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To establish the Food Safety Administration to protect the public health by ensuring the safety of food, preventing foodborne illness, maintaining safety reviews and reassessments of food additives, enforcing pesticide residue tolerances, improving the surveillance of foodborne pathogens, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. DeLauro introduced the following bill; which was referred to the Committee on

A BILL

To establish the Food Safety Administration to protect the public health by ensuring the safety of food, preventing foodborne illness, maintaining safety reviews and reassessments of food additives, enforcing pesticide residue tolerances, improving the surveillance of foodborne pathogens, and for other purposes.

1 Be it enacted by the Senate and House of Representa-

tives of the United States of America in Congress assembled,
SECTION 1. SHORT TITLE.

This Act may be cited as the “Food Safety Administration Act of 2022”.

SEC. 2. DEFINITIONS.

In this Act:

(1) ADMINISTRATION.—The term “Administration” means the Food Safety Administration established under section 101(a)(1).

(2) ADMINISTRATOR.—The term “Administrator” means the Administrator of Food Safety appointed under section 101(a)(2).

(3) FACILITY.—The term “facility” means any factory, warehouse, or establishment that is subject to the requirements of section 415 or 419 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d; 350h).

SEC. 3. EFFECTIVE DATE.

This Act, including the amendments made by this Act, shall take effect 180 days after the date of enactment of this Act.

SEC. 4. FUNDING.

(a) TRANSFER OF FUNDS.—The appropriations, allocations, and other funds that relate to the authorities, functions and agencies transferred under section 102 shall be transferred to the Administration.
(b) Authorization of Appropriations.—There are authorized to be appropriated to carry out this section, such sums as may be necessary for fiscal year 2023 and each fiscal year thereafter.

TITLE I—ESTABLISHMENT OF FOOD SAFETY ADMINISTRATION

SEC. 101. ESTABLISHMENT OF FOOD SAFETY ADMINISTRATION.

(a) Establishment.—

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

(2) Head of Administration.—The Administration shall be headed by the Administrator of Food Safety, who shall have food safety expertise, and be appointed by the President, by and with the advice and consent of the Senate.

(3) Effect.—The Federal Food and Drug Administration shall be renamed “Federal Drug Administration” and retain responsibility for carrying out its responsibilities related to drugs, cosmetics, devices, biological products, color additives, and tobacco. The Commissioner of Food and Drugs shall be renamed the “Commissioner of Drugs”, and shall
retain the responsibilities of the Commissioner of Food and Drugs, except such responsibilities that relate to food, which shall be assumed by the Administrator of Food Safety. Each reference in statute to the “Food and Drug Administration” shall be deemed a reference to the “Federal Drug Administration”, and each reference in statute to the “Commissioner of Food and Drugs” shall be deemed a reference to the “Commissioner of Drugs”.

(b) DUTIES OF THE ADMINISTRATOR.—The Administrator shall—

(1) administer and enforce all authorities under chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.);

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

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

(4) oversee—

(A) implementation of Federal food safety;

(B) inspection, labeling, enforcement, and research efforts to protect the public health;
(C) development of consistent and science-based standards for safe food;

(D) safety reviews and reassessments of food additives;

(E) establishment and enforcement of tolerances for poisonous or deleterious substances;

(F) monitoring and enforcement of pesticide residue tolerances in or on foods;

(G) coordination and prioritization of food safety research and education programs with other Federal agencies;

(H) prioritization of Federal food safety efforts and deployment of Federal food safety resources to achieve the greatest benefit in reducing foodborne illness;

(I) coordination of the Federal response to foodborne illness outbreaks with other Federal and State agencies;

(J) integration of Federal food safety activities with State and local agencies; and

(K) assignment of tolerances for animal drugs used in food-producing animals.
SEC. 102. TRANSFER OF AUTHORITY, FUNCTIONS AND AGENCIES.

(a) Transfer of Authority.—The Agency shall assume responsibility for carrying out chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) and maintain all enforcement authorities with respect to food held by the Food and Drug Administration on the date of enactment of this Act.

(b) Transfer of Functions.—For each Federal agency, office, and center specified in subsection (c), there are transferred to the Administration all functions that the head of the Federal agency exercised on the day before the date of enactment of this Act (including all related functions of any officer or employee of the Federal agency) that relate to administration or enforcement of the food safety law, as determined by the President.

(e) Transferred Agencies.—The Federal agencies referred to in subsection (b) are—

(1) the resources and facilities of the Center for Food Safety and Applied Nutrition of the Food and Drug Administration that administer chapter IV of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 341 et seq.);

(2) the resources and facilities of the Office of Regulatory Affairs of the Food and Drug Adminis-
tration that administer and conduct inspections of
food and feed facilities and imports;

(3) the resources and facilities of the Center for
Veterinary Medicine of the Food and Drug Adminis-
tration that administer chapter IV of the Federal
Food, Drug, and Cosmetics Act (21 U.S.C. 341 et
seq.);

(4) the Office of Food Policy and Response of
the Food and Drug Administration; and

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

(d) CONFORMING AMENDMENT.—Subchapter A of
chapter VII of the Federal Food, Drug, and Cosmetic Act
(21 U.S.C. 371 et seq.) is amended by adding at the end
the following:

“SEC. 703. REGULATION OF FOOD.

“Notwithstanding any other provision of this Act, be-

ginning on the date that is 180 days after the date of
enactment of the Food Safety Administration Act of 2022,
any authority under this Act that relates to food shall be
under the authority of the Food Safety Administration,
and shall be carried out by the Administrator of Food
Safety. Any reference in this Act to authorities related to
food held by the Secretary shall be deemed to be references to authorities held by the Administrator of Food Safety.”.

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 Administration 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 representative 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 development of regulatory science and processes, research, communications, performance standards, and inspection.

TITLE II—ADMINISTRATION OF FOOD SAFETY PROGRAM

SEC. 201. ESTABLISHMENT OF INSPECTION PROGRAM.

(a) IN GENERAL.—The Administrator shall establish an inspection program, which shall include inspections of food facilities subject to subsection (b) and in accordance with section 202.

(b) FACILITY CATEGORIES.—Not later than 6 months after the date of enactment of this Act, the Ad-
ministrator shall issue formal guidance defining the cri-
teria by which food facilities will be divided into “high-

(c) INSPECTION FREQUENCIES.—Frequency of ins-
spections of food facilities under this Act shall be based
on the categories defined pursuant to subsection (b) and
in accordance with section 202.

SEC. 202. INSPECTIONS OF FOOD FACILITIES.

(a) FREQUENCY OF INSPECTIONS.—

(1) HIGH-RISK FACILITIES.—The Administrator
shall inspect high-risk facilities not less than once
per a year.

(2) “INTERMEDIATE-RISK FACILITIES .—The
Administrator shall inspect intermediate-risk facili-
ties not less than once every 2 years.

(3) “LOW-RISK FACILITIES.—The Administrator
shall inspect low risk facilities, which shall include
warehouses or similar facilities that engage in pack-
aging or distribution, and pose very minimal public
health risk, not less than once every 3 years.

(b) INFANT FORMULA MANUFACTURING FACILI-
ties.—The Administrator shall inspect the facilities of
each manufacturer of infant formula not less than every
6 months.
(c) **Federal and State Cooperation.**—The Administrator shall contract with State officials to carry out half of the safety inspections required under this section.

**SEC. 203. COMPLIANCE CHECKS.**

Not later than 30 days after issuing a form that is equivalent to an FDA Form 483 to a facility, pursuant to an inspection under section 704 of Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374), the Administrator shall conduct a follow-up compliance check with the facility.

**SEC. 204. TRACEABILITY RULE.**

Not later than November 7, 2022, the Administrator shall promulgate a final rule that is based on the proposed rule issued by the Food and Drug Administration titled, “Requirements for Additional Traceability Records for Certain Foods” (85 Fed. Reg. 59984 (Sept. 23, 2021)).

**SEC. 205. NOTICE OF CIRCUMSTANCES THAT COULD LEAD TO A SHORTAGE.**

Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

“**SEC. 424. NOTICE OF CIRCUMSTANCES THAT COULD LEAD TO A SHORTAGE.**

“(a) Notice Requirement.—Not later than 5 business days after a manufacturer of infant formula or essen-
tial medical food becomes aware of circumstances that could lead to a shortage of infant formula or essential medical food in the United States, such manufacturer shall give written notice of such circumstances to the Administrator.

“(b) FINES.—If the Administrator finds that a manufacturer of infant formula or essential medical food is in violation of the requirement of this section to give written notice, such violation shall be treated as an infraction for purposes of imposing a fine in accordance with title 18, United States Code.

“(c) DEFINITIONS.—In this section:

“(1) The term ‘Administrator’ means the Administrator of Food Safety.

“(2) The term ‘essential medical food’ means a food that—

“(A) is formulated to be consumed or administered enterally under the supervision of a physician;

“(B) is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation; and
“(C) is identified by the Administrator as being essential for any urgent medical condition.”.