Act had not been enacted or
13 the agency had not been transferred, and any such
14 order shall continue in effect until amended, modi-
15 fied, superseded, terminated, set aside, or revoked by
16 an officer of the United States or a court of com-
17 petent jurisdiction, or by operation of law.

18 (c) PENDING CIVIL ACTIONS.—Subject to the author-
19 ity of the Administrator under this Act, any civil action
20 commenced with regard to that agency pending before
21 that agency on the day before the transfer date with re-
22 spect to the transferred functions shall continue notwith-
23 standing the enactment of this Act or the transfer of an
24 agency to the Administration.

25 (d) REFERENCES.—

1 (1) IN GENERAL.—After the transfer of func-
2 tions from a Federal agency under this Act, any ref-
3 erence in any other Federal law, Executive order,
4 rule, regulation, directive, document, or other mate-
5 rial to that Federal agency or the head of that agen-
6 cy in connection with the administration or enforce-
7 ment of the food safety law shall be deemed to be
8 a reference to the Administration or the Adminis-
9 trator, respectively.

10 (2) STATUTORY REPORTING REQUIREMENTS.—
11 Statutory reporting requirements that applied in re-
12 lation to such an agency immediately before the date
13 of the enactment of this Act shall continue to apply
14 following such transfer if they refer to the agency by
15 name.

16 **SEC. 504. CONFORMING AMENDMENTS.**

17 (a) EXECUTIVE SCHEDULE.—Section 5313 of title 5,
18 United States Code, is amended by inserting at the end
19 the following new item: “Administrator of Food Safety.”.

20 **SEC. 505. ADDITIONAL TECHNICAL AND CONFORMING**
21 **AMENDMENTS.**

22 Not later than 60 days after the submission of the
23 reorganization plan under section 501, the President shall
24 prepare and submit proposed legislation to Congress con-
25 taining necessary and appropriate technical and con-

1 forming amendments to the Acts listed in section 3(15)
2 of this Act to reflect the changes made by this Act.

3 **SEC. 506. REGULATIONS.**

4 The Administrator may promulgate such regulations
5 as the Administrator determines are necessary or appro-
6 priate to perform the duties of the Administrator.

7 **SEC. 507. AUTHORIZATION OF APPROPRIATIONS.**

8 There are authorized to be appropriated such sums
9 as are necessary to carry out this Act.

10 **SEC. 508. LIMITATION ON AUTHORIZATION OF APPROPRIA-**
11 **TIONS.**

12 For the fiscal year that includes the date of the enact-
13 ment of this Act, the amount authorized to be appro-
14 priated to carry out this Act shall not exceed—

15 (1) the amount appropriated for that fiscal year
16 for the Federal agencies identified in section 102(b)
17 for the purpose of administering or enforcing the
18 food safety law; or

19 (2) the amount appropriated for those agencies
20 for that purpose for the preceding fiscal year, if, as
21 of the date of the enactment of this Act, appropria-
22 tions for those agencies for the fiscal year that in-
23 cludes such date have not yet been made.

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