H. R. 875

To establish the Food Safety Administration within the Department of Health and Human Services to protect the public health by preventing food-borne illness, ensuring the safety of food, improving research on contaminants leading to food-borne illness, and improving security of food from intentional contamination, and for other purposes.
Be it enacted by the Senate and House of Representa-
tives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

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

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

TITLE I—ESTABLISHMENT OF THE FOOD SAFETY ADMINISTRATION

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

TITLE II—ADMINISTRATION OF FOOD SAFETY PROGRAM

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

TITLE III—RESEARCH AND EDUCATION

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

TITLE IV—ENFORCEMENT

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

(a) FINDINGS.—Congress finds that—

(1) the safety of the food supply of the United States is vital to the public health, to public confidence in the food supply, and to the success of the food sector of the Nation’s economy;

(2) lapses in the protection of the food supply and loss of public confidence in food safety are damaging to consumers and the food industry, and place a burden on interstate commerce and international trade;

(3) recent ongoing events demonstrate that the food safety program at the Food and Drug Administration is not effective in controlling hazards in food coming from farms and factories in the United States and food and food ingredients coming from foreign countries, and these events have adversely affected consumer confidence;
(4) the safety and security of the food supply require a systemwide approach to prevent food-borne illness involving the integrated efforts of Federal, State and local agencies; a thorough, broad-based, and coordinated approach to basic and applied science; and intensive, effective, and efficient management of the Nation’s food safety program;

(5) the task of preserving the safety of the food supply of the United States faces tremendous pressures with regard to—

(A) emerging pathogens and other contaminants and the ability to detect all forms of contamination;

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

(C) a growing number of people at high risk for food-borne illnesses, including an increasing population of aging and immune-compromised consumers, together with infants and children;

(D) an increasing volume of imported food, without adequate monitoring, inspection, and systems for prevention of food safety problems; and
(E) maintenance of rigorous inspection of
the domestic food processing and food service
industries;

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

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

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

(9) in the food safety area, the Food and Drug
Administration implements provisions of the Federal
Food, Drug, and Cosmetic Act that are 70 years old
and that antiquated law limits the Food and Drug
Administration’s role largely to reacting to and correcting food safety problems after they occur, rather than working with the food industry to systematically prevent problems;

(10) the Food and Drug Administration’s effectiveness is further impaired by fragmentation of leadership and management within the Administration, as major food safety responsibilities are dispersed across the Administration’s Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, and Office of Regulatory Affairs;

(11) there is no official with the full-time responsibility and budget authority for food safety at the Food and Drug Administration and food safety competes unsuccessfully with the drug and medical device programs for senior agency management attention and resources; and

(12) improving Federal oversight of food safety requires a modern food safety mandate, clear authorities, and a dedicated official within the Department of Health and Human Services with budget authority to manage an integrated organizational structure and report directly to the Secretary.

(b) PURPOSES.—The purposes of this Act are—
(1) to establish an agency within the Department of Health and Human Services to be known as the “Food Safety Administration” to—

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

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

(C) lead an integrated, systemwide approach to food safety and to make more effective and efficient use of resources to prevent food-borne illness;

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

(E) provide an integrated food safety research capability, including internally generated, scientifically and statistically valid studies, in cooperation with academic institutions and other scientific entities of the Federal and State governments;

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

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

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

SEC. 3. DEFINITIONS.

In this Act:

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

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

(3) ADULTERATED.—

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

(B) Inclusion.—The term “adulterated” includes bearing or containing a contaminant that causes illness or death among sensitive populations.

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

(5) Category 1 Food Establishment.—The term “category 1 food establishment” means a food establishment (other than a seafood processing establishment) that slaughters, for the purpose of producing food, animals that are not subject to inspection under the Federal Meat Inspection Act or poultry that are not subject to inspection under the Poultry Products Inspection Act.

(6) Category 2 Food Establishment.—The term “category 2 food establishment” means a seafood processing establishment or other food establishment (other than a category 1 establishment) not subject to inspection under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act, that processes raw seafood or other raw animal products, whether fresh
or frozen, or other products that the Administrator
determines by regulation to pose a significant risk of
hazardous contamination.

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

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

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

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

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

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

(13) **FOOD ESTABLISHMENT.**—

(A) **IN GENERAL.**—The term “food establishment” means a slaughterhouse (except those regulated under the Federal Meat Inspection Act or the Poultry Products Inspection Act), factory, warehouse, or facility owned or operated by a person located in any State that processes food or a facility that holds, stores, or transports food or food ingredients.

(B) **EXCLUSIONS.**—For the purposes of registration, the term “food establishment” does not include a food production facility as defined in paragraph (14), restaurant, other retail food establishment, nonprofit food estab-
lishment in which food is prepared for or served
directly to the consumer, or fishing vessel
(other than a fishing vessel engaged in proc-
ressing, as that term is defined in section 123.3

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

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

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

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

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

(D) the provisions of this Act.

(16) FOREIGN FOOD ESTABLISHMENT.—The term “foreign food establishment” means any category 1 through 5 food establishment or food production facility located outside the United States that processes or produces food or food ingredients for consumption in the United States.

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

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

(19) PROCESS.—The term “process” or “processing” means the commercial slaughter, packing, preparation, or manufacture of food.

(20) STATE.—The term “State” means—

(A) a State;

(B) the District of Columbia;

(C) the Commonwealth of Puerto Rico;

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

TITLE I—ESTABLISHMENT OF THE FOOD SAFETY ADMINISTRATION

SEC. 101. ESTABLISHMENT OF THE FOOD SAFETY ADMINISTRATION.

(a) Establishment.—

(1) In general.—There is established in the Department of Health and Human Services an agency to be known as the “Food Safety Administration”.

(2) Head of the administration.—The administration shall be headed by the Administrator of Food Safety, who shall be appointed by the President, by and with the advice and consent of the Senate, for a term of 5 years, and who may be reappointed.

(3) Delegation.—All the authorities and responsibilities assigned to the Secretary of Health and Human Services in the food safety law are hereby assigned to the Administrator.

(b) Duties of administrator.—The administrator shall—

(1) administer and enforce the food safety law;
(2) serve as the food safety leader within the Department of Health and Human Services and co-
ordinator of all Department activities related to ensuring the safety, quality, and proper labeling of the food supply;

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

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

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

(A) in consultation with the Director of the Centers for Disease Control and Prevention, all activities related to foodborne illness surveillance and investigation of foodborne illness outbreaks;

(B) implementation of food safety inspection, enforcement, and research efforts to protect the public health;

(C) development of consistent and science-based standards for safe food;
(D) coordination and prioritization of food safety research and education programs with other Federal agencies;

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

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

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

SEC. 102. CONSOLIDATION OF FOOD SAFETY FUNCTIONS.

(a) TRANSFER OF FUNCTIONS AND RESOURCES.—

For each component of the Department of Health and Human Services or the Department of Commerce specified in subsection (b), there are transferred to the Administration all functions, personnel, and assets (including facilities and financial resources) of those components as of the day before the date of the enactment of this Act (including all related functions of any officer or employee of the component) that relate to administration or enforcement of the food safety law, as determined by the President.

(b) TRANSFERRED FUNCTIONS AND RESOURCES.—

The components referred to in subsection (a) are—
(1) the Center for Food Safety and Applied Nutrition of the Food and Drug Administration;

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

(3) the National Center for Toxicological Research of the Food and Drug Administration;

(4) the personnel and assets of the Office of Regulatory Affairs of the Food and Drug Administration used to administer and conduct inspections of food establishments and imports and conduct laboratory analyses and other investigations relating to food safety and enforcement of the food safety law;

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

(A) the Center for Food Safety and Applied Nutrition;

(B) the Center for Veterinary Medicine;

(C) the National Center for Toxicological Research; and

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

(6) the personnel and assets of the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration of the Department
of Commerce used to administer the seafood inspection program.

(c) **RENAMEING AND RESERVATION OF AGENCY IDENTITY.**—The Food and Drug Administration in the Department of Health and Human Services is hereby renamed the Federal Drug and Device Administration and may be referred to as “FDA”.

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

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

(a) **OFFICERS AND EMPLOYEES.**—The Administrator may—

(1) appoint officers and employees for the Administration in accordance with the provisions of title 5, United States Code, relating to appointment in the competitive service; and

(2) fix the compensation of those officers and employees in accordance with chapter 51 and with subchapter III of chapter 53 of that title, relating to classification and General Schedule pay rates.
(b) EXPERTS AND CONSULTANTS.—The Administrator may—

1. procure the services of temporary or intermittent experts and consultants as authorized by section 3109 of title 5, United States Code; and

2. pay in connection with those services the travel expenses of the experts and consultants, including transportation and per diem in lieu of subsistence while away from the homes or regular places of business of the individuals, as authorized by section 5703 of that title.

(c) BUREAUS, OFFICES, AND DIVISIONS.—The Administrator may establish within the Administration such bureaus, offices, and divisions as the Administrator determines are necessary to perform the duties of the Administrator.

(d) ADVISORY COMMITTEES.—

1. IN GENERAL.—The Administrator shall establish advisory committees that consist of representatives of scientific expert bodies, academics, industry specialists, and consumers.

2. DUTIES.—The duties of an advisory committee established under paragraph (1) may include developing recommendations with respect to the de-
development of new processes, research, communications, performance standards, and inspection.

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

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

(a) IN GENERAL.—The Administrator shall—

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

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

(b) COMPREHENSIVE ANALYSIS.—The program shall be based on a comprehensive analysis of the hazards associated with different food and with the processing of different food, including the identification and evaluation of—

(1) the severity of the potential health risks;

(2) the sources of potentially hazardous contamination or practices extending from the farm or ranch to the consumer that may increase the risk of food-borne illness;
(3) the potential for persistence, multiplication, or concentration of naturally occurring or added contaminants in food;

(4) the potential for hazardous contamination to have cumulative toxic effects, multigenerational effects, or effects on specific categories of consumers;

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

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

(c) PROGRAM ELEMENTS.—In carrying out the program, the Administrator shall—

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

(2) adopt and implement a national system for regular unannounced inspection of food establishments;

(3) require and enforce the adoption of preventive process controls in food establishments, based on the best available scientific and public health considerations and best available technologies;
(4) establish and enforce science-based standards for—

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

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

(5) implement a statistically valid sampling program with the stringency and frequency to independently monitor that industry programs and procedures that prevent food contamination are effective on an ongoing basis and that food meets the standards established under this Act;

(6) implement appropriate surveillance procedures and requirements to ensure the safety and security of imported food;

(7) coordinate and collaborate with other agencies and State or local governments in carrying out inspection, enforcement, research, and monitoring;

(8) implement a national system to identify the food products posing the greatest public health risk and to analyze the effectiveness of existing food safety programs, in conjunction with the Centers for Disease Control and Prevention and other Federal agencies;
(9) develop public education, risk communication, and advisory programs;

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

(11) coordinate and prioritize food safety research and educational programs with other Federal agencies and with State and local governments; and

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

SEC. 202. REGISTRATION OF FOOD ESTABLISHMENTS AND FOREIGN FOOD ESTABLISHMENTS.

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

(b) REGISTRATION REQUIREMENTS.—

(1) IN GENERAL.—To be registered under subsection (a), a food establishment shall submit a registration or reregistration to the Administrator.

(2) REGISTRATION.—Registration under this section shall begin within 90 days of the enactment
of this Act. Each such registration shall be submitted to the Secretary through an electronic portal and shall contain such information as the Secretary, by guidance, determines to be appropriate. Such registration shall contain the following information:

(A) The name, address, and emergency contact information of each domestic food establishment or foreign food establishment that the registrant owns or operates under this Act and all trade names under which the registrant conducts business in the United States relating to food.

(B) The primary purpose and business activity of each domestic food establishment or foreign food establishment, including the dates of operation if the domestic food establishment or foreign food establishment is seasonal.

(C) The types of food processed or sold at each domestic food establishment or, for foreign food establishments selling food for consumption in the United States, the specific food categories of that food as listed under section 170.3(n) of title 21, Code of Federal Regulations, or such other categories as the Administrator may designate in guidance, action level,
or regulations for evaluating potential threats to food protection.

(D) The name, address, and 24-hour emergency contact information of the United States distribution agent for each domestic food establishment or foreign food establishment, who shall maintain information on the distribution of food, including lot information, and wholesaler and retailer distribution.

(E) An assurance that the registrant will notify the Administrator of any change in the products, function, or legal status of the domestic food establishment or foreign food establishment (including cessation of business activities) not later than 30 days after such change.

(3) PROCEDURE.—Upon receipt of a completed registration described in paragraph (1), the Administrator shall notify the registrant of the receipt of the registration, designate each establishment as a category 1, 2, 3, 4, or 5 food establishment, and assign a registration number to each domestic food establishment and foreign food establishment.

(4) LIST.—The Administrator shall annually compile a list of domestic food establishments and a list of foreign food establishments that are registered
under this section. The Administrator may establish the manner of and any fees required for reregistration and any circumstances by which either such list may be shared with other governmental authorities. The Administrator may remove from either list the name of any establishment that fails to reregister, and such delisting shall be treated as a suspension.

(5) Disclosure exemption.—The disclosure requirements under section 552 of title 5, United States Code, shall not apply to—

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

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

(6) Suspension of registration.—

(A) In general.—The Administrator may suspend the registration of a domestic food establishment or foreign food establishment, including the facility of an importer, for violation of a food safety law that is either repeated or could result in serious adverse health consequences or death to humans or animals.

(B) Notice and opportunity for hearing.—The Administrator shall provide no-
lice of an intent to suspend the registration of
an establishment under this paragraph to a reg-
istrant and provide the registrant with an op-
portunity for an administrative hearing within 3
days. The Administrator may issue a written
order of suspension following the hearing, if the
Administrator finds that a violation described
in subparagraph (A) has occurred.

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

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

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

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

SEC. 203. PREVENTIVE PROCESS CONTROLS TO REDUCE ADULTERATION OF FOOD.

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

(b) REGULATIONS.—Not later than 1 year after the date of the enactment of this Act, the Administrator shall promulgate regulations that require all food establishments, within time frames determined by the Administrator—

(1) to adopt preventive process controls that—

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

(B) are adequate to protect the public health;

(C) meet relevant regulatory and food safety standards;
(D) limit the presence and growth of contaminants in food prepared in a food establishment using the best reasonably available techniques and technologies; and

(E) are tailored to the hazards and processes in particular establishments or environments;

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

(3) to meet performance standards for hazardous contamination established under section 204;

(4) to implement recordkeeping to monitor compliance with regulatory requirements;

(5) to implement recordkeeping and labeling of all food and food ingredients to facilitate their identification and traceability in the event of a recall or market removal;

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

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

(8) to provide for agency access to records kept by the food establishments and submission of copies of records to the Administrator, as the Administrator determines appropriate.

(c) Specific Hazard Controls.—The Administrator may require any person with responsibility for or control over food or food ingredients to adopt specific hazard controls, if such controls are needed to ensure the protection of the public health.

SEC. 204. PERFORMANCE STANDARDS FOR CONTAMINANTS IN FOOD.

(a) In General.—To protect the public health, the Administrator shall establish by guidance document, action level, or regulation and enforce performance standards that define, with respect to specific foods and contaminants in food, the level of food safety performance that a person responsible for producing, processing, or selling food shall meet.

(b) Identification of Contaminants; Performance Standards.—

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

(2) PERFORMANCE STANDARDS.—

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

(B) TIMING.—The Administrator shall es-

Establish a performance standard under subpara-
graph (A) for each contaminant in the list
under paragraph (1)—

(i) as soon as practicable; or

(ii) in the case of a contaminant de-
scribed in subparagraph (C), by the date
described in such subparagraph.
(C) **SIGNIFICANT CONTAMINANTS.**—The list under paragraph (1) (and any revision thereto) shall identify the 5 most significant contaminants in the list (in terms of the number and severity of illnesses and number of deaths associated with foods regulated under this Act). Not later than 3 years after a contaminant is so identified, the Administrator shall promulgate a performance standard under subparagraph (A) for the contaminant.

(3) REVIEW; REVISION.—Not less than every 3 years, the Administrator shall review and, if necessary, revise—

(A) the list of contaminants under paragraph (1); and

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

(c) **PERFORMANCE STANDARDS.**—

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

(A) health-based standards that set the level of a contaminant that can safely and lawfully be present in food;

(B) zero tolerances, including any zero tolerance performance standards in effect on the
day before the date of the enactment of this Act, when necessary to protect against significant adverse health outcomes;

(C) process standards, such as log reduction criteria for cooked products, when sufficient to ensure the safety of processed food; and

(D) in the absence of data to support a performance standard described in subparagraph (A), (B), or (C), standards that define required performance on the basis of reliable information on the best reasonably achievable performance, using best available technologies, interventions, and practices.

(2) BEST REASONABLY ACHIEVABLE PERFORMANCE STANDARDS.—In developing best reasonably achievable performance standards under paragraph (1)(D), the Administrator shall collect, or contract for the collection of, data on current best practices and food safety outcomes related to the contaminants and foods in question, as the Administrator determines necessary.

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

(d) Enforcement.—

(1) In general.—In conjunction with the es-
tablishment of a performance standard under this
section, the Administrator shall develop a statist-
tically valid sampling program with the stringency
and frequency sufficient to independently monitor
whether food establishments are complying with the
performance standard and implement the program
within 1 year of the promulgation of the standard.

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

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

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

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

(D) withdraw the mark of inspection from
the food establishment, if in use; or
(E) take other appropriate enforcement action concerning the food establishment, including withdrawal of registration.

(e) Newly Identified Contaminants.—Notwithstanding any other provision of this section, the Administrator shall establish interim performance standards for newly identified contaminants as necessary to protect the public health.

SEC. 205. INSPECTIONS OF FOOD ESTABLISHMENTS.

(a) In General.—The Administrator shall establish an inspection program, which shall include statistically valid sampling of food and facilities to enforce performance standards. The inspection program shall be designed to determine if each food establishment—

(1) is operated in a sanitary manner;

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

(3) is in compliance with applicable performance standards established under section 204, and other regulatory requirements;

(4) is processing food that is not adulterated or misbranded;
(5) maintains records of process control plans under section 203, and other records related to the processing, sampling, and handling of food; and

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

(b) Establishment Categories and Inspection Frequencies.—The resource plan required under section 209, including the description of resources required to carry out inspections of food establishments, shall be based on the following categories and inspection frequencies, subject to subsections (c), (d), and (e):

(1) Category 1 Food Establishments.—A category 1 food establishment shall be subject to antemortem, postmortem, and continuous inspection of each slaughter line during all operating hours, and other inspection on a daily basis, sufficient to verify that—

(A) diseased animals are not offered for slaughter;

(B) the food establishment has successfully identified and removed from the slaughter line visibly defective or contaminated carcasses, has avoided cross-contamination, and has destroyed or reprocessed such carcasses in a manner acceptable to the Administrator; and
(C) applicable performance standards and other provisions of the food safety law, including those intended to eliminate or reduce pathogens, have been satisfied.

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

(A) have ongoing verification that its processes are controlled; and

(B) be randomly inspected at least weekly.

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

(A) have ongoing verification that its processes are controlled; and

(B) be randomly inspected at least monthly.

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

(A) have ongoing verification that its processes are controlled; and

(B) be randomly inspected at least quarterly.

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

(A) have ongoing verification that its processes are controlled; and
(B) be randomly inspected at least annually.

(c) Establishment of Inspection Procedures.—The Administrator shall establish procedures under which inspectors shall take random samples, photographs, and copies of records in food establishments.

(d) Alternative Inspection Frequencies.—With respect to a subcategory of food establishment under category 2, 3, 4, or 5, the Administrator may establish alternative increasing or decreasing inspection frequencies for subcategories of food establishments or individual establishments, to foster risk-based allocation of resources. Before establishing an alternative inspection frequency for a subcategory of food establishments or individual establishments, the Administrator shall take into consideration the evidence described in paragraph (2)(D) and the overall record of compliance described in paragraph (2)(E) for such subcategory. In establishing alternative inspection frequencies under this subsection, the Administrator shall comply with the following criteria and procedures:

(1) Subcategories of food establishments and their alternative inspection frequencies shall be defined by regulation, subject to paragraphs (2) and (3).
(2) In defining subcategories of food establishments and their alternative inspection frequencies under paragraphs (1) and (2), the Administrator shall consider—

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

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

(C) the inherent likelihood that the products will contribute to the risk of food-borne illness;

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

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

(3) The Administrator may adopt alternative inspection frequencies for increased or decreased inspection for a specific establishment and shall annually publish a list of establishments subject to alternative inspections.
(4) In adopting alternative inspection frequencies for a specific establishment, the Administrator shall consider—

   (A) the criteria in paragraph (2), together with any evidence submitted from the individual food establishment supporting a request for an alternative inspection frequency, including the establishment’s record for implementing effective preventive process control systems;

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

   (C) the establishment’s record of compliance with food safety law, including compliance with applicable performance standards and the frequency of recalls.

(e) Effective Date.—The inspection mandates shall go into effect 2 years after the date of the enactment of this Act.

(f) Maintenance and Inspection of Records.—

   (1) In General.—

   (A) Records.—A food establishment shall—

   (i) maintain such records as the Administrator shall require by regulation, in-
including all records relating to the processing, distributing, receipt, or importation of any food; and

(ii) permit the Administrator, in addition to any authority transferred to the Administrator pursuant to section 102, upon presentation of appropriate credentials and at reasonable times and in a reasonable manner, to have access to and copy all records maintained by or on behalf of such food establishment representative in any format (including paper or electronic) and at any location, that are necessary to assist the Administrator—

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

(II) to track the food in commerce.

(B) REQUIRED DISCLOSURE.—A food establishment shall have an affirmative obligation to disclose to the Administrator the results of testing or sampling of food, equipment, or material in contact with food, that is positive for any contaminant.
(2) MAINTENANCE OF RECORDS.—The records in paragraph (1) shall be maintained for a reasonable period of time, as determined by the Administrator.

(3) REQUIREMENTS.—The records in paragraph (1) shall include records describing—

(A) the origin, receipt, delivery, sale, movement, holding, and disposition of food or ingredients;

(B) the identity and quantity of ingredients used in the food;

(C) the processing of the food;

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

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

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

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

(g) PROTECTION OF SENSITIVE INFORMATION.—
(1) IN GENERAL.—The Administrator shall de-
velop and maintain procedures to prevent the unau-
thorized disclosure of any trade secret or commer-
cially valuable confidential information obtained by
the Administrator.

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

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

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

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

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

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

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

SEC. 206. FOOD PRODUCTION FACILITIES.

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

(1) visit and inspect food production facilities in
the United States and in foreign countries to deter-
mine if they are operating in compliance with the re-
quirements of the food safety law;
(2) review food safety records as required to be kept by the Administrator under section 210 and for other food safety purposes;

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

(4) conduct monitoring and surveillance of animals, plants, products, or the environment, as appropriate; and

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

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

(1) to determine whether the food is contaminated, adulterated, or otherwise not in compliance with the food safety law; or

(2) to track the food in commerce.

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

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

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

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

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

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

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

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

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

(1) be in writing;

(2) describe the reasons the variance is necessary;

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

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

(e) APPROVAL OR DISAPPROVAL OF VARIANCES.—If the Administrator determines after review of a request under subsection (d) that the requested variance provides equivalent protections to those promulgated under subsection (c), the Administrator may approve the request. The Administrator shall deny a request if it is—
(1) not sufficiently detailed to permit a determination;  
(2) fails to cite sufficient grounds for allowing a variance; or  
(3) does not provide reasonable assurances that the produce will not be adulterated.

(f) ENFORCEMENT.—The Administrator may coordinate with the agency or department designated by the Governor of each State to perform activities to ensure compliance with this section.

(g) IMPORTED PRODUCE.—Not later than 1 year after the date of the enactment of this Act, the Administrator shall promulgate regulations to ensure that raw agricultural commodities and minimally processed produce imported into the United States can meet standards for food safety, inspection, labeling, and consumer protection that are at least equal to standards applicable to such commodities and produce produced in the United States.
(B) enhance the identification and investigation of, and response to, food-borne illness outbreaks.

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

(b) FOOD-BORNE ILLNESS SURVEILLANCE SYSTEMS.—The Administrator, in collaboration with the Centers for Disease Control and Prevention, shall enhance food-borne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on food-borne illnesses by—

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

(A) produce better information on illnesses associated with foods, including sources and risk factors for infections by emerging pathogens; and

(B) facilitate sharing of data acquisition and findings on a more timely basis among governmental agencies, including the Food Safety Administration, the Food Safety and Inspection
Service, and State and local agencies, and with
the public;

(2) augmenting such systems to improve attrib-
ution of a food-borne illness outbreak to a specific
food;

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

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

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

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

(7) exploring establishment of registries for
long-term case follow-up to better characterize late
complications of food-borne illness;
(8) increasing participation in national networks of public health and food regulatory agencies and laboratories to—

(A) allow public health officials at the Federal, State, and local levels to share and accept laboratory analytic findings; and

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

(9) establishing a flexible mechanism for rapidly supporting scientific research by academic centers of excellence, which may include staff representing academic clinical researchers, food microbiologists, animal and plant disease specialists, ecologists, and other allied disciplines.

(c) IMPROVING STATE SURVEILLANCE CAPACITY.—The Administrator, in collaboration with the Director of the Centers for Disease Control and Prevention, shall improve capacity for surveillance in the States by—

(1) supporting outbreak investigations with needed specialty expertise, including epidemiological, microbiological, and environmental expertise, to as-
sist identification of underlying common sources and contributing factors;

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

(A) facilitating rapid shipment of clinical isolates from clinical laboratories to State public health laboratories to avoid delays in testing;

(B) conducting rapid and more standardized interviewing of cases associated with major enteric pathogens, including prior to designation of clusters as food-borne illness outbreaks;

(C) conducting and evaluating rapid and standardized interviews of healthy control persons;

(D) sharing information on a timely basis—

(i) within public health and food regulatory agencies;

(ii) among such agencies;

(iii) with the food industry;

(iv) with healthcare providers; and

(v) with the public;

(3) developing, regularly updating, and disseminating training curricula on food-borne illness sur-
veillance investigations, including standard sampling methods and laboratory procedures;

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

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

(6) determining minimum core competencies for public health laboratories, and developing self-evaluation and proficiency-testing tools for such laboratories;

(7) facilitating regional public health laboratory partnerships to leverage resources, including equipment and physical space, and increase surge capacity;

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

(9) partnering with the Food Safety Administration to increase communication, coordination, and
integration of food-borne illness surveillance and outbreak investigation activities; and

(10) developing and periodically updating response and interview procedures so that such procedures are standardized and tested.

(d) Program Activities.—The Administrator shall carry out activities to support core food safety functions of State and local public health laboratories, including—

(1) establishing fellowships, stipends, and scholarships to address critical workforce shortages;

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

(3) establishing partnerships between private and public laboratories to facilitate sharing of positive enteric specimens and improve surge capacity;

(4) strengthening capacity to participate in existing or new food-borne illness surveillance systems; and

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

(e) Plan To Improve Food Safety Capacity At The State And Local Level.—

(1) Goals.—The Administrator shall leverage and enhance the food safety capacity and roles of State and local agencies and integrate State and
local agencies as fully as possible into national food
safety efforts, in order to achieve the following goals:

(A) Improve food-borne illness outbreak re-
response and containment.

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

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

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

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

(2) SURVEY.—In preparation for development
of the plan required by paragraph (3), the Adminis-
trator shall, not later than 1 year after the date of
enactment of this part, complete a survey of State
and local capacities, and needs for enhancement,
with respect to—
(A) staffing levels and expertise available
to perform food safety functions;

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

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

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

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

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

(A) Criteria for assessing the adequacy of
State and local capacity to perform food safety
functions as part of a national food safety sys-
tem.

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

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

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

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

(i) joint planning and priority setting
to ensure that the collective effort has the
greatest possible impact on achieving com-
pliance with food safety standards and re-
ducing food-borne illness;
(ii) elimination of barriers to the free
flow of information among the Food Safety
Administration and State and local agen-
cies with respect to inspection and compli-
ance programs and integration of State
and Federal inspection and laboratory data
systems;

(iii) steps to expand, and ensure the
vigor and consistency of, State inspection
of processing establishments under con-
tact to the Food Safety Administration;
and

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

(4) Food Safety Capacity Building
Grants.—The Administrator shall make grants to
State and local agencies to enhance State and local
food safety capacity and programs and support
achievement of the goals established in paragraph
(1). In awarding such grants, the Administrator
shall take into account the criteria and priorities es-
tablished by the Administrator under paragraph (3).
(5) Report to Congress.—Not later than 1 year after the date of enactment of this part, and on an annual basis thereafter, the Administrator shall submit to Congress a report that describes—

(A) progress made in implementing this section, including any obstacles to such implementation; and

(B) any legislative recommendations or additional resources needed for full implementation.

(f) Service Agreements.—

(1) In general.—The Administrator may, under agreements entered into with Federal, State, or local agencies, use on a reimbursable basis or otherwise the qualified personnel and services of those agencies in carrying out this Act.

(2) Training.—Agreements with a State under this subsection shall provide for training of State employees.

(3) Maintenance of agreements.—The Administrator shall maintain any agreement described in paragraph (1) that is in effect on the day before the date of the enactment of this Act until the Administrator evaluates such agreement and deter-
mines whether to maintain or substitute such agree-
ment.

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

SEC. 208. IMPORTS.

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

(b) CERTIFICATION SYSTEM.—Not later than 2 years
after the date of the enactment of this Act, the Adminis-
trator shall establish a system under which food products
offered for importation into the United States shall be cer-
tified by the accredited foreign government in the country
of export or by an accredited certifying agent meeting all
applicable standards under this section.
(1) Category 1, 2, and 3 food establishments shall secure certification of products from the accredited foreign government in the country where the products are produced and must enter the United States through ports designated by the Administrator.

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

(A) the accredited foreign government in the country where the products are produced;

or

(B) a certifying agent that has been accredited under subsection (c).

(3) Beginning not later than 5 years after the date of the enactment of this Act, food from category 4 and 5 food establishments that is not certified by an accredited entity described in subsection (c) shall not enter the United States except through ports of entry that are located in a metropolitan area with an accredited food testing laboratory.

(c) Certification Standard.—

(1) In general.—A foreign government or third party agent requesting accreditation to certify food for entry into the United States shall demonstrate, in a manner determined appropriate by the
Administrator, that food produced under the supervision of the foreign government or third party agent, respectively, can meet standards for food safety, inspection, labeling, and consumer protection that are at least equal to standards applicable to food produced in the United States.

(2) Request by foreign government.—Prior to accrediting a foreign government, the Administrator shall—

(A) review and audit the food safety program of the requesting foreign government (including all statutes, regulations, and inspection authority); and

(B) determine that the exporting country—

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

(ii) ensures sanitary operations of facilities;

(iii) utilizes testing and verification programs; and

(iv) administers an effective enforcement program.
(3) Request by a Certifying Agent.—Prior to accrediting a certifying agent, the Administrator shall—

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

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

(C) conduct reviews of internal systems and such other investigation as the Administrator deems necessary to determine that the certifying agent is capable of auditing food establishments—

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

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

(4) Certification to Accompany Each Shipment.—As a condition of accrediting any foreign government or certifying agent, such government or agent shall agree to issue a written and electronic certification to accompany each shipment intended
for import to the United States from any food establish- 
ment which the government or agent certifies, subject to requirements set forth by the Adminis-
trator.

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

(1) conduct an on-site audit of any food establish-
ment registered under section 202, with or with-
out the certifying agent; or

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

(e) LIMITATION.—A foreign government or other cer-
tifying agent accredited by the Administrator to certify
food for import to the United States under this section
may certify only the food products or food categories for
importation to the United States that are specified in the
grant of accreditation.
(f) **Withdrawal of Accreditation.**—The Administrator may withdraw accreditation from a foreign government or certifying agent—

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

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

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

(g) **Renewal of Accreditation.**—The Administrator shall audit foreign governments and certifying agents whenever needed, but no less than once every 3 years, to ensure the continued compliance with the requirements set forth in this section. Renewal of accreditation shall occur following each satisfactory audit.

(h) **Required Routine Inspection.**—The Administrator shall routinely inspect food before or at entry into the United States to ensure ongoing compliance with food
safety law and where appropriate, as part of the audit of
any certifying entity.

(i) ENFORCEMENT.—The Administrator may—

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

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

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

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

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

(k) CERTIFYING AGENTS.—Entities eligible for accreditation as a certifying agent under subsection (c) may include—

(1) a State or regional food authority; or

(2) a foreign or domestic cooperative that aggregates the products of growers or processors for importation.

(l) AVOIDING CONFLICTS OF INTEREST WITH CERTIFYING AGENTS.—

(1) IN GENERAL.—To be eligible for accreditation under subsection (c), a certifying agent shall—

(A) not be owned, managed, or controlled by any person that owns or operates an establishment whose products are to be certified by such agent;

(B) have procedures to ensure against the use, in carrying out audits of food establishments under this section, of any officer or employee of such agent that has a financial conflict of interest regarding an establishment whose products are to be certified by such agent; and
(C) annually make available to the Secretary, disclosures of the extent to which such agent, and the officers and employees of such agent, have maintained compliance with subparagraphs (A) and (B) relating to financial conflicts of interest.

(2) REGULATIONS.—The Secretary shall promulgate regulations not later than 18 months after the date of the enactment of this Act to ensure that there are protections against conflicts of interest between a certifying agent and the establishments whose products are to be certified by such agent. Such regulations shall include—

(A) requiring that domestic audits performed under this section be unannounced;

(B) a structure, including timing and public disclosure, for fees paid by food establishments to certifying agents to decrease the potential for conflicts of interest; and

(C) appropriate limits on financial affiliations between a certifying agent and any person that owns or operates an establishment whose products are to be certified by such agent.
SEC. 209. RESOURCE PLAN.

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

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

(1) describe quantitatively the personnel, financial, and other resources required to carry out the inspection of food establishments under section 205 and other requirements of this Act;

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

(3) describe the personnel, facilities, equipment, and other resources needed to carry out inspection and other oversight activities, at a total resource level equal to at least 50 percent of the resources required to carry out inspections in food establishments under section 205 and food production facilities under section 206—

(A) in foreign establishments and production facilities; and

(B) at the point of importation.
(c) GRANTS.—The resource plan shall include recommendations for funding to provide grants to States and local governments to carry out food safety activities and inspections of food establishments and food production facilities and include resources to audit such programs.

(d) SUBMISSION OF PLAN.—The Administrator shall submit annually to the Committee on Appropriations of the Senate, the Committee on Appropriations of the House of Representatives, and other relevant committees of Congress, the resource plan required under this section.

SEC. 210. TRACEBACK REQUIREMENTS.

(a) IN GENERAL.—The Administrator, in order to protect the public health, shall establish a national traceability system that enables the Administrator to retrieve the history, use, and location of an article of food through all stages of its production, processing, and distribution.

(b) APPLICABILITY.—Traceability requirements under this section shall apply to food from food production facilities, food establishments, and foreign food establishments.

(c) REQUIREMENTS.—

(1) STANDARDS.—The Administrator shall establish standards for the type of information, format, and timeframe for food production facilities
and food establishments to submit records to aid the
Administrator in effectively retrieving the history,
use, and location of an item of food.

(2) **Rule of Construction.**—Nothing in this
section shall be construed as requiring the Adminis-
trator to prescribe a specific technology for the
maintenance of records or labeling of food to carry
out the requirements of this section.

(3) **Availability of Records for Inspection.**—Any records that are required by the Admin-
istrator under this section shall be available for in-
spection by the Administrator upon oral or written
request.

(4) **Demonstration of Ability.**—The Ad-
ministrator, during any inspection, may require a
food establishment to demonstrate its ability to trace
an item of food and submit the information in the
format and timeframe required under paragraph (1).

(d) **Relationship to Other Requirements.**—

(1) **Consistency with Existing Statutes
and Regulations.**—To the extent possible, the Ad-
ministrator should establish the national traceability
system under this section to be consistent with exist-
ing statutes and regulations that require record-
keeping or labeling for identifying the origin or history of food or food animals.

(2) EXISTING LAWS.—For purposes of this subsection, the Administrator should review the following:

(A) Country of origin labeling requirements of subtitle D of the Agricultural Marketing Act of 1946 (7 U.S.C. 1638 et seq.).

(B) The Perishable Agricultural Commodities Act of 1930 (7 U.S.C. 499a–t).


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

(3) CERTAIN REQUIREMENTS.—Nothing contained in this section prevents or interferes with implementation of the country of origin labeling requirements of subtitle D of the Agricultural Marketing Act of 1946 (7 U.S.C. 1638 et seq.).

SEC. 211. ACCREDITED LABORATORIES.

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

(1) standards for appropriate sampling and analytical procedures;

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

(3) annual onsite visits to audit the performance of an accredited laboratory; and

(4) such additional requirements as the Administrator determines to be appropriate.

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

(1) prepare and submit an application for accreditation to the Administrator;

(2) meet required tests and standards established by the Administrator; and

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

(c) ACCREDITING BODIES.—The Administrator may approve State agencies or private, nonprofit entities as accrediting bodies to act on behalf of the Administrator in accrediting laboratories under this section. The Administrator shall—

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

(B) have the right to obtain from an accrediting body acting on behalf of the Administrator and from any laboratory that may be certified by such a body all records and materials that may be necessary for the oversight and review required by subparagraph (A);

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

(A) the Administrator determines a laboratory accredited by the accrediting body is no longer in compliance with this section;

(B) the Administrator determines the accrediting body is no longer in compliance with the requirements of this section; or

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

(3) promptly revoke the approval of any accreditation body found not to be in compliance with the requirements of this section.
(d) Revocation of Accreditation.—The Administrator shall revoke the accreditation of any laboratory that fails to meet the requirements this section.

TITLE III—RESEARCH AND EDUCATION

SEC. 301. PUBLIC HEALTH ASSESSMENT SYSTEM.

(a) In General.—The Administrator, acting in coordination with the Director of the Centers for Disease Control and Prevention and with food safety and research programs of the Department of Agriculture, shall—

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

(2) have full access for purposes of implementing the food safety law to the applicable data and data systems of the Centers for Disease Control and Prevention, including data made available to the Centers by a State;

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

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

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

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

(b) PUBLIC HEALTH SAMPLING.——

(1) IN GENERAL.—Not later than 1 year after
the enactment of this Act, the Administrator shall
establish guidelines for a sampling system under
which the Administrator shall take and analyze sam-
ples of food——
(A) to assist the Administrator in carrying out this Act; and

(B) to assess the nature, frequency of occurrence, and quantities of contaminants in food.

(2) REQUIREMENTS.—The sampling system described in paragraph (1) shall provide—

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

(B) at the request of the Administrator, such other information, including analysis of monitoring and verification samples, as the Administrator determines may be useful in assessing the occurrence of contaminants in food.

(c) ASSESSMENT OF HEALTH HAZARDS.—

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

(A) rank food categories based on the hazard to human health presented by the food category and specific chemical and microbiological
hazards associated with foods in those categories;

(B) identify appropriate industry and regulatory approaches to minimize hazards in the food supply; and

(C) assess the conditions affecting the likelihood that emerging pathogens and diseases, including zoonosis, will affect the safety of the food supply and possible strategies for minimizing the potential risk to public health associated with emerging pathogens and diseases.

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

(A) a comparison of the safety of commercial processing with the health hazards associated with food that is harvested for recreational or subsistence purposes and prepared non-commercially;

(B) a comparison of the safety of food that is domestically processed with the health hazards associated with food that is processed outside the United States;

(C) a description of contamination originating from handling practices that occur prior to or after the sale of food to consumers; and
(D) use of comparative risk assessments.

SEC. 302. PUBLIC EDUCATION AND ADVISORY SYSTEM.

(a) Public Education.—

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

(2) Requirements.—The program shall pro-
vide—

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

(B) information for health professionals—

(i) to improve diagnosis and treatment

of food-related illness; and

(ii) to advise individuals at special

risk for food-related illnesses; and

(C) such other information or advice, in-
cluding on safe food handling practices, to con-
sumers and other persons as the Administrator
determines will promote the purposes of this
Act.
(b) Health Advisories.—The Administrator, in consultation with other Federal departments and agencies as the Administrator determines necessary, shall work with the States and other appropriate entities—

(1) to develop and distribute regional and national advisories concerning food safety;

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

(3) to incorporate State and local advisories into the national public education program established under subsection (a); and

(4) to present prompt, specific information regarding food found to pose a threat to the public health, including by identifying the retailers and food establishments where such food has been sold.

SEC. 303. Research.

(a) In General.—The Administrator shall conduct research to carry out this Act, including studies to—

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

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

(3) develop efficient, rapid, and sensitive methods to detect contaminants in food;
(4) determine the sources of contamination of contaminated food;

(5) develop food consumption data;

(6) identify ways that animal production techniques could improve the safety of the food supply;

(7) draw upon research and educational programs that exist at the State and local level;

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

(9) address common and emerging zoonotic diseases;

(10) develop methods to reduce or destroy harmful pathogens before, during, and after processing;

(11) analyze the incidence of antibiotic resistance as it pertains to the food supply and develop new methods to reduce the transfer of antibiotic resistance to humans; and

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

(b) CONTRACT AUTHORITY.—The Administrator may enter into contracts and agreements with any State, university, Federal Government agency, or person to carry out this section.
SEC. 304. WORKING GROUP ON IMPROVING FOODBORNE ILLNESS SURVEILLANCE.

Not later than 180 days after the date of enactment of this Act, the Administrator shall establish a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food industry, consumer organizations, and academia. Such working group shall provide the Administrator, through at least annual meetings of the working group and an annual public report, advice and recommendations on an ongoing and regular basis regarding the improvement of food-borne illness surveillance, including advice and recommendations on—

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

(2) opportunities to improve the effectiveness of initiatives at the Federal, State, and local levels, including coordination and integration of activities among Federal agencies, and between the Federal, State, and local levels of government;

(3) improvement in the timeliness and depth of access by regulatory and health agencies, the food industry, academic researchers, and consumers to food-borne illness surveillance data collected by gov-
ernment agencies at all levels, including data compiled by the Centers for Disease Control and Prevention;

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

(5) specific actions to reduce barriers to such improvement, implement the working group’s recommendations, with measurable objectives and timelines, and identification of resource and staffing needs.

SEC. 305. CAREER-SPANNING TRAINING FOR FOOD INSPECTORS.

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

(b) USE OF FUNDS.—The Administrator may make a grant under this section to an applicant only if the applicant agrees to use the grant to provide regular, standardized, graduated, career-spanning training, based on a curriculum developed by the Association of Food and Drug Officials, to Federal, State, and local food inspectors.

(c) ELIGIBLE ENTITY.—An entity described in this subsection is an entity that—
(1) is described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3));

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

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

SEC. 306. FOOD-BORNE ILLNESS HEALTH REGISTRY.

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

(b) REGISTRY.—For the purpose described in subsection (a), the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, shall develop and maintain a registry, to be known as the Food-Borne Illness Health Registry, consisting of data on the trends, sources, health outcomes, and preventive strategies related to food-borne disease.

SEC. 307. STUDY ON FEDERAL RESOURCES.

Not later than one year after the date of the enactment of this Act, the Comptroller General of the United States shall complete a study on the Federal resources being dedicated to food-borne illness and food safety re-
search and submit a report on the results of such study to the Congress.

**TITLE IV—ENFORCEMENT**

**SEC. 401. PROHIBITED ACTS.**

It is prohibited—

(1) to manufacture, introduce, deliver for introduction, or receive in interstate commerce any food that is adulterated, misbranded, or otherwise unsafe;

(2) to adulterate or misbrand any food in interstate commerce;

(3) for a food establishment or foreign food establishment to fail to register under section 202, or to operate without a valid registration;

(4) to refuse to permit access to a food establishment or food production facility for the inspection and copying of a record as required under sections 205(f) and 206(a);

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

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

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

(8) to fail to comply with a provision, regulation, or order of the Administrator under section 202, 203, 204, 206, or 208;

(9) to slaughter an animal that is capable for use in whole or in part as human food at a food establishment processing any food for commerce, except in compliance with the food safety law;

(10) to transfer food in violation of an administrative detention order under section 402 or to remove or alter a required mark or label identifying the food as detained;

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

(12) to otherwise violate the food safety law.

SEC. 402. FOOD DETENTION, SEIZURE, AND CONDEMNATION.

(a) Administrative Detention of Food.—

(1) Expanded authority.—The Administrator shall have authority under section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) to administratively detain and seize any food regulated under this Act that the Administrator has reason to believe is unsafe, is adulterated or mis-
branded, or otherwise fails to meet the requirements of the food safety law.

(2) DETENTION AUTHORITY.—If, during an inspection conducted in accordance with section 205 or 208, an officer, employee, or agent of the Administration making the inspection has reason to believe that a domestic food, imported food, or food offered for import is unsafe, is adulterated or misbranded, or otherwise fails to meet the requirements of this the food safety law, the officer, employee, or agent may order the food detained.

(3) PERIOD OF DETENTION.—

(A) IN GENERAL.—A food may be detained under paragraph (1) or (2) for a reasonable period, not to exceed 20 days, unless a longer period, not to exceed 30 days, is necessary for the Administrator to institute a seizure action.

(B) PERISHABLE FOOD.—The Administrator shall provide by regulation for procedures to institute a seizure action on an expedited basis with respect to perishable food.

(4) SECURITY OF DETAINED FOOD.—

(A) IN GENERAL.—A detention order under this subsection—
(i) may require that the food be labeled or marked as detained; and

(ii) shall require that the food be removed to a secure facility, if appropriate.

(B) Food subject to an order.—A food subject to a detention order under this subsection shall not be transferred by any person from the place at which the food is removed, until released by the Administrator or until the expiration of the detention period applicable under the order, whichever occurs first.

(C) Delivery of food.—This subsection does not authorize the delivery of a food in accordance with execution of a bond while the article is subject to the order.

(b) Appeal of detention order.—

(1) In general.—A person who would be entitled to be a claimant for a food subject to a detention order under subsection (a) if the food were seized under section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334), may appeal the order to the Administrator.

(2) Action by the Administrator.—Not later than 5 days after an appeal is filed under paragraph (1), the Administrator, after providing an op-
portunity for an informal hearing, shall confirm, modify, or terminate the order involved.

(3) Final Agency Action.—Confirmation, modification, or termination by the Administrator under paragraph (2) shall be considered a final agency action for purposes of section 702 of title 5, United States Code.

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

(A) to provide an opportunity for an informal hearing; or
(B) to confirm, modify, or terminate the order.

(5) Effect of Instituting Court Action.—If the Administrator initiates an action under section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332) or section 304(a) of that Act (21 U.S.C. 334(a)) for a food subject to a detention order under subsection (a), the process for the appeal of the detention order with respect to such food shall terminate.

(e) Condemnation of Food.—
(1) IN GENERAL.—After confirming a detention order, the Administrator may order the food condemned.

(2) DESTRUCTION OF FOOD.—Any food condemned shall be destroyed under the supervision of the Administrator.

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

(d) TEMPORARY HOLDS AT PORTS OF ENTRY.—

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

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

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

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

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

SEC. 403. NOTIFICATION AND RECALL.

(a) NOTICE TO ADMINISTRATOR OF VIOLATION.—

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

(2) MANNER OF NOTIFICATION.—Notification under paragraph (1) shall be made in such manner and by such means as the Administrator may require by regulation.

(b) RECALL AND CONSUMER NOTIFICATION.—

(1) VOLUNTARY ACTIONS.—If the Administrator determines that food is in violation of the food safety law when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce and that there is a reasonable probability that the food, if consumed, would present a threat to public health, as determined by the Administrator, the Administrator shall give the appropriate persons (including the manufacturers, importers, distributors, or retailers of the food) an opportunity to—

(A) cease distribution of the food;

(B) notify all persons—

(i) processing, distributing, or otherwise handling the food to immediately
cease such activities with respect to the
food; or

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

(C) recall the food;

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

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

(ii) to State and local public health of-

ficials; or

(E) take any combination of the measures
described in this paragraph, as determined by
the Administrator to be appropriate in the cir-

cumstances.

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

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

(i) at the expense of the food estab-
ishment; or

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

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

(i) cease distribution of the food; and

(ii) notify all persons—

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

(II) if the food has been distri-
buted, transported, or sold, to imme-
diately cease distribution of the food.

(3) Notification to consumers by Adminis-
trator.—The Administrator shall, as the Adminis-
trator determines to be necessary—

(A) provide notice of the finding of the Ad-
ministrator under paragraph (1)—
(i) to consumers to whom the food was, or may have been, distributed; and

(ii) to State and local public health officials; and

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

(4) NONDISTRIBUTION BY NOTIFIED PERSONS.—A person that processes, distributes, or otherwise handles the food, or to which the food has been distributed, transported, or sold, and that is notified under paragraph (1)(B) or (2)(B) shall immediately cease distribution of the food.

(5) AVAILABILITY OF RECORDS TO ADMINISTRATOR.—Each person referred to in paragraph (1) that processed, distributed, or otherwise handled food shall make available to the Administrator information necessary to carry out this subsection, as determined by the Administrator, regarding—

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

(B) persons to which the food has been transported, sold, distributed, or otherwise handled.
(c) **Informal Hearings on Orders.**—

(1) **In General.**—The Administrator shall provide any person subject to an order under subsection (b) with an opportunity for an informal hearing, to be held as soon as practicable but not later than 2 business days after the issuance of the order.

(2) **Scope of the Hearing.**—In a hearing under paragraph (1), the Administrator shall consider the actions required by the order and any reasons why the food that is the subject of the order should not be recalled.

(d) **Post-Hearing Recall Orders.**—

(1) **Amendment of Order.**—If, after providing an opportunity for an informal hearing under subsection (c), the Administrator determines that there is a reasonable probability that the food that is the subject of an order under subsection (b), if consumed, would present a threat to the public health, the Administrator, as the Administrator determines to be necessary, may—

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

(B) specify a timetable in which the recall shall occur;
(C) require periodic reports to the Administrator describing the progress of the recall; and

(D) provide notice of the recall to consumers to whom the food was, or may have been, distributed.

(2) VACATION OF ORDERS.—If, after providing an opportunity for an informal hearing under subsection (c), the Administrator determines that adequate grounds do not exist to continue the actions required by the order, the Administrator shall vacate the order.

(e) REMEDIES NOT EXCLUSIVE.—The remedies provided in this section shall be in addition to, and not exclusive of, other remedies that may be available.

SEC. 404. INJUNCTION PROCEEDINGS.

(a) JURISDICTION.—The district courts of the United States, and the United States courts of the territories and possessions of the United States, shall have jurisdiction, for cause shown, to restrain a violation of section 202, 203, 204, 208, or 401 (or a regulation promulgated thereunder).

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

SEC. 405. CIVIL AND CRIMINAL PENALTIES.

(a) Civil Sanctions.—

(1) Civil penalty.—

(A) In general.—Any person that commits an act that violates the food safety law (including a regulation promulgated or order issued under the food safety law) may be assessed a civil penalty by the Administrator of not more than $1,000,000 for each such act.

(B) Separate offense.—Each act described in subparagraph (A) and each day during which that act continues shall be considered a separate offense.

(2) Other requirements.—

(A) Written order.—The civil penalty described in paragraph (1) shall be assessed by the Administrator by a written order, which shall specify the amount of the penalty and the basis for the penalty under subparagraph (B) considered by the Administrator.

(B) Amount of penalty.—Subject to paragraph (1)(A), the amount of the civil pen-
ality shall be determined by the Administrator, after considering—

(i) the gravity of the violation;

(ii) the degree of culpability of the person;

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

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

(C) Review of order.—The order may be reviewed only in accordance with subsection (c).

(b) Criminal Sanctions.—

(1) Offense resulting in serious illness.—Notwithstanding section 303(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(a)), if a violation of any provision of section 301 of such Act (21 U.S.C. 301) with respect to an adulterated or misbranded food results in serious illness, the person committing the violation shall be imprisoned for not more than 5 years, fined in accordance with title 18, United States Code, or both.

(2) Offense resulting in death.—Notwithstanding section 303(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(a)), if a violation
of any provision of section 301 of such Act (21 U.S.C. 331) with respect to an adulterated or misbranded food results in death, the person committing the violation shall be imprisoned for not more than 10 years, fined in accordance with title 18, United States Code, or both.

(e) JUDICIAL REVIEW.—

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

(A) not later than 30 days after the effective date of the order, files a petition for judicial review of the order in the United States court of appeals for the circuit in which that person resides or has its principal place of business or the United States Court of Appeals for the District of Columbia; and

(B) simultaneously serves a copy of the petition by certified mail to the Administrator.

(2) FILING OF RECORD.—Not later than 45 days after the service of a copy of the petition under paragraph (1)(B), the Administrator shall file in the court a certified copy of the administrative record upon which the order was issued.
(3) **Standard of Review.**—The findings of the Administrator relating to the order shall be set aside only if found to be unsupported by substantial evidence on the record as a whole.

(d) **Collection Actions for Failure To Pay.**—

(1) **In General.**—If any person fails to pay a civil penalty assessed under subsection (a) after the order assessing the penalty has become a final order, or after the court of appeals described in subsection (b) has entered final judgment in favor of the Administrator, the Administrator shall refer the matter to the Attorney General, who shall institute in a United States district court of competent jurisdiction a civil action to recover the amount assessed.

(2) **Limitation on Review.**—In a civil action under paragraph (1), the validity and appropriateness of the order of the Administrator assessing the civil penalty shall not be subject to judicial review.

(e) **Penalties Paid Into Account.**—The Administrator—

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

(2) may use the funds in the account, without further appropriation or fiscal year limitation—
(A) to carry out enforcement activities under the food safety law; or

(B) to provide assistance to States to inspect retail commercial food establishments or other food or firms under the jurisdiction of State food safety programs.

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

(g) REMEDIES NOT EXCLUSIVE.—The remedies provided in this section are in addition to, and not exclusive of, other remedies that may be available.

SEC. 406. PRESUMPTION.

In any action to enforce the requirements of the food safety law, the connection with interstate commerce required for jurisdiction shall be presumed to exist.

SEC. 407. WHISTLEBLOWER PROTECTION.

(a) IN GENERAL.—

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

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

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

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

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

(B) file, cause to be filed, testify, partici-
pate in, or otherwise assist in a proceeding or
action filed or about to be filed relating to a
violation of any law, rule, or regulation; or
(C) refused to violate or assist in the violation of any law, rule, or regulation.

(2) DEFINITION.—For the purposes of this section, the term “covered individual” means an individual who is an employee of—

(A) a food establishment;

(B) a food production facility;

(C) a restaurant;

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

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

(F) a fishing vessel; or

(G) an agent of any of the above.

(b) ENFORCEMENT ACTION.—

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

(2) Procedure.—

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

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

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

(D) Statute of limitations.—An action
under paragraph (1) shall be commenced not
later than 90 days after the date on which the
violation occurs.

(c) Remedies.—

(1) In general.—A covered individual pre-
vailing in any action under subsection (b)(1) shall be
entitled to all relief necessary to make the covered
individual whole.

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

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

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

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

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

SEC. 408. ADMINISTRATION AND ENFORCEMENT.

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

(b) INQUIRIES AND ACTIONS.—

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

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

SEC. 409. CITIZEN CIVIL ACTIONS.

(a) CIVIL ACTIONS.—A person may commence a civil
action against—
(1) a person that violates a regulation (including a regulation establishing a performance standard), order, or other action of the Administrator to ensure the safety of food; or

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

(b) COURT.—In an action commenced under this section:

(1) IN GENERAL.—The action shall be commenced—

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

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

(2) JURISDICTION.—The court shall have jurisdiction, without regard to the amount in controversy, or the citizenship of the parties, to enforce a regulation (including a regulation establishing a performance standard), order, or other action of the Administrator, or to order the Administrator to perform the act or duty.
(3) DAMAGES.—The court may—
(A) award damages, in the amount of damages actually sustained; and
(B) if the court determines it to be in the interest of justice, award the plaintiff the costs of suit, including reasonable attorney’s fees, reasonable expert witness fees, and penalties.
(c) REMEDIES NOT EXCLUSIVE.—The remedies provided for in this section shall be in addition to, and not exclusive of, other remedies that may be available.

TITLE V—IMPLEMENTATION
SEC. 501. REORGANIZATION PLAN.
(a) SUBMISSION OF PLAN.—Not later than 180 days after the enactment of this Act, the President shall transmit to the appropriate congressional committees a reorganization plan regarding the following:
(1) The transfer of agencies, personnel, assets, and obligations to the Administration pursuant to this Act.
(2) Any consolidation, reorganization, or streamlining of agencies transferred to the Administration pursuant to this Act.
(b) PLAN ELEMENTS.—The plan transmitted under subsection (a) shall contain, consistent with this Act, such
elements as the President determines appropriate, includ-
ing the following:

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

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

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

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

(5) Specification of any proposed disposition of
property, facilities, contracts, records, and other as-
sets and obligations of agencies transferred under
the plan.
(6) Specification of the proposed allocations within the Administration of the functions of the agencies and subdivisions that are not related directly to ensuring the safety of food.

(c) Modification of plan.—The President may, on the basis of consultations with the appropriate congressional committees, modify or revise any part of the plan until that part of the plan becomes effective in accordance with subsection (d).

(d) Effective date.—

(1) In general.—The reorganization plan described in this section, including any modifications or revisions of the plan under subsection (c), shall become effective for an agency on the earlier of—

(A) the date specified in the plan (or the plan as modified pursuant to subsection (c)), except that such date may not be earlier than 90 days after the date the President has transmitted the reorganization plan to the appropriate congressional committees pursuant to subsection (a); or

(B) the end of the 12-month period beginning on the date of the enactment of this Act.

(2) Statutory construction.—Nothing in this subsection may be construed to require the
transfer of functions, personnel, records, balances of appropriations, or other assets of an agency on a single date.

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

**SEC. 502. TRANSITIONAL AUTHORITIES.**

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

(b) **SERVICES AND PERSONNEL.**—During the transition period, upon the request of the Administrator, the head of any executive agency may provide services or detail personnel to assist with the transition.

(c) **ACTING OFFICIALS.**—

(1) **IN GENERAL.**—During the transition period, pending the advice and consent of the Senate to the appointment of an officer required by this Act to be appointed by and with such advice and consent, the President may designate any officer whose
appointment was required to be made by and with
such advice and consent and who was such an officer
immediately before the date of the enactment of this
Act (and who continues to be in office) or imme-
diately before such designation, to act in such office
until the same is filled as provided in this Act.

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

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

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

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

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

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

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

SEC. 503. SAVINGS PROVISIONS.

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

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

(1) pending proceedings in an agency, including
notices of proposed rulemaking, and applications for
licenses, permits, certificates, grants, and financial assistance, shall continue notwithstanding the enactment of this Act or the transfer of the agency to the Administration, unless discontinued or modified under the same terms and conditions and to the same extent that such discontinuance or modification could have occurred if such enactment or transfer had not occurred; and

(2) orders issued in such proceedings, and appeals therefrom, and payments made pursuant to such orders, shall issue in the same manner on the same terms as if this Act had not been enacted or the agency had not been transferred, and any such order shall continue in effect until amended, modified, superseded, terminated, set aside, or revoked by an officer of the United States or a court of competent jurisdiction, or by operation of law.

(c) PENDING CIVIL ACTIONS.—Subject to the authority of the Administrator under this Act, any civil action commenced with regard to that agency pending before that agency on the day before the transfer date with respect to the transferred functions shall continue notwithstanding the enactment of this Act or the transfer of an agency to the Administration.

(d) REFERENCES.—
(1) IN GENERAL.—After the transfer of functions from a Federal agency under this Act, any reference in any other Federal law, Executive order, rule, regulation, directive, document, or other material to that Federal agency or the head of that agency in connection with the administration or enforcement of the food safety law shall be deemed to be a reference to the Administration or the Administrator, respectively.

(2) STATUTORY REPORTING REQUIREMENTS.—Statutory reporting requirements that applied in relation to such an agency immediately before the date of the enactment of this Act shall continue to apply following such transfer if they refer to the agency by name.

SEC. 504. CONFORMING AMENDMENTS.

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

SEC. 505. ADDITIONAL TECHNICAL AND CONFORMING AMENDMENTS.

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

SEC. 506. REGULATIONS.

The Administrator may promulgate such regulations as the Administrator determines are necessary or appropriate to perform the duties of the Administrator.

SEC. 507. AUTHORIZATION OF APPROPRIATIONS.

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

SEC. 508. LIMITATION ON AUTHORIZATION OF APPROPRIATIONS.

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

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

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