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To establish the Food Safety Administration to protect the public health by preventing food-borne illness, ensuring the safety of food intended for human consumption, improving research on contaminants leading to food-borne illness, and improving security of food from intentional contamination.

IN THE SENATE OF THE UNITED STATES

OCTOBER 7, 2004

Mr. DURBIN introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To establish the Food Safety Administration to protect the public health by preventing food-borne illness, ensuring the safety of food intended for human consumption, improving research on contaminants leading to food-borne illness, and improving security of food from intentional contamination.

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 “Safe Food Act of 2004”.

1 (b) TABLE OF CONTENTS.—The table of contents of
 2 this Act is as follows:

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

TITLE I—ESTABLISHMENT OF FOOD SAFETY ADMINISTRATION

- Sec. 101. Establishment of Food Safety Administration.
- Sec. 102. Consolidation of separate food safety and inspection services and agencies.
- 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. Preventative 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.

TITLE III—RESEARCH AND EDUCATION

- Sec. 301. Public health assessment system.
- Sec. 302. Public education and advisory system.
- Sec. 303. Research.

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

Sec. 509. Limitation on authorization of appropriations.

Sec. 510. Effective date.

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;

11 (3) the safety and security of the food supply
12 requires an integrated, system-wide approach to pre-
13 venting food-borne illness, a thorough and broad-
14 based approach to basic and applied research, and
15 intensive, effective, and efficient management of the
16 Nation’s food safety program;

17 (4) the task of preserving the safety of the food
18 supply of the United States faces tremendous pres-
19 sures with regard to—

20 (A) emerging pathogens and other con-
21 taminants and the ability to detect all forms of
22 contamination;

1 (B) an aging and immune compromised
2 population, with a growing number of people at
3 high-risk for food-borne illnesses;

4 (C) an increasing volume of imported food,
5 without adequate monitoring and inspection;
6 and

7 (D) maintenance of rigorous inspection of
8 the domestic food processing and food service
9 industries;

10 (5) Federal food safety standard setting, in-
11 spection, enforcement, and research efforts should be
12 based on the best available science and public health
13 considerations and food safety resources should be
14 systematically deployed in ways that most effectively
15 prevent food-borne illness;

16 (6) the Federal food safety system is frag-
17 mented, with at least 12 Federal agencies sharing
18 responsibility for food safety, and operates under
19 laws that do not reflect current conditions in the
20 food system or current scientific knowledge about
21 the cause and prevention of food-borne illness;

22 (7) the fragmented Federal food safety system
23 and outdated laws preclude an integrated, system-
24 wide approach to preventing food-borne illness, to
25 the effective and efficient operation of the Nation's

1 food safety program, and to the most beneficial de-
2 ployment of food safety resources;

3 (8) the National Academy of Sciences rec-
4 ommended in the report “Ensuring Safe Food from
5 Production to Consumption” that Congress establish
6 by statute a unified and central framework for man-
7 aging Federal food safety programs, and rec-
8 ommended modifying Federal statutes so that in-
9 spection, enforcement, and research efforts are
10 based on scientifically supportable assessments of
11 risks to public health; and

12 (9) the lack of a single focal point for food safe-
13 ty leadership in the United States undercuts the
14 ability of the United States to exert food safety lead-
15 ership internationally, which is detrimental to the
16 public health and the international trade interests of
17 the United States.

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

19 (1) to establish a single agency to be known as
20 the “Food Safety Administration”—

21 (A) to regulate food safety and labeling to
22 protect the public health;

23 (B) to ensure that food establishments ful-
24 fill their responsibility to produce food in a

1 manner that protects the public health of all
2 people in the United States;

3 (C) to lead an integrated, system-wide ap-
4 proach to food safety and to make more effec-
5 tive and efficient use of resources to prevent
6 food-borne illness; and

7 (D) to provide a single focal point for food
8 safety leadership, both nationally and inter-
9 nationally;

10 (2) to transfer to the Food Safety Administra-
11 tion the food safety, labeling, inspection, and en-
12 forcement functions that, as of the day before the ef-
13 fective date of this Act, are performed by other Fed-
14 eral agencies; and

15 (3) to modernize the Federal food safety laws
16 to achieve more effective application and efficient
17 management of the laws for the protection and im-
18 provement of public health.

19 **SEC. 3. DEFINITIONS.**

20 In this Act:

21 (1) **ADMINISTRATION.**—The term “Administra-
22 tion” means the Food Safety Administration estab-
23 lished under section 101(a)(1).

1 (2) ADMINISTRATOR.—The term “Adminis-
2 trator” means the Administrator of Food Safety ap-
3 pointed under section 101(a)(3).

4 (3) ADULTERATED.—

5 (A) IN GENERAL.—The term “adulter-
6 ated” has the meaning described in subsections
7 (a) through (c) of section 402 of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C.
9 342(a)–(c)).

10 (B) INCLUSION.—The term “adulterated”
11 includes bearing or containing a contaminant
12 that causes illness or death among sensitive
13 populations.

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

17 (5) CATEGORY 1 FOOD ESTABLISHMENT.—The
18 term “category 1 food establishment” means a food
19 establishment that routinely slaughters animals for
20 human consumption.

21 (6) CATEGORY 2 FOOD ESTABLISHMENT.—The
22 term “category 2 food establishment” means a food
23 establishment that processes raw meat, poultry, sea-
24 food products, and other products that the Adminis-
25 trator determines by regulation to be at high risk of

1 contamination and the processes of which do not in-
2 clude a step validated to destroy contaminants.

3 (7) CATEGORY 3 FOOD ESTABLISHMENT.—The
4 term “category 3 food establishment” means a food
5 establishment that processes meat, poultry, seafood
6 products, and other products that the Administrator
7 determines by regulation to be at high risk of con-
8 tamination and whose processes include a step vali-
9 dated to destroy contaminants.

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

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

19 (10) CONTAMINANT.—The term “contaminant”
20 includes a bacterium, chemical, natural or manufac-
21 tured toxin, virus, parasite, prion, physical hazard,
22 or other human pathogen that when found on or in
23 food can cause human illness, injury, or death.

24 (11) CONTAMINATION.—The term “contamina-
25 tion” refers to a presence of a contaminant in food.

1 (12) FOOD.—

2 (A) IN GENERAL.—The term “food”
3 means a product intended to be used for food
4 or drink for a human.

5 (B) INCLUSIONS.—The term “food” in-
6 cludes any product (including a meat food prod-
7 uct, as defined in section 1(j) of the Federal
8 Meat Inspection Act (21 U.S.C. 601(j))), capa-
9 ble for use as human food that is made in whole
10 or in part from any animal, including cattle,
11 sheep, swine, or goat, or poultry (as defined in
12 section 4 of the Poultry Products Inspection
13 Act (21 U.S.C. 453)).

14 (C) EXCLUSION.—The term “food” does
15 not include dietary supplements, as defined in
16 section 201(ff) of the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 321(ff)).

18 (13) FOOD ESTABLISHMENT.—

19 (A) IN GENERAL.—The term “food estab-
20 lishment” means a slaughterhouse, factory,
21 warehouse, or facility owned or operated by a
22 person located in any State that processes food.

23 (B) EXCLUSIONS.—For the purposes of
24 registration, the term “food establishment”
25 does not include a farm, restaurant, other retail

1 food establishment, nonprofit food establish-
2 ment in which food is prepared for or served di-
3 rectly to the consumer, or fishing vessel (other
4 than a fishing vessel engaged in processing, as
5 that term is defined in section 123.3 of title 21,
6 Code of Federal Regulations).

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

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

14 (A) the provisions of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 301 et
16 seq.) related to and requiring the safety, label-
17 ing, and inspection of food, infant formulas,
18 food additives, pesticide residues, and other
19 substances present in food under that Act;

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

1 (C) the Poultry Products Inspection Act
2 (21 U.S.C. 451 et seq.);

3 (D) the Federal Meat Inspection Act (21
4 U.S.C. 601 et seq.);

5 (E) the Egg Products Inspection Act (21
6 U.S.C. 1031 et seq.);

7 (F) the Sanitary Food Transportation Act
8 of 1990 (49 U.S.C. App. 2801 et seq.);

9 (G) the provisions of the Humane Methods
10 of Slaughter Act of 1978 (Public Law 95–448)
11 administered by the Food Safety and Inspection
12 Service;

13 (H) the provisions of this Act; and

14 (I) such other provisions of law related to
15 and requiring food safety, labeling, inspection,
16 and enforcement as the President designates by
17 Executive order as appropriate to include within
18 the jurisdiction of the Administration.

19 (16) FOREIGN FOOD ESTABLISHMENT.—

20 (A) IN GENERAL.—The term “foreign food
21 establishment” means a slaughterhouse, fac-
22 tory, warehouse, or facility located outside the
23 United States that processes food that is im-
24 ported into the United States without further

1 processing or packaging inside the United
2 States.

3 (B) FURTHER PROCESSING OR PACK-
4 AGING.—A food shall not be considered to have
5 undergone further processing or packaging sole-
6 ly because labeling was added or a similar activ-
7 ity of a de minimis nature was carried out with
8 respect to the food.

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

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

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

20 (20) SAFE.—The term “safe” refers to human
21 health.

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

23 (A) a State;

24 (B) the District of Columbia;

1 (C) the Commonwealth of Puerto Rico;
 2 and
 3 (D) any other territory or possession of the
 4 United States.

5 **TITLE I—ESTABLISHMENT OF**
 6 **FOOD SAFETY ADMINISTRATION**

7 **SEC. 101. ESTABLISHMENT OF FOOD SAFETY ADMINISTRA-**
 8 **TION.**

9 (a) ESTABLISHMENT.—

10 (1) IN GENERAL.—There is established in the
 11 executive branch an agency to be known as the
 12 “Food Safety Administration”.

13 (2) STATUS.—The Administration shall be an
 14 independent establishment (as defined in section 104
 15 of title 5, United States Code).

16 (3) HEAD OF ADMINISTRATION.—The Adminis-
 17 tration shall be headed by the Administrator of Food
 18 Safety, who shall be appointed by the President, by
 19 and with the advice and consent of the Senate.

20 (b) DUTIES OF ADMINISTRATOR.—The Adminis-
 21 trator shall—

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

23 (2) serve as a representative to international
 24 food safety bodies and discussions;

1 (3) promulgate regulations to ensure the secu-
2 rity of the food supply from all forms of contamina-
3 tion, including intentional contamination; and

4 (4) oversee—

5 (A) implementation of Federal food safety
6 inspection, enforcement, and research efforts, to
7 protect the public health;

8 (B) development of consistent and science-
9 based standards for safe food;

10 (C) coordination and prioritization of food
11 safety research and education programs with
12 other Federal agencies;

13 (D) prioritization of Federal food safety ef-
14 forts and deployment of Federal food safety re-
15 sources to achieve the greatest possible benefit
16 in reducing food-borne illness;

17 (E) coordination of the Federal response to
18 food-borne illness outbreaks with other Federal
19 and State agencies; and

20 (F) integration of Federal food safety ac-
21 tivities with State and local agencies.

22 **SEC. 102. CONSOLIDATION OF SEPARATE FOOD SAFETY**
23 **AND INSPECTION SERVICES AND AGENCIES.**

24 (a) **TRANSFER OF FUNCTIONS.**—For each Federal
25 agency specified in subsection (b), there are transferred

1 to the Administration all functions that the head of the
2 Federal agency exercised on the day before the effective
3 date of this Act (including all related functions of any offi-
4 cer or employee of the Federal agency) that relate to ad-
5 ministration or enforcement of the food safety law, as de-
6 termined by the President.

7 (b) TRANSFERRED AGENCIES.—The Federal agen-
8 cies referred to in subsection (a) are—

9 (1) the Food Safety and Inspection Service of
10 the Department of Agriculture;

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

13 (3) the part of the Agriculture Marketing Serv-
14 ice that administers shell egg surveillance services
15 established under the Egg Products Inspection Act
16 (21 U.S.C. 1031 et seq.);

17 (4) the resources and facilities of the Office of
18 Regulatory Affairs of the Food and Drug Adminis-
19 tration that administer and conduct inspections of
20 food establishments and imports;

21 (5) the resources and facilities of the Office of
22 the Commissioner of the Food and Drug Adminis-
23 tration that support—

24 (A) the Center for Food Safety and Ap-
25 plied Nutrition;

1 (B) the Center for Veterinary Medicine;
2 and

3 (C) the Office of Regulatory Affairs facili-
4 ties and resources described in paragraph (4);
5 (6) the Center for Veterinary Medicine of the
6 Food and Drug Administration;

7 (7) the resources and facilities of the Environ-
8 mental Protection Agency that control and regulate
9 pesticide residues in food;

10 (8) the part of the Research, Education, and
11 Economics mission area of the Department of Agri-
12 culture related to food safety and animal feed re-
13 search;

14 (9) the part of the National Marine Fisheries
15 Service of the National Oceanic and Atmospheric
16 Administration of the Department of Commerce that
17 administers the seafood inspection program; and

18 (10) such other offices, services, or agencies as
19 the President designates by Executive order to carry
20 out this Act.

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

22 (a) OFFICERS AND EMPLOYEES.—The Administrator
23 may—

24 (1) appoint officers and employees for the Ad-
25 ministration in accordance with the provisions of

1 title 5, United States Code, relating to appointment
2 in the competitive service; and

3 (2) fix the compensation of those officers and
4 employees in accordance with chapter 51 and with
5 subchapter III of chapter 53 of that title, relating to
6 classification and General Schedule pay rates.

7 (b) EXPERTS AND CONSULTANTS.—The Adminis-
8 trator may—

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

12 (2) pay in connection with those services the
13 travel expenses of the experts and consultants, in-
14 cluding transportation and per diem in lieu of sub-
15 sistence while away from the homes or regular
16 places of business of the individuals, as authorized
17 by section 5703 of that title.

18 (c) BUREAUS, OFFICES, AND DIVISIONS.—The Ad-
19 ministrator may establish within the Administration such
20 bureaus, offices, and divisions as the Administrator deter-
21 mines are necessary to perform the duties of the Adminis-
22 trator.

1 **TITLE II—ADMINISTRATION OF**
2 **FOOD SAFETY PROGRAM**

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

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

5 (1) administer a national food safety program
6 (referred to in this section as the “program”) to
7 protect public health; and

8 (2) ensure that persons who produce or process
9 food for human consumption meet their responsi-
10 bility to prevent or minimize food safety hazards re-
11 lated to their products.

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

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

18 (2) the sources and specific points of potential
19 contamination extending from the farm or ranch to
20 the consumer that may render food unsafe for
21 human consumption;

22 (3) the potential for persistence, multiplication,
23 or concentration of naturally occurring or added
24 contaminants in food;

1 (4) opportunities across the food production,
2 processing, distribution, and retail system to reduce
3 potential health risks; and

4 (5) opportunities for intentional contamination.

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

7 (1) implement a national system for the reg-
8 istration of food establishments and foreign food es-
9 tablishments and regular unannounced inspection of
10 food establishments;

11 (2) enforce the adoption of process controls in
12 food establishments, based on best available sci-
13 entific and public health considerations and best
14 available technologies;

15 (3) establish and enforce science-based stand-
16 ards for—

17 (A) substances that may contaminate food;

18 and

19 (B) safety and sanitation in the processing
20 and handling of food;

21 (4) implement a sampling program to ensure
22 that industry programs and procedures that prevent
23 food contamination are effective on an ongoing basis
24 and that food meets the standards established under
25 this Act;

1 (5) implement procedures and requirements to
2 ensure the safety and security of imported food;

3 (6) coordinate with other agencies and State or
4 local governments in carrying out inspection, en-
5 forcement, and monitoring;

6 (7) have access to the surveillance data of the
7 Centers for Disease Control and Prevention, and
8 other Federal Government agencies, in order to im-
9 plement a national surveillance system to assess the
10 health risks associated with the human consumption
11 of food;

12 (8) develop public education risk communica-
13 tion and advisory programs;

14 (9) implement a research program to further
15 the purposes of this Act; and

16 (10) coordinate and prioritize food safety re-
17 search and educational programs with other agen-
18 cies, including State or local agencies.

19 **SEC. 202. REGISTRATION OF FOOD ESTABLISHMENTS AND**
20 **FOREIGN FOOD ESTABLISHMENTS.**

21 (a) IN GENERAL.—The Administrator shall by regu-
22 lation require that any food establishment or foreign food
23 establishment engaged in processing food for human con-
24 sumption in the United States be registered with the Ad-
25 ministrator.

1 (b) REGISTRATION REQUIREMENTS.—

2 (1) IN GENERAL.—To be registered under sub-
3 section (a)—

4 (A) in the case of a food establishment, the
5 owner, operator, or agent in charge of the food
6 establishment shall submit a registration to the
7 Administrator; and

8 (B) in the case of a foreign food establish-
9 ment, the owner, operator, or agent in charge
10 of the foreign food establishment shall—

11 (i) submit a registration to the Ad-
12 ministrator; and

13 (ii) provide the name, address, and
14 emergency contact information of the
15 United States agent for the foreign food
16 establishment.

17 (2) REGISTRATION.—A food establishment or
18 foreign food establishment shall submit a registra-
19 tion under paragraph (1) to the Administrator
20 that—

21 (A) identifies the name, address, and emer-
22 gency contact information of each food estab-
23 lishment or foreign food establishment that the
24 registrant operates under this Act and all trade

1 names under which the registrant conducts
2 business relating to food;

3 (B) lists the primary purpose and business
4 activity of each food establishment or foreign
5 food establishment, including the dates of oper-
6 ation if the food establishment or foreign food
7 establishment is seasonal;

8 (C) lists the types of food processed or sold
9 at each food establishment or, for foreign food
10 establishments selling food for consumption in
11 the United States, identifies the specific food
12 categories of that food as listed under section
13 170.3 of title 21, Code of Federal Regulations;
14 and

15 (D) not later than 30 days after a change
16 in the products, function, or legal status of the
17 food establishment or foreign food establish-
18 ment (including cessation of business activities),
19 notifies the Administrator of the change.

20 (3) PROCEDURE.—Upon receipt of a completed
21 registration described in paragraph (1), the Admin-
22 istrator shall notify the registrant of the receipt of
23 the registration and assign a registration number to
24 each food establishment and foreign food establish-
25 ment.

1 (4) LIST.—The Administrator shall compile and
2 maintain an up-to-date list of food establishments
3 and foreign food establishments that are registered
4 under this section.

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

8 (A) the list compiled under paragraph (4);
9 and

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

14 (6) SUSPENSION OF REGISTRATION.—

15 (A) IN GENERAL.—The Administrator may
16 suspend the registration of a food establishment
17 or foreign food establishment, including the fa-
18 cility of an importer, for violation of a food
19 safety law.

20 (B) NOTICE AND OPPORTUNITY FOR
21 HEARING.—The Administrator shall provide no-
22 tice to a registrant immediately upon the sus-
23 pension of the registration of the facility and
24 provide registrant with an opportunity for a
25 hearing within 3 days of the suspension.

1 tions for handling and preparation for consumption
2 that, when adhered to, will destroy contaminants.

3 (b) REGULATIONS.—Not later than 1 year after the
4 effective date of this Act, the Administrator shall promul-
5 gate regulations that—

6 (1) require all food establishments to adopt pre-
7 ventative process controls that are—

8 (A) adequate to protect the public health;

9 (B) meet relevant regulatory and food
10 safety standards; and

11 (C) limit the presence and growth of con-
12 taminants in food prepared in a food establish-
13 ment;

14 (2) set standards for sanitation;

15 (3) meet any performance standards for con-
16 taminants established under section 204;

17 (4) require recordkeeping to monitor compli-
18 ance;

19 (5) require sampling and testing at a frequency
20 and in a manner sufficient to ensure that process
21 controls are effective on an ongoing basis and that
22 regulatory standards are being met; and

23 (6) provide for agency access to records kept by
24 food establishments and submission of copies of the

1 records to the Administrator, as the Administrator
2 determines appropriate.

3 (c) PROCESSING CONTROLS.—The Administrator
4 may require any person with responsibility for or control
5 over food or food ingredients to adopt process controls,
6 if the process controls are needed to ensure the protection
7 of the public health.

8 **SEC. 204. PERFORMANCE STANDARDS FOR CONTAMINANTS**
9 **IN FOOD.**

10 (a) IN GENERAL.—To protect the public health, the
11 Administrator shall establish by regulation and enforce
12 performance standards that define, with respect to specific
13 food-borne contaminants and foods, the level of food safety
14 performance that a person responsible for producing, proc-
15 essing, or selling food shall meet.

16 (b) IDENTIFICATION OF CONTAMINANTS; PERFORM-
17 ANCE STANDARDS.—

18 (1) IN GENERAL.—Not later than 6 months
19 after the date of enactment of this Act, the Adminis-
20 trator shall identify the food-borne contaminants
21 and food that contribute significantly to the risk of
22 food-borne illness.

23 (2) PERFORMANCE STANDARDS.—As soon as
24 practicable after the identification of the contami-
25 nants under paragraph (1), the Administrator shall

1 establish appropriate performance standards to pro-
2 tect against all food-borne contaminants.

3 (3) SIGNIFICANT CONTAMINANTS.—The Admin-
4 istrator shall establish performance standards for
5 the 5 most significant contaminants associated with
6 raw meat, poultry, and seafood not later than 3
7 years after the date of enactment of this Act.

8 (c) PERFORMANCE STANDARDS.—

9 (1) IN GENERAL.—The performance standards
10 established under this section shall include—

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

14 (B) zero tolerances, in addition to any
15 zero-tolerance standards in effect on the day be-
16 fore the date of enactment of this Act, when
17 necessary to protect against significant adverse
18 health outcomes;

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

22 (D) in the absence of data to support a
23 performance standard described in subpara-
24 graph (A), (B), or (C), standards that define
25 required performance in terms of “best reason-

1 ably achievable performance”, using best avail-
2 able technologies, interventions, and practices.

3 (2) BEST REASONABLY ACHIEVABLE PERFORM-
4 ANCE STANDARDS.—In developing best reasonably
5 achievable performance standards, the Administrator
6 shall collect, or contract for the collection of, data on
7 current best practices and food safety outcomes re-
8 lated to the contaminants and foods in question, as
9 the Administrator determines necessary.

10 (3) REVOCATION BY ADMINISTRATOR.—All per-
11 formance standards, tolerances, action levels, or
12 other similar standards in effect on the date of en-
13 actment of this Act shall remain in effect until re-
14 vised or revoked by the Administrator.

15 (d) ENFORCEMENT.—

16 (1) IN GENERAL.—Not later than 1 year after
17 the promulgation of a performance standard under
18 this section, the Administrator shall implement a
19 sampling program to determine whether food estab-
20 lishments are complying with the performance stand-
21 ards promulgated under this section. The program
22 established under this paragraph shall be at least as
23 stringent as the Hazard Analysis and Critical Con-
24 trol Point System requirements established under

1 part 417 of title 9, Code of Federal Regulations (or
2 successor regulation).

3 (2) INSPECTIONS.—If the Administrator deter-
4 mines that a food establishment fails to meet a
5 standard promulgated under this section, and such
6 establishment fails to take appropriate corrective ac-
7 tion as determined by the Administrator, the Admin-
8 istrator shall, as appropriate—

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

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

13 (C) increase the inspection frequency for
14 the food establishment;

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

17 (E) take other appropriate enforcement ac-
18 tion concerning the food establishment.

19 (e) NEWLY IDENTIFIED CONTAMINANTS.—Notwith-
20 standing any other provision of this section, the Adminis-
21 trator shall promulgate interim performance standards for
22 newly identified contaminants as necessary to protect the
23 public health.

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

2 (a) IN GENERAL.—The Administrator shall establish
3 an inspection program, which shall include sampling and
4 testing of food and food establishments, to determine if
5 each food establishment—

6 (1) is operating in a sanitary manner;

7 (2) has continuous systems, interventions, and
8 processes in place to minimize or eliminate contami-
9 nants in food;

10 (3) is in compliance with applicable perform-
11 ance standards established under section 203, and
12 other regulatory requirements;

13 (4) is processing food that is safe for human
14 consumption and not adulterated or misbranded;

15 (5) maintains records of process control plans
16 under section 203, and other records related to the
17 processing, sampling, and handling of food; and

18 (6) is in compliance with the requirements of
19 the food safety law.

20 (b) ESTABLISHMENT CATEGORIES AND INSPECTION
21 FREQUENCIES.—The resource plan required under section
22 209, including the description of resources required to
23 carry out inspections of food establishments, shall be
24 based on the following categories and inspection fre-
25 quencies, subject to subsections (c) and (d):

1 (1) CATEGORY 1 FOOD ESTABLISHMENTS.—A
2 category 1 food establishment shall be subject to
3 antemortem and continuous inspection of each
4 slaughter line during all operating hours, and other
5 inspection on a daily basis, sufficient to verify
6 that—

7 (A) diseased animals are not offered for
8 slaughter;

9 (B) the food establishment has successfully
10 identified and removed from the slaughter line
11 visibly defective or contaminated carcasses and
12 destroyed or reprocessed them in a manner ac-
13 ceptable to the Administrator; and

14 (C) that applicable performance standards
15 and other provisions of the food safety law have
16 been satisfied.

17 (2) CATEGORY 2 FOOD ESTABLISHMENTS.—A
18 category 2 food establishment shall be randomly in-
19 spected at least daily.

20 (3) CATEGORY 3 FOOD ESTABLISHMENTS.—A
21 category 3 food establishment shall—

22 (A) have ongoing verification that its proc-
23 esses are controlled; and

24 (B) be randomly inspected at least month-
25 ly.

1 (4) CATEGORY 4 FOOD ESTABLISHMENTS.—A
2 category 4 food establishment shall be randomly in-
3 spected at least quarterly.

4 (5) CATEGORY 5 FOOD ESTABLISHMENTS.—A
5 category 5 food establishment shall be randomly in-
6 spected at least annually.

7 (c) ALTERNATIVE INSPECTION FREQUENCIES.—
8 With respect to a category 2, 3, 4, or 5 food establishment,
9 the Administrator may establish alternative inspection fre-
10 quencies for subcategories of food establishments or indi-
11 vidual establishments, to foster risk-based allocation of re-
12 sources, subject to the following criteria and procedures:

13 (1) Subcategories of food establishments and
14 their alternative inspection frequencies shall be de-
15 fined by regulation, subject to paragraphs (2) and
16 (3).

17 (2) Regulations of alternative inspection fre-
18 quencies for subcategories of food establishments
19 under paragraph (1) and for a specific food estab-
20 lishment under paragraph (4) shall provide that—

21 (A) category 2 food establishments shall be
22 inspected at least monthly; and

23 (B) category 3, 4, and 5 food establish-
24 ments shall be inspected at least annually.

1 (3) 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 pro-
14 duced in the proposed subcategory of establish-
15 ments; and

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

21 (4) The Administrator may adopt alternative
22 inspection frequencies for a specific establishment,
23 subject to paragraphs (2) and (5) and shall periodi-
24 cally publish a list of establishments subject to alter-
25 native inspections.

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

4 (A) the criteria in paragraph (3);

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

8 (C) the record of the establishment of com-
9 pliance with the food safety law, including com-
10 pliance with applicable performance standards
11 and the frequency of recalls.

12 (6) Before establishing alternative inspection
13 frequencies for subcategories of establishments or in-
14 dividual establishments, the Administrator shall—

15 (A) determine, based on the best available
16 evidence, that the alternative uses of the re-
17 sources required to carry out the inspection ac-
18 tivity would make a greater contribution to pro-
19 tecting the public health and reducing the risk
20 of food-borne illness than the use of resources
21 described in subsection (b);

22 (B) describe the alternative uses of re-
23 sources in general terms when issuing the regu-
24 lation or order that establishes the alternative
25 inspection frequency;

1 (C) consider the supporting evidence that
2 an individual food establishment shall submit
3 related to whether an alternative inspection fre-
4 quency should be established for such establish-
5 ment by the Administrator; and

6 (D) include a description of the alternative
7 uses in the annual resource plan required in
8 section 209.

9 (d) INSPECTION TRANSITION.—The Administrator
10 shall manage the transition to the inspection system de-
11 scribed in this Act as follows:

12 (1) In the case of a category 1 or 2 food estab-
13 lishment, the Administrator shall continue to imple-
14 ment the applicable inspection mandates of the Fed-
15 eral Meat Inspection Act (21 U.S.C. 601 et seq.),
16 the Poultry Products Inspection Act (21 U.S.C. 451
17 et seq.), and the Federal Food, Drug, and Cosmetic
18 Act (21 U.S.C. 301 et seq.) until—

19 (A) regulations required to implement this
20 section have been promulgated;

21 (B) the performance standards required by
22 section 204(c) have been promulgated and im-
23 plemented for 1 year; and

1 (C) the establishment has achieved compli-
2 ance with the other applicable provisions of the
3 food safety law.

4 (2) In the case of a category 1 or 2 food estab-
5 lishment that, within 2 years after the promulgation
6 of the performance standards required by section
7 204(c), has not achieved compliance with the food
8 safety law, the Administrator shall—

9 (A) issue an order prohibiting the estab-
10 lishment from operating pending a demonstra-
11 tion by the establishment that sufficient
12 changes in facilities, procedures, personnel, or
13 other aspects of the process control system have
14 been made such that the Administrator deter-
15 mines that compliance with the food safety law
16 is achieved; and

17 (B) following the demonstration required
18 in subparagraph (A), issue an order authorizing
19 the food establishment to operate subject, at a
20 minimum, to—

21 (i) the inspection requirement applica-
22 ble to the establishment under subsection
23 (b) (1) or (2); and

24 (ii) such other inspection or compli-
25 ance measures determined by the Adminis-

1 trator necessary to assure compliance with
2 the applicable food safety law.

3 (3) In the case of a category 3 food establish-
4 ment, the Administrator shall continue to implement
5 the applicable inspection mandates of the Federal
6 Meat Inspection Act (21 U.S.C. 601 et seq.), the
7 Poultry Products Inspection Act (21 U.S.C. 451 et
8 seq.), and the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 301 et seq.) until—

10 (A) the regulations required to implement
11 this section have been promulgated;

12 (B) the first resource plan under section
13 209 has been submitted; and

14 (C) for individual establishments, compli-
15 ance with the food safety law has been dem-
16 onstrated.

17 (4) In the case of a category 3 food establish-
18 ment that, within 1 year after the promulgation of
19 the regulations required to implement this section,
20 have not demonstrated compliance with the food
21 safety law, the Administrator shall—

22 (A) issue an order prohibiting the estab-
23 lishment from operating, pending a demonstra-
24 tion by the establishment that sufficient
25 changes in facilities, procedures, personnel, or

1 other aspects of the process control system have
2 been made such that the Administrator deter-
3 mines that compliance with the food safety law
4 is achieved; and

5 (B) following the demonstration required
6 in subparagraph (A), issue an order authorizing
7 the establishment to operate subject, at a min-
8 imum, to—

9 (i) the inspection requirement applica-
10 ble to the establishment under subsection
11 (b)(3); and

12 (ii) such other inspection or compli-
13 ance measures determined by the Adminis-
14 trator necessary to assure compliance with
15 the food safety law.

16 (5) In the case of a category 4 or 5 food estab-
17 lishment, the inspection requirements of this Act
18 shall be implemented as soon as possible after—

19 (A) the promulgation of the regulations re-
20 quired to implement this section;

21 (B) the publication of the first resource
22 plan under section 209; and

23 (C) the commencement of the first fiscal
24 year in which the Administration is operating
25 with budgetary resources that Congress has ap-

1 appropriated following consideration of the re-
2 source plan under section 209.

3 (e) OFFICIAL MARK.—

4 (1) IN GENERAL.—

5 (A) ESTABLISHMENT.—Before the comple-
6 tion of the transition process under paragraphs
7 (1) through (3) of subsection (d), the Adminis-
8 trator shall by regulation establish an official
9 mark that shall be affixed to a food product
10 produced in a category 1, 2, or 3 establishment,
11 subject to subparagraph (B).

12 (B) PREREQUISITE.—The official mark re-
13 quired under subparagraph (A) shall be affixed
14 to a food product by the Administrator if the
15 establishment has been inspected by the Admin-
16 istrator in accordance with the inspection fre-
17 quencies under this section and the establish-
18 ment is in compliance with the food safety law.

19 (2) CATEGORY 1, 2, OR 3 FOOD ESTABLISH-
20 MENTS.—In the case of products produced in a cat-
21 egory 1, 2, or 3 food establishment—

22 (A) products subject to Federal Meat In-
23 spection Act (21 U.S.C. 601 et seq.), the Poul-
24 try Products Inspection Act (21 U.S.C. 451 et
25 seq.), the Egg Products Inspection Act (21

1 U.S.C. 1031 et seq.), and the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 301 et
3 seq.) as of the date of enactment of this Act
4 shall remain subject to the requirement under
5 those Acts that they bear the mark of inspec-
6 tion pending completion of the transition proc-
7 ess under paragraphs (1) through (3) of sub-
8 section (d);

9 (B) the Administrator shall publicly certify
10 on a monthly basis that the inspection fre-
11 quencies required under this Act have been
12 achieved; and

13 (C) a product from an establishment that
14 has not been inspected in accordance with the
15 required frequencies under this section shall not
16 bear the official mark and shall not be shipped
17 in interstate commerce.

18 (3) CATEGORY 4 AND 5 FOOD ESTABLISH-
19 MENTS.—In the case of a product produced in a cat-
20 egory 4 or 5 food establishment the Administrator
21 shall provide by regulation for the voluntary use of
22 the official mark established under paragraph (1),
23 subject to—

1 (A) such minimum inspection frequencies
2 as determined appropriate by the Adminis-
3 trator;

4 (B) compliance with applicable perform-
5 ance standards and other provisions of the food
6 safety law; and

7 (C) such other requirements the Adminis-
8 trator considers appropriate.

9 (f) IMPLEMENTATION.—Not later than 1 year after
10 the effective date of this Act, the Administrator shall issue
11 regulations to implement subsections (b) through (d).

12 (g) MAINTENANCE AND INSPECTION OF RECORDS.—

13 (1) IN GENERAL.—

14 (A) RECORDS.—A food establishment
15 shall—

16 (i) maintain such records as the Ad-
17 ministrator shall require by regulation, in-
18 cluding all records relating to the proc-
19 essing, distributing, receipt, or importation
20 of any food; and

21 (ii) permit the Administrator, in addi-
22 tion to any authority of the food safety
23 agencies in effect on the day before the
24 date of enactment of this Act, upon pres-
25 entation of appropriate credentials and at

1 reasonable times and in a reasonable man-
2 ner, to have access to and copy all records
3 maintained by or on behalf of such food es-
4 tablishment representative in any format
5 (including paper or electronic) and at any
6 location, that are necessary to assist the
7 Administrator—

8 (I) to determine whether the food
9 is contaminated or not in compliance
10 with the food safety law; or

11 (II) to track the food in com-
12 merce.

13 (B) REQUIRED DISCLOSURE.—A food es-
14 tablishment shall have an affirmative obligation
15 to disclose to the Administrator the results of
16 testing or sampling of food, equipment, or ma-
17 terial in contact with food, that is positive for
18 any contaminant.

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

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

1 (A) the origin, receipt, delivery, sale, move-
2 ment, holding, and disposition of food or ingre-
3 dients;

4 (B) the identity and quantity of ingredi-
5 ents used in the food;

6 (C) the processing of the food;

7 (D) the results of laboratory, sanitation, or
8 other tests performed on the food or in the food
9 establishment;

10 (E) consumer complaints concerning the
11 food or packaging of the food;

12 (F) the production codes, open date codes,
13 and locations of food production; and

14 (G) other matters reasonably related to
15 whether food is unsafe for human consumption,
16 is adulterated or misbranded, or otherwise fails
17 to meet the requirements of this Act.

18 (h) PROTECTION OF SENSITIVE INFORMATION.—

19 (1) IN GENERAL.—The Administrator shall de-
20 velop and maintain procedures to prevent the unau-
21 thorized disclosure of any trade secret or confiden-
22 tial information obtained by the Administrator.

23 (2) LIMITATION.—The requirement under this
24 subsection does not—

1 (A) limit the authority of the Adminis-
2 trator to inspect or copy records or to require
3 the establishment or maintenance of records
4 under this Act;

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

7 (C) extend to any food recipe, financial
8 data, pricing data, personnel data, or sales data
9 (other than shipment dates relating to sales); or

10 (D) limit the public disclosure of distribu-
11 tion records or other records related to food
12 subject to a voluntary or mandatory recall
13 under section 403.

14 (i) BRIBERY OF OR GIFTS TO INSPECTOR OR OTHER
15 OFFICERS AND ACCEPTANCE OF GIFTS.—Section 22 of
16 the Federal Meat Inspection Act (21 U.S.C. 622) shall
17 apply to an inspection under this Act.

18 **SEC. 206. FOOD PRODUCTION FACILITIES.**

19 In carrying out the duties of the Administrator and
20 the purposes of this Act, the Administrator shall have the
21 authority, with respect to food production facilities, to—

22 (1) visit and inspect food production facilities in
23 the United States and in foreign countries to inves-
24 tigate bioterrorism threats and for other critical food
25 safety purposes;

1 (2) review food safety records as required to be
2 kept by the Administrator to carry out traceback
3 and for other critical 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 **SEC. 207. FEDERAL AND STATE COOPERATION.**

12 (a) IN GENERAL.—The Administrator shall work
13 with the States to carry out activities and programs that
14 contribute to the national food safety program so that
15 Federal and State programs function in a coordinated and
16 cost-effective manner.

17 (b) STATE ACTION.—The Administrator shall work
18 with States to—

19 (1) continue, strengthen, or establish State food
20 safety programs, especially with respect to the regu-
21 lation of retail commercial food establishments,
22 transportation, harvesting, and fresh markets;

23 (2) establish inspection programs and require-
24 ments to ensure that food under the jurisdiction of
25 the State is safe for human consumption; and

1 (3) support recall authorities at the State and
2 local levels.

3 (c) ASSISTANCE.—To assist in planning, developing,
4 and implementing a food safety program, the Adminis-
5 trator may provide to a State—

6 (1) advisory assistance;

7 (2) technical and laboratory assistance and
8 training (including necessary materials and equip-
9 ment); and

10 (3) financial and other aid.

11 (d) 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 personnel and services of those agencies
16 in carrying out this Act.

17 (2) TRAINING.—Agreements with a State under
18 this subsection may provide for training of State em-
19 ployees.

20 (3) MAINTENANCE OF AGREEMENTS.—The Ad-
21 ministrator shall maintain any agreement that is in
22 effect on the day before the date of enactment of
23 this Act until the Administrator evaluates such
24 agreement and determines whether to maintain or
25 substitute such agreement.

1 (e) AUDITS.—

2 (1) IN GENERAL.—The Administrator shall an-
3 nually conduct a comprehensive review of each State
4 program that provides services to the Administrator
5 in carrying out the responsibilities under this Act,
6 including mandated inspections under section 205.

7 (2) REQUIREMENTS.—The review shall—

8 (A) include a determination of the effec-
9 tiveness of the State program; and

10 (B) identify any changes necessary to en-
11 sure enforcement of Federal requirements
12 under this Act.

13 **SEC. 208. IMPORTS.**

14 (a) IN GENERAL.—Not later than 2 years after the
15 effective date of this Act, the Administrator shall establish
16 a system under which a foreign government or foreign
17 food establishment seeking to import food to the United
18 States shall submit a request for certification to the Ad-
19 ministrator.

20 (b) CERTIFICATION STANDARD.—A foreign govern-
21 ment or foreign food establishment requesting a certifi-
22 cation to import food to the United States shall dem-
23 onstrate, in a manner determined appropriate by the Ad-
24 ministrator, that food produced under the supervision of
25 a foreign government or by the foreign food establishment

1 has met standards for food safety, inspection, labeling,
2 and consumer protection that are at least equivalent to
3 standards applicable to food produced in the United
4 States.

5 (c) CERTIFICATION APPROVAL.—

6 (1) REQUEST BY FOREIGN GOVERNMENT.—

7 Prior to granting the certification request of a for-
8 eign government, the Administrator shall review,
9 audit, and certify the food safety program of a re-
10 questing foreign government (including all statutes,
11 regulations, and inspection authority) as at least
12 equivalent to the food safety program in the United
13 States, as demonstrated by the foreign government.

14 (2) REQUEST BY FOREIGN FOOD ESTABLISH-

15 MENT.—Prior to granting the certification request of
16 a foreign food establishment, the Administrator shall
17 certify, based on an onsite inspection, the food safe-
18 ty programs and procedures of a requesting foreign
19 firm as at least equivalent to the food safety pro-
20 grams and procedures of the United States.

21 (d) LIMITATION.—A foreign government or foreign

22 firm approved by the Administrator to import food to the
23 United States under this section shall be certified to ex-
24 port only the approved food products to the United States
25 for a period not to exceed 5 years.

1 (e) WITHDRAWAL OF CERTIFICATION.—The Admin-
2 istrator may withdraw certification of any food from a for-
3 eign government or foreign firm—

4 (1) if such food is linked to an outbreak of
5 human illness;

6 (2) following an investigation by the Adminis-
7 trator that finds that the foreign government pro-
8 grams and procedures or foreign food establishment
9 is no longer equivalent to the food safety programs
10 and procedures in the United States; or

11 (3) following a refusal to allow United States
12 officials to conduct such audits and investigations as
13 may be necessary to fulfill the requirements under
14 this section.

15 (f) RENEWAL OF CERTIFICATION.—The Adminis-
16 trator shall audit foreign governments and foreign food
17 establishments at least every 5 years to ensure the contin-
18 ued compliance with the standards set forth in this sec-
19 tion.

20 (g) REQUIRED ROUTINE INSPECTION.—The Admin-
21 istrator shall routinely inspect food before it enters the
22 United States to ensure that it is—

23 (1) safe for human consumption;

24 (2) labeled as required for food produced in the
25 United States; and

1 (3) otherwise meets requirements under the
2 food safety law.

3 (h) ENFORCEMENT.—The Administrator—

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

9 (2) may deny importation of food from any for-
10 eign government or foreign firm that does not con-
11 sent to an investigation by the Administration when
12 food from that foreign country or foreign firm is
13 linked to a food-borne illness outbreak or is other-
14 wise found to be adulterated or mislabeled; and

15 (3) is authorized to promulgate rules and regu-
16 lations to carry out the purposes of this section, in-
17 cluding setting terms and conditions for the destruc-
18 tion of products that fail to meet the standards of
19 this Act.

20 (i) DETENTION AND SEIZURE.—Any food imported
21 for consumption in the United States may be detained,
22 seized, or condemned pursuant to section 402.

23 **SEC. 209. RESOURCE PLAN.**

24 (a) IN GENERAL.—The Administrator shall prepare
25 and update annually a resource plan describing the re-

1 sources required, in the best professional judgment of the
2 Administrator, to develop and fully implement the national
3 food safety program established under this Act.

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

5 (1) describe quantitatively the personnel, finan-
6 cial, and other resources required to carry out the
7 inspection of food establishments under section 205
8 and other requirements of the national food safety
9 program;

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

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

21 (A) in foreign establishments;

22 (B) at the point of importation; and

23 (C) at the point of production on farms,
24 ranches, and feedlots.

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 in re-
4 tail and food service facilities and the required inspections
5 in food establishments.

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.**

12 (a) IN GENERAL.—The Administrator, in order to
13 protect the public health, shall establish requirements for
14 tracing food and food producing animals from point of ori-
15 gin to retail sale, subject to subsection (b).

16 (b) APPLICABILITY.—Traceability requirements
17 shall—

18 (1) be established in accordance with regula-
19 tions and guidelines issued by the Administrator;
20 and

21 (2) apply to food production facilities and food
22 establishments.

23 (c) RELATIONSHIP TO COUNTRY OF ORIGIN LABEL-
24 ING.—Nothing contained in this section prevents or inter-
25 feres with implementation of the country of origin labeling

1 requirements of subtitle D of the Agricultural Marketing
2 Act of 1946 (7 U.S.C. 1638 et seq.).

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

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

6 (a) IN GENERAL.—The Administrator, acting in co-
7 ordination with the Director of the Centers for Disease
8 Control and Prevention and with the Research Education
9 and Economics mission area of the Department of Agri-
10 culture, shall—

11 (1) have access to the applicable data systems
12 of the Centers for Disease Control and Prevention;

13 (2) maintain an active surveillance system of
14 food, food products, and epidemiological evidence
15 submitted by States to the Centers for Disease Con-
16 trol and Prevention based on a representative pro-
17 portion of the population of the United States;

18 (3) assess the frequency and sources of human
19 illness in the United States associated with the con-
20 sumption of food; and

21 (4) maintain a state-of-the-art DNA matching
22 system and epidemiological system dedicated to food-
23 borne illness identification, outbreaks, and contain-
24 ment.

25 (b) PUBLIC HEALTH SAMPLING.—

1 (1) IN GENERAL.—Not later than 1 year after
2 the effective date of this Act, the Administrator shall
3 establish guidelines for a sampling system under
4 which the Administrator shall take and analyze sam-
5 ples of food—

6 (A) to assist the Administrator in carrying
7 out this Act; and

8 (B) to assess the nature, frequency of oc-
9 currence, and quantities of contaminants in
10 food.

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

13 (A) statistically valid monitoring, including
14 market-based studies, on the nature, frequency
15 of occurrence, and quantities of contaminants
16 in food available to consumers; and

17 (B) at the request of the Administrator,
18 such other information, including analysis of
19 monitoring and verification samples, as the Ad-
20 ministrator determines may be useful in assess-
21 ing the occurrence of contaminants in food.

22 (c) ASSESSMENT OF HEALTH HAZARDS.—

23 (1) IN GENERAL.—Through the surveillance
24 system referred to in subsection (a) and the sam-

1 pling system described in subsection (b), the Admin-
2 istrator shall—

3 (A) rank food categories based on the haz-
4 ard to human health presented by the food cat-
5 egory;

6 (B) identify appropriate industry and regu-
7 latory approaches to minimize hazards in the
8 food supply; and

9 (C) assess the public health environment
10 for emerging diseases, including zoonosis, for
11 their risk of appearance in the United States
12 food supply.

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

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

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

- 1 (C) a description of contamination origi-
2 nating from handling practices that occur prior
3 to or after the sale of food to consumers; and
4 (D) use of comparative risk assessments.

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

6 (a) PUBLIC EDUCATION.—

7 (1) IN GENERAL.—The Administrator, in co-
8 operation with private and public organizations, in-
9 cluding the cooperative extension services and appro-
10 priate State and local entities, shall establish a na-
11 tional public education program on food safety.

12 (2) REQUIREMENTS.—The program shall pro-
13 vide—

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

18 (B) information for health professionals—

19 (i) to improve diagnosis and treatment
20 of food-related illness; and

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

23 (C) such other information or advice to
24 consumers and other persons as the Adminis-

1 trator determines will promote the purposes of
2 this Act.

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

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

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

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

14 (4) to present prompt, specific information re-
15 garding foods found to pose a threat to the public
16 health.

17 **SEC. 303. RESEARCH.**

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

20 (1) to improve sanitation and food safety prac-
21 tices in the processing of food;

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

24 (3) to develop efficient, rapid, and sensitive
25 methods to detect contaminants in food;

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

3 (5) to develop food consumption data;

4 (6) to identify ways that animal production
5 techniques could improve the safety of the food sup-
6 ply; and

7 (7) to conduct other research that supports the
8 purposes of this Act.

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

13 **TITLE IV—ENFORCEMENT**

14 **SEC. 401. PROHIBITED ACTS.**

15 It is prohibited—

16 (1) to manufacture, introduce, deliver for intro-
17 duction, or receive into interstate commerce any food
18 that is adulterated, misbranded, or otherwise unsafe
19 for human consumption;

20 (2) to adulterate or misbrand any food in inter-
21 state commerce;

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

1 (4) to refuse to permit access to a food estab-
2 lishment for the inspection and copying of a record
3 as required under section 205(g);

4 (5) to fail to establish or maintain any record
5 or to make any report as required under section
6 205(g);

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

9 (7) to fail to provide to the Administrator the
10 results of a testing or sampling of a food, equip-
11 ment, or material in contact with contaminated food
12 under section 205(h);

13 (8) to fail to comply with a provision, regula-
14 tion, or order of the Administrator under section
15 202, 203, 204, or 208;

16 (9) to slaughter an animal that is capable for
17 use in whole or in part as human food at a food es-
18 tablishment processing any such food for commerce,
19 except in compliance with the food safety law;

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

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

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

2 **SEC. 402. FOOD DETENTION, SEIZURE, AND CONDEMNATION.**
3 **TION.**

4 (a) ADMINISTRATIVE DETENTION OF FOOD.—

5 (1) EXPANDED AUTHORITY.—The Adminis-
6 trator shall have authority under section 304 of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 334) to administratively detain and seize any food
9 that the Administrator has reason to believe is un-
10 safe for human consumption, is adulterated or mis-
11 branded, or otherwise fails to meet the requirements
12 of the food safety law.

13 (2) DETENTION AUTHORITY.—If, during an in-
14 spection conducted in accordance with section 205 or
15 208, an officer, employee, or agent of the Adminis-
16 tration making the inspection has reason to believe
17 that a domestic food, imported food, or food offered
18 for import is unsafe for human consumption, is
19 adulterated or misbranded, or otherwise fails to meet
20 the requirements of this Act, the officer or employee
21 may order the food detained.

22 (3) PERIOD OF DETENTION.—

23 (A) IN GENERAL.—A food may be detained
24 for a reasonable period, not to exceed 20 days,
25 unless a longer period, not to exceed 30 days,

1 is necessary for the Administrator to institute a
2 seizure action.

3 (B) PERISHABLE FOOD.—The Adminis-
4 trator shall provide by regulation for procedures
5 to institute a seizure action on an expedited
6 basis with respect to perishable food.

7 (4) SECURITY OF DETAINED FOOD.—

8 (A) IN GENERAL.—A detention order—

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

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

13 (B) FOOD SUBJECT TO AN ORDER.—A
14 food subject to a detention order shall not be
15 transferred by any person from the place at
16 which the food is removed, until released by the
17 Administrator or until the expiration of the de-
18 tention period applicable under the order,
19 whichever occurs first.

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

24 (b) APPEAL OF DETENTION ORDER.—

1 (1) IN GENERAL.—A person who would be enti-
2 tled to be a claimant for a food subject to a deten-
3 tion order if the food were seized under section 304
4 of the Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 334), may appeal the order to the Adminis-
6 trator.

7 (2) ACTION BY THE ADMINISTRATOR.—Not
8 later than 5 days after an appeal is filed under para-
9 graph (1), the Administrator, after providing an op-
10 portunity for an informal hearing, shall confirm,
11 modify, or terminate the order involved.

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

17 (4) TERMINATION.—The order shall be consid-
18 ered to be terminated if, after 5 days, the Adminis-
19 trator has failed—

20 (A) to provide an opportunity for an infor-
21 mal hearing; or

22 (B) to confirm, modify, or terminate the
23 order.

24 (5) EFFECT OF INSTITUTING COURT ACTION.—
25 If the Administrator initiates an action under sec-

1 tion 302 of the Federal Food, Drug, and Cosmetic
2 Act (21 U.S.C. 332) or section 304(a) of that Act
3 (21 U.S.C. 334(a)), the process for the appeal of the
4 detention order shall terminate.

5 (c) CONDEMNATION OF FOOD.—

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

9 (2) DESTRUCTION OF FOOD.—Any food con-
10 demned shall be destroyed under the supervision of
11 the Administrator.

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

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

20 (1) IN GENERAL.—If an officer or qualified em-
21 ployee of the Administration has reason to believe
22 that a food is unsafe for human consumption, is
23 adulterated or misbranded, or otherwise fails to meet
24 the requirements of this Act, and the officer or
25 qualified employee is unable to inspect, examine, or

1 investigate the food when the food is offered for im-
2 port at a port of entry into the United States, the
3 officer or qualified employee shall request the Sec-
4 retary of Homeland Security to hold the food at the
5 port of entry for a reasonable period of time, not to
6 exceed 24 hours, to enable the Administrator to in-
7 spect or investigate the food as appropriate.

8 (2) REMOVAL TO SECURE FACILITY.—The Ad-
9 ministrator shall work in coordination with the Sec-
10 retary of Homeland Security to remove a food held
11 in accordance with paragraph (1) to a secure facility
12 as appropriate.

13 (3) PROHIBITION ON TRANSFER.—During the
14 period in which the food is held, the food shall not
15 be transferred by any person from the port of entry
16 into the United States, or from the secure facility to
17 which the food has been removed.

18 (4) DELIVERY IN ACCORDANCE WITH A
19 BOND.—The delivery of the food in accordance with
20 the execution of a bond while the food is held is not
21 authorized.

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

23 (a) NOTICE TO ADMINISTRATOR OF VIOLATION.—

24 (1) IN GENERAL.—A person (other than a
25 household consumer or other individual who is the

1 intended consumer of a food) that has reason to be-
2 lieve that any food introduced into or in interstate
3 commerce, or held for sale (whether or not the first
4 sale) after shipment in interstate commerce, may be
5 in violation of the food safety law shall immediately
6 notify the Administrator of the identity and location
7 of the food.

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

12 (b) RECALL AND CONSUMER NOTIFICATION.—

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

24 (A) cease distribution of the food;

25 (B) notify all persons—

1 (i) processing, distributing, or other-
2 wise handling the food to immediately
3 cease such activities with respect to the
4 food; or

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

8 (C) recall the food;

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

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

14 (ii) to State and local public health of-
15 ficials; or

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

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

1 (A) have authority to control and possess
2 the food, including ordering the shipment of the
3 food from the food establishment to the Admin-
4 istrator—

5 (i) at the expense of the food estab-
6 lishment; or

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

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

13 (i) cease distribution of the food; and

14 (ii) notify all persons—

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

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

22 (3) NOTIFICATION TO CONSUMERS BY ADMINIS-
23 TRATOR.—The Administrator shall, as the Adminis-
24 trator determines to be necessary, provide notice of

1 the finding of the Administrator under paragraph
2 (1)—

3 (A) to consumers to whom the food was, or
4 may have been, distributed; and

5 (B) to State and local public health offi-
6 cials.

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

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

19 (A) persons that processed, distributed, or
20 otherwise handled the food; and

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

24 (c) INFORMAL HEARINGS ON ORDERS.—

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

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

11 (d) POST-HEARING RECALL ORDERS.—

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

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

22 (B) specify a timetable in which the recall
23 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, 207, or 401 (or a regulation promulgated under
22 that section).

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 a Federal food safety law) may be
10 assessed a civil penalty by the Administrator of
11 not more than \$10,000 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) IN GENERAL.—Except as provided in para-
15 graphs (2) and (3), a person that knowingly pro-
16 duces or introduces into commerce food that is un-
17 safe for human consumption or otherwise adulter-
18 ated or misbranded shall be imprisoned for not more
19 than 1 year or fined not more than \$10,000, or
20 both.

21 (2) SEVERE VIOLATIONS.—A person that com-
22 mits a violation described in paragraph (1) after a
23 conviction of that person under this section has be-
24 come final, or commits such a violation with the in-
25 tent to defraud or mislead, shall be imprisoned for

1 not more than 3 years or fined not more than
2 \$100,000, or both.

3 (3) EXCEPTION.—No person shall be subject to
4 the penalties of this subsection—

5 (A) for having received, proffered, or deliv-
6 ered in interstate commerce any food, if the re-
7 ceipt, proffer, or delivery was made in good
8 faith, unless that person refuses to furnish (on
9 request of an officer or employee designated by
10 the Administrator)—

11 (i) the name, address and contact in-
12 formation of the person from whom that
13 person purchased or received the food;

14 (ii) copies of all documents relating to
15 the person from whom that person pur-
16 chased or received the food; and

17 (iii) copies of all documents pertaining
18 to the delivery of the food to that person;
19 or

20 (B) if that person establishes a guaranty
21 signed by, and containing the name and address
22 of, the person from whom that person received
23 in good faith the food, stating that the food is
24 not adulterated or misbranded within the mean-
25 ing of this Act.

1 (c) JUDICIAL REVIEW.—

2 (1) IN GENERAL.—An order assessing a civil
3 penalty under subsection (a) shall be a final order
4 unless the person—

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

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

14 (2) FILING OF RECORD.—Not later than 45
15 days after the service of a copy of the petition under
16 paragraph (1)(B), the Administrator shall file in the
17 court a certified copy of the administrative record
18 upon which the order was issued.

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

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

24 (1) IN GENERAL.—If any person fails to pay a
25 civil penalty assessed under subsection (a) after the

1 order assessing the penalty has become a final order,
2 or after the court of appeals described in subsection
3 (b) has entered final judgment in favor of the Ad-
4 ministrator, the Administrator shall refer the matter
5 to the Attorney General, who shall institute in a
6 United States district court of competent jurisdic-
7 tion a civil action to recover the amount assessed.

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

12 (e) PENALTIES PAID INTO ACCOUNT.—The Adminis-
13 trator—

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

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

18 (A) to carry out enforcement activities
19 under food safety law; or

20 (B) to provide assistance to States to in-
21 spect retail commercial food establishments or
22 other food or firms under the jurisdiction of
23 State food safety programs.

24 (f) DISCRETION OF THE ADMINISTRATOR TO PROS-
25 ECUTE.—Nothing in this Act requires the Administrator

1 to report for prosecution, or for the commencement of an
2 action, the violation of the food safety law in a case in
3 which the Administrator finds that the public interest will
4 be adequately served by the assessment of a civil penalty
5 under this section.

6 (g) REMEDIES NOT EXCLUSIVE.—The remedies pro-
7 vided in this section may be in addition to, and not exclu-
8 sive of, other remedies that may be available.

9 **SEC. 406. PRESUMPTION.**

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

13 **SEC. 407. WHISTLEBLOWER PROTECTION.**

14 (a) IN GENERAL.—No employee or inspector of a
15 food establishment or other person may be harassed, pros-
16 ecuted, held liable, or discriminated against in any way
17 because that person—

18 (1) has commenced, caused to be commenced,
19 or is about to commence a proceeding, has testified
20 or is about to testify at a proceeding, or has assisted
21 or participated or is about to assist or participate in
22 any manner in a proceeding or other action, to carry
23 out the objectives, functions, or responsibilities spec-
24 ified in the food safety law; or

1 (2) is refusing to violate or assist in the viola-
2 tion of a law described in paragraph (1), including
3 a regulation issued under that law.

4 (b) PROCEDURES.—

5 (1) IN GENERAL.—A person alleging a violation
6 of subsection (a) may file a complaint in accordance
7 with section 31105(b) of title 49, United States
8 Code.

9 (2) ADMINISTRATION.—Except as provided in
10 paragraphs (3) and (4), the process, procedures, and
11 remedies under subsections (b), (c), and (d) of sec-
12 tion 31105 of title 49, United States Code, with re-
13 spect to allegations of violations of subsection (a) of
14 that section shall be the process, procedures, and
15 remedies that apply with respect to allegations of
16 violations of subsection (a).

17 (3) ALTERNATIVE PROCESS.—The person filing
18 a complaint under paragraph (1) may elect to use an
19 alternative dispute resolution procedure, including
20 mediation or arbitration, in lieu of the hearing de-
21 scribed in section 31105(b) of title 49, United States
22 Code.

23 (4) ADMINISTRATOR.—The powers and duties
24 that apply to the Secretary of Labor under section

1 31105 of title 49, United States Code, shall apply to
2 the Administrator under the food safety law.

3 (c) BURDENS OF PROOF.—The legal burdens of proof
4 with respect to a violation of subsection (a) shall be gov-
5 erned by the applicable provisions of sections 1214 and
6 1221 of title 5, United States Code.

7 **SEC. 408. ADMINISTRATION AND ENFORCEMENT.**

8 (a) IN GENERAL.—For the efficient administration
9 and enforcement of the food safety law, the provisions (in-
10 cluding provisions relating to penalties) of sections 6, 8,
11 9, and 10 of the Federal Trade Commission Act (15
12 U.S.C. 46, 48, 49, and 50) (except subsections (c) through
13 (h) of section 6 of that Act), relating to the jurisdiction,
14 powers, and duties of the Federal Trade Commission and
15 the Attorney General to administer and enforce that Act,
16 and to the rights and duties of persons with respect to
17 whom the powers are exercised, shall apply to the jurisdic-
18 tion, powers, and duties of the Administrator and the At-
19 torney General in administering and enforcing the provi-
20 sions of the food safety law and to the rights and duties
21 of persons with respect to whom the powers are exercised,
22 respectively.

23 (b) INQUIRIES AND ACTIONS.—

24 (1) IN GENERAL.—The Administrator, in per-
25 son or by such agents as the Administrator may des-

1 ignite, may prosecute any inquiry necessary to carry
2 out the duties of the Administrator under the food
3 safety law in any part of the United States.

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

10 **SEC. 409. CITIZEN CIVIL ACTIONS.**

11 (a) CIVIL ACTIONS.—A person may commence a civil
12 action against—

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

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

21 (b) COURT.—

22 (1) IN GENERAL.—The action shall be com-
23 menced in the United States district court for the
24 district in which the defendant resides, is found, or
25 has an agent.

1 (2) JURISDICTION.—The court shall have juris-
 2 diction, without regard to the amount in con-
 3 troversy, or the citizenship of the parties, to enforce
 4 a regulation (including a regulation establishing a
 5 performance standard), order, or other action of the
 6 Administrator, or to order the Administrator to per-
 7 form the act or duty.

8 (3) DAMAGES.—The court may—

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

11 (B) if the court determines it to be in the
 12 interest of justice, award the plaintiff the costs
 13 of suit, including reasonable attorney’s fees,
 14 reasonable expert witness fees, and penalties.

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

18 **TITLE V—IMPLEMENTATION**

19 **SEC. 501. DEFINITION.**

20 For purposes of this title, the term “transition pe-
 21 riod” means the 12-month period beginning on the effec-
 22 tive date of this Act.

23 **SEC. 502. REORGANIZATION PLAN.**

24 (a) SUBMISSION OF PLAN.—Not later than 180 days
 25 after the effective date of this Act, the President shall

1 transmit to the appropriate congressional committees a re-
2 organization plan regarding the following:

3 (1) The transfer of agencies, personnel, assets,
4 and obligations to the Administration pursuant to
5 this Act.

6 (2) Any consolidation, reorganization, or
7 streamlining of agencies transferred to the Adminis-
8 tration pursuant to this Act.

9 (b) PLAN ELEMENTS.—The plan transmitted under
10 subsection (a) shall contain, consistent with this Act, such
11 elements as the President determines appropriate, includ-
12 ing the following:

13 (1) Identification of any functions of agencies
14 designated to be transferred to the Administration
15 pursuant to this Act that will not be transferred to
16 the Administration under the plan.

17 (2) Specification of the steps to be taken by the
18 Administrator to organize the Administration, in-
19 cluding the delegation or assignment of functions
20 transferred to the Administration among the officers
21 of the Administration in order to permit the Admin-
22 istration to carry out the functions transferred
23 under the plan.

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

4 (4) Specification of the proposed allocations
5 within the Administration of unexpended funds
6 transferred in connection with transfers under the
7 plan.

8 (5) Specification of any proposed disposition of
9 property, facilities, contracts, records, and other as-
10 sets and obligations of agencies transferred under
11 the plan.

12 (6) Specification of the proposed allocations
13 within the Administration of the functions of the
14 agencies and subdivisions that are not related di-
15 rectly to ensuring the safety of food intended for
16 human consumption.

17 (c) MODIFICATION OF PLAN.—The President may,
18 on the basis of consultations with the appropriate congres-
19 sional committees, modify, or revise any part of the plan
20 until that part of the plan becomes effective in accordance
21 with subsection (d).

22 (d) EFFECTIVE DATE.—

23 (1) IN GENERAL.—The reorganization plan de-
24 scribed in this section, including any modifications

1 or revisions of the plan under subsection (c), shall
2 become effective for an agency on the earlier of—

3 (A) the date specified in the plan (or the
4 plan as modified pursuant to subsection (c)),
5 except that such date may not be earlier than
6 90 days after the date the President has trans-
7 mitted the reorganization plan to the appro-
8 priate congressional committees pursuant to
9 subsection (a); or

10 (B) the end of the transition period.

11 (2) STATUTORY CONSTRUCTION.—Nothing in
12 this subsection may be construed to require the
13 transfer of functions, personnel, records, balances of
14 appropriations, or other assets of an agency on a
15 single date.

16 (3) SUPERCEDES EXISTING LAW.—Paragraph
17 (1) shall apply notwithstanding section 905(b) of
18 title 5, United States Code.

19 **SEC. 503. TRANSITIONAL AUTHORITIES.**

20 (a) PROVISION OF ASSISTANCE BY OFFICIALS.—
21 Until the transfer of an agency to the Administration, any
22 official having authority over or function relating to the
23 agency immediately before the effective date of this Act
24 shall provide the Administrator such assistance, including
25 the use of personnel and assets, as the Administrator may

1 request in preparing for the transfer and integration of
2 the agency to the Administration.

3 (b) SERVICES AND PERSONNEL.—During the transi-
4 tion period, upon the request of the Administrator, the
5 head of any executive agency may, on a reimbursable
6 basis, provide services or detail personnel to assist with
7 the transition.

8 (c) ACTING OFFICIALS.—

9 (1) IN GENERAL.—During the transition pe-
10 riod, pending the advice and consent of the Senate
11 to the appointment of an officer required by this Act
12 to be appointed by and with such advice and con-
13 sent, the President may designate any officer whose
14 appointment was required to be made by and with
15 such advice and consent and who was such an officer
16 immediately before the effective date of this Act
17 (and who continues to be in office) or immediately
18 before such designation, to act in such office until
19 the same is filled as provided in this Act.

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

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

1 (B) the rates provided for the offices held
2 at the time of designation.

3 (3) LIMITATION.—Nothing in this Act shall be
4 construed to require the advice and consent of the
5 Senate to the appointment by the President to a po-
6 sition in the Administration of any officer whose
7 agency is transferred to the Administration pursuant
8 to this Act and whose duties following such transfer
9 are germane to those performed before such trans-
10 fer.

11 (d) TRANSFER OF PERSONNEL, ASSETS, OBLIGA-
12 TIONS, AND FUNCTION.—

13 (1) IN GENERAL.—Consistent with section 1531
14 of title 31, United States Code, the personnel, as-
15 sets, liabilities, contracts, property, records, and un-
16 expended balances of appropriations, authorizations,
17 allocations, and other funds that relate to the func-
18 tions transferred under subsection (a) from a Fed-
19 eral agency shall be transferred to the Administra-
20 tion.

21 (2) UNEXPENDED FUNDS.—Unexpended funds
22 transferred under this subsection shall be used by
23 the Administration only for the purposes for which
24 the funds were originally authorized and appro-
25 priated.

1 **SEC. 504. SAVINGS PROVISIONS.**

2 (a) COMPLETED ADMINISTRATIVE ACTIONS.—The
3 enactment of this Act or the transfer of functions under
4 this Act shall not affect any order, determination, rule,
5 regulation, permit, personnel action, agreement, grant,
6 contract, certificate, license, registration, privilege, or
7 other administrative action issued, made, granted, or oth-
8 erwise in effect or final with respect to that agency on
9 the day before the transfer date with respect to the trans-
10 ferred functions

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

13 (1) pending proceedings in an agency, including
14 notices of proposed rulemaking, and applications for
15 licenses, permits, certificates, grants, and financial
16 assistance, shall continue notwithstanding the enact-
17 ment of this Act or the transfer of the agency to the
18 Administration, unless discontinued or modified
19 under the same terms and conditions and to the
20 same extent that such discontinuance could have oc-
21 curred if such enactment or transfer had not oc-
22 curred; and

23 (2) orders issued in such proceedings, and ap-
24 peals therefrom, and payments made pursuant to
25 such orders, shall issue in the same manner on the
26 same terms as if this Act had not been enacted or

1 the agency had not been transferred, and any such
2 order shall continue in effect until amended, modi-
3 fied, superceded, terminated, set aside, or revoked by
4 an officer of the United States or a court of com-
5 petent jurisdiction, or by operation of law.

6 (c) PENDING CIVIL ACTIONS.—Subject to the author-
7 ity of the Administrator under this Act, any civil action
8 commenced with regard to that agency pending before
9 that agency on the day before the transfer date with re-
10 spect to the transferred functions shall continue notwith-
11 standing the enactment of this Act or the transfer of an
12 agency to the Administration.

13 (d) REFERENCES.—

14 (1) IN GENERAL.—After the transfer of func-
15 tions from a Federal agency under this Act, any ref-
16 erence in any other Federal law, Executive order,
17 rule, regulation, directive, document, or other mate-
18 rial to that Federal agency or the head of that agen-
19 cy in connection with the administration or enforce-
20 ment of the food safety laws shall be deemed to be
21 a reference to the Administration or the Adminis-
22 trator, respectively.

23 (2) STATUTORY REPORTING REQUIREMENTS.—
24 Statutory reporting requirements that applied in re-
25 lation to such an agency immediately before the ef-

1 **SEC. 508. AUTHORIZATION OF APPROPRIATIONS.**

2 There are authorized to be appropriated such sums
3 as are necessary to carry out this Act.

4 **SEC. 509. LIMITATION ON AUTHORIZATION OF APPROPRIA-**
5 **TIONS.**

6 For the fiscal year that includes the effective date
7 of this Act, the amount authorized to be appropriated to
8 carry out this Act shall not exceed—

9 (1) the amount appropriated for that fiscal year
10 for the Federal agencies identified in section 102(b)
11 for the purpose of administering or enforcing the
12 food safety law; or

13 (2) the amount appropriated for those agencies
14 for that purpose for the preceding fiscal year, if, as
15 of the effective date of this Act, appropriations for
16 those agencies for the fiscal year that includes the
17 effective date have not yet been made.

18 **SEC. 510. EFFECTIVE DATE.**

19 This Act takes effect on the date of enactment of this
20 Act.

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