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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 the chronic health outcomes associated with foodborne illnesses, improving the surveillance of foodborne pathogens (including foodborne pathogens identified as antibiotic resistant), and improving security of food from intentional contamination, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

JUNE 26, 2019

Mr. DURBIN (for himself, Mr. BLUMENTHAL, Mrs. FEINSTEIN, and Mrs. GILLIBRAND) 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 the chronic health outcomes associated with foodborne illnesses, improving the surveillance of foodborne pathogens (including foodborne pathogens identified as antibiotic resistant), 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,*

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

2 (a) **SHORT TITLE.**—This Act may be cited as the  
3 “Safe Food Act of 2019”.

4 (b) **TABLE OF CONTENTS.**—The table of contents of  
5 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.

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;

1 (B) an aging and immune-compromised  
2 population, with a growing number of people at  
3 high risk for foodborne illnesses, including in-  
4 fants and children;

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

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

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

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

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

1           (7) the fragmented Federal food safety system  
2           and outdated laws preclude an integrated, system-  
3           wide approach to preventing foodborne illness, to the  
4           effective and efficient operation of the Nation’s food  
5           safety program, and to the most beneficial deploy-  
6           ment of food safety resources;

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

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

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

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

1 (A) regulate food safety and related label-  
2 ing to strengthen the protection of the public  
3 health;

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

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

12 (D) provide a single focal point for food  
13 safety leadership, both nationally and inter-  
14 nationally; and

15 (E) provide an integrated food safety re-  
16 search capability, utilizing internally generated,  
17 scientifically and statistically valid studies or  
18 other food safety initiatives, in cooperation with  
19 academic institutions, food safety nonprofit or-  
20 ganizations, and other scientific entities of the  
21 Federal and State governments, to achieve the  
22 continuous improvement of research on  
23 foodborne illness and contaminants;

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

1        enforcement functions that, as of the day before the  
2        date of enactment of this Act, are performed by  
3        other Federal agencies; and

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

8        **SEC. 3. DEFINITIONS.**

9        In this Act:

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

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

16            (3) ADULTERATED.—

17            (A) IN GENERAL.—The term “adulter-  
18        ated” has the meaning given the term in—

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

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

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

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

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

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

17 (5) CATEGORY 1 FOOD FACILITY.—The term  
18 “category 1 food facility” means a facility that  
19 slaughters animals for food.

20 (6) CATEGORY 2 FOOD FACILITY.—The term  
21 “category 2 food facility” means a facility that proc-  
22 esses—

23 (A) raw meat, poultry, or seafood in a  
24 manner that may reduce but is not validated to  
25 destroy contaminants; or

1           (B) other products that the Administrator  
2           determines by regulation to be at high risk of  
3           contamination.

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

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

10          (B) whose processes include one or more  
11          steps validated to destroy contaminants.

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

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

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

1           (11) CONTAMINATION.—The term “contamina-  
2           tion” refers to a presence of a contaminant in food,  
3           which may occur naturally or be introduced into a  
4           food.

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

8                   (A) if operating in the United States, man-  
9                   ufactures, slaughters, processes, or holds animal  
10                  feed or feed ingredients; or

11                  (B) if operating elsewhere, manufactures,  
12                  slaughters, processes, or holds animal feed or  
13                  feed ingredients intended for consumption in  
14                  the United States.

15           (13) FOOD.—

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

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

1 defined in section 4 of the Poultry Products In-  
2 spection Act (21 U.S.C. 453)), and animal feed.

3 (14) FOOD FACILITY.—

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

8 (i) if operating in the United States,  
9 manufactures, slaughters, processes, or  
10 holds food or food ingredients; or

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

15 (B) EXCLUSIONS.—For the purposes of  
16 registration, the term “food facility” does not  
17 include—

18 (i) a farm, restaurant, other retail  
19 food establishment, or nonprofit food es-  
20 tablishment in which food is prepared for  
21 or served directly to the consumer; or

22 (ii) a fishing vessel (other than a fish-  
23 ing vessel engaged in processing, as that  
24 term is defined in section 123.3(k) of title  
25 21, Code of Federal Regulations).

1 (15) FOOD PRODUCTION ESTABLISHMENT.—

2 The term “food production establishment” means  
3 any farm, ranch, orchard, vineyard, aquaculture fa-  
4 cility, or confined animal-feeding operation.

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

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

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

18 (C) the Poultry Products Inspection Act  
19 (21 U.S.C. 451 et seq.);

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

22 (E) the FDA Food Safety Modernization  
23 Act (Public Law 111–353; 124 Stat. 3885);

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

1 (G) chapter 57 of title 49, United States  
2 Code (formerly known as the “Sanitary Food  
3 Transportation Act of 1990”);

4 (H) Public Law 85–765 (commonly known  
5 as the “Humane Methods of Slaughter Act of  
6 1958”) (7 U.S.C. 1901 et seq.);

7 (I) this Act; and

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

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

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

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

22 (B) section 1(n) of the Federal Meat In-  
23 spection Act (21 U.S.C. 601(n)) for food regu-  
24 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 date of  
25 enactment of this Act (including all related functions of

1 any officer or employee of the Federal agency) that relate  
2 to administration or enforcement of the food safety law,  
3 as determined 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 Office of Food Policy and Response of  
21 the Food and Drug Administration;

22 (7) the part of the Research, Education, and  
23 Economics mission area of the Department of Agri-  
24 culture related to food and feed safety;

1           (8) the part of the National Marine Fisheries  
2           Service of the National Oceanic and Atmospheric  
3           Administration of the Department of Commerce that  
4           administers the seafood inspection program;

5           (9) the part of the Animal and Plant Inspection  
6           Health Service of the Department of Agriculture re-  
7           lated to the management of animals going into the  
8           food supply; and

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

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

13          (a) OFFICERS AND EMPLOYEES.—The Administrator  
14          may—

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

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

23          (b) EXPERTS AND CONSULTANTS.—The Adminis-  
24          trator may—

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

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

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

15          (d) ADVISORY COMMITTEES.—

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

20                 (2) DUTIES.—The duties of an advisory com-  
21         mittee established under paragraph (1) may include  
22         developing recommendations with respect to the de-  
23         velopment of regulatory science and processes, re-  
24         search, communications, performance standards, and  
25         inspection.

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

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

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

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

8 (2) ensure that persons who produce or process  
9 food meet their responsibility to prevent or minimize  
10 food safety hazards related to their products.

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

16 (1) the severity of the health risks;

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

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

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

1           (5) opportunities for intentional contamination.

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

4           (1) adopt and implement a national system for  
5 the registration of food facilities and regular unan-  
6 nounced inspection of food facilities;

7           (2) verify and enforce the adoption of preven-  
8 tive process controls in food facilities, based on the  
9 best available scientific and public health consider-  
10 ations and best available technologies;

11          (3) establish and enforce science-based stand-  
12 ards for—

13           (A) substances that may contaminate food;  
14          and

15           (B) safety and sanitation in the processing  
16 and handling of food;

17          (4) implement a statistically valid sampling pro-  
18 gram to ensure that industry programs and proce-  
19 dures that prevent food contamination are effective  
20 on an ongoing basis and that food meets the per-  
21 formance standards established under this Act;

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

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

4           (7) access the surveillance data of the Centers  
5 for Disease Control and Prevention, and other Fed-  
6 eral Government agencies, in order to develop and  
7 implement a national surveillance system to assess  
8 the health risks associated with the human consump-  
9 tion of food or to create surveillance data and stud-  
10 ies to mitigate food threats (such as antibiotic resist-  
11 ance) or to identify the ways that food contamina-  
12 tion spreads through environments;

13          (8) partner with relevant agencies to identify  
14 and prevent terrorist threats to food;

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

20          (10) develop public education risk communica-  
21 tion and advisory programs;

22          (11) implement a basic and applied research  
23 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 (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 has destroyed

1 or reprocessed contaminated carcasses in a  
2 manner acceptable to the Administrator; and

3 (C) applicable performance standards and  
4 other provisions of the food safety law, includ-  
5 ing those intended to eliminate or reduce patho-  
6 gens, 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 (1) IN GENERAL.—With respect to a category  
5 2, 3, 4, or 5 food facility, to foster a risk-based allo-  
6 cation of resources, the Administrator may establish,  
7 in accordance with this subsection, alternative in-  
8 creased or decreased inspection frequencies for—

9 (A) 1 or more subcategories of food facili-  
10 ties under paragraph (2); and

11 (B) 1 or more specific food facilities under  
12 paragraph (3).

13 (2) DETERMINATION OF SUBCATEGORIES AND  
14 FREQUENCIES.—

15 (A) IN GENERAL.—The Administrator  
16 shall define, by regulation, each subcategory of  
17 food facilities established under paragraph  
18 (1)(A) and the alternative inspection frequency  
19 of that subcategory.

20 (B) CONSIDERATIONS.—In defining a sub-  
21 category of food facilities and the alternative in-  
22 spection frequency of that subcategory under  
23 subparagraph (A), the Administrator shall con-  
24 sider—

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

3 (ii) the manner in which foods are  
4 processed, stored, or transported;

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

8 (iv) the best available evidence con-  
9 cerning reported illnesses associated with  
10 the foods produced in the proposed sub-  
11 category of facilities; and

12 (v) the overall record of compliance  
13 with the food safety law among facilities in  
14 the proposed subcategory, including com-  
15 pliance with applicable performance stand-  
16 ards and the frequency of recalls.

17 (3) SPECIFIC FACILITIES.—

18 (A) IN GENERAL.—The Administrator—

19 (i) may establish an alternative in-  
20 spection frequency for increased or de-  
21 creased inspection for a specific food facil-  
22 ity; and

23 (ii) shall annually publish a list of  
24 food facilities subject to alternative inspec-  
25 tion frequencies under clause (i).

1 (B) CONSIDERATIONS.—In establishing an  
2 alternative inspection frequency for a specific  
3 food facility, the Administrator shall consider—

4 (i) the supporting evidence that the  
5 specific food facility shall submit to the  
6 Administrator relating to whether an alter-  
7 native inspection frequency should be es-  
8 tablished for that facility by the Adminis-  
9 trator;

10 (ii) whether products from the specific  
11 food facility have been associated with a  
12 case or an outbreak of foodborne illness;

13 (iii) the record of the facility of com-  
14 pliance with the food safety law, including  
15 compliance with applicable performance  
16 standards and the frequency of recalls; and

17 (iv) the considerations described in  
18 clauses (i) through (iii) of paragraph  
19 (2)(B).

20 (4) FREQUENCY REQUIREMENTS FOR CAT-  
21 EGORIES 2, 3, AND 4.—An alternative inspection fre-  
22 quency for a subcategory of food facilities or a spe-  
23 cific food facility under this subsection shall be—

24 (A) in the case of a category 2 food facil-  
25 ity, not less frequently than monthly; and

1 (B) in the case of a category 3 or 4 food  
2 facility, not less frequently than annually.

3 (5) REQUIREMENTS FOR DECREASED FRE-  
4 QUENCIES.—Before issuing a regulation or order es-  
5 tablishing a decreased alternative inspection fre-  
6 quency for a subcategory of food facilities or an indi-  
7 vidual food facility under this subsection, the Admin-  
8 istrator shall—

9 (A) describe, in general terms, the alter-  
10 native uses of resources of the Administration  
11 that would have been required to carry out the  
12 inspection activity; and

13 (B) determine, based on the best available  
14 evidence, that the alternative uses of the re-  
15 sources would make a greater contribution to  
16 protecting the public health and reducing the  
17 risk of foodborne illness.

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

21 (1) REGULATIONS.—The Administrator shall  
22 promulgate regulations to implement this section no  
23 later than 24 months after the date of enactment of  
24 this Act.

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

14          (f) OFFICIAL MARK.—

15                 (1) IN GENERAL.—

16                         (A) ESTABLISHMENT.—Before the comple-  
17                         tion of the transition process under subsection  
18                         (e), the Administrator shall by regulation estab-  
19                         lish an official mark that can be affixed to a  
20                         food produced in a category 1, 2, or 3 food fa-  
21                         cility if—

22                                 (i) the facility is in compliance with  
23                                 the food safety law; and

1                   (ii) has been inspected in accordance  
2                   with the inspection frequencies under this  
3                   section.

4                   (B) REMOVAL OF OFFICIAL MARK.—The  
5                   Administrator shall promulgate regulations that  
6                   provide for the removal of the official mark  
7                   under this subsection if—

8                   (i) the Administrator makes a finding  
9                   that the facility is not in compliance with  
10                  the food safety law; or

11                  (ii) the Administrator suspends the  
12                  registration of the facility.

13                  (2) CATEGORY 1, 2, OR 3 FOOD FACILITIES.—  
14                  In the case of products manufactured, slaughtered,  
15                  processed, or held in a category 1, 2, or 3 food facil-  
16                  ity—

17                  (A) products subject to the Federal Meat  
18                  Inspection Act (21 U.S.C. 601 et seq.), the  
19                  Poultry Products Inspection Act (21 U.S.C.  
20                  451 et seq.), the Egg Products Inspection Act  
21                  (21 U.S.C. 1031 et seq.), and the Federal  
22                  Food, Drug, and Cosmetic Act (21 U.S.C. 301  
23                  et seq.) as of the date of enactment of this Act  
24                  shall remain subject to the requirement under  
25                  those Acts that they bear the mark of inspec-

1           tion pending completion of the transition pro-  
2           cess under subsection (e);

3           (B) the Administrator shall publicly certify  
4           on a monthly basis that the inspection fre-  
5           quencies required under this section have been  
6           achieved; and

7           (C) a product from a facility that has not  
8           been inspected in accordance with the required  
9           frequencies under this section shall not bear the  
10          official mark and shall not be shipped in inter-  
11          state commerce.

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

18                (A) such minimum inspection frequencies  
19                as determined appropriate by the Adminis-  
20                trator;

21                (B) compliance with applicable perform-  
22                ance standards and other provisions of the food  
23                safety law; and

24                (C) such other requirements as the Admin-  
25                istrator considers appropriate.

1 (g) MAINTENANCE AND INSPECTION OF RECORDS.—

2 (1) IN GENERAL.—

3 (A) RECORDS.—A food facility shall—

4 (i) maintain such records as the Ad-  
5 ministrator requires by regulation, includ-  
6 ing all records relating to the processing,  
7 distributing, receipt, or importation of any  
8 food; and

9 (ii) permit the Administrator, in addi-  
10 tion to any authority of the food safety  
11 agencies in effect on the day before the  
12 date of enactment of this Act, upon pres-  
13 entation of appropriate credentials and at  
14 reasonable times and in a reasonable man-  
15 ner, to have access to and copy all records  
16 maintained by or on behalf of such food fa-  
17 cility representative in any format (includ-  
18 ing paper or electronic) and at any loca-  
19 tion, that are necessary to assist the Ad-  
20 ministrator to determine whether the food  
21 is contaminated or not in compliance with  
22 the food safety law.

23 (B) REQUIRED DISCLOSURE.—A food facil-  
24 ity shall have an affirmative obligation to dis-  
25 close to the Administrator the results of testing

1 or sampling of food, equipment, or material in  
2 contact with food that is positive for any con-  
3 taminant.

4 (2) MAINTENANCE OF RECORDS.—The records  
5 required by paragraph (1) shall be maintained for a  
6 reasonable period of time, as determined by the Ad-  
7 ministrator.

8 (3) REQUIREMENTS.—The records required by  
9 paragraph (1) shall include records describing—

10 (A) the origin, receipt, delivery, sale, move-  
11 ment, holding, and disposition of food or ingre-  
12 dients;

13 (B) the identity and quantity of ingredi-  
14 ents used in the food;

15 (C) the processing of the food;

16 (D) the results of laboratory, sanitation, or  
17 other tests performed on the food or in the food  
18 facility;

19 (E) consumer complaints concerning the  
20 food or packaging of the food;

21 (F) the production codes, open date codes,  
22 and locations of food production; and

23 (G) other matters reasonably related to  
24 whether food is unsafe, is adulterated or mis-

1           branded, or otherwise fails to meet the require-  
2           ments of this Act.

3           (h) PROTECTION OF SENSITIVE INFORMATION.—

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

8           (2) LIMITATION.—The requirement under this  
9           subsection does not—

10           (A) limit the authority of the Adminis-  
11           trator to inspect or copy records or to require  
12           the facility or maintenance of records under  
13           this Act;

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

16           (C) extend to any food recipe, financial  
17           data, pricing data, personnel data, or sales data  
18           (other than shipment dates relating to sales);

19           (D) limit the public disclosure of distribu-  
20           tion records or other records related to food  
21           subject to a voluntary or mandatory recall  
22           under section 402; or

23           (E) limit the authority of the Adminis-  
24           trator to promulgate regulations to permit the

1           sharing of data with other governmental au-  
2           thorities.

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

7 **SEC. 206. FOOD PRODUCTION ESTABLISHMENTS.**

8           In carrying out the duties of the Administrator and  
9 the purposes of this Act, the Administrator shall have the  
10 authority, with respect to food production establishments,  
11 to—

12           (1) visit and inspect food production establish-  
13           ments in the United States and in foreign countries  
14           for food safety purposes;

15           (2) review food safety records as needed to  
16           carry out traceback and for other food safety pur-  
17           poses;

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

20           (4) partner with appropriate agencies to mon-  
21           itor animals, plants, products, or the environment,  
22           as appropriate; and

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

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

2 (a) IN GENERAL.—The Administrator shall work  
3 with the States to carry out activities and programs that  
4 create a national food safety program so that Federal and  
5 State programs function in a coordinated and cost-effec-  
6 tive manner.

7 (b) STATE ACTION.—The Administrator shall work  
8 with States to—

9 (1) continue, strengthen, or establish State food  
10 safety programs, especially with respect to the regu-  
11 lation of retail commercial food establishments,  
12 transportation, harvesting, and fresh markets;

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

16 (3) support recall authorities at the State and  
17 local levels.

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

21 (1) advisory assistance;

22 (2) technical and laboratory assistance and  
23 training (including necessary materials and equip-  
24 ment); and

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

1 (d) SERVICE AGREEMENTS.—

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

7 (2) TRAINING.—Agreements with a State under  
8 this subsection may provide for training of State em-  
9 ployees.

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

16 (e) AUDITS.—

17 (1) IN GENERAL.—The Administrator shall an-  
18 nually conduct a comprehensive review of each State  
19 program that provides services to the Administrator  
20 in carrying out the responsibilities under this Act,  
21 including mandated inspections under section 205.

22 (2) REQUIREMENTS.—The review shall—

23 (A) include a determination of the effec-  
24 tiveness of the State program; and

1           (B) identify any changes necessary to en-  
2           sure enforcement of Federal requirements  
3           under this Act.

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

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

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

15           (b) RULE OF CONSTRUCTION.—In applying sub-  
16 section (a) with respect to products subject to the Federal  
17 Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry  
18 Products Inspection Act (21 U.S.C. 451 et seq.), or the  
19 Egg Products Inspection Act (21 U.S.C. 1031 et seq.),  
20 references in section 805 of the Federal Food, Drug, and  
21 Cosmetic Act (21 U.S.C. 384a) to sections 402, 403(w),  
22 418, and 419 of such Act (21 U.S.C. 342, 343(w), 350g,  
23 and 350h) shall be construed to be references to the cor-  
24 responding provisions of the food safety law, if any, that

1 apply to such products, as determined by the Adminis-  
2 trator.

3 (c) REPEAL OF EXEMPTIONS.—Section 805 of the  
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384a)  
5 is amended—

6 (1) in subsection (a)(1), by striking “sub-  
7 sections (e) and (f)” and inserting “subsection (e)”;

8 (2) by striking subsection (e); and

9 (3) by redesignating subsections (f) and (g) as  
10 subsections (e) and (f), respectively.

11 **SEC. 209. IMPORTS.**

12 (a) IN GENERAL.—Not later than 2 years after the  
13 date of enactment of this Act, the Administrator shall es-  
14 tablish a system under which a foreign government seek-  
15 ing to certify food for importation into the United States  
16 shall submit a request for accreditation to the Adminis-  
17 trator.

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

1           (c) REQUEST BY FOREIGN GOVERNMENT.—Prior to  
2 granting accreditation to a foreign government under this  
3 section, the Administrator shall review and audit the food  
4 safety program of the requesting foreign government and  
5 certify that such program (including all statutes, regula-  
6 tions, and inspection authority) meets the standard speci-  
7 fied in subsection (b).

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

10           (1) specify the foods covered by the accredita-  
11 tion; and

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

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

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

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

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

1 (f) RENEWAL OF ACCREDITATION.—The Adminis-  
2 trator shall audit foreign governments accredited under  
3 this section at least every 5 years to ensure the continued  
4 compliance by such governments with the standard set  
5 forth in subsection (b).

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

11 (1) are safe;

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

14 (3) otherwise meet the requirements of the food  
15 safety law.

16 (h) ENFORCEMENT.—The Administrator may—

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

22 (2) deny importation of food from any country  
23 or foreign facility that does not consent to an inves-  
24 tigation by the Administrator when food from that  
25 country or foreign facility is linked to a foodborne

1 illness outbreak or is otherwise found to be adulter-  
2 ated or mislabeled; and

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

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

11 **SEC. 210. TRACEBACK.**

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

17 (b) **APPLICABILITY.**—Traceability requirements  
18 shall—

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

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

1 **SEC. 211. FOOD SAFETY TECHNOLOGY.**

2 (a) IN GENERAL.—The Administrator shall establish  
3 and implement a program, to be known as the Food Safety  
4 Technology Program, to foster innovation in food tech-  
5 nologies and foods that have the potential to improve food  
6 safety at the point of production, processing, transport,  
7 storage, or final preparation.

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

13 **TITLE III—RESEARCH AND**  
14 **EDUCATION**

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

16 (a) IN GENERAL.—The Administrator, acting in co-  
17 ordination with the Director of the Centers for Disease  
18 Control and Prevention and the Deputy Under Secretary  
19 of Agriculture for Research, Education, and Economics,  
20 shall—

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

24 (2) partner with relevant agencies to maintain  
25 or access an active surveillance system of food and  
26 epidemiological evidence submitted by States to the

1 Centers for Disease Control and Prevention based  
2 on a representative proportion of the population of  
3 the United States;

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

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

12 (5) have access to the surveillance data created  
13 via monitoring and statistical studies conducted as  
14 part of its own inspection.

15 (b) PUBLIC HEALTH SAMPLING.—

16 (1) IN GENERAL.—Not later than 1 year after  
17 the date of enactment of this Act, the Administrator  
18 shall establish guidelines for a sampling system  
19 under which the Administrator shall take and ana-  
20 lyze samples of food—

21 (A) to assist the Administrator in carrying  
22 out this Act; and

23 (B) to assess the nature, frequency of oc-  
24 currence, and quantities of contaminants in  
25 food.

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

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

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

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

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

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

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

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

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

1           (1) in cooperation with private and public orga-  
2           nizations, including the cooperative extension serv-  
3           ices and building on the efforts of appropriate State  
4           and local entities, establish a national public edu-  
5           cation program on food safety; and

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

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

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

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

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

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

1 **SEC. 303. RESEARCH.**

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

4 (1) improve sanitation and food safety practices  
5 in the processing of food;

6 (2) develop improved techniques to monitor and  
7 inspect food;

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

10 (4) determine the sources of contamination of  
11 contaminated food;

12 (5) develop food consumption data;

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

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

17 (8) determine the food safety education needs  
18 of vulnerable populations, including children less  
19 than 10 years of age, pregnant women, adults 65  
20 years of age and older, and individuals with com-  
21 promised immune systems;

22 (9) utilize the partial or full genome sequencing  
23 system and other processes to identify and control  
24 pathogens;

25 (10) address common and emerging zoonotic  
26 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, insti-  
12 tution of higher education, Federal Government agency,  
13 or person to carry out this section.

## 14           **TITLE IV—ENFORCEMENT**

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

16       It shall be unlawful—

17           (1) for a person—

18               (A) to manufacture, introduce, deliver for  
19 introduction, or receive into interstate com-  
20 merce any food that is adulterated, misbranded,  
21 or otherwise unsafe;

22               (B) to adulterate or misbrand any food in  
23 interstate commerce;

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

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

7 (E) to refuse to permit entry to or inspec-  
8 tion of a food facility as required under section  
9 205;

10 (F) to fail to provide to the Administrator  
11 the results of a testing or sampling of a food,  
12 equipment, or material in contact with contami-  
13 nated food under section 205(g)(1)(B);

14 (G) to fail to comply with an applicable  
15 provision of, or a regulation or order of the Ad-  
16 ministrator under, section 202, 204, or 208;

17 (H) to slaughter an animal that is capable  
18 for use in whole or in part as human food at  
19 a food facility processing any such food for  
20 commerce, except in compliance with the food  
21 safety law;

22 (I) to fail to comply with a recall or other  
23 order under section 402; or

24 (J) to otherwise violate the food safety law;  
25 and

1           (2) for a food facility or foreign food facility to  
2           fail to register under section 202, or to operate with-  
3           out a valid registration.

4 **SEC. 402. MANDATORY RECALL AUTHORITY.**

5           (a) VOLUNTARY PROCEDURES.—If the Administrator  
6           determines that there is a reasonable probability that an  
7           article of food (other than infant formula) is adulterated  
8           or misbranded and the use of or exposure to such article  
9           will cause serious adverse health consequences or death  
10          to humans or animals, the Administrator shall provide to  
11          the owner, operator, or agent in charge of the facility that  
12          created, caused, or was otherwise responsible for that arti-  
13          cle of food an opportunity to cease distribution and recall  
14          that article of food in a manner and within a time period  
15          determined by the Administrator.

16          (b) PREHEARING ORDER TO CEASE DISTRIBUTION  
17          AND GIVE NOTICE.—

18               (1) IN GENERAL.—If the owner, operator, or  
19               agent in charge of a facility refuses to, or does not  
20               voluntarily, cease distribution or recall an article of  
21               food in the manner and within the time period deter-  
22               mined by the Administrator under subsection (a),  
23               the Administrator may by order require, as the Ad-  
24               ministrator determines to be necessary—

25                       (A) that owner, operator, or agent—

1 (i) to immediately cease distribution  
2 of that article of food; and

3 (ii) as applicable, to immediately no-  
4 tify all persons manufacturing, processing,  
5 packing, transporting, distributing, receiv-  
6 ing, holding, or importing and selling that  
7 article of food; and

8 (B) any person to which that article of  
9 food has been distributed, transported, or sold,  
10 to immediately cease distribution of that article  
11 of food.

12 (2) REQUIRED ADDITIONAL INFORMATION.—

13 (A) IN GENERAL.—If an article of food  
14 covered by a recall order issued under para-  
15 graph (1) has been distributed to a warehouse-  
16 based, third-party logistics provider without  
17 providing such provider sufficient information  
18 to know or reasonably determine the precise  
19 identity of the article of food covered by a recall  
20 order that is in its possession, the notice pro-  
21 vided by the owner, operator, or agent of a fa-  
22 cility under paragraph (1)(A)(ii) shall include  
23 such information as is necessary for the ware-  
24 house-based, third-party logistics provider to  
25 identify the article of food.

1 (B) RULES OF CONSTRUCTION.—Nothing  
2 in this paragraph shall be construed—

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

6 (ii) to exempt a warehouse-based,  
7 third-party logistics provider from being  
8 the subject of a mandatory recall order.

9 (3) DETERMINATION TO LIMIT AREAS AF-  
10 FECTED.—If the Administrator requires an owner,  
11 operator, or agent in charge of the facility to cease  
12 distribution under paragraph (1)(A)(i) of an article  
13 of food identified under subsection (a), the Adminis-  
14 trator may limit the size of the geographic area and  
15 the markets affected by such cessation if such limi-  
16 tation would not compromise the public health.

17 (c) HEARING ON ORDER.—The Administrator shall  
18 provide the owner, operator, or agent in charge of the fa-  
19 cility subject to an order under subsection (b) with an op-  
20 portunity for an informal hearing, to be held as soon as  
21 possible, but not later than 2 days after the issuance of  
22 the order, on the actions required by the order and on  
23 why the article that is the subject of the order should not  
24 be recalled.

1 (d) POST-HEARING RECALL ORDER AND MODIFICA-  
2 TION OF ORDER.—

3 (1) AMENDMENT OF ORDER.—If, after pro-  
4 viding opportunity for an informal hearing under  
5 subsection (c), the Administrator determines that re-  
6 moval of the applicable article of food from com-  
7 merce is necessary, the Administrator shall, as ap-  
8 propriate—

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

11 (B) specify a timetable in which the recall  
12 shall occur;

13 (C) require periodic reports to the Admin-  
14 istrator describing the progress of the recall;  
15 and

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

18 (2) VACATING OF ORDER.—If, after an informal  
19 hearing under subsection (c), the Administrator de-  
20 termines that adequate grounds do not exist to con-  
21 tinue the actions required by the applicable order, or  
22 that such actions should be modified, the Adminis-  
23 trator shall vacate the order or modify the order, as  
24 appropriate.

1 (e) RULE REGARDING ALCOHOLIC BEVERAGES.—

2 The Administrator shall not initiate a mandatory recall  
3 or take any other action under this section with respect  
4 to any alcohol beverage until the Administrator has pro-  
5 vided the Administrator of the Alcohol and Tobacco Tax  
6 and Trade Bureau with a reasonable opportunity to cease  
7 distribution and recall the alcohol beverage under the au-  
8 thority of the Administrator of the Alcohol and Tobacco  
9 Tax and Trade Bureau.

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

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

15 (1) ensure that a press release is published re-  
16 garding the recall, as well as alerts and public no-  
17 tices, as appropriate, in order to provide notifica-  
18 tion—

19 (A) of the recall to consumers and retailers  
20 to whom the applicable article of food was, or  
21 may have been, distributed; and

22 (B) that includes, at a minimum—

23 (i) the name of the article of food sub-  
24 ject to the recall;

1 (ii) a description of the risk associated  
2 with such article; and

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

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

11 (3) if available, publish on the internet website  
12 of the Administration an image of the article that is  
13 the subject of the press release described in para-  
14 graph (1).

15 (h) NO DELEGATION.—The authority conferred by  
16 this section to order a recall or vacate a recall order shall  
17 not be delegated to any officer or employee other than the  
18 Administrator.

19 (i) EFFECT.—Nothing in this section shall affect the  
20 authority of the Administrator to request or participate  
21 in a voluntary recall, or to issue an order to cease distribu-  
22 tion or to recall under any other provision of the food safe-  
23 ty law or under the Public Health Service Act (42 U.S.C.  
24 201 et seq.).

25 (j) COORDINATED COMMUNICATION.—

1           (1) IN GENERAL.—To assist in carrying out the  
2 requirements of this subsection, the Administrator  
3 shall establish an incident command operation or a  
4 similar operation that will operate not later than 24  
5 hours after the initiation of a mandatory recall or  
6 the recall of an article of food for which the use of,  
7 or exposure to, such article will cause serious ad-  
8 verse health consequences or death to humans or  
9 animals.

10           (2) REQUIREMENTS.—To reduce the potential  
11 for miscommunication during recalls or regarding in-  
12 vestigations of a foodborne illness outbreak associ-  
13 ated with a food that is subject to a recall, each inci-  
14 dent command operation or similar operation under  
15 paragraph (1) shall use regular staff and resources  
16 of the Administration to—

17           (A) ensure timely and coordinated commu-  
18 nication within the Administration, including  
19 enhanced communication and coordination be-  
20 tween different agencies and organizations with-  
21 in the Administration;

22           (B) ensure timely and coordinated commu-  
23 nication from the Administration, including  
24 public statements, throughout the duration of

1 the investigation and related foodborne illness  
2 outbreak;

3 (C) identify a single point of contact within  
4 the Administration for public inquiries regard-  
5 ing any actions by the Administrator related to  
6 a recall;

7 (D) coordinate with Federal, State, local,  
8 and Tribal authorities, as appropriate, that  
9 have responsibilities related to the recall of a  
10 food or a foodborne illness outbreak associated  
11 with a food that is subject to the recall, includ-  
12 ing notification of the Secretary of Agriculture  
13 and the Secretary of Education in the event  
14 such recalled food is a commodity intended for  
15 use in a child nutrition program (as defined in  
16 section 25(b) of the Richard B. Russell Na-  
17 tional School Lunch Act (42 U.S.C. 1769f(b)));  
18 and

19 (E) conclude operations at such time as  
20 the Administrator determines appropriate.

21 (3) MULTIPLE RECALLS.—The Administrator  
22 may establish multiple or concurrent incident com-  
23 mand operations or similar operations in the event  
24 of multiple recalls or foodborne illness outbreaks.

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

6                   (A) the term “responsible party” means  
7                   “owner, operator, or agent in charge of the fa-  
8                   cility”; and

9                   (B) references to section 423 of the Fed-  
10                  eral Food, Drug, and Cosmetic Act (21 U.S.C.  
11                  350l) are references to section 402 of this Act.

12 **SEC. 403. INJUNCTION PROCEEDINGS.**

13           (a) JURISDICTION.—The district courts of the United  
14           States, and the United States courts of the territories and  
15           possessions of the United States, shall have jurisdiction,  
16           for cause shown, to restrain a violation of section 202,  
17           203, 204, 207, or 401 (or a regulation promulgated under  
18           that section).

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

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

24           (a) CIVIL SANCTIONS.—

25                   (1) CIVIL PENALTY.—

1 (A) IN GENERAL.—Any person that vio-  
2 lates section 401 may be assessed a civil pen-  
3 alty by the Administrator of not more than  
4 \$250,000 for each violation.

5 (B) SEPARATE OFFENSE.—Each violation  
6 described in subparagraph (A) and each day  
7 during which that violation continues shall be  
8 considered a separate offense.

9 (2) OTHER REQUIREMENTS.—

10 (A) WRITTEN ORDER.—The civil penalty  
11 described in paragraph (1) shall be assessed by  
12 the Administrator by a written order, which  
13 shall specify the amount of the penalty and the  
14 basis for the penalty under subparagraph (B)  
15 considered by the Administrator.

16 (B) AMOUNT OF PENALTY.—Subject to  
17 paragraph (1)(A), the amount of the civil pen-  
18 alty shall be determined by the Administrator,  
19 after considering—

20 (i) the gravity of the violation;

21 (ii) the degree of culpability of the  
22 person;

23 (iii) the size and type of the business  
24 of the person; and

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

3 (C) REVIEW OF ORDER.—A written order  
4 under subparagraph (A) may be reviewed only  
5 in accordance with subsection (c).

6 (b) CRIMINAL SANCTIONS.—

7 (1) IN GENERAL.—Except as provided in para-  
8 graphs (2) and (3), a person that violates subpara-  
9 graph (A) or (B) of section 401(1) shall be impris-  
10 oned for not more than 1 year, fined not more than  
11 \$10,000, or both.

12 (2) SEVERE VIOLATIONS.—A person that com-  
13 mits a violation described in paragraph (1) after a  
14 conviction of that person under this section has be-  
15 come final, or commits such a violation with the in-  
16 tent to defraud or mislead, shall be imprisoned for  
17 not more than 3 years, fined not more than  
18 \$100,000, or both.

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

21 (A) for having received, proffered, or deliv-  
22 ered in interstate commerce any food, if the re-  
23 ceipt, proffer, or delivery was made in good  
24 faith, unless that person refuses to furnish (on

1 request of an officer or employee designated by  
2 the Administrator)—

3 (i) the name, address, and contact in-  
4 formation of the person from whom that  
5 person purchased or received the food;

6 (ii) copies of all documents relating to  
7 the person from whom that person pur-  
8 chased or received the food; and

9 (iii) copies of all documents pertaining  
10 to the delivery of the food to that person;  
11 or

12 (B) if that person establishes a guaranty  
13 signed by, and containing the name and address  
14 of, the person from whom that person received  
15 in good faith the food, stating that the food is  
16 not adulterated or misbranded within the mean-  
17 ing of this Act.

18 (c) JUDICIAL REVIEW.—

19 (1) IN GENERAL.—An order assessing a civil  
20 penalty under subsection (a) shall be a final order  
21 unless the person—

22 (A) not later than 30 days after the effec-  
23 tive date of the order, files a petition for judi-  
24 cial review of the order in—

1 (i) the court of appeals of the United  
2 States for the judicial circuit in which that  
3 person resides or has its principal place of  
4 business; or

5 (ii) the United States Court of Ap-  
6 peals for the District of Columbia Circuit;  
7 and

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

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

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

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

20 (1) IN GENERAL.—If any person fails to pay a  
21 civil penalty assessed under subsection (a) after the  
22 order assessing the penalty has become a final order,  
23 or after the court of appeals described in subsection  
24 (c) has entered final judgment in favor of the Ad-  
25 ministrator, the Administrator shall refer the matter

1 to the Attorney General, who shall institute in a dis-  
2 trict court of the United States of competent juris-  
3 diction a civil action to recover the amount assessed.

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

8 (e) PENALTIES PAID INTO ACCOUNT.—The Adminis-  
9 trator—

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

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

14 (A) to carry out enforcement activities  
15 under food safety law; or

16 (B) to provide assistance to States to in-  
17 spect retail commercial food establishments or  
18 other food or firms under the jurisdiction of  
19 State food safety programs.

20 (f) DISCRETION OF THE ADMINISTRATOR TO PROS-  
21 ECUTE.—Nothing in this Act requires the Administrator  
22 to report for prosecution, or for the commencement of an  
23 action, the violation of the food safety law in a case in  
24 which the Administrator finds that the public interest will

1 be adequately served by the assessment of a civil penalty  
2 under this section.

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

6 **SEC. 405. PRESUMPTION.**

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

10 **SEC. 406. WHISTLEBLOWER PROTECTION.**

11 Section 1013 of the Federal Food, Drug, and Cos-  
12 metic Act (21 U.S.C. 399d) shall apply with respect to  
13 any violation of, or any act or omission an employee rea-  
14 sonably believes to be a violation of, any provision of this  
15 Act to the same extent and in the same manner as that  
16 section applies with respect to a violation of, or any act  
17 or omission an employee reasonably believes to be a viola-  
18 tion of, any provision of the Federal Food, Drug, and Cos-  
19 metic Act (21 U.S.C. 301 et seq.).

20 **SEC. 407. ADMINISTRATION AND ENFORCEMENT.**

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

1 (h) of section 6 of that Act (15 U.S.C. 46)), relating to  
2 the jurisdiction, powers, and duties of the Federal Trade  
3 Commission and the Attorney General to administer and  
4 enforce that Act, and to the rights and duties of persons  
5 with respect to whom the powers are exercised, shall apply  
6 to the jurisdiction, powers, and duties of the Adminis-  
7 trator and the Attorney General in administering and en-  
8 forcing the provisions of the food safety law and to the  
9 rights and duties of persons with respect to whom the  
10 powers are exercised, respectively.

11 (b) INQUIRIES AND ACTIONS.—

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

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

23 **SEC. 408. CITIZEN CIVIL ACTIONS.**

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

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

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

9           (b) COURT.—

10           (1) IN GENERAL.—The action shall be com-  
11           menced in the district court of the United States for  
12           the judicial district in which the defendant resides,  
13           is found, or has an agent.

14           (2) JURISDICTION.—The court described in  
15           paragraph (1) shall have jurisdiction, without regard  
16           to the amount in controversy or the citizenship of  
17           the parties, to enforce a regulation (including a reg-  
18           ulation establishing a performance standard), order,  
19           or other action of the Administrator, or to order the  
20           Administrator to perform the act or duty.

21           (3) DAMAGES.—The court described in para-  
22           graph (1) may—

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

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

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

## 8 **TITLE V—IMPLEMENTATION**

### 9 **SEC. 501. DEFINITION.**

10 In this title, the term “transition period” means the  
11 12-month period beginning on the date of enactment of  
12 this Act.

### 13 **SEC. 502. REORGANIZATION PLAN.**

14 (a) SUBMISSION OF PLAN.—Not later than 180 days  
15 after the date of enactment of this Act, the President shall  
16 transmit to the appropriate congressional committees a re-  
17 organization plan regarding the following:

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

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

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

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

3           (1) Identification of any functions of agencies  
4           designated to be transferred to the Administration  
5           pursuant to this Act that will not be transferred to  
6           the Administration under the plan.

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

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

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

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

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

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

10          (d) EFFECTIVE DATE.—

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

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

22           (B) the end of the transition period.

23           (2) STATUTORY CONSTRUCTION.—Nothing in  
24           this subsection may be construed to require the  
25           transfer of functions, personnel, records, balances of

1 appropriations, or other assets of an agency on a  
2 single date.

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

6 **SEC. 503. TRANSITIONAL AUTHORITIES.**

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

15 (b) SERVICES AND PERSONNEL.—During the transi-  
16 tion period, upon the request of the Administrator, the  
17 head of any Executive agency may, on a reimbursable  
18 basis, provide services or detail personnel to assist with  
19 the transition.

20 (c) ACTING OFFICIALS.—

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

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

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

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

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

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

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

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

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

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

12 **SEC. 504. SAVINGS PROVISIONS.**

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

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

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

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

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

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

25 (d) REFERENCES.—

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

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

16 **SEC. 505. CONFORMING AMENDMENTS.**

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

19           “Administrator of Food Safety.”.

20 **SEC. 506. ADDITIONAL TECHNICAL AND CONFORMING**  
21 **AMENDMENTS.**

22           Not later than 60 days after the submission of the  
23           reorganization plan under section 502, the President shall  
24           prepare and submit proposed legislation to Congress con-  
25           taining necessary and appropriate technical and con-

1 forming amendments to any food safety law to reflect the  
2 changes made by this Act.

3 **SEC. 507. REGULATIONS.**

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

7 **SEC. 508. AUTHORIZATION OF APPROPRIATIONS.**

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

10 **SEC. 509. LIMITATION ON AUTHORIZATION OF APPROPRIA-**  
11 **TIONS.**

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

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

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

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