

110<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 7143

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

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 26, 2008

Ms. DELAURO introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Agriculture, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

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

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

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

2 (a) **SHORT TITLE.**—This Act may be cited as the  
 3 “Food Safety Modernization Act of 2007”.

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 THE FOOD SAFETY  
ADMINISTRATION

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

TITLE II—ADMINISTRATION OF FOOD SAFETY PROGRAM

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

TITLE III—RESEARCH AND EDUCATION

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

TITLE IV—ENFORCEMENT

- Sec. 401. Prohibited acts.
- Sec. 402. Food detention, seizure, and condemnation.
- Sec. 403. Notification and recall.
- Sec. 404. Injunction proceedings.
- Sec. 405. Civil and criminal penalties.
- Sec. 406. Presumption.
- Sec. 407. Whistleblower protection.
- Sec. 408. Administration and enforcement.
- Sec. 409. Citizen civil actions.

TITLE V—IMPLEMENTATION

- Sec. 501. Reorganization plan.
- Sec. 502. Transitional authorities.

Sec. 503. Savings provisions.  
Sec. 504. Conforming amendments.  
Sec. 505. Additional technical and conforming amendments.  
Sec. 506. Regulations.  
Sec. 507. Authorization of appropriations.  
Sec. 508. Limitation on authorization of appropriations.

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

2 (a) FINDINGS.—Congress finds that—

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

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

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

19 (4) the safety and security of the food supply  
20 require a systemwide approach to prevent food-borne  
21 illness involving the integrated efforts of Federal,  
22 State and local agencies; a thorough, broad-based,

1 and coordinated approach to basic and applied  
2 science; and intensive, effective, and efficient man-  
3 agement of the Nation's food safety program;

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

7 (A) emerging pathogens and other con-  
8 taminants and the ability to detect all forms of  
9 contamination;

10 (B) the threat of intentional contamination  
11 of the food supply;

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

17 (D) an increasing volume of imported food,  
18 without adequate monitoring, inspection, and  
19 systems for prevention of food safety problems;  
20 and

21 (E) maintenance of rigorous inspection of  
22 the domestic food processing and food service  
23 industries;

24 (6) Federal food safety standard setting, in-  
25 spection, enforcement, and research efforts should be

1 based on the best available science and public health  
2 considerations, and food safety resources should be  
3 systematically deployed in ways that most effectively  
4 prevent food-borne illness;

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

12 (8) rapid technological advance and the expan-  
13 sion and globalization of industries in all areas of  
14 Food and Drug Administration jurisdiction present  
15 challenges and require leadership beyond the capac-  
16 ity of any one agency or agency head to provide;

17 (9) in the food safety area, the Food and Drug  
18 Administration implements provisions of the Federal  
19 Food, Drug, and Cosmetic Act that are 70 years old  
20 and that antiquated law limits the Food and Drug  
21 Administration's role largely to reacting to and cor-  
22 recting food safety problems after they occur, rather  
23 than working with the food industry to systemati-  
24 cally prevent problems;

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

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

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

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

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

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

1 (B) ensure that food establishments fulfill  
2 their responsibility to process, store, hold, and  
3 transport food in a manner that protects the  
4 public health of all people in the United States;

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

9 (D) provide a single focal point within the  
10 Department of Health and Human Services for  
11 food safety leadership, both nationally and  
12 internationally; and

13 (E) provide an integrated food safety re-  
14 search capability, utilizing internally generated,  
15 scientifically and statistically valid studies, in  
16 cooperation with academic institutions and  
17 other scientific entities of the Federal and State  
18 governments;

19 (2) to transfer to the Food Safety Administra-  
20 tion the food safety, labeling, inspection, and en-  
21 forcement functions that, as of the day before the  
22 date of the enactment of this Act, are performed by  
23 various components of the Food and Drug Adminis-  
24 tration and the National Oceanic and Atmospheric  
25 Administration;

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

5           (4) to establish that food establishments have  
6 responsibility to ensure that all stages of production,  
7 processing, and distribution of their products or  
8 products under their control satisfy the requirements  
9 of this law.

10 **SEC. 3. DEFINITIONS.**

11 In this Act:

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

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

18           (3) **ADULTERATED.**—

19           (A) **IN GENERAL.**—The term “adulter-  
20 ated” has the meaning given that term in sec-  
21 tion 402 of the Federal Food, Drug, and Cos-  
22 metic Act (21 U.S.C. 342).

23           (B) **INCLUSION.**—The term “adulterated”  
24 includes bearing or containing a contaminant

1           that causes illness or death among sensitive  
2           populations.

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

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

14          (6) CATEGORY 2 FOOD ESTABLISHMENT.—The  
15          term “category 2 food establishment” means a sea-  
16          food processing establishment or other food estab-  
17          lishment (other than a category 1 establishment) not  
18          subject to inspection under the Federal Meat Inspec-  
19          tion Act, the Poultry Products Inspection Act, or the  
20          Egg Products Inspection Act, that processes raw  
21          seafood or other raw animal products, whether fresh  
22          or frozen, or other products that the Administrator  
23          determines by regulation to pose a significant risk of  
24          hazardous contamination.

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

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

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

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

24           (11) HAZARDOUS CONTAMINATION.—The term  
25 “hazardous contamination” refers to the presence of

1 a contaminant in food at levels that pose a risk of  
2 human illness, injury, or death or are capable of  
3 reaching levels that pose such risk during the shelf  
4 life of the product.

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

8 (13) FOOD ESTABLISHMENT.—

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

17 (B) EXCLUSIONS.—For the purposes of  
18 registration, the term “food establishment”  
19 does not include a food production facility as  
20 defined in paragraph (14), restaurant, other re-  
21 tail food establishment, nonprofit food estab-  
22 lishment in which food is prepared for or served  
23 directly to the consumer, or fishing vessel  
24 (other than a fishing vessel engaged in proc-

1           essing, as that term is defined in section 123.3  
2           of title 21, Code of Federal Regulations).

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

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

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

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

21                  (C) the provisions of the Public Health  
22                  Service Act that relate in any way to surveying,  
23                  containing, or preventing food-borne illness; and

24                  (D) the provisions of this Act.

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

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

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

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

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

19                   (A) a State;

20                   (B) the District of Columbia;

21                   (C) the Commonwealth of Puerto Rico;

22                   and

23                   (D) any other territory or possession of the  
24 United States.

1 **TITLE I—ESTABLISHMENT OF**  
2 **THE FOOD SAFETY ADMINIS-**  
3 **TRATION**

4 **SEC. 101. ESTABLISHMENT OF THE FOOD SAFETY ADMINIS-**  
5 **TRATION.**

6 (a) ESTABLISHMENT.—

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

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

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

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

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

24 (2) serve as the food safety leader within the  
25 Department of Health and Human Services and co-

1       ordinator of all Department activities related to en-  
2       suring the safety, quality, and proper labeling of the  
3       food supply;

4           (3) represent the United States in international  
5       food safety bodies and discussions;

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

10          (5) oversee within the Department of Health  
11       and Human Services—

12           (A) all activities related to foodborne ill-  
13       ness surveillance and investigation of foodborne  
14       illness outbreaks;

15           (B) implementation of food safety inspec-  
16       tion, enforcement, and research efforts to pro-  
17       tect the public health;

18           (C) development of consistent and science-  
19       based standards for safe food;

20           (D) coordination and prioritization of food  
21       safety research and education programs with  
22       other Federal agencies;

23           (E) prioritization of food safety efforts and  
24       deployment of food safety resources to achieve

1 the greatest possible benefit in reducing food-  
2 borne illness;

3 (F) coordination of the response to food-  
4 borne illness outbreaks with other Federal and  
5 State agencies; and

6 (G) integration of food safety activities  
7 with State and local agencies.

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

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

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

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

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

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

23 (2) the Center for Veterinary Medicine of the  
24 Food and Drug Administration;

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

3           (4) the personnel and assets of the Office of  
4           Regulatory Affairs of the Food and Drug Adminis-  
5           tration used to administer and conduct inspections  
6           of food establishments and imports and conduct lab-  
7           oratory analyses and other investigations relating to  
8           food safety;

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

11                 (A) the Center for Food Safety and Ap-  
12                 plied Nutrition;

13                 (B) the Center for Veterinary Medicine;

14                 (C) the National Center for Toxicological  
15                 Research; and

16                 (D) the personnel and assets of the Office  
17                 of Regulatory Affairs described in paragraph  
18                 (4); and

19          (6) the personnel and assets of the National  
20          Marine Fisheries Service of the National Oceanic  
21          and Atmospheric Administration of the Department  
22          of Commerce used to administer the seafood inspec-  
23          tion program.

24          (c) RENAMING AND RESERVATION OF AGENCY IDEN-  
25          TITY.—The Food and Drug Administration in the Depart-

1 ment of Health and Human Services is hereby renamed  
2 the Federal Drug and Device Administration and may be  
3 referred to as “FDA”.

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

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

11 (a) OFFICERS AND EMPLOYEES.—The Administrator  
12 may—

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

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

21 (b) EXPERTS AND CONSULTANTS.—The Adminis-  
22 trator may—

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

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

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

12           (d) ADVISORY COMMITTEES.—

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

17           (2) DUTIES.—The duties of an advisory com-  
18 mittee established under paragraph (1) may include  
19 developing recommendations with respect to the de-  
20 velopment of new processes, research, communica-  
21 tions, performance standards, and inspection.

## 22       **TITLE II—ADMINISTRATION OF** 23       **FOOD SAFETY PROGRAM**

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

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

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

4           (2) ensure that persons who produce, process,  
5 or distribute food meet their responsibility to pre-  
6 vent or minimize food safety hazards related to their  
7 products.

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

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

14           (2) the sources of potentially hazardous con-  
15 tamination or practices extending from the farm or  
16 ranch to the consumer that may increase the risk of  
17 food-borne illness;

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

21           (4) the potential for hazardous contamination  
22 to have cumulative toxic effects, multigenerational  
23 effects, or effects on specific categories of con-  
24 sumers;

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

4           (6) opportunities for intentional contamination  
5           of food or food ingredients.

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

8           (1) adopt and implement a national system for  
9           the registration of food establishments and foreign  
10          food establishments, as provided in section 202 of  
11          this Act;

12          (2) adopt and implement a national system for  
13          regular unannounced inspection of food establish-  
14          ments;

15          (3) require and enforce the adoption of preven-  
16          tive process controls in food establishments, based  
17          on the best available scientific and public health con-  
18          siderations and best available technologies;

19          (4) establish and enforce science-based stand-  
20          ards for—

21                  (A) potentially hazardous substances that  
22                  may contaminate food; and

23                  (B) safety and sanitation in the processing  
24                  and handling of food;

1           (5) implement a statistically valid sampling pro-  
2           gram with the stringency and frequency to independ-  
3           ently monitor that industry programs and proce-  
4           dures that prevent food contamination are effective  
5           on an ongoing basis and that food meets the stand-  
6           ards established under this Act;

7           (6) implement appropriate surveillance proce-  
8           dures and requirements to ensure the safety and se-  
9           curity of imported food;

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

13          (8) implement a national system to identify the  
14          food products posing the greatest public health risk  
15          and to analyze the effectiveness of existing food safe-  
16          ty programs, in conjunction with the Centers for  
17          Disease Control and Prevention and other Federal  
18          agencies;

19          (9) develop public education, risk communica-  
20          tion, and advisory programs;

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

23          (11) coordinate and prioritize food safety re-  
24          search and educational programs with other Federal  
25          agencies and with State and local governments; and

1           (12) provide technical assistance to farmers and  
2 food establishments that are small business concerns  
3 (meeting the requirements of section 3(a) of the  
4 Small Business Act and the regulations promulgated  
5 thereunder) to assist with compliance with the re-  
6 quirements of this Act.

7 **SEC. 202. REGISTRATION OF FOOD ESTABLISHMENTS AND**  
8 **FOREIGN FOOD ESTABLISHMENTS.**

9           (a) IN GENERAL.—Any food establishment or foreign  
10 food establishment engaged in manufacturing, processing,  
11 packing, or holding food for consumption in the United  
12 States shall register annually with the Administrator.

13           (b) REGISTRATION REQUIREMENTS.—

14           (1) IN GENERAL.—To be registered under sub-  
15 section (a), a food establishment shall submit a reg-  
16 istration or reregistration to the Administrator.

17           (2) REGISTRATION.—Registration under this  
18 section shall begin within 90 days of the enactment  
19 of this Act. Each such registration shall be sub-  
20 mitted to the Secretary through an electronic portal  
21 and shall contain such information as the Secretary,  
22 by guidance, determines to be appropriate. Such reg-  
23 istration shall contain the following information:

24           (A) The name, address, and emergency  
25 contact information of each domestic food es-

1           tabishment or foreign food establishment that  
2           the registrant owns or operates under this Act  
3           and all trade names under which the registrant  
4           conducts business in the United States relating  
5           to food.

6           (B) The primary purpose and business ac-  
7           tivity of each domestic food establishment or  
8           foreign food establishment, including the dates  
9           of operation if the domestic food establishment  
10          or foreign food establishment is seasonal.

11          (C) The types of food processed or sold at  
12          each domestic food establishment or, for foreign  
13          food establishments selling food for consump-  
14          tion in the United States, the specific food cat-  
15          egories of that food as listed under section  
16          170.3(n) of title 21, Code of Federal Regula-  
17          tions, or such other categories as the Adminis-  
18          trator may designate in guidance, action level,  
19          or regulations for evaluating potential threats  
20          to food protection.

21          (D) The name, address, and 24-hour emer-  
22          gency contact information of the United States  
23          distribution agent for each domestic food estab-  
24          lishment or foreign food establishment, who  
25          shall maintain information on the distribution

1 of food, including lot information, and whole-  
2 saler and retailer distribution.

3 (E) An assurance that the registrant will  
4 notify the Administrator of any change in the  
5 products, function, or legal status of the domes-  
6 tic food establishment or foreign food establish-  
7 ment (including cessation of business activities)  
8 not later than 30 days after such change.

9 (3) PROCEDURE.—Upon receipt of a completed  
10 registration described in paragraph (1), the Admin-  
11 istrator shall notify the registrant of the receipt of  
12 the registration, designate each establishment as a  
13 category 1, 2, 3, 4, or 5 food establishment, and as-  
14 sign a registration number to each domestic food es-  
15 tablishment and foreign food establishment.

16 (4) LIST.—The Administrator shall annually  
17 compile a list of domestic food establishments and a  
18 list of foreign food establishments that are registered  
19 under this section. The Administrator may establish  
20 the manner of and any fees required for reregistra-  
21 tion and any circumstances by which either such list  
22 may be shared with other governmental authorities.  
23 The Administrator may remove from either such list  
24 the name of any establishment that fails to rereg-

1       ister, and such delisting shall be treated as a sus-  
2       pension.

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

6                       (A) the list compiled under paragraph (4);  
7       and

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

11               (6) SUSPENSION OF REGISTRATION.—

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

19                       (B) NOTICE AND OPPORTUNITY FOR  
20      HEARING.—The Administrator shall provide no-  
21      tice of an intent to suspend the registration of  
22      an establishment under this paragraph to a reg-  
23      istrant and provide the registrant with an op-  
24      portunity for an administrative hearing within 3  
25      days. The Administrator may issue a written

1 order of suspension following the hearing, if the  
2 Administrator finds that a violation described  
3 in subparagraph (A) has occurred.

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

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

16 (c) TRANSITIONAL PROVISION.—During the 6-month  
17 period following the date of the enactment of this Act, a  
18 food establishment is deemed to be registered in accord-  
19 ance with this section if the establishment is registered  
20 under section 415 of the Federal Food, Drug, and Cos-  
21 metic Act (21 U.S.C. 350d).

22 (d) REPEAL.—Effective at the end of the 6-month  
23 period following the date of the enactment of this Act, sec-  
24 tion 415 of the Federal Food, Drug, and Cosmetic Act  
25 (21 U.S.C. 350d) is repealed.

1 **SEC. 203. PREVENTIVE PROCESS CONTROLS TO REDUCE**  
2 **ADULTERATION OF FOOD.**

3 (a) IN GENERAL.—The Administrator shall, upon the  
4 basis of best available public health, scientific, and techno-  
5 logical data, promulgate regulations to ensure that food  
6 establishments carry out their responsibilities under the  
7 food safety law.

8 (b) REGULATIONS.—Not later than 1 year after the  
9 date of the enactment of this Act, the Administrator shall  
10 promulgate regulations that require all food establish-  
11 ments, within time frames determined by the Adminis-  
12 trator—

13 (1) to adopt preventive process controls that—

14 (A) reflect the standards and procedures  
15 recognized by relevant authoritative bodies;

16 (B) are adequate to protect the public  
17 health;

18 (C) meet relevant regulatory and food safe-  
19 ty standards;

20 (D) limit the presence and growth of con-  
21 taminants in food prepared in a food establish-  
22 ment using the best reasonably available tech-  
23 niques and technologies; and

24 (E) are tailored to the hazards and proc-  
25 esses in particular establishments or environ-  
26 ments;

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

3           (3) to meet performance standards for haz-  
4 arduous contamination established under section 204;

5           (4) to implement recordkeeping to monitor com-  
6 pliance with regulatory requirements;

7           (5) to implement recordkeeping and labeling of  
8 all food and food ingredients to facilitate their iden-  
9 tification and traceability in the event of a recall or  
10 market removal;

11          (6) to implement product and environmental  
12 sampling at a frequency and in a manner sufficient  
13 to ensure that process controls are effective on an  
14 ongoing basis and that regulatory standards are  
15 being met;

16          (7) to label food intended for final processing  
17 outside commercial food establishments with instruc-  
18 tions for handling and preparation for consumption  
19 that will destroy microbial contaminants; and

20          (8) to provide for agency access to records kept  
21 by the food establishments and submission of copies  
22 of records to the Administrator, as the Adminis-  
23 trator determines appropriate.

24       (c) SPECIFIC HAZARD CONTROLS.—The Adminis-  
25 trator may require any person with responsibility for or

1 control over food or food ingredients to adopt specific haz-  
2 ard controls, if such controls are needed to ensure the pro-  
3 tection of the public health.

4 **SEC. 204. PERFORMANCE STANDARDS FOR CONTAMINANTS**  
5 **IN FOOD.**

6 (a) IN GENERAL.—To protect the public health, the  
7 Administrator shall establish by guidance document, ac-  
8 tion level, or regulation and enforce performance stand-  
9 ards that define, with respect to specific foods and con-  
10 taminants in food, the level of food safety performance  
11 that a person responsible for producing, processing, or  
12 selling food shall meet.

13 (b) IDENTIFICATION OF CONTAMINANTS; PERFORM-  
14 ANCE STANDARDS.—

15 (1) LIST OF CONTAMINANTS.—Not later than 6  
16 months after the date of the enactment of this Act,  
17 the Administrator shall publish in the Federal Reg-  
18 ister a list of the contaminants in foods that have  
19 the greatest adverse impact on public health in  
20 terms of the number and severity of illnesses and  
21 number of deaths associated with foods regulated  
22 under this Act. Where appropriate, the Adminis-  
23 trator shall indicate whether the risk posed by a con-  
24 taminant is generalized or specific to particular  
25 foods or ingredients.

1 (2) PERFORMANCE STANDARDS.—

2 (A) ESTABLISHMENT.—The Administrator  
3 shall establish by guidance document, action  
4 level, or regulation a performance standard for  
5 each contaminant in the list under paragraph  
6 (1) at levels appropriate to protect against the  
7 potential adverse health effects of the contami-  
8 nant.

9 (B) TIMING.—The Administrator shall es-  
10 tablish a performance standard under subpara-  
11 graph (A) for each contaminant in the list  
12 under paragraph (1)—

13 (i) as soon as practicable; or

14 (ii) in the case of a contaminant de-  
15 scribed in subparagraph (C), by the date  
16 described in such subparagraph.

17 (C) SIGNIFICANT CONTAMINANTS.—The  
18 list under paragraph (1) (and any revision  
19 thereto) shall identify the 5 most significant  
20 contaminants in the list (in terms of the num-  
21 ber and severity of illnesses and number of  
22 deaths associated with foods regulated under  
23 this Act). Not later than 3 years after a con-  
24 taminant is so identified, the Administrator

1 shall promulgate a performance standard under  
2 subparagraph (A) for the contaminant.

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

6 (A) the list of contaminants under para-  
7 graph (1); and

8 (B) each performance standard established  
9 under paragraph (2) or

10 (c) PERFORMANCE STANDARDS.—

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

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

16 (B) zero tolerances, including any zero tol-  
17 erance performance standards in effect on the  
18 day before the date of the enactment of this  
19 Act, when necessary to protect against signifi-  
20 cant adverse health outcomes;

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

24 (D) in the absence of data to support a  
25 performance standard described in subpara-

1 graph (A), (B), or (C), standards that define  
2 required performance on the basis of reliable in-  
3 formation on the best reasonably achievable  
4 performance, using best available technologies,  
5 interventions, and practices.

6 (2) BEST REASONABLY ACHIEVABLE PERFORM-  
7 ANCE STANDARDS.—In developing best reasonably  
8 achievable performance standards under paragraph  
9 (1)(D), the Administrator shall collect, or contract  
10 for the collection of, data on current best practices  
11 and food safety outcomes related to the contami-  
12 nants and foods in question, as the Administrator  
13 determines necessary.

14 (3) REVOCATION BY ADMINISTRATOR.—All per-  
15 formance standards, tolerances, action levels, or  
16 other similar standards in effect on the date of the  
17 enactment of this Act shall remain in effect until re-  
18 vised or revoked by the Administrator.

19 (d) ENFORCEMENT.—

20 (1) IN GENERAL.—In conjunction with the es-  
21 tablishment of a performance standard under this  
22 section, the Administrator shall develop a statis-  
23 tically valid sampling program with the stringency  
24 and frequency sufficient to independently monitor  
25 whether food establishments are complying with the

1 performance standard and implement the program  
2 within 1 year of the promulgation of the standard.

3 (2) INSPECTIONS.—If the Administrator deter-  
4 mines that a food establishment fails to meet a  
5 standard promulgated under this section, the Ad-  
6 ministrator shall, as appropriate—

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

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

11 (C) increase the inspection frequency for  
12 the food establishment;

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

15 (E) take other appropriate enforcement ac-  
16 tion concerning the food establishment, includ-  
17 ing withdrawal of registration.

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

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

24 (a) IN GENERAL.—The Administrator shall establish  
25 an inspection program, which shall include statistically

1 valid sampling of food and facilities to enforce perform-  
2 ance standards. The inspection program shall be designed  
3 to determine if each food establishment—

4 (1) is operated in a sanitary manner;

5 (2) has continuous preventive control systems,  
6 interventions, and processes in place to minimize or  
7 eliminate contaminants in food;

8 (3) is in compliance with applicable perform-  
9 ance standards established under section 204, and  
10 other regulatory requirements;

11 (4) is processing food that is not adulterated or  
12 misbranded;

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

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

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

24 (1) CATEGORY 1 FOOD ESTABLISHMENTS.—A  
25 category 1 food establishment shall be subject to

1       antemortem, postmortem, and continuous inspection  
2       of each slaughter line during all operating hours,  
3       and other inspection on a daily basis, sufficient to  
4       verify that—

5               (A) diseased animals are not offered for  
6               slaughter;

7               (B) the food establishment has successfully  
8               identified and removed from the slaughter line  
9               visibly defective or contaminated carcasses, has  
10              avoided cross-contamination, and has destroyed  
11              or reprocessed such carcasses in a manner ac-  
12              ceptable to the Administrator; and

13              (C) applicable performance standards and  
14              other provisions of the food safety law, includ-  
15              ing those intended to eliminate or reduce patho-  
16              gens, have been satisfied.

17       (2) CATEGORY 2 FOOD ESTABLISHMENTS.—A  
18       category 2 food establishment shall—

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

21              (B) be randomly inspected at least weekly.

22       (3) CATEGORY 3 FOOD ESTABLISHMENTS.—A  
23       category 3 food establishment shall—

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

1 (B) be randomly inspected at least month-  
2 ly.

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

5 (A) have ongoing verification that its proc-  
6 esses are controlled; and

7 (B) be randomly inspected at least quar-  
8 terly.

9 (5) CATEGORY 5 FOOD ESTABLISHMENTS.—A  
10 category 5 food establishment shall—

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

13 (B) be randomly inspected at least annu-  
14 ally.

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

19 (d) ALTERNATIVE INSPECTION FREQUENCIES.—  
20 With respect to a subcategory of food establishment under  
21 category 2, 3, 4, or 5, the Administrator may establish  
22 alternative increasing or decreasing inspection frequencies  
23 for subcategories of food establishments or individual es-  
24 tablishments, to foster risk-based allocation of resources.  
25 Before establishing an alternative inspection frequency for

1 a subcategory of food establishments or individual estab-  
2 lishments, the Administrator shall take into consideration  
3 the evidence described in paragraph (2)(D) and the overall  
4 record of compliance described in paragraph (2)(E) for  
5 such subcategory. In establishing alternative inspection  
6 frequencies under this subsection, the Administrator shall  
7 comply with the following criteria and procedures:

8 (1) Subcategories of food establishments and  
9 their alternative inspection frequencies shall be de-  
10 fined by regulation, subject to paragraphs (2) and  
11 (3).

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

16 (A) the nature of the food products being  
17 processed, stored, or transported;

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

20 (C) the inherent likelihood that the prod-  
21 ucts will contribute to the risk of food-borne ill-  
22 ness;

23 (D) the best available evidence concerning  
24 reported illnesses associated with the foods

1 processed, stored, held, or transported in the  
2 proposed subcategory of establishments; and

3 (E) the overall record of compliance with  
4 food safety law among establishments in the  
5 proposed subcategory, including compliance  
6 with applicable performance standards and the  
7 frequency of recalls.

8 (3) The Administrator may adopt alternative  
9 inspection frequencies for increased or decreased in-  
10 spection for a specific establishment and shall annu-  
11 ally publish a list of establishments subject to alter-  
12 native inspections.

13 (4) In adopting alternative inspection fre-  
14 quencies for a specific establishment, the Adminis-  
15 trator shall consider—

16 (A) the criteria in paragraph (3), together  
17 with any evidence submitted from the individual  
18 food establishment supporting a request for an  
19 alternative inspection frequency, including the  
20 establishment's record for implementing effec-  
21 tive preventative process control systems;

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

1           (C) the establishment’s record of compli-  
2           ance with food safety law, including compliance  
3           with applicable performance standards and the  
4           frequency of recalls.

5           (e) EFFECTIVE DATE.—The inspection mandates  
6 shall go into effect 2 years after the date of the enactment  
7 of this Act.

8           (f) MAINTENANCE AND INSPECTION OF RECORDS.—

9           (1) IN GENERAL.—

10           (A) RECORDS.—A food establishment  
11 shall—

12                   (i) maintain such records as the Ad-  
13                   ministrators shall require by regulation, in-  
14                   cluding all records relating to the proc-  
15                   essing, distributing, receipt, or importation  
16                   of any food; and

17                   (ii) permit the Administrator, in addi-  
18                   tion to any authority transferred to the  
19                   Administrator pursuant to section 102,  
20                   upon presentation of appropriate creden-  
21                   tials and at reasonable times and in a rea-  
22                   sonable manner, to have access to and  
23                   copy all records maintained by or on behalf  
24                   of such food establishment representative  
25                   in any format (including paper or elec-

1                   tronic) and at any location, that are nec-  
2                   essary to assist the Administrator—

3                   (I) to determine whether the food  
4                   is contaminated or not in compliance  
5                   with the food safety law; or

6                   (II) to track the food in com-  
7                   merce.

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

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

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

20                 (A) the origin, receipt, delivery, sale, move-  
21                 ment, holding, and disposition of food or ingre-  
22                 dients;

23                 (B) the identity and quantity of ingredi-  
24                 ents used in the food;

25                 (C) the processing of the food;

1 (D) the results of laboratory, sanitation, or  
2 other tests performed on the food or in the food  
3 establishment;

4 (E) consumer complaints concerning the  
5 food or packaging of the food;

6 (F) the production codes, open date codes,  
7 and locations of food production; and

8 (G) other matters reasonably related to  
9 whether food is adulterated or misbranded, or  
10 otherwise fails to meet the requirements of this  
11 Act.

12 (g) PROTECTION OF SENSITIVE INFORMATION.—

13 (1) IN GENERAL.—The Administrator shall de-  
14 velop and maintain procedures to prevent the unau-  
15 thorized disclosure of any trade secret or commer-  
16 cially valuable confidential information obtained by  
17 the Administrator.

18 (2) LIMITATION.—The requirements under this  
19 subsection and subsection (f) do not—

20 (A) limit the authority of the Adminis-  
21 trator to inspect or copy records or to require  
22 the establishment or maintenance of records  
23 under this Act;

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

1 (C) extend to any food recipe, financial  
2 data, pricing data, or personnel data;

3 (D) limit the public disclosure of distribu-  
4 tion records or other records related to food  
5 subject to a voluntary or mandatory recall  
6 under section 403; or

7 (E) limit the authority of the Adminis-  
8 trator to promulgate regulations to permit the  
9 sharing of data with other governmental au-  
10 thorities.

11 (h) BRIBERY OF OR GIFTS TO INSPECTOR OR OTHER  
12 OFFICERS AND ACCEPTANCE OF GIFTS.—Any person or  
13 agent or employee thereof that gives, pays, or offers, di-  
14 rectly or indirectly, to the Administrator or any employee  
15 or other designee thereof authorized to perform any duty  
16 under the food safety law any money or other thing of  
17 value, with intent to influence the discharge of any duty  
18 under such law, shall be imprisoned for not more than 5  
19 years, fined in accordance with title 18, United States  
20 Code, or both. Any Administrator, employee, or other des-  
21 ignee that solicits or accepts any money or other thing  
22 of value from any person, with intent to influence the dis-  
23 charge of any duty under the food safety law, shall be  
24 summarily discharged from office and imprisoned for not

1 more than 5 years, fined in accordance with title 18,  
2 United States Code, or both.

3 **SEC. 206. FOOD PRODUCTION FACILITIES.**

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

8 (1) visit and inspect food production facilities in  
9 the United States and in foreign countries to deter-  
10 mine if they are operating in compliance with the re-  
11 quirements of the food safety law;

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

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

17 (4) conduct monitoring and surveillance of ani-  
18 mals, plants, products, or the environment, as ap-  
19 propriate; and

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

22 (b) **INSPECTION OF RECORDS.**—A food production  
23 facility shall permit the Administrator upon presentation  
24 of appropriate credentials and at reasonable times and in  
25 a reasonable manner, to have access to and ability to copy

1 all records maintained by or on behalf of such food pro-  
2 duction establishment in any format (including paper or  
3 electronic) and at any location, that are necessary to assist  
4 the Administrator—

5           (1) to determine whether the food is contami-  
6 nated, adulterated, or otherwise not in compliance  
7 with the food safety law; or

8           (2) to track the food in commerce.

9       (c) REGULATIONS.—Not later than 1 year after the  
10 date of the enactment of this Act, the Administrator, in  
11 consultation with the Secretary of Agriculture and rep-  
12 resentatives of State departments of agriculture, shall pro-  
13 mulgate regulations to establish science-based minimum  
14 standards for the safe production of food by food produc-  
15 tion facilities. Such regulations shall—

16           (1) consider all relevant hazards, including  
17 those occurring naturally, and those that may be un-  
18 intentionally or intentionally introduced;

19           (2) require each food production facility to have  
20 a written food safety plan that describes the likely  
21 hazards and preventive controls implemented to ad-  
22 dress those hazards;

23           (3) include, with respect to growing, harvesting,  
24 sorting, and storage operations, minimum standards  
25 related to fertilizer use, nutrients, hygiene, pack-

1 aging, temperature controls, animal encroachment,  
2 and water;

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

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

10 (6) provide for coordination of education and  
11 enforcement activities by State and local officials, as  
12 designated by the Governors of the respective States;  
13 and

14 (7) include a description of the variance process  
15 under subsection (d) and the types of permissible  
16 variances which the Administrator may grant under  
17 such process.

18 (d) VARIANCES.—States and foreign countries that  
19 export produce intended for consumption in the United  
20 States may request from the Administrator variances from  
21 the requirements of the regulations under subsection (c).

22 A request shall—

23 (1) be in writing;

24 (2) describe the reasons the variance is nec-  
25 essary;

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

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

6           (e) APPROVAL OR DISAPPROVAL OF VARIANCES.—If  
7           the Administrator determines after review of a request  
8           under subsection (d) that the requested variance provides  
9           equivalent protections to those promulgated under sub-  
10          section (c), the Administrator may approve the request.  
11          The Administrator shall deny a request if it is—

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

14           (2) fails to cite sufficient grounds for allowing  
15           a variance; or

16           (3) does not provide reasonable assurances that  
17           the produce will not be adulterated.

18          (f) ENFORCEMENT.—The Administrator may coordi-  
19          nate with the agency or department designated by the  
20          Governor of each State to perform activities to ensure  
21          compliance with this section.

22          (g) IMPORTED PRODUCE.—Not later than 1 year  
23          after the date of the enactment of this Act, the Adminis-  
24          trator shall by regulation establish procedures for equiva-  
25          lency with foreign countries that intend to export raw agri-

1 cultural commodities and minimally processed produce to  
2 the United States.

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

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

9 (b) STATE ACTION.—The Administrator shall work  
10 with States to—

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

15 (2) continue, strengthen, or establish inspection  
16 programs and requirements to ensure that food  
17 under the jurisdiction of the State complies with the  
18 food safety law; and

19 (3) support recall authorities at the State and  
20 local levels.

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

24 (1) advisory assistance;

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

4           (3) financial, in-kind, and other aid.

5       (d) SERVICE AGREEMENTS.—

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

11          (2) TRAINING.—Agreements with a State under  
12 this subsection shall provide for training of State  
13 employees.

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

20          (4) COMMISSIONING.—Where necessary and ap-  
21 propriate to fulfill the provisions of this Act or other  
22 food safety law, the Administrator shall, as part of  
23 any service agreement, commission qualified State  
24 and local regulatory officials and inspectors to assist  
25 the Administrator in carrying out the food safety

1 law and accord such commissioned officials and in-  
2 spectors access to information in possession of the  
3 Administrator as if they were Federal employees.

4 (e) AUDITS.—

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

10 (2) REQUIREMENTS.—The review shall—

11 (A) include a determination of the effec-  
12 tiveness of the State program; and

13 (B) identify any changes necessary to en-  
14 sure enforcement of Federal requirements  
15 under this Act.

16 (f) NO FEDERAL PREEMPTION.—Nothing in this Act  
17 shall be construed to preempt the enforcement of State  
18 laws and standards regarding food safety that are at least  
19 as stringent as those under this Act.

20 **SEC. 208. IMPORTS.**

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

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

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

14 (2) Category 4 and 5 food establishments shall  
15 be certified either by—

16 (A) the accredited foreign government in  
17 the country where the products are produced;  
18 or

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

21 (3) Beginning not later than 5 years after the  
22 date of the enactment of this Act, food from cat-  
23 egory 4 and 5 food establishments that is not cer-  
24 tified by an accredited entity described in subsection  
25 (c) shall not enter the United States except through

1 ports of entry that are located in a metropolitan  
2 area with an accredited food testing laboratory.

3 (c) CERTIFICATION STANDARD.—

4 (1) IN GENERAL.—A foreign government or  
5 third party agent requesting accreditation to certify  
6 food for entry into the United States shall dem-  
7 onstrate, in a manner determined appropriate by the  
8 Administrator, that food produced under the super-  
9 vision of the foreign government or third party  
10 agent, respectively, has met standards for food safe-  
11 ty, inspection, labeling, and consumer protection  
12 that are at least equal to standards applicable to  
13 food produced in the United States.

14 (2) REQUEST BY FOREIGN GOVERNMENT.—

15 Prior to accrediting a foreign government, the Ad-  
16 ministrator shall—

17 (A) review and audit the food safety pro-  
18 gram of the requesting foreign government (in-  
19 cluding all statutes, regulations, and inspection  
20 authority); and

21 (B) determine that the exporting coun-  
22 try—

23 (i) administers a food control program  
24 that requires food exporters to implement

1 hazard control measures for physical,  
2 chemical, and biological contaminants;

3 (ii) ensures sanitary operations of fa-  
4 cilities;

5 (iii) utilizes testing and verification  
6 programs; and

7 (iv) administers an effective enforce-  
8 ment program.

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

12 (A) review the training and qualifications  
13 of auditors and other employees used by the  
14 agent;

15 (B) ensure that any such auditors have  
16 completed such training as may be required by  
17 the Administrator for the conduct of food safety  
18 inspections; and

19 (C) conduct reviews of internal systems  
20 and such other investigation as the Adminis-  
21 trator deems necessary to determine that the  
22 certifying agent is capable of auditing food es-  
23 tablishments—

24 (i) to assess the adequacy of systems  
25 and standards in use; and

1                   (ii) to ensure that food approved by  
2                   the agent for import to the United States  
3                   meets the requirements of this Act.

4                   (4) CERTIFICATION TO ACCOMPANY EACH SHIP-  
5                   MENT.—As a condition of accrediting any foreign  
6                   government or certifying agent, such government or  
7                   agent shall agree to issue a written and electronic  
8                   certification to accompany each shipment intended  
9                   for import to the United States from any food estab-  
10                  lishment which the government or agent certifies,  
11                  subject to requirements set forth by the Adminis-  
12                  trator.

13                  (d) AUDITS; INSPECTIONS.—Following any accredita-  
14                  tion under subsection (c), the Administrator may at any  
15                  time—

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

19                  (2) require a certifying agent to submit an on-  
20                  site audit report and any other reports or documents  
21                  which the agent requires as part of the audit proc-  
22                  ess, including documentation that the food establish-  
23                  ment is in compliance with registration requirements  
24                  and prior notice requirements for food imported to  
25                  the United States.

1 (e) LIMITATION.—A foreign government or other cer-  
2 tifying agent accredited by the Administrator to certify  
3 food for import to the United States under this section  
4 may certify only the food products or food categories for  
5 importation to the United States that are specified in the  
6 grant of accreditation.

7 (f) WITHDRAWAL OF ACCREDITATION.—The Admin-  
8 istrator may withdraw accreditation from a foreign gov-  
9 ernment or certifying agent—

10 (1) if food approved by the foreign government  
11 or certifying agent is linked to an outbreak of  
12 human illness;

13 (2) following an investigation and finding by  
14 the Administrator that the programs of the foreign  
15 government, or a foreign food establishment certified  
16 by the certifying agent, are no longer equal to those  
17 applied to food grown, manufactured, processed,  
18 packed, or held in the United States; or

19 (3) following a refusal to allow United States  
20 officials to conduct such audits and investigations as  
21 may be necessary to ensure continued compliance  
22 with the requirements of this section.

23 (g) RENEWAL OF ACCREDITATION.—The Adminis-  
24 trator shall audit foreign governments and certifying  
25 agents whenever needed, but no less than once every 3

1 years, to ensure the continued compliance with the re-  
2 quirements set forth in this section. Renewal of accredita-  
3 tion shall occur following each satisfactory audit.

4 (h) REQUIRED ROUTINE INSPECTION.—The Admin-  
5 istrator shall routinely inspect food before or at entry into  
6 the United States to ensure ongoing compliance with food  
7 safety law and where appropriate, as part of the audit of  
8 any certifying entity.

9 (i) ENFORCEMENT.—The Administrator may—

10 (1) deny importation of food from any foreign  
11 country if the government of such country does not  
12 permit United States officials to enter the foreign  
13 country to conduct such audits and inspections as  
14 may be necessary to fulfill requirements under this  
15 section;

16 (2) deny importation of food from any foreign  
17 country or foreign food establishment that does not  
18 consent to a timely investigation by the Administra-  
19 tion when food from that foreign country or foreign  
20 food establishment is linked to a food-borne illness  
21 outbreak or is otherwise found to be adulterated or  
22 misbranded;

23 (3) promulgate regulations to carry out the pur-  
24 poses of this section, including setting terms and

1 conditions for the destruction of products that fail to  
2 meet the requirements of this Act; and

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

6 (j) DETENTION AND SEIZURE.—Any food imported  
7 for consumption in the United States may be detained,  
8 seized, or condemned pursuant to section 402 or recalled  
9 pursuant to section 403.

10 (k) CERTIFYING AGENTS.—Entities eligible for ac-  
11 creditation as a certifying agent under subsection (c) may  
12 include—

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

14 (2) a foreign or domestic cooperative that ag-  
15 gregates the products of growers or processors for  
16 importation.

17 (l) AVOIDING CONFLICTS OF INTEREST WITH CERTI-  
18 FYING AGENTS.—

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

21 (A) not be owned, managed, or controlled  
22 by any person that owns or operates an estab-  
23 lishment whose products are to be certified by  
24 such agent;

1 (B) have procedures to ensure against the  
2 use, in carrying out audits of food establish-  
3 ments under this section, of any officer or em-  
4 ployee of such agent that has a financial con-  
5 flict of interest regarding an establishment  
6 whose products are to be certified by such  
7 agent; and

8 (C) annually make available to the Sec-  
9 retary, disclosures of the extent to which such  
10 agent, and the officers and employees of such  
11 agent, have maintained compliance with sub-  
12 paragraphs (A) and (B) relating to financial  
13 conflicts of interest.

14 (2) REGULATIONS.—The Secretary shall pro-  
15 mulgate regulations not later than 18 months after  
16 the date of the enactment of this Act to ensure that  
17 there are protections against conflicts of interest be-  
18 tween a certifying agent and the establishments  
19 whose products are to be certified by such agent.  
20 Such regulations shall include—

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

23 (B) a structure, including timing and pub-  
24 lic disclosure, for fees paid by food establish-

1           ments to certifying agents to decrease the po-  
2           tential for conflicts of interest; and

3           (C) appropriate limits on financial affili-  
4           ations between a certifying agent and any per-  
5           son that owns or operates an establishment  
6           whose products are to be certified by such  
7           agent.

8 **SEC. 209. RESOURCE PLAN.**

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

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

15               (1) describe quantitatively the personnel, finan-  
16               cial, and other resources required to carry out the  
17               inspection of food establishments under section 205  
18               and other requirements of this Act;

19               (2) allocate inspection resources in a manner  
20               reflecting the distribution of risk and opportunities  
21               to reduce risk across the food supply to the extent  
22               feasible based on the best available information, and  
23               subject to section 205; and

24               (3) describe the personnel, facilities, equipment,  
25               and other resources needed to carry out inspection

1 and other oversight activities, at a total resource  
2 level equal to at least 50 percent of the resources re-  
3 quired to carry out inspections in food establish-  
4 ments under section 205 and food production facili-  
5 ties under section 206—

6 (A) in foreign establishments and produc-  
7 tion facilities; and

8 (B) at the point of importation.

9 (c) GRANTS.—The resource plan shall include rec-  
10 ommendations for funding to provide grants to States and  
11 local governments to carry out food safety activities and  
12 inspections of food establishments and food production fa-  
13 cilities and include resources to audit such programs.

14 (d) SUBMISSION OF PLAN.—The Administrator shall  
15 submit annually to the Committee on Appropriations of  
16 the Senate, the Committee on Appropriations of the House  
17 of Representatives, and other relevant committees of Con-  
18 gress, the resource plan required under this section.

19 **SEC. 210. TRACEBACK REQUIREMENTS.**

20 (a) IN GENERAL.—The Administrator, in order to  
21 protect the public health, shall establish a national  
22 traceability system that enables the Administrator to re-  
23 trieve the history, use, and location of an article of food  
24 through all stages of its production, processing, and dis-  
25 tribution.

1       (b) APPLICABILITY.—Traceability requirements  
2 under this section shall apply to food from food production  
3 facilities, food establishments, and foreign food establish-  
4 ments.

5       (c) REQUIREMENTS.—

6           (1) STANDARDS.—The Administrator shall es-  
7 tablish standards for the type of information, for-  
8 mat, and timeframe for food production facilities  
9 and food establishments to submit records to aid the  
10 Administrator in effectively retrieving the history,  
11 use, and location of an item of food.

12          (2) RULE OF CONSTRUCTION.—Nothing in this  
13 section shall be construed as requiring the Adminis-  
14 trator to prescribe a specific technology for the  
15 maintenance of records or labeling of food to carry  
16 out the requirements of this section.

17          (3) AVAILABILITY OF RECORDS FOR INSPEC-  
18 TION.—Any records that are required by the Admin-  
19 istrator under this section shall be available for in-  
20 spection by the Administrator upon oral or written  
21 request.

22          (4) DEMONSTRATION OF ABILITY.—The Ad-  
23 ministrator, during any inspection, may require a  
24 food establishment to demonstrate its ability to trace

1 an item of food and submit the information in the  
2 format and timeframe required under paragraph (1).

3 (d) RELATIONSHIP TO OTHER REQUIREMENTS.—

4 (1) CONSISTENCY WITH EXISTING STATUTES  
5 AND REGULATIONS.—To the extent possible, the Ad-  
6 ministrator should establish the national traceability  
7 system under this section to be consistent with exist-  
8 ing statutes and regulations that require record-  
9 keeping or labeling for identifying the origin or his-  
10 tory of food or food animals.

11 (2) EXISTING LAWS.—For purposes of this sub-  
12 section, the Administrator should review the fol-  
13 lowing:

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

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

19 (C) Country of origin labeling require-  
20 ments of section 304 of the Tariff Act of 1930  
21 (19 U.S.C. 1340).

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

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

6 **SEC. 211. ACCREDITED LABORATORIES.**

7           (a) ESTABLISHMENT OF PROGRAM.—The Adminis-  
8           trator shall establish a program for accrediting labora-  
9           tories to perform sampling and testing for purposes of this  
10          Act. Such program shall include—

11           (1) standards for appropriate sampling and an-  
12           alytical procedures;

13           (2) training and experience qualification levels  
14           for individuals who conduct sampling and analysis;

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

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

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

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

23           (2) meet required tests and standards estab-  
24           lished by the Administrator; and

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

3           (c) ACCREDITING BODIES.—The Administrator may  
4           approve State agencies or private, nonprofit entities as ac-  
5           crediting bodies to act on behalf of the Administrator in  
6           accrediting laboratories under this section. The Adminis-  
7           trator shall—

8           (1) in making such approvals—

9                   (A) oversee and review the performance of  
10                  any accrediting body acting on behalf of the  
11                  Administrator to ensure that such accrediting  
12                  body is in compliance with the requirements of  
13                  this section; and

14                   (B) have the right to obtain from an ac-  
15                  crediting body acting on behalf of the Adminis-  
16                  trator and from any laboratory that may be cer-  
17                  tified by such a body all records and materials  
18                  that may be necessary for the oversight and re-  
19                  view required by subparagraph (A);

20           (2) reevaluate accreditation bodies approved  
21           under paragraph (1) whenever—

22                   (A) the Administrator determines a labora-  
23                  tory accredited by the accrediting body is no  
24                  longer in compliance with this section;

1 (B) the Administrator determines the ac-  
2 crediting body is no longer in compliance with  
3 the requirements of this section; or

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

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

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

## 11 **TITLE III—RESEARCH AND** 12 **EDUCATION**

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

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

18 (1) identify on an ongoing basis the priorities  
19 for collection of epidemiological data and for other  
20 food safety research and data collection that are  
21 most important to implementing the food safety law  
22 and reducing the public health burden of food-borne  
23 illness;

24 (2) have full access for purposes of imple-  
25 menting the food safety law to the applicable data

1 and data systems of the Centers for Disease Control  
2 and Prevention, including data made available to the  
3 Centers by a State;

4 (3) provide appropriate support and input on  
5 the design and implementation by the Centers for  
6 Disease Control and Prevention and the States of an  
7 active surveillance system that provides information  
8 on the incidence and causes of food-borne illness  
9 which is timely, detailed, and representative of the  
10 population of the United States;

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

19 (5) maintain a state-of-the-art DNA matching  
20 system and epidemiological system dedicated to food-  
21 borne illness identification, outbreaks, and contain-  
22 ment; and

23 (6) utilize surveillance data created by means of  
24 monitoring and statistical studies conducted as part  
25 of its own inspection.

1 (b) PUBLIC HEALTH SAMPLING.—

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

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

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

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

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

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

23 (c) ASSESSMENT OF HEALTH HAZARDS.—

24 (1) IN GENERAL.—Through the surveillance  
25 system and analyses referred to in subsection (a)

1 and the sampling system described in subsection (b),  
2 the Administrator shall—

3 (A) rank food categories based on the haz-  
4 ard to human health presented by the food cat-  
5 egory and specific chemical and microbiological  
6 hazards associated with foods in those cat-  
7 egories;

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

11 (C) assess the conditions affecting the like-  
12 lihood that emerging pathogens and diseases,  
13 including zoonosis, will affect the safety of the  
14 food supply and possible strategies for mini-  
15 mizing the potential risk to public health associ-  
16 ated with emerging pathogens and diseases.

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

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

24 (B) a comparison of the safety of food that  
25 is domestically processed with the health haz-

1           ards associated with food that is processed out-  
2           side the United States;

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

6                   (D) use of comparative risk assessments.

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

8           (a) PUBLIC EDUCATION.—

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

15                   (2) REQUIREMENTS.—The program shall pro-  
16           vide—

17                           (A) information to the public regarding  
18           Federal standards and best practices, and pro-  
19           motion of public awareness and understanding  
20           of those standards and practices;

21                           (B) information for health professionals—  
22                                   (i) to improve diagnosis and treatment  
23                                   of food-related illness; and

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

1 (C) such other information or advice, in-  
2 cluding on safe food handling practices, to con-  
3 sumers and other persons as the Administrator  
4 determines will promote the purposes of this  
5 Act.

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

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

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

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

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

21 **SEC. 303. RESEARCH.**

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

24 (1) improve sanitation and food safety practices  
25 in the processing of food;

- 1           (2) develop improved techniques to monitor and  
2 inspect food;
- 3           (3) develop efficient, rapid, and sensitive meth-  
4 ods to detect contaminants in food;
- 5           (4) determine the sources of contamination of  
6 contaminated food;
- 7           (5) develop food consumption data;
- 8           (6) identify ways that animal production tech-  
9 niques could improve the safety of the food supply;
- 10          (7) draw upon research and educational pro-  
11 grams that exist at the State and local level;
- 12          (8) utilize the DNA matching system and other  
13 processes to identify and control pathogens;
- 14          (9) address common and emerging zoonotic dis-  
15 eases;
- 16          (10) develop methods to reduce or destroy  
17 harmful pathogens before, during, and after proc-  
18 essing;
- 19          (11) analyze the incidence of antibiotic  
20 resistance as it pertains to the food supply and de-  
21 velop new methods to reduce the transfer of anti-  
22 biotic resistance to humans; and
- 23          (12) conduct other research that supports the  
24 purposes of this Act.

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

## 5 **TITLE IV—ENFORCEMENT**

### 6 **SEC. 401. PROHIBITED ACTS.**

7 It is prohibited—

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

11 (2) to adulterate or misbrand any food in inter-  
12 state commerce;

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

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

20 (5) to fail to establish or maintain any record  
21 or to make any report as required under sections  
22 205(f) and 206(b);

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

1 (7) to fail to provide to the Administrator the  
2 results of testing or sampling of food, equipment, or  
3 material in contact with food, that is positive for any  
4 contaminant under section 205(f)(1)(B);

5 (8) to fail to comply with a provision, regula-  
6 tion, or order of the Administrator under section  
7 202, 203, 204, 206, or 208;

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

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

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

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

19 **SEC. 402. FOOD DETENTION, SEIZURE, AND CONDEMNA-**  
20 **TION.**

21 (a) ADMINISTRATIVE DETENTION OF FOOD.—

22 (1) EXPANDED AUTHORITY.—The Adminis-  
23 trator shall have authority under section 304 of the  
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
25 334) to administratively detain and seize any food

1 regulated under this Act that the Administrator has  
2 reason to believe is unsafe, is adulterated or mis-  
3 branded, or otherwise fails to meet the requirements  
4 of the food safety law.

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

14 (3) PERIOD OF DETENTION.—

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

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

24 (4) SECURITY OF DETAINED FOOD.—

1 (A) IN GENERAL.—A detention order  
2 under this subsection—

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

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

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

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

18 (b) APPEAL OF DETENTION ORDER.—

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

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

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

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

14                   (A) to provide an opportunity for an infor-  
15 mal hearing; or

16                   (B) to confirm, modify, or terminate the  
17 order.

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

1 (c) CONDEMNATION OF FOOD.—

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

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

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

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

16 (1) IN GENERAL.—If an officer or qualified em-  
17 ployee of the Administration has reason to believe  
18 that a food is unsafe, is adulterated or misbranded,  
19 or otherwise fails to meet the requirements of this  
20 Act, and the officer or qualified employee is unable  
21 to inspect, examine, or investigate the food when the  
22 food is offered for import at a port of entry into the  
23 United States, the officer or qualified employee shall  
24 request the Secretary of Homeland Security to hold  
25 the food at the port of entry for a reasonable period

1 of time, not to exceed 24 hours, to enable the Ad-  
2 ministrator to inspect or investigate the food as ap-  
3 propriate.

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

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

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

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

23 **SEC. 403. NOTIFICATION AND RECALL.**

24 (a) NOTICE TO ADMINISTRATOR OF VIOLATION.—

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

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

12           (b) RECALL AND CONSUMER NOTIFICATION.—

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

24                   (A) cease distribution of the food;

25                   (B) notify all persons—

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

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

8 (C) recall the food;

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

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

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

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

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

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

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

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

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

13 (i) cease distribution of the food; and

14 (ii) notify all persons—

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

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

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

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

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

5 (ii) to State and local public health of-  
6 ficials; and

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

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

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

23 (A) persons that processed, distributed, or  
24 otherwise handled the food; and

1           (B) persons to which the food has been  
2           transported, sold, distributed, or otherwise han-  
3           dled.

4           (c) INFORMAL HEARINGS ON ORDERS.—

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

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

15          (d) POST-HEARING RECALL ORDERS.—

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

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

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

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

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

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

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

18 **SEC. 404. INJUNCTION PROCEEDINGS.**

19 (a) JURISDICTION.—The district courts of the United  
20 States, and the United States courts of the territories and  
21 possessions of the United States, shall have jurisdiction,  
22 for cause shown, to restrain a violation of section 202,  
23 203, 204, 208, or 401 (or a regulation promulgated there-  
24 under).

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

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

6 (a) CIVIL SANCTIONS.—

7 (1) CIVIL PENALTY.—

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

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

18 (2) OTHER REQUIREMENTS.—

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

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

5 (i) the gravity of the violation;

6 (ii) the degree of culpability of the  
7 person;

8 (iii) the size and type of the business  
9 of the person; and

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

12 (C) REVIEW OF ORDER.—The order may  
13 be reviewed only in accordance with subsection  
14 (e).

15 (b) CRIMINAL SANCTIONS.—

16 (1) IN GENERAL.—Except as provided in para-  
17 graphs (2) and (3), a person that knowingly pro-  
18 duces or introduces into commerce food that is un-  
19 safe or otherwise adulterated or misbranded shall be  
20 imprisoned for not more than 1 year, fined in ac-  
21 cordance with title 18, United States Code, or both.

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

1 tent to defraud or mislead, shall be imprisoned for  
2 not more than 5 years, fined in accordance with title  
3 18, United States Code, or both.

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

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

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

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

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

21 (B) if that person establishes a guaranty  
22 or undertaking signed by, and containing the  
23 name and address of, the person from whom  
24 the food was received in good faith, stating that

1           the food is not adulterated or misbranded under  
2           the food safety law.

3           (c) JUDICIAL REVIEW.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 **SEC. 406. PRESUMPTION.**

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

15 **SEC. 407. WHISTLEBLOWER PROTECTION.**

16           (a) IN GENERAL.—

17               (1) PROHIBITION.—No Federal employee, em-  
18 ployee of a Federal contractor or subcontractor, or  
19 covered individual may be discharged, demoted, sus-  
20 pended, threatened, harassed, or in any other man-  
21 ner discriminated against, because of any lawful act  
22 done by the employee or covered individual to—

23                       (A) provide information, cause information  
24                       to be provided, or otherwise assist in an inves-  
25                       tigation regarding any conduct that the covered

1 individual reasonably believes constitutes a vio-  
2 lation of any law, rule, or regulation, or that  
3 the covered individual reasonably believes con-  
4 stitutes a threat to the public health, when the  
5 information or assistance is provided to, or the  
6 investigation is conducted by—

7 (i) a Federal regulatory or law en-  
8 forcement agency;

9 (ii) a Member or committee of Con-  
10 gress; or

11 (iii) a person with supervisory author-  
12 ity over the covered individual (or such  
13 other individual who has the authority to  
14 investigate, discover, or terminate mis-  
15 conduct);

16 (B) file, cause to be filed, testify, partici-  
17 pate in, or otherwise assist in a proceeding or  
18 action filed or about to be filed relating to a  
19 violation of any law, rule, or regulation; or

20 (C) refuse to violate or assist in the viola-  
21 tion of any law, rule, or regulation.

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

25 (A) a food establishment;

1 (B) a food production facility;

2 (C) a restaurant;

3 (D) a retail food establishment other than  
4 a restaurant;

5 (E) a nonprofit food establishment in  
6 which food is prepared for or served directly to  
7 the consumer;

8 (F) a fishing vessel; or

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

10 (b) ENFORCEMENT ACTION.—

11 (1) IN GENERAL.—A covered individual who al-  
12 leges discharge or other discrimination by any per-  
13 son in violation of subsection (a) may seek relief  
14 under subsection (c) by filing a complaint with the  
15 Secretary of Labor. If the Secretary of Labor has  
16 not issued a final decision within 180 days after the  
17 date on which the complaint is filed and there is no  
18 showing that such delay is due to the bad faith of  
19 the claimant, the claimant may bring an action at  
20 law or equity for de novo review in the appropriate  
21 district court of the United States, which shall have  
22 jurisdiction over such an action without regard to  
23 the amount in controversy.

24 (2) PROCEDURE.—

1           (A) IN GENERAL.—An action under para-  
2 graph (1) shall be governed under the rules and  
3 procedures set forth in section 42121(b) of title  
4 49, United States Code.

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

9           (C) BURDENS OF PROOF.—An action  
10 brought under paragraph (1) shall be governed  
11 by the legal burdens of proof set for in section  
12 42121(b) of title 49, United States Code.

13           (D) STATUTE OF LIMITATIONS.—An action  
14 under paragraph (1) shall be commenced not  
15 later than 90 days after the date on which the  
16 violation occurs.

17 (e) REMEDIES.—

18           (1) IN GENERAL.—A covered individual pre-  
19 vailing in any action under subsection (b)(1) shall be  
20 entitled to all relief necessary to make the covered  
21 individual whole.

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

1 (A) reinstatement with the same seniority  
2 status that the covered individual would have  
3 had, but for the discrimination;

4 (B) the amount of any backpay, with inter-  
5 est; and

6 (C) compensation for any special damages  
7 sustained as a result of the discrimination, in-  
8 cluding litigation costs, expert witness fees, and  
9 reasonable attorney's fees.

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

15 **SEC. 408. ADMINISTRATION AND ENFORCEMENT.**

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

1 tion, powers, and duties of the Administrator and the At-  
2 torney General in administering and enforcing the provi-  
3 sions of the food safety law and to the rights and duties  
4 of persons with respect to whom the powers are exercised,  
5 respectively.

6 (b) INQUIRIES AND ACTIONS.—

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

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

18 **SEC. 409. CITIZEN CIVIL ACTIONS.**

19 (a) CIVIL ACTIONS.—A person may commence a civil  
20 action against—

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

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

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

7           (1) IN GENERAL.—The action shall be com-  
8           menced—

9                   (A) in the case of a civil action against a  
10                   person, the United States district court for the  
11                   district in which the defendant resides, is  
12                   found, or has an agent; and

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

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

22           (3) DAMAGES.—The court 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. REORGANIZATION PLAN.**

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

14 (1) The transfer of agencies, personnel, assets,  
15 and obligations to the Administration pursuant to  
16 this Act.

17 (2) Any consolidation, reorganization, or  
18 streamlining of agencies transferred to the Adminis-  
19 tration pursuant to this Act.

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

24 (1) The timetable for transfer and identification  
25 of any functions of agencies designated to be trans-

1       ferred to the Administration pursuant to this Act  
2       that will not be transferred promptly to the Admin-  
3       istration under the plan.

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

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

14              (4) Specification of the proposed allocations  
15      within the Administration of unexpended funds  
16      transferred in connection with transfers under the  
17      plan.

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

22              (6) Specification of the proposed allocations  
23      within the Administration of the functions of the  
24      agencies and subdivisions that are not related di-  
25      rectly to ensuring the safety of food.

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

6           (d) EFFECTIVE DATE.—

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

11                   (A) the date specified in the plan (or the  
12 plan as modified pursuant to subsection (c)),  
13 except that such date may not be earlier than  
14 90 days after the date the President has trans-  
15 mitted the reorganization plan to the appro-  
16 priate congressional committees pursuant to  
17 subsection (a); or

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

20           (2) STATUTORY CONSTRUCTION.—Nothing in  
21 this subsection may be construed to require the  
22 transfer of functions, personnel, records, balances of  
23 appropriations, or other assets of an agency on a  
24 single date.

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

4 **SEC. 502. TRANSITIONAL AUTHORITIES.**

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

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

17          (c) ACTING OFFICIALS.—

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

1 Act (and who continues to be in office) or imme-  
2 diately before such designation, to act in such office  
3 until the same is filled as provided in this Act.

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

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

9 (B) the rates provided for the offices held  
10 at the time of designation.

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

19 (d) TRANSFER OF PERSONNEL, ASSETS, OBLIGA-  
20 TIONS, AND FUNCTION.—

21 (1) IN GENERAL.—Consistent with section 1531  
22 of title 31, United States Code, the personnel, as-  
23 sets, liabilities, contracts, property, records, and un-  
24 expended balances of appropriations, authorizations,  
25 allocations, and other funds that relate to the func-

1 tions transferred under subsection (a) from a Fed-  
2 eral agency shall be transferred to the Administra-  
3 tion.

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

9 **SEC. 503. SAVINGS PROVISIONS.**

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

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

21 (1) pending proceedings in an agency, including  
22 notices of proposed rulemaking, and applications for  
23 licenses, permits, certificates, grants, and financial  
24 assistance, shall continue notwithstanding the enact-  
25 ment of this Act or the transfer of the agency to the

1 Administration, unless discontinued or modified  
2 under the same terms and conditions and to the  
3 same extent that such discontinuance or modifica-  
4 tion could have occurred if such enactment or trans-  
5 fer had not occurred; and

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

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

22 (d) REFERENCES.—

23 (1) IN GENERAL.—After the transfer of func-  
24 tions from a Federal agency under this Act, any ref-  
25 erence in any other Federal law, Executive order,

1 rule, regulation, directive, document, or other mate-  
2 rial to that Federal agency or the head of that agen-  
3 cy in connection with the administration or enforce-  
4 ment of the food safety law shall be deemed to be  
5 a reference to the Administration or the Adminis-  
6 trator, respectively.

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

13 **SEC. 504. CONFORMING AMENDMENTS.**

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

17 **SEC. 505. ADDITIONAL TECHNICAL AND CONFORMING**  
18 **AMENDMENTS.**

19 Not later than 60 days after the submission of the  
20 reorganization plan under section 501, the President shall  
21 prepare and submit proposed legislation to Congress con-  
22 taining necessary and appropriate technical and con-  
23 forming amendments to the Acts listed in section 3(15)  
24 of this Act to reflect the changes made by this Act.

1 **SEC. 506. REGULATIONS.**

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

5 **SEC. 507. AUTHORIZATION OF APPROPRIATIONS.**

6       There are authorized to be appropriated such sums  
7 as are necessary to carry out this Act.

8 **SEC. 508. LIMITATION ON AUTHORIZATION OF APPROPRIA-**  
9 **TIONS.**

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

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

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

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