

114TH CONGRESS  
1ST SESSION

# S. 287

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

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## IN THE SENATE OF THE UNITED STATES

JANUARY 28, 2015

Mr. DURBIN (for himself, Mrs. FEINSTEIN, Mrs. GILLIBRAND, and Mr. BLUMENTHAL) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

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## A BILL

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

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

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Safe Food Act of 2015”.

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 facilities.
- Sec. 203. Preventive process controls to reduce adulteration of food.
- Sec. 204. Performance standards for contaminants in food.
- Sec. 205. Inspections of food facilities.
- Sec. 206. Food production establishments.
- Sec. 207. Federal and State cooperation.
- Sec. 208. Foreign supplier verification program.
- Sec. 209. Imports.
- Sec. 210. Traceback.
- Sec. 211. Food safety technology.

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. Mandatory recall authority.
- Sec. 403. Injunction proceedings.
- Sec. 404. Civil and criminal penalties.
- Sec. 405. Presumption.
- Sec. 406. Whistleblower protection.
- Sec. 407. Administration and enforcement.
- Sec. 408. 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, systemwide approach to pre-  
13 venting foodborne 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;

23 (B) an aging and immune-compromised  
24 population, with a growing number of people at

1 high risk for foodborne illnesses, including in-  
2 fants and children;

3 (C) a concern regarding food fraud for eco-  
4 nomic gain, especially with mislabeling and in-  
5 tentionally misleading claims;

6 (D) an increasing volume of imported food,  
7 without adequate monitoring and inspection;  
8 and

9 (E) maintenance of rigorous inspection of  
10 the domestic food processing and food service  
11 industries;

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

18 (6) the Federal food safety system is frag-  
19 mented, with at least 15 Federal agencies sharing  
20 responsibility for food safety, and operates under  
21 laws that do not reflect current conditions in the  
22 food system or current scientific knowledge about  
23 the cause and prevention of foodborne illness;

24 (7) the fragmented Federal food safety system  
25 and outdated laws preclude an integrated, system-

1 wide approach to preventing foodborne illness, to the  
2 effective and efficient operation of the Nation’s food  
3 safety program, and to the most beneficial deploy-  
4 ment of food safety resources;

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

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

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

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

23 (A) regulate food safety and related label-  
24 ing to strengthen the protection of the public  
25 health;

1           (B) ensure that food facilities fulfill their  
2           responsibility to produce food in a manner that  
3           protects the public health of all people in the  
4           United States;

5           (C) lead an integrated, systemwide ap-  
6           proach to food safety and to make more effec-  
7           tive and efficient use of resources to prevent  
8           foodborne illness;

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

12          (E) provide an integrated food safety re-  
13          search capability, utilizing internally generated,  
14          scientifically and statistically valid studies, in  
15          cooperation with academic institutions and  
16          other scientific entities of the Federal and State  
17          governments, to achieve the continuous im-  
18          provement of research on foodborne illness and  
19          contaminants;

20          (2) to transfer to the Food Safety Administra-  
21          tion the food safety, labeling, inspection, and en-  
22          forcement functions that, as of the day before the ef-  
23          fective date of this Act, are performed by other Fed-  
24          eral agencies; and

1           (3) to modernize and strengthen the Federal  
2 food safety laws to achieve more effective application  
3 and efficient management of the laws for the protec-  
4 tion and improvement of public health.

5 **SEC. 3. DEFINITIONS.**

6 In this Act:

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

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

13           (3) ADULTERATED.—

14           (A) IN GENERAL.—The term “adulter-  
15 ated” has the meaning given such term in—

16                   (i) section 402 of the Federal Food,  
17 Drug, and Cosmetic Act (21 U.S.C. 342)  
18 for food regulated under such Act;

19                   (ii) section 1(m) of the Federal Meat  
20 Inspection Act (21 U.S.C. 601(m)) for  
21 food regulated under such Act;

22                   (iii) section 4(g) of the Poultry Prod-  
23 ucts Inspection Act (21 U.S.C. 453(g)) for  
24 food regulated under such Act; and

1 (iv) section 4(a) of the Egg Products  
2 Inspection Act (21 U.S.C. 1033(a)) for  
3 food regulated under such Act.

4 (B) INCLUSION.—In applying the defini-  
5 tions cited in subparagraph (A), poisonous or  
6 deleterious substances in food shall be treated  
7 as an added substance if the poisonous or dele-  
8 terious substances are known to cause serious  
9 illness or death in persons, including in sen-  
10 sitive populations.

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

14 (5) CATEGORY 1 FOOD FACILITY.—The term  
15 “category 1 food facility” means a facility that  
16 slaughters animals for food.

17 (6) CATEGORY 2 FOOD FACILITY.—The term  
18 “category 2 food facility” means a facility that proc-  
19 esses—

20 (A) raw meat, poultry, or seafood in a  
21 manner that may reduce but is not validated to  
22 destroy contaminants; or

23 (B) other products that the Administrator  
24 determines by regulation to be at high risk of  
25 contamination.



1           (7) CATEGORY 3 FOOD FACILITY.—The term  
2 “category 3 food facility” means a facility—

3           (A) that processes meat, poultry, or sea-  
4 food, or other products that the Administrator  
5 determines by regulation to be at high risk of  
6 contamination; and

7           (B) whose processes include one or more  
8 steps validated to destroy contaminants.

9           (8) CATEGORY 4 FOOD FACILITY.—The term  
10 “category 4 food facility” means a facility that proc-  
11 esses food but is not a category 1, 2, or 3 food facil-  
12 ity.

13           (9) CATEGORY 5 FOOD FACILITY.—The term  
14 “category 5 food facility” means a facility that  
15 stores, holds, or transports food prior to delivery for  
16 retail sale.

17           (10) CONTAMINANT.—The term “contaminant”  
18 includes biological, chemical, physical, or radiological  
19 hazards, natural toxins, pesticides, drug residues,  
20 decomposition, parasites, allergens, and unapproved  
21 food or color additives.

22           (11) CONTAMINATION.—The term “contamina-  
23 tion” refers to a presence of a contaminant in food,  
24 which may occur naturally or be introduced into a  
25 food.

1           (12) FEED FACILITY.—The term “feed facility”  
2 means a domestic or foreign feed manufacturer,  
3 processor, packer, warehouse, or other facility that—

4           (A) if operating in the United States, man-  
5 ufactures, slaughters, processes, or holds animal  
6 feed or feed ingredients; or

7           (B) if operating elsewhere, manufactures,  
8 slaughters, processes, or holds animal feed or  
9 feed ingredients intended for consumption in  
10 the United States.

11       (13) FOOD.—

12           (A) IN GENERAL.—The term “food”  
13 means a product intended to be used for food  
14 or drink for a human or an animal.

15           (B) INCLUSIONS.—The term “food” in-  
16 cludes any product (including a meat food prod-  
17 uct, as defined in section 1(j) of the Federal  
18 Meat Inspection Act (21 U.S.C. 601(j))), capa-  
19 ble for use as human and animal food that is  
20 made in whole or in part from any animal, in-  
21 cluding cattle, sheep, swine, goat, or poultry (as  
22 defined in section 4 of the Poultry Products In-  
23 spection Act (21 U.S.C. 453)), and animal feed.

24       (14) FOOD FACILITY.—

1 (A) IN GENERAL.—The term “food facil-  
2 ity” means a domestic or foreign food manufac-  
3 turer, slaughterhouse, processor, packer, ware-  
4 house, or other facility that—

5 (i) if operating in the United States,  
6 manufactures, slaughters, processes, or  
7 holds food or food ingredients; or

8 (ii) if operating outside the United  
9 States, manufactures, slaughters, proc-  
10 esses, or holds food intended for consump-  
11 tion in the United States.

12 (B) EXCLUSIONS.—For the purposes of  
13 registration, the term “food facility” does not  
14 include—

15 (i) a farm, restaurant, other retail  
16 food establishment, nonprofit food estab-  
17 lishment in which food is prepared for or  
18 served directly to the consumer; or

19 (ii) a fishing vessel (other than a fish-  
20 ing vessel engaged in processing, as that  
21 term is defined in section 123.3(k) of title  
22 21, Code of Federal Regulations).

23 (15) FOOD PRODUCTION ESTABLISHMENT.—  
24 The term “food production establishment” means

1 any farm, ranch, orchard, vineyard, aquaculture fa-  
2 cility, or confined animal-feeding operation.

3 (16) FOOD SAFETY LAW.—The term “food safe-  
4 ty law” means—

5 (A) the provisions of the Federal Food,  
6 Drug, and Cosmetic Act (21 U.S.C. 301 et  
7 seq.) related to and requiring the safety, label-  
8 ing, and inspection of food, infant formulas,  
9 food additives, pesticide residues, and other  
10 substances present in food under that Act;

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

16 (C) the Poultry Products Inspection Act  
17 (21 U.S.C. 451 et seq.);

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

20 (E) the FDA Food Safety Modernization  
21 Act (Public Law 111–353);

22 (F) the Egg Products Inspection Act (21  
23 U.S.C. 1031 et seq.);

24 (G) the Sanitary Food Transportation Act  
25 of 1990 (49 U.S.C. App. 2801 et seq.);

1 (H) chapter 57 of title 49, United States  
2 Code;

3 (I) Public Law 85–765 (commonly known  
4 as the “Humane Methods of Slaughter Act of  
5 1958”) (7 U.S.C. 1901 et seq.);

6 (J) the provisions of this Act; and

7 (K) such other provisions of law related to  
8 and requiring food safety, labeling, inspection,  
9 and enforcement as the President designates by  
10 Executive order as appropriate to include within  
11 the jurisdiction of the Administration.

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

16 (18) MISBRANDED.—The term “misbranded”  
17 has the meaning given to it in—

18 (A) section 403 of the Federal Food,  
19 Drug, and Cosmetic Act (21 U.S.C. 343) for  
20 food regulated under such Act;

21 (B) section 1(n) of the Federal Meat In-  
22 spection Act (21 U.S.C. 601(n)) for food regu-  
23 lated under such Act;

1 (C) section 4(h) of the Poultry Products  
2 Inspection Act (21 U.S.C. 453(h)) for food reg-  
3 ulated under such Act; and

4 (D) section 4(l) of the Egg Products In-  
5 spection Act (21 U.S.C. 1033(l)) for food regu-  
6 lated under such Act.

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

10 (20) SAFE.—The term “safe” refers to human  
11 and animal health.

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

13 (A) a State;

14 (B) the District of Columbia;

15 (C) the Commonwealth of Puerto Rico;

16 and

17 (D) any other territory or possession of the  
18 United States.

19 (22) VALIDATION.—The term “validation”  
20 means the act of obtaining evidence that the process  
21 control measure or measures selected to control a  
22 contaminant in food is capable of effectively and  
23 consistently controlling the contaminant.

24 (23) STATISTICALLY VALID.—The term “statis-  
25 tically valid” means evaluated and conducted under

1 standards set by the National Institute of Standards  
2 and Technology.

3 **TITLE I—ESTABLISHMENT OF**  
4 **FOOD SAFETY ADMINISTRATION**

5 **SEC. 101. ESTABLISHMENT OF FOOD SAFETY ADMINISTRA-**  
6 **TION.**

7 (a) ESTABLISHMENT.—

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

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

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

18 (b) DUTIES OF ADMINISTRATOR.—The Adminis-  
19 trator shall—

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

21 (2) serve as a representative to international  
22 food safety bodies and discussions;

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

1 (4) oversee—

2 (A) implementation of Federal food safety  
3 inspection, labeling, enforcement, and research  
4 efforts to protect the public health;

5 (B) development of consistent and science-  
6 based standards for safe food;

7 (C) coordination and prioritization of food  
8 safety research and education programs with  
9 other Federal agencies;

10 (D) prioritization of Federal food safety ef-  
11 forts and deployment of Federal food safety re-  
12 sources to achieve the greatest benefit in reduc-  
13 ing foodborne illness;

14 (E) coordination of the Federal response to  
15 foodborne illness outbreaks with other Federal  
16 and State agencies; and

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

19 **SEC. 102. CONSOLIDATION OF SEPARATE FOOD SAFETY**  
20 **AND INSPECTION SERVICES AND AGENCIES.**

21 (a) **TRANSFER OF FUNCTIONS.**—For each Federal  
22 agency specified in subsection (b), there are transferred  
23 to the Administration all functions that the head of the  
24 Federal agency exercised on the day before the effective  
25 date of this Act (including all related functions of any offi-



1 cer or employee of the Federal agency) that relate to ad-  
2 ministration or enforcement of the food safety law, as de-  
3 termined by the President.

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

6 (1) the Food Safety and Inspection Service of  
7 the Department of Agriculture;

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

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

14 (4) the resources and facilities of the Office of  
15 Regulatory Affairs of the Food and Drug Adminis-  
16 tration that administer and conduct inspections of  
17 food and feed facilities and imports;

18 (5) the Center for Veterinary Medicine of the  
19 Food and Drug Administration;

20 (6) the resources and facilities of the Office of  
21 the Commissioner of the Food and Drug Adminis-  
22 tration, known as the Office of Food and Veterinary  
23 Medicine, 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 (7) the part of the Research, Education, and  
6 Economics mission area of the Department of Agri-  
7 culture related to food and feed safety;

8 (8) the part of the National Marine Fisheries  
9 Service of the National Oceanic and Atmospheric  
10 Administration of the Department of Commerce that  
11 administers the seafood inspection program;

12 (9) the part of the Animal and Plant Inspection  
13 Health Service of the Department of Agriculture re-  
14 lated to the management of animals going into the  
15 food supply; and

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

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

20 (a) OFFICERS AND EMPLOYEES.—The Administrator  
21 may—

22 (1) appoint officers and employees for the Ad-  
23 ministration in accordance with the provisions of  
24 title 5, United States Code, relating to appointment  
25 in the competitive service; and

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

5           (b) EXPERTS AND CONSULTANTS.—The Adminis-  
6 trator may—

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

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

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

21           (d) ADVISORY COMMITTEES.—

22           (1) IN GENERAL.—The Administrator shall es-  
23 tablish advisory committees that consist of rep-  
24 resentatives of scientific expert bodies, academics,  
25 industry specialists, and consumers.

1           (2) DUTIES.—The duties of an advisory com-  
2           mittee established under paragraph (1) may include  
3           developing recommendations with respect to the de-  
4           velopment of regulatory science and processes, re-  
5           search, communications, performance standards, and  
6           inspection.

## 7           **TITLE II—ADMINISTRATION OF** 8           **FOOD SAFETY PROGRAM**

### 9           **SEC. 201. ADMINISTRATION OF NATIONAL PROGRAM.**

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

11               (1) administer a national food safety program  
12               (referred to in this section as the “program”) to  
13               protect public health; and

14               (2) ensure that persons who produce or process  
15               food meet their responsibility to prevent or minimize  
16               food safety hazards related to their products.

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

22               (1) the severity of the health risks;

23               (2) the sources and specific points of potential  
24               contamination extending from the farm or ranch to  
25               the consumer that may render food unsafe;

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

4           (4) opportunities across the food production,  
5 processing, distribution, and retail system to manage  
6 and reduce potential health risks; and

7           (5) opportunities for intentional contamination.

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

10           (1) adopt and implement a national system for  
11 the registration of food facilities and regular unan-  
12 nounced inspection of food facilities;

13           (2) verify and enforce the adoption of preven-  
14 tive process controls in food facilities, based on the  
15 best available scientific and public health consider-  
16 ations and best available technologies;

17           (3) establish and enforce science-based stand-  
18 ards for—

19                   (A) substances that may contaminate food;  
20 and

21                   (B) safety and sanitation in the processing  
22 and handling of food;

23           (4) implement a statistically valid sampling pro-  
24 gram to ensure that industry programs and proce-  
25 dures that prevent food contamination are effective

1 on an ongoing basis and that food meets the per-  
2 formance standards established under this Act;

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

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

8 (7) access the surveillance data of the Centers  
9 for Disease Control and Prevention, and other Fed-  
10 eral Government agencies, in order to develop and  
11 implement a national surveillance system to assess  
12 the health risks associated with the human consump-  
13 tion of food or to create surveillance data and stud-  
14 ies;

15 (8) partner with relevant agencies to identify  
16 and prevent terrorist threats to food;

17 (9) establish a process for providing a single  
18 point of contact to assist impacted consumers in  
19 navigating Federal, State, and local agencies in-  
20 volved in responding to or monitoring a foodborne  
21 outbreak;

22 (10) develop public education risk communica-  
23 tion and advisory programs;

24 (11) implement a basic and applied research  
25 program to further the purposes of this Act; and

1           (12) coordinate and prioritize food safety re-  
2           search and educational programs with other agen-  
3           cies, including State or local agencies.

4 **SEC. 202. REGISTRATION OF FOOD FACILITIES.**

5           (a) IN GENERAL.—The Administrator shall require  
6           that all food and feed facilities register before the facility  
7           can operate in the United States or import food, feed, or  
8           ingredients into the United States.

9           (b) REGISTRATION REQUIREMENTS.—

10           (1) IN GENERAL.—To be registered under sub-  
11           section (a)—

12                   (A) all food facilities covered under this  
13                   Act shall comply with registration requirements  
14                   in section 415 of the Federal Food, Drug, and  
15                   Cosmetic Act (21 U.S.C. 350d);

16                   (B) for food facilities that have not reg-  
17                   istered under such section 415 prior to the date  
18                   of enactment of this Act, the requirement in  
19                   subparagraph (A) applies beginning on the day  
20                   that is 180 days after the date of enactment of  
21                   this Act; and

22                   (C) for food facilities that have registered  
23                   under such section 415 prior to the date of en-  
24                   actment of this Act, such facilities shall file an  
25                   amended registration within 180 days of such

1           date of enactment to deliver the information re-  
2           quired by paragraph (2).

3           (2) CATEGORIES.—In addition to the informa-  
4           tion required under section 415 of the Federal Food,  
5           Drug, and Cosmetic Act (21 U.S.C. 350d) to be in-  
6           cluded in registration, a food facility shall—

7                   (A) list the facility’s primary purpose and  
8                   business activity, including the dates of oper-  
9                   ation if the food facility is operating seasonally;  
10                  and

11                   (B) list the types of food handled at the  
12                   facility and identify the activities conducted in  
13                   the facility, that are relevant to determining  
14                   whether the facility is a category 1, 2, 3, 4, or  
15                   5 facility.

16           (3) PROCEDURE.—Upon receipt of a completed  
17           or amended registration described in paragraph (1),  
18           the Administrator shall notify the registrant of the  
19           receipt of the registration, review the activities iden-  
20           tified in the registration, designate the facility as a  
21           category 1, 2, 3, 4, or 5 food facility for the pur-  
22           poses of inspection, and assign a registration num-  
23           ber to each food facility.

24           (4) LIST.—The Administrator—



1 (A) shall compile and maintain an up-to-  
2 date list of food facilities that are registered  
3 under this section, in accordance with section  
4 415(a)(5) of the Federal Food, Drug, and Cos-  
5 metic Act (21 U.S.C. 350d(a)(5)); and

6 (B) may establish regulations on how the  
7 list may be shared with other governmental au-  
8 thorities.

9 **SEC. 203. PREVENTIVE PROCESS CONTROLS TO REDUCE**  
10 **ADULTERATION OF FOOD.**

11 (a) IN GENERAL.—The Administrator shall review  
12 existing regulations on hazard analysis and process con-  
13 trols and amend existing regulations as appropriate, upon  
14 the basis of best available public health, scientific, and  
15 technological information, to ensure that those regulations  
16 are working effectively to—

17 (1) ensure food facilities operate in a sanitary  
18 manner so that food is not adulterated;

19 (2) limit the presence of contaminants in food;

20 (3) meet the performance standards established  
21 under section 204;

22 (4) ensure fully processed or ready-to-eat foods  
23 are processed using reasonably available techniques  
24 and technologies to eliminate contaminants;

1           (5) label food intended for final processing out-  
2           side commercial food facilities with instructions for  
3           handling and preparation for consumption that will  
4           destroy contaminants;

5           (6) require sampling and testing at a frequency  
6           and in a manner sufficient to ensure that process  
7           controls are effective on an ongoing basis and that  
8           performance standards are being met; and

9           (7) provide for agency access to records kept by  
10          food facilities and submission of copies of the  
11          records to the Administrator, as the Administrator  
12          determines appropriate.

13          (b) PROCESSING CONTROLS.—The Administrator  
14          may require any person with responsibility for or control  
15          over food or food ingredients to adopt process controls,  
16          if the process controls are needed to ensure the protection  
17          of the public health.

18          **SEC. 204. PERFORMANCE STANDARDS FOR CONTAMINANTS**

19                           **IN FOOD.**

20          (a) PERFORMANCE STANDARDS.—Whenever the Ad-  
21          ministrator determines that a foodborne contaminant pre-  
22          sents the risk of serious adverse health consequences or  
23          death to consumers, causes food to be adulterated, or  
24          could promote the spread of communicable disease de-  
25          scribed in section 361 of the Public Health Service Act

1 (42 U.S.C. 264), the Administrator shall issue a perform-  
2 ance standard (in the form of guidance, action levels, or  
3 regulations) to prevent or control the contaminant.

4 (b) ENFORCEMENT.—

5 (1) IN GENERAL.—Not later than 1 year after  
6 the promulgation of a performance standard under  
7 this section, the Administrator shall implement a  
8 statistically significant sampling program to deter-  
9 mine whether food facilities are complying with the  
10 standards promulgated under this section.

11 (2) ACTIONS.—If the Administrator determines  
12 that a food facility fails to meet a standard promul-  
13 gated under this section, and such facility fails to  
14 take appropriate corrective action as determined by  
15 the Administrator, the Administrator shall, as ap-  
16 propriate—

17 (A) detain, seize, or condemn food from  
18 the food facility under section 209(i);

19 (B) order a recall of food from the food fa-  
20 cility under section 402;

21 (C) increase the inspection frequency for  
22 the food facility;

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

1                   (E) take other appropriate enforcement ac-  
2                   tion concerning the food facility, including sus-  
3                   pension of registration.

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

9           (d) REVOCATION BY ADMINISTRATOR.—All perform-  
10          ance standards, tolerances, action levels, or other similar  
11          standards with respect to food in effect on the date of en-  
12          actment of this Act shall remain in effect until revised or  
13          revoked by the Administrator.

14   **SEC. 205. INSPECTIONS OF FOOD FACILITIES.**

15          (a) IN GENERAL.—The Administrator shall establish  
16          an inspection program, which shall include sampling and  
17          testing of food and food facilities, to determine if each food  
18          facility—

19               (1) is operating in a sanitary manner;

20               (2) has continuous systems, interventions, and  
21          processes in place to minimize or eliminate contami-  
22          nants in food;

23               (3) uses validated process controls and ongoing  
24          verification;

1           (4) is in compliance with applicable perform-  
2           ance standards established under section 204, proc-  
3           ess control regulations, and other requirements;

4           (5) is processing food that is safe and not adul-  
5           terated or misbranded;

6           (6) maintains records of process control plans  
7           under section 203, and other records related to the  
8           processing, sampling, and handling of food; and

9           (7) is in compliance with the requirements of  
10          the applicable food safety law.

11          (b) FACILITY CATEGORIES AND INSPECTION FRE-  
12          QUENCIES.—Inspections of food facilities under this Act  
13          shall be based on the following categories and inspection  
14          frequencies, subject to subsections (c), (d), and (e):

15               (1) CATEGORY 1 FOOD FACILITIES.—A category  
16               1 food facility shall be subject to antemortem, post-  
17               mortem, and continuous inspection of each slaughter  
18               line during all operating hours, and other inspection  
19               on a daily basis, sufficient to verify that—

20                       (A) diseased animals are not offered for  
21                       slaughter;

22                       (B) the food facility has successfully iden-  
23                       tified and removed from the slaughter line visi-  
24                       bly defective or contaminated carcasses, has  
25                       avoided cross-contamination, and destroyed or

1 reprocessed contaminated carcasses in a man-  
2 ner acceptable to the Administrator; and

3 (C) that applicable performance standards  
4 and other provisions of the food safety law, in-  
5 cluding those intended to eliminate or reduce  
6 pathogens, have been satisfied.

7 (2) CATEGORY 2 FOOD FACILITIES.—A category  
8 2 food facility shall be randomly inspected at least  
9 daily.

10 (3) CATEGORY 3 FOOD FACILITIES.—A category  
11 3 food facility shall—

12 (A) provide documentation to the Adminis-  
13 trator on request that ongoing verification  
14 shows that its processes are controlled; and

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

17 (4) CATEGORY 4 FOOD FACILITIES.—A category  
18 4 food facility shall be randomly inspected at least  
19 quarterly.

20 (5) CATEGORY 5 FOOD FACILITIES.—A category  
21 5 food facility shall be randomly inspected at least  
22 annually.

23 (c) ESTABLISHMENT OF INSPECTION PROCE-  
24 DURES.—The Administrator shall establish procedures  
25 under which inspectors or safety officers inspect food fa-

1 cilities, which shall allow the taking of random samples,  
2 photographs, and copies of records in food facilities.

3 (d) ALTERNATIVE INSPECTION FREQUENCIES.—

4 With respect to a category 2, 3, 4, or 5 food facility, the  
5 Administrator may establish alternative increased or de-  
6 creased inspection frequencies for subcategories of food fa-  
7 cilities or for individual facilities, to foster risk-based allo-  
8 cation of resources, subject to the following criteria and  
9 procedures:

10 (1) Subcategories of food facilities and their al-  
11 ternative inspection frequencies shall be defined by  
12 regulation, subject to paragraphs (2) and (3).

13 (2) Alternative inspection frequencies for sub-  
14 categories of food facilities under paragraph (1) and  
15 for a specific food facility under paragraph (4) shall  
16 provide that—

17 (A) category 2 food facilities shall be in-  
18 spected at least monthly; and

19 (B) category 3 and 4 food facilities shall  
20 be inspected at least annually.

21 (3) In defining subcategories of food facilities  
22 and their alternative inspection frequencies under  
23 paragraphs (1) and (2), the Administrator shall con-  
24 sider—

1 (A) the nature of the foods being proc-  
2 essed, stored, or transported;

3 (B) the manner in which foods are proc-  
4 essed, stored, or transported;

5 (C) the inherent likelihood that the foods  
6 will contribute to the risk of foodborne illness;

7 (D) the best available evidence concerning  
8 reported illnesses associated with the foods pro-  
9 duced in the proposed subcategory of facilities;  
10 and

11 (E) the overall record of compliance with  
12 the food safety law among facilities in the pro-  
13 posed subcategory, including compliance with  
14 applicable performance standards and the fre-  
15 quency of recalls.

16 (4) The Administrator may adopt alternative  
17 inspection frequencies for increased or decreased in-  
18 spection for a specific facility, subject to paragraphs  
19 (2) and (5), and shall annually publish a list of fa-  
20 cilities subject to alternative inspections.

21 (5) In adopting alternative inspection fre-  
22 quencies for a specific facility, the Administrator  
23 shall consider—

24 (A) the supporting evidence that an indi-  
25 vidual food facility shall submit related to



1           whether an alternative inspection frequency  
2           should be established for such facility by the  
3           Administrator;

4           (B) whether products from the specific fa-  
5           cility have been associated with a case or an  
6           outbreak of foodborne illness;

7           (C) the record of the facility of compliance  
8           with the food safety law, including compliance  
9           with applicable performance standards and the  
10          frequency of recalls; and

11          (D) the criteria in paragraph (3).

12          (6) Before establishing decreased alternative in-  
13          spection frequencies for subcategories of facilities or  
14          individual facilities, the Administrator shall—

15               (A) describe the alternative uses of re-  
16               sources in general terms when issuing the regu-  
17               lation or order that establishes the alternative  
18               inspection frequency; and

19               (B) determine, based on the best available  
20               evidence, that the alternative uses of the re-  
21               sources required to carry out the inspection ac-  
22               tivity would make a greater contribution to pro-  
23               tecting the public health and reducing the risk  
24               of foodborne illness.

1 (e) INSPECTION TRANSITION.—The Administrator  
2 shall manage the transition to the inspection system de-  
3 scribed in this Act as follows:

4 (1) REGULATIONS.—The Administrator shall  
5 promulgate regulations to implement this section no  
6 later than 24 months after the date of enactment of  
7 this Act.

8 (2) LIMIT ON REDUCTION IN INSPECTION FRE-  
9 QUENCY.—For any food facility, the Administrator  
10 shall not reduce the inspection frequency from the  
11 frequency required pursuant to the Federal Meat In-  
12 spection Act (21 U.S.C. 601 et seq.), the Poultry  
13 Products Inspection Act (21 U.S.C. 451 et seq.),  
14 and the Federal Food, Drug, and Cosmetic Act (21  
15 U.S.C. 301 et seq.) until the food facility has dem-  
16 onstrated that sufficient changes in facilities, proce-  
17 dures, personnel, or other aspects of the process con-  
18 trol system have been made such that the Adminis-  
19 trator determines that compliance with the food  
20 safety law is achieved.

21 (f) OFFICIAL MARK.—

22 (1) IN GENERAL.—

23 (A) ESTABLISHMENT.—Before the comple-  
24 tion of the transition process under subsection  
25 (e), the Administrator shall by regulation estab-

1           lish an official mark that can be affixed to a  
2           food produced in a category 1, 2, or 3 food fa-  
3           cility if—

4                   (i) the facility is in compliance with  
5                   the food safety law; and

6                   (ii) has been inspected in accordance  
7                   with the inspection frequencies under this  
8                   section.

9                   (B) REMOVAL OF OFFICIAL MARK.—The  
10           Administrator shall promulgate regulations that  
11           provide for the removal of the official mark  
12           under this subsection if—

13                   (i) the Administrator makes a finding  
14                   that the facility is not in compliance with  
15                   the food safety law; or

16                   (ii) the Administrator suspends the  
17                   registration of the facility.

18                   (2) CATEGORY 1, 2, OR 3 FOOD FACILITIES.—  
19           In the case of products manufactured, slaughtered,  
20           processed, or held in a category 1, 2, or 3 food facil-  
21           ity—

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 subsection (e);

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

12 (C) a product from a facility that has not  
13 been inspected in accordance with the required  
14 frequencies under this section shall not bear the  
15 official mark and shall not be shipped in inter-  
16 state commerce.

17 (3) CATEGORY 4 AND 5 FOOD FACILITIES.—In  
18 the case of a product manufactured, slaughtered,  
19 processed, or held in a category 4 or 5 food facility,  
20 the Administrator shall provide by regulation for the  
21 voluntary use of the official mark established under  
22 paragraph (1), subject to—

23 (A) such minimum inspection frequencies  
24 as determined appropriate by the Adminis-  
25 trator;

1 (B) compliance with applicable perform-  
2 ance standards and other provisions of the food  
3 safety law; and

4 (C) such other requirements as the Admin-  
5 istrator considers appropriate.

6 (g) MAINTENANCE AND INSPECTION OF RECORDS.—

7 (1) IN GENERAL.—

8 (A) RECORDS.—A food facility shall—

9 (i) maintain such records as the Ad-  
10 ministrator requires by regulation, includ-  
11 ing all records relating to the processing,  
12 distributing, receipt, or importation of any  
13 food; and

14 (ii) permit the Administrator, in addi-  
15 tion to any authority of the food safety  
16 agencies in effect on the day before the  
17 date of enactment of this Act, upon pres-  
18 entation of appropriate credentials and at  
19 reasonable times and in a reasonable man-  
20 ner, to have access to and copy all records  
21 maintained by or on behalf of such food fa-  
22 cility representative in any format (includ-  
23 ing paper or electronic) and at any loca-  
24 tion, that are necessary to assist the Ad-  
25 ministrator to determine whether the food

1 is contaminated or not in compliance with  
2 the food safety law.

3 (B) REQUIRED DISCLOSURE.—A food facil-  
4 ity shall have an affirmative obligation to dis-  
5 close to the Administrator the results of testing  
6 or sampling of food, equipment, or material in  
7 contact with food, that is positive for any con-  
8 taminant.

9 (2) MAINTENANCE OF RECORDS.—The records  
10 required by paragraph (1) shall be maintained for a  
11 reasonable period of time, as determined by the Ad-  
12 ministrator.

13 (3) REQUIREMENTS.—The records required by  
14 paragraph (1) shall include records describing—

15 (A) the origin, receipt, delivery, sale, move-  
16 ment, holding, and disposition of food or ingre-  
17 dients;

18 (B) the identity and quantity of ingredi-  
19 ents used in the food;

20 (C) the processing of the food;

21 (D) the results of laboratory, sanitation, or  
22 other tests performed on the food or in the food  
23 facility;

24 (E) consumer complaints concerning the  
25 food or packaging of the food;

1 (F) the production codes, open date codes,  
2 and locations of food production; and

3 (G) other matters reasonably related to  
4 whether food is unsafe, is adulterated or mis-  
5 branded, or otherwise fails to meet the require-  
6 ments of this Act.

7 (h) PROTECTION OF SENSITIVE INFORMATION.—

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

12 (2) LIMITATION.—The requirement under this  
13 subsection does not—

14 (A) limit the authority of the Adminis-  
15 trator to inspect or copy records or to require  
16 the facility or maintenance of records under  
17 this Act;

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

20 (C) extend to any food recipe, financial  
21 data, pricing data, personnel data, or sales data  
22 (other than shipment dates relating to sales);

23 (D) limit the public disclosure of distribu-  
24 tion records or other records related to food

1 subject to a voluntary or mandatory recall  
2 under section 402; or

3 (E) limit the authority of the Adminis-  
4 trator to promulgate regulations to permit the  
5 sharing of data with other governmental au-  
6 thorities.

7 (i) BRIBERY OF OR GIFTS TO INSPECTOR OR OTHER  
8 OFFICERS AND ACCEPTANCE OF GIFTS.—Section 22 of  
9 the Federal Meat Inspection Act (21 U.S.C. 622) shall  
10 apply under this Act.

11 **SEC. 206. FOOD PRODUCTION ESTABLISHMENTS.**

12 In carrying out the duties of the Administrator and  
13 the purposes of this Act, the Administrator shall have the  
14 authority, with respect to food production establishments,  
15 to—

16 (1) visit and inspect food production establish-  
17 ments in the United States and in foreign countries  
18 for food safety purposes;

19 (2) review food safety records as needed to  
20 carry out traceback and for other food safety pur-  
21 poses;

22 (3) set good practice standards to protect the  
23 public and promote food safety;



1           (4) partner with appropriate agencies to mon-  
2           itor animals, plants, products, or the environment,  
3           as appropriate; and

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

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

7           (a) IN GENERAL.—The Administrator shall work  
8           with the States to carry out activities and programs that  
9           create a national food safety program so that Federal and  
10          State programs function in a coordinated and cost-effec-  
11          tive manner.

12          (b) STATE ACTION.—The Administrator shall work  
13          with States to—

14                (1) continue, strengthen, or establish State food  
15                safety programs, especially with respect to the regu-  
16                lation of retail commercial food establishments,  
17                transportation, harvesting, and fresh markets;

18                (2) continue, strengthen, or establish inspection  
19                programs and requirements to ensure that food  
20                under the jurisdiction of the State is safe; and

21                (3) support recall authorities at the State and  
22                local levels.

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

1 (1) advisory assistance;

2 (2) technical and laboratory assistance and  
3 training (including necessary materials and equip-  
4 ment); and

5 (3) financial assistance, in kind, and other aid.

6 (d) SERVICE AGREEMENTS.—

7 (1) IN GENERAL.—The Administrator may,  
8 under agreements entered into with Federal, State,  
9 or local agencies, use on a reimbursable basis or oth-  
10 erwise, the personnel and services of those agencies  
11 in carrying out this Act.

12 (2) TRAINING.—Agreements with a State under  
13 this subsection may provide for training of State em-  
14 ployees.

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

21 (e) AUDITS.—

22 (1) IN GENERAL.—The Administrator shall an-  
23 nually conduct a comprehensive review of each State  
24 program that provides services to the Administrator

1 in carrying out the responsibilities under this Act,  
2 including mandated inspections under section 205.

3 (2) REQUIREMENTS.—The review shall—

4 (A) include a determination of the effec-  
5 tiveness of the State program; and

6 (B) identify any changes necessary to en-  
7 sure enforcement of Federal requirements  
8 under this Act.

9 (f) NO FEDERAL PREEMPTION.—Nothing in this Act  
10 shall be construed to preempt the enforcement of State  
11 food safety laws and standards that are at least as strin-  
12 gent as those under this Act.

13 **SEC. 208. FOREIGN SUPPLIER VERIFICATION PROGRAM.**

14 (a) IN GENERAL.—The Administrator shall require  
15 that each importer of products from a feed facility, food  
16 facility, or food producer establishment be in compliance  
17 with the foreign supplier verification program require-  
18 ments under section 805 of the Federal Food, Drug, and  
19 Cosmetic Act (21 U.S.C. 384a).

20 (b) RULE OF CONSTRUCTION.—In applying sub-  
21 section (a) with respect to products subject to the Federal  
22 Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry  
23 Products Inspection Act (21 U.S.C. 451 et seq.), or the  
24 Egg Products Inspection Act (21 U.S.C. 1031 et seq.),  
25 references in section 805 of the Federal Food, Drug, and

1 Cosmetic Act (21 U.S.C. 384a) to sections 402, 403(w),  
2 418, and 419 of such Act (21 U.S.C. 342, 343(w), 350g,  
3 and 350h) shall be construed to be references to the cor-  
4 responding provisions of the food safety law, if any, that  
5 apply to such products, as determined by the Adminis-  
6 trator.

7 (c) REPEAL OF EXEMPTIONS.—Subsection (e) of sec-  
8 tion 805 of the Federal Food, Drug, and Cosmetic Act  
9 (21 U.S.C. 384a) is hereby repealed.

10 **SEC. 209. IMPORTS.**

11 (a) IN GENERAL.—Not later than 2 years after the  
12 effective date of this Act, the Administrator shall establish  
13 a system under which a foreign government seeking to cer-  
14 tify food for importation into the United States shall sub-  
15 mit a request for accreditation to the Administrator.

16 (b) ACCREDITATION STANDARD.—A foreign govern-  
17 ment requesting to be accredited to certify food for impor-  
18 tation into the United States shall demonstrate, in a man-  
19 ner determined appropriate by the Administrator, that the  
20 foreign government (or an agency thereof) is capable of  
21 adequately ensuring that eligible entities or foods certified  
22 by such government (or agency) meet the requirements of  
23 the food safety law.

24 (c) REQUEST BY FOREIGN GOVERNMENT.—Prior to  
25 granting accreditation to a foreign government under this

1 section, the Administrator shall review and audit the food  
2 safety program of the requesting foreign government and  
3 certify that such program (including all statutes, regula-  
4 tions, and inspection authority) meets the standard speci-  
5 fied in subsection (b).

6 (d) LIMITATIONS.—Any accreditation of a foreign  
7 government under this section shall—

8 (1) specify the foods covered by the accredita-  
9 tion; and

10 (2) be limited to a period not to exceed 5 years.

11 (e) WITHDRAWAL OF ACCREDITATION.—The Admin-  
12 istrator may withdraw accreditation fully or partially from  
13 a foreign government if the Administrator finds that—

14 (1) food covered by the accreditation is linked  
15 to an outbreak of human illness;

16 (2) the programs or procedures of the foreign  
17 government no longer meet the standards of the food  
18 safety programs and procedures of the United  
19 States; or

20 (3) the foreign government refuses to allow  
21 United States officials to conduct such audits and  
22 investigations as may be necessary to fulfill the re-  
23 quirements under this section.

24 (f) RENEWAL OF ACCREDITATION.—The Adminis-  
25 trator shall audit foreign governments accredited under

1 this section at least every 5 years to ensure the continued  
2 compliance by such governments with the standard set  
3 forth in subsection (b).

4 (g) REQUIRED ROUTINE INSPECTION.—The Admin-  
5 istrator shall routinely inspect food or food animals by  
6 physical examination before the food or food animals enter  
7 the United States to ensure that the food or food ani-  
8 mals—

9 (1) are safe;

10 (2) are labeled as required for food produced in  
11 the United States; and

12 (3) otherwise meet the requirements of the food  
13 safety law.

14 (h) ENFORCEMENT.—The Administrator may—

15 (1) deny importation of food from any country  
16 if the country's government does not permit United  
17 States officials to enter the country to conduct such  
18 audits and inspections as may be necessary to fulfill  
19 the requirements under this section;

20 (2) deny importation of food from any country  
21 or foreign facility that does not consent to an inves-  
22 tigation by the Administrator when food from that  
23 country or foreign facility is linked to a foodborne  
24 illness outbreak or is otherwise found to be adulter-  
25 ated or mislabeled; and

1           (3) promulgate regulations to carry out the pur-  
2           poses of this section, including setting terms and  
3           conditions for the destruction of products that fail to  
4           meet the standards of the food safety law.

5           (i) **DETENTION AND SEIZURE.**—Any food imported  
6           for consumption in the United States that fails to meet  
7           the standards of the food safety law may be detained,  
8           seized, or condemned.

9           **SEC. 210. TRACEBACK.**

10          (a) **IN GENERAL.**—The Administrator, in order to  
11          protect the public health, shall establish requirements for  
12          a national system for tracing food, animals, or ingredients  
13          from point of origin to retail sale, subject to subsection  
14          (b).

15          (b)    **APPLICABILITY.**—Traceability requirements  
16          shall—

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

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

22           **SEC. 211. FOOD SAFETY TECHNOLOGY.**

23          (a) **IN GENERAL.**—The Administrator shall establish  
24          and implement a program, to be known as the Food Safety  
25          Technology Program, to foster innovation in food tech-

1 nologies and foods that have the potential to improve food  
2 safety at the point of production, processing, transport,  
3 storage, or final preparation.

4 (b) PROGRAM DESCRIBED.—The program under this  
5 section shall consist of technical guidance to and consulta-  
6 tion with technology developers to assist them in meeting  
7 requirements for approval of technologies and products de-  
8 scribed in subsection (a).

## 9 **TITLE III—RESEARCH AND** 10 **EDUCATION**

### 11 **SEC. 301. PUBLIC HEALTH ASSESSMENT SYSTEM.**

12 (a) IN GENERAL.—The Administrator, acting in co-  
13 ordination with the Director of the Centers for Disease  
14 Control and Prevention and with the Research Education  
15 and Economics mission area of the Department of Agri-  
16 culture, shall—

17 (1) have access to the applicable data systems  
18 of the Centers for Disease Control and Prevention  
19 and to the databases made available by a State;

20 (2) partner with relevant agencies to maintain  
21 or access an active surveillance system of food and  
22 epidemiological evidence submitted by States to the  
23 Centers for Disease Control and Prevention based  
24 on a representative proportion of the population of  
25 the United States;



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

4           (4) partner with relevant agencies to maintain  
5 or access a state-of-the-art partial or full genome se-  
6 quencing system and epidemiological system dedi-  
7 cated to foodborne illness identification, outbreaks,  
8 and containment; and

9           (5) have access to the surveillance data created  
10 via monitoring and statistical studies conducted as  
11 part of its own inspection.

12       (b) PUBLIC HEALTH SAMPLING.—

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

18                   (A) to assist the Administrator in carrying  
19 out this Act; and

20                   (B) to assess the nature, frequency of oc-  
21 currence, and quantities of contaminants in  
22 food.

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

1 (A) statistically valid monitoring, including  
2 market-based studies, on the nature, frequency  
3 of occurrence, and quantities of contaminants  
4 in food available to consumers; and

5 (B) at the request of the Administrator,  
6 such other information, including analysis of  
7 monitoring and verification samples, as the Ad-  
8 ministrator determines may be useful in assess-  
9 ing the occurrence of contaminants in food.

10 (c) ASSESSMENT OF HEALTH HAZARDS.—Through  
11 the surveillance system referred to in subsection (a), the  
12 sampling system described in subsection (b), and other  
13 available data, the Administrator shall—

14 (1) rank food categories based on the hazard to  
15 human health presented by the food category;

16 (2) identify appropriate industry and regulatory  
17 approaches to minimize hazards in the food supply;  
18 and

19 (3) assess the public health environment for  
20 emerging diseases, including zoonosis, for their risk  
21 of appearance in the United States food supply.

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

23 (a) PUBLIC EDUCATION.—The Administrator shall—

24 (1) in cooperation with private and public orga-  
25 nizations, including the cooperative extension serv-

1 ices and building on the efforts of appropriate State  
2 and local entities, establish a national public edu-  
3 cation program on food safety; and

4 (2) coordinate with other Federal departments  
5 and agencies to integrate food safety messaging into  
6 all food-related agricultural, nutrition, and health  
7 promotion programs.

8 (b) HEALTH ADVISORIES.—The Administrator, in  
9 consultation with such other Federal departments and  
10 agencies as the Administrator determines necessary, shall  
11 work with the States and other appropriate entities—

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

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

16 (3) to incorporate State and local advisories  
17 into the national public education program estab-  
18 lished under subsection (a); and

19 (4) to present prompt, specific information re-  
20 garding foods found to pose a threat to the public  
21 health.

22 **SEC. 303. RESEARCH.**

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

- 1           (1) improve sanitation and food safety practices  
2           in the processing of food;
- 3           (2) develop improved techniques to monitor and  
4           inspect food;
- 5           (3) develop efficient, rapid, and sensitive meth-  
6           ods to detect contaminants in food;
- 7           (4) determine the sources of contamination of  
8           contaminated food;
- 9           (5) develop food consumption data;
- 10          (6) identify ways that animal production tech-  
11          niques could improve the safety of the food supply;
- 12          (7) draw upon research and educational pro-  
13          grams that exist at the State and local level;
- 14          (8) determine the food safety education needs  
15          of vulnerable populations, including children less  
16          than 10 years of age, pregnant women, adults 65  
17          years of age and older, and individuals with com-  
18          promised immune systems;
- 19          (9) utilize the partial or full genome sequencing  
20          system and other processes to identify and control  
21          pathogens;
- 22          (10) address common and emerging zoonotic  
23          diseases;

1           (11) develop methods to reduce or destroy  
2 harmful pathogens before, during, and after proc-  
3 essing;

4           (12) analyze the incidence of antibiotic resist-  
5 ance as it pertains to the food supply and develop  
6 new methods to reduce infection by antibiotic resist-  
7 ant bacteria in humans and animals; and

8           (13) conduct other research that supports the  
9 purposes of this Act.

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

## 14           **TITLE IV—ENFORCEMENT**

### 15       **SEC. 401. PROHIBITED ACTS.**

16       It is prohibited—

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

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

22           (3) for a food facility or foreign food facility to  
23 fail to register under section 202, or to operate with-  
24 out a valid registration;

1 (4) to refuse to permit access to a food facility  
2 for the inspection and copying of a record as re-  
3 quired 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 facility 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(g)(1)(B);

13 (8) to fail to comply with an applicable provi-  
14 sion of, or a regulation or order of the Administrator  
15 under, section 202, 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 fa-  
18 cility processing any such food for commerce, except  
19 in compliance with the food safety law;

20 (10) to fail to comply with a recall or other  
21 order under section 402; or

22 (11) to otherwise violate the food safety law.

23 **SEC. 402. MANDATORY RECALL AUTHORITY.**

24 (a) VOLUNTARY PROCEDURES.—If the Administrator  
25 determines that there is a reasonable probability that an

1 article of food (other than infant formula) is adulterated  
2 or misbranded and the use of or exposure to such article  
3 will cause serious adverse health consequences or death  
4 to humans or animals, the Administrator shall provide the  
5 owner, operator, or agent in charge of the facility that cre-  
6 ated, caused, or was otherwise responsible for such food  
7 with an opportunity to cease distribution and recall such  
8 article.

9 (b) PREHEARING ORDER TO CEASE DISTRIBUTION  
10 AND GIVE NOTICE.—

11 (1) IN GENERAL.—If the owner, operator, or  
12 agent in charge of the facility refuses to or does not  
13 voluntarily cease distribution or recall such article  
14 within the time and in the manner prescribed by the  
15 Administrator (if so prescribed), the Administrator  
16 may by order require, as the Administrator deems  
17 necessary, such person to—

18 (A) immediately cease distribution of such  
19 article;

20 (B) as applicable, immediately notify all  
21 persons manufacturing, processing, packing,  
22 transporting, distributing, receiving, holding, or  
23 importing and selling such article; and

1 (C) to which such article has been distrib-  
2 uted, transported, or sold, immediately cease  
3 distribution of such article.

4 (2) REQUIRED ADDITIONAL INFORMATION.—

5 (A) IN GENERAL.—If an article of food  
6 covered by a recall order issued under para-  
7 graph (1)(B) has been distributed to a ware-  
8 house-based, third-party logistics provider with-  
9 out providing such provider sufficient informa-  
10 tion to know or reasonably determine the pre-  
11 cise identity of the article of food covered by a  
12 recall order that is in its possession, the notice  
13 provided by the responsible party subject to the  
14 order issued under paragraph (1)(B) shall in-  
15 clude such information as is necessary for the  
16 warehouse-based, third-party logistics provider  
17 to identify the food.

18 (B) RULES OF CONSTRUCTION.—Nothing  
19 in this paragraph shall be construed—

20 (i) to exempt a warehouse-based,  
21 third-party logistics provider from the re-  
22 quirements of food safety law; or

23 (ii) to exempt a warehouse-based,  
24 third-party logistics provider from being  
25 the subject of a mandatory recall order.



1           (3) DETERMINATION TO LIMIT AREAS AF-  
2           FECTED.—If the Administrator requires an owner,  
3           operator, or agent in charge of the facility to cease  
4           distribution under paragraph (1)(A) of an article of  
5           food identified in subsection (a), the Administrator  
6           may limit the size of the geographic area and the  
7           markets affected by such cessation if such limitation  
8           would not compromise the public health.

9           (c) HEARING ON ORDER.—The Administrator shall  
10          provide the owner, operator, or agent in charge of the fa-  
11          cility subject to an order under subsection (b) with an op-  
12          portunity for an informal hearing, to be held as soon as  
13          possible, but not later than 2 days after the issuance of  
14          the order, on the actions required by the order and on  
15          why the article that is the subject of the order should not  
16          be recalled.

17          (d) POST-HEARING RECALL ORDER AND MODIFICA-  
18          TION OF ORDER.—

19               (1) AMENDMENT OF ORDER.—If, after pro-  
20          viding opportunity for an informal hearing under  
21          subsection (c), the Administrator determines that re-  
22          moval of the article from commerce is necessary, the  
23          Administrator shall, as appropriate—

24                       (A) amend the order to require recall of  
25                       such article or other appropriate action;

1 (B) specify a timetable in which the recall  
2 shall occur;

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

6 (D) provide notice to consumers to whom  
7 such article was, or may have been, distributed.

8 (2) VACATING OF ORDER.—If, after such hear-  
9 ing, the Administrator determines that adequate  
10 grounds do not exist to continue the actions required  
11 by the order, or that such actions should be modi-  
12 fied, the Administrator shall vacate the order or  
13 modify the order.

14 (e) RULE REGARDING ALCOHOLIC BEVERAGES.—  
15 The Administrator shall not initiate a mandatory recall  
16 or take any other action under this section with respect  
17 to any alcohol beverage until the Administrator has pro-  
18 vided the Alcohol and Tobacco Tax and Trade Bureau  
19 with a reasonable opportunity to cease distribution and re-  
20 call such article under the Alcohol and Tobacco Tax and  
21 Trade Bureau's authority.

22 (f) COOPERATION AND CONSULTATION.—The Ad-  
23 ministrator shall work with State and local public health  
24 officials in carrying out this section, as appropriate.

1 (g) PUBLIC NOTIFICATION.—In conducting a recall  
2 under this section, the Administrator shall—

3 (1) ensure that a press release is published re-  
4 garding the recall, as well as alerts and public no-  
5 tices, as appropriate, in order to provide notifica-  
6 tion—

7 (A) of the recall to consumers and retailers  
8 to whom such article was, or may have been,  
9 distributed; and

10 (B) that includes, at a minimum—

11 (i) the name of the article of food sub-  
12 ject to the recall;

13 (ii) a description of the risk associated  
14 with such article; and

15 (iii) to the extent practicable, informa-  
16 tion for consumers about similar articles of  
17 food that are not affected by the recall;

18 (2) provide to the public a list of retail con-  
19 signees receiving products for which there is deter-  
20 mined to be a reasonable probability that eating the  
21 food will cause serious adverse health consequences  
22 or death to humans or animals; and

23 (3) if available, publish on the Internet website  
24 of the Administration an image of the article that is

1 the subject of the press release described in para-  
2 graph (1).

3 (h) NO DELEGATION.—The authority conferred by  
4 this section to order a recall or vacate a recall order shall  
5 not be delegated to any officer or employee other than the  
6 Administrator.

7 (i) EFFECT.—Nothing in this section shall affect the  
8 authority of the Administrator to request or participate  
9 in a voluntary recall, or to issue an order to cease distribu-  
10 tion or to recall under any other provision of the food safe-  
11 ty law or under the Public Health Service Act (42 U.S.C.  
12 201 et seq.).

13 (j) COORDINATED COMMUNICATION.—

14 (1) IN GENERAL.—To assist in carrying out the  
15 requirements of this subsection, the Administrator  
16 shall establish an incident command operation or a  
17 similar operation that will operate not later than 24  
18 hours after the initiation of a mandatory recall or  
19 the recall of an article of food for which the use of,  
20 or exposure to, such article will cause serious ad-  
21 verse health consequences or death to humans or  
22 animals.

23 (2) REQUIREMENTS.—To reduce the potential  
24 for miscommunication during recalls or regarding in-  
25 vestigations of a foodborne illness outbreak associ-

1       ated with a food that is subject to a recall, each inci-  
2       dent command operation or similar operation under  
3       paragraph (1) shall use regular staff and resources  
4       of the Administration to—

5               (A) ensure timely and coordinated commu-  
6               nication within the Administration, including  
7               enhanced communication and coordination be-  
8               tween different agencies and organizations with-  
9               in the Administration;

10              (B) ensure timely and coordinated commu-  
11              nication from the Administration, including  
12              public statements, throughout the duration of  
13              the investigation and related foodborne illness  
14              outbreak;

15              (C) identify a single point of contact within  
16              the Administration for public inquiries regard-  
17              ing any actions by the Administrator related to  
18              a recall;

19              (D) coordinate with Federal, State, local,  
20              and tribal authorities, as appropriate, that have  
21              responsibilities related to the recall of a food or  
22              a foodborne illness outbreak associated with a  
23              food that is subject to the recall, including noti-  
24              fication of the Secretary of Agriculture and the  
25              Secretary of Education in the event such re-

1 called food is a commodity intended for use in  
2 a child nutrition program (as defined in section  
3 25(b) of the Richard B. Russell National School  
4 Lunch Act (42 U.S.C. 1769f(b))); and

5 (E) conclude operations at such time as  
6 the Administrator determines appropriate.

7 (3) MULTIPLE RECALLS.—The Administrator  
8 may establish multiple or concurrent incident com-  
9 mand operations or similar operations in the event  
10 of multiple recalls or foodborne illness outbreaks.

11 (4) FEES APPLICABLE TO ALL FACILITIES.—  
12 Fees described in section 743 of Federal Food,  
13 Drug, and Cosmetic Act (21 U.S.C. 379j–31) for  
14 not complying with a recall order are applicable to  
15 all food facilities under this Act as if—

16 (A) the term “responsible party” means  
17 “owner, operator, or agent in charge of the fa-  
18 cility”; and

19 (B) references to section 423 of the Fed-  
20 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
21 350l) are references to section 402 of this Act.

22 **SEC. 403. INJUNCTION PROCEEDINGS.**

23 (a) JURISDICTION.—The district courts of the United  
24 States, and the United States courts of the territories and  
25 possessions of the United States, shall have jurisdiction,

1 for cause shown, to restrain a violation of section 202,  
2 203, 204, 207, or 401 (or a regulation promulgated under  
3 that section).

4 (b) TRIAL.—In a case in which violation of an injunc-  
5 tion or restraining order issued under this section also  
6 constitutes a violation of the food safety law, trial shall  
7 be by the court or, upon demand of the accused, by a jury.

8 **SEC. 404. CIVIL AND CRIMINAL PENALTIES.**

9 (a) CIVIL SANCTIONS.—

10 (1) CIVIL PENALTY.—

11 (A) IN GENERAL.—Any person that com-  
12 mits an act that violates the food safety law  
13 may be assessed a civil penalty by the Adminis-  
14 trator of not more than \$10,000 for each such  
15 act.

16 (B) SEPARATE OFFENSE.—Each act de-  
17 scribed in subparagraph (A) and each day dur-  
18 ing which that act continues shall be considered  
19 a separate offense.

20 (2) OTHER REQUIREMENTS.—

21 (A) WRITTEN ORDER.—The civil penalty  
22 described in paragraph (1) shall be assessed by  
23 the Administrator by a written order, which  
24 shall specify the amount of the penalty and the

1 basis for the penalty under subparagraph (B)  
2 considered by the Administrator.

3 (B) AMOUNT OF PENALTY.—Subject to  
4 paragraph (1)(A), the amount of the civil pen-  
5 alty shall be determined by the Administrator,  
6 after considering—

7 (i) the gravity of the violation;

8 (ii) the degree of culpability of the  
9 person;

10 (iii) the size and type of the business  
11 of the person; and

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

14 (C) REVIEW OF ORDER.—The order may  
15 be reviewed only in accordance with subsection  
16 (c).

17 (b) CRIMINAL SANCTIONS.—

18 (1) IN GENERAL.—Except as provided in para-  
19 graphs (2) and (3), a person that knowingly pro-  
20 duces or introduces into commerce food that is un-  
21 safe or otherwise adulterated or misbranded shall be  
22 imprisoned for not more than 1 year or fined not  
23 more than \$10,000, or both.

24 (2) SEVERE VIOLATIONS.—A person that com-  
25 mits a violation described in paragraph (1) after a



1 conviction of that person under this section has be-  
2 come final, or commits such a violation with the in-  
3 tent to defraud or mislead, shall be imprisoned for  
4 not more than 3 years or fined not more than  
5 \$100,000, or both.

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

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

14 (i) the name, address, and contact in-  
15 formation of the person from whom that  
16 person purchased or received the food;

17 (ii) copies of all documents relating to  
18 the person from whom that person pur-  
19 chased or received the food; and

20 (iii) copies of all documents pertaining  
21 to the delivery of the food to that person;

22 or

23 (B) if that person establishes a guaranty  
24 signed by, and containing the name and address  
25 of, the person from whom that person received

1           in good faith the food, stating that the food is  
2           not adulterated or misbranded within the mean-  
3           ing of this Act.

4           (c) JUDICIAL REVIEW.—

5           (1) IN GENERAL.—An order assessing a civil  
6           penalty under subsection (a) shall be a final order  
7           unless the person—

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

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

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

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

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

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

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

15 (e) PENALTIES PAID INTO ACCOUNT.—The Adminis-  
16 trator—

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

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

21 (A) to carry out enforcement activities  
22 under food safety law; or

23 (B) to provide assistance to States to in-  
24 spect retail commercial food establishments or

1           other food or firms under the jurisdiction of  
2           State food safety programs.

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

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

13 **SEC. 405. PRESUMPTION.**

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

17 **SEC. 406. WHISTLEBLOWER PROTECTION.**

18          Section 1012 of the Federal Food, Drug, and Cos-  
19 metic Act (21 U.S.C. 399d) shall apply with respect to  
20 any violation of, or any act or omission an employee rea-  
21 sonably believes to be a violation of, any provision of this  
22 Act to the same extent and in the same manner as such  
23 section 1012 applies with respect to a violation of, or any  
24 act or omission an employee reasonably believes to be a

1 violation of, any provision of the Federal Food, Drug, and  
2 Cosmetic Act (21 U.S.C. 301 et seq.).

3 **SEC. 407. ADMINISTRATION AND ENFORCEMENT.**

4 (a) IN GENERAL.—For the efficient administration  
5 and enforcement of the food safety law, the provisions (in-  
6 cluding provisions relating to penalties) of sections 6, 8,  
7 9, and 10 of the Federal Trade Commission Act (15  
8 U.S.C. 46, 48, 49, and 50) (except subsections (c) through  
9 (h) of section 6 of that Act (15 U.S.C. 46)), relating to  
10 the jurisdiction, powers, and duties of the Federal Trade  
11 Commission and the Attorney General to administer and  
12 enforce that Act, and to the rights and duties of persons  
13 with respect to whom the powers are exercised, shall apply  
14 to the jurisdiction, powers, and duties of the Adminis-  
15 trator and the Attorney General in administering and en-  
16 forcing the provisions of the food safety law and to the  
17 rights and duties of persons with respect to whom the  
18 powers are exercised, respectively.

19 (b) INQUIRIES AND ACTIONS.—

20 (1) IN GENERAL.—The Administrator, in per-  
21 son or by such agents as the Administrator may des-  
22 ignate, may prosecute any inquiry necessary to carry  
23 out the duties of the Administrator under the food  
24 safety law in any part of the United States.

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

7 **SEC. 408. CITIZEN CIVIL ACTIONS.**

8           (a) **CIVIL ACTIONS.**—A person may commence a civil  
9           action against—

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

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

18           (b) **COURT.**—

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

23           (2) **JURISDICTION.**—The court shall have juris-  
24           diction, without regard to the amount in controversy  
25           or the citizenship of the parties, to enforce a regula-

1       tion (including a regulation establishing a perform-  
 2       ance standard), order, or other action of the Admin-  
 3       istrator, or to order the Administrator to perform  
 4       the act or duty.

5           (3) DAMAGES.—The court may—

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

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

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

## 15       **TITLE V—IMPLEMENTATION**

### 16       **SEC. 501. DEFINITION.**

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

### 20       **SEC. 502. REORGANIZATION PLAN.**

21       (a) SUBMISSION OF PLAN.—Not later than 180 days  
 22       after the effective date of this Act, the President shall  
 23       transmit to the appropriate congressional committees a re-  
 24       organization plan regarding the following:

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

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

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

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

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

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



1           (4) Specification of the proposed allocations  
2 within the Administration of unexpended funds  
3 transferred in connection with transfers under the  
4 plan.

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

9           (6) Specification of the proposed allocations  
10 within the Administration of the functions of the  
11 agencies and subdivisions that are not related di-  
12 rectly to ensuring the safety of food.

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

18       (d) EFFECTIVE DATE.—

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

23           (A) the date specified in the plan (or the  
24 plan as modified pursuant to subsection (c)),  
25 except that such date may not be earlier than

1           90 days after the date the President has trans-  
2           mitted the reorganization plan to the appro-  
3           priate congressional committees pursuant to  
4           subsection (a); or

5                   (B) the end of the transition period.

6           (2) STATUTORY CONSTRUCTION.—Nothing in  
7           this subsection may be construed to require the  
8           transfer of functions, personnel, records, balances of  
9           appropriations, or other assets of an agency on a  
10          single date.

11          (3) SUPERCEDES EXISTING LAW.—Paragraph  
12          (1) shall apply notwithstanding section 905(b) of  
13          title 5, United States Code.

14 **SEC. 503. TRANSITIONAL AUTHORITIES.**

15          (a) PROVISION OF ASSISTANCE BY OFFICIALS.—  
16          Until the transfer of an agency to the Administration, any  
17          official having authority over or function relating to the  
18          agency immediately before the effective date of this Act  
19          shall provide the Administrator such assistance, including  
20          the use of personnel and assets, as the Administrator may  
21          request in preparing for the transfer and integration of  
22          the agency to the Administration.

23          (b) SERVICES AND PERSONNEL.—During the transi-  
24          tion period, upon the request of the Administrator, the  
25          head of any Executive agency may, on a reimbursable

1 basis, provide services or detail personnel to assist with  
2 the transition.

3 (c) ACTING OFFICIALS.—

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

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

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

20 (B) the rates provided for the offices held  
21 at the time of designation.

22 (3) LIMITATION.—Nothing in this Act shall be  
23 construed to require the advice and consent of the  
24 Senate to the appointment by the President to a po-  
25 sition in the Administration of any officer whose

1 agency is transferred to the Administration pursuant  
2 to this Act and whose duties following such transfer  
3 are germane to those performed before such trans-  
4 fer.

5 (d) TRANSFER OF PERSONNEL, ASSETS, OBLIGA-  
6 TIONS, AND FUNCTION.—

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

15 (2) UNEXPENDED FUNDS.—Unexpended funds  
16 transferred under this subsection shall be used by  
17 the Administration only for the purposes for which  
18 the funds were originally authorized and appro-  
19 priated.

20 **SEC. 504. SAVINGS PROVISIONS.**

21 (a) COMPLETED ADMINISTRATIVE ACTIONS.—The  
22 enactment of this Act or the transfer of functions under  
23 this Act shall not affect any order, determination, rule,  
24 regulation, permit, personnel action, agreement, grant,  
25 contract, certificate, license, registration, privilege, or

1 other administrative action issued, made, granted, or oth-  
2 erwise in effect or final with respect to that agency on  
3 the day before the transfer date with respect to the trans-  
4 ferred functions.

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

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

17 (2) orders issued in such proceedings, and ap-  
18 peals from those orders, and payments made pursu-  
19 ant to such orders, shall be issued in the same man-  
20 ner on the same terms as if this Act had not been  
21 enacted or the agency had not been transferred, and  
22 any such order shall continue in effect until amend-  
23 ed, modified, superceded, terminated, set aside, or  
24 revoked by an officer of the United States or a court  
25 of competent jurisdiction, or by operation of law.

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

8           (d) REFERENCES.—

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

18           (2) STATUTORY REPORTING REQUIREMENTS.—  
19 Statutory reporting requirements that applied in re-  
20 lation to such an agency immediately before the ef-  
21 fective date of this Act shall continue to apply fol-  
22 lowing such transfer if the reporting requirements  
23 refer to the agency by name.

1 **SEC. 505. CONFORMING AMENDMENTS.**

2 Section 5313 of title 5, United States Code, is  
3 amended by adding at the end the following new item:

4 “Administrator of Food Safety.”.

5 **SEC. 506. ADDITIONAL TECHNICAL AND CONFORMING**  
6 **AMENDMENTS.**

7 Not later than 60 days after the submission of the  
8 reorganization plan under section 502, the President shall  
9 prepare and submit proposed legislation to Congress con-  
10 taining necessary and appropriate technical and con-  
11 forming amendments to any food safety law to reflect the  
12 changes made by this Act.

13 **SEC. 507. REGULATIONS.**

14 The Administrator may promulgate such regulations  
15 as the Administrator determines are necessary or appro-  
16 priate to perform the duties of the Administrator.

17 **SEC. 508. AUTHORIZATION OF APPROPRIATIONS.**

18 There are authorized to be appropriated such sums  
19 as are necessary to carry out this Act.

20 **SEC. 509. LIMITATION ON AUTHORIZATION OF APPROPRIA-**  
21 **TIONS.**

22 For the fiscal year that includes the effective date  
23 of this Act, the amount authorized to be appropriated to  
24 carry out this Act shall not exceed—

25 (1) the amount appropriated for that fiscal year  
26 for the Federal agencies identified in section 102(b)

1 for the purpose of administering or enforcing the  
2 food safety law; or

3 (2) the amount appropriated for those agencies  
4 for that purpose for the preceding fiscal year, if, as  
5 of the effective date of this Act, appropriations for  
6 those agencies for the fiscal year that includes the  
7 effective date have not yet been made.

8 **SEC. 510. EFFECTIVE DATE.**

9 This Act and the amendments made by this Act take  
10 effect on the date of enactment of this Act.

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