

117TH CONGRESS
2D SESSION

S. 4520

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 SENATE OF THE UNITED STATES

JULY 13, 2022

Mr. DURBIN (for himself and Mr. BLUMENTHAL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Food Safety Adminis-
5 tration Act of 2022”.

1 **SEC. 2. DEFINITIONS.**

2 In this Act:

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

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

9 (3) FACILITY.—The term “facility” means any
10 factory, warehouse, or establishment that is subject
11 to the requirements of section 415 or 419 of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 350d; 350h).

14 **SEC. 3. EFFECTIVE DATE.**

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

18 **SEC. 4. FUNDING.**

19 (a) TRANSFER OF FUNDS.—The appropriations, allo-
20 cations, and other funds that relate to the authorities,
21 functions and agencies transferred under section 102 shall
22 be transferred to the Administration.

23 (b) AUTHORIZATION OF APPROPRIATIONS.—There
24 are authorized to be appropriated to carry out this section,
25 such sums as may be necessary for fiscal year 2023 and
26 each fiscal year thereafter.

1 **TITLE I—ESTABLISHMENT OF**
2 **FOOD SAFETY ADMINISTRATION**

3 **SEC. 101. ESTABLISHMENT OF FOOD SAFETY ADMINISTRA-**
4 **TION.**

5 (a) ESTABLISHMENT.—

6 (1) IN GENERAL.—There is established within
7 the Department of Health and Human Services an
8 agency to be known as the “Food Safety Adminis-
9 tration”.

10 (2) HEAD OF ADMINISTRATION.—The Adminis-
11 tration shall be headed by the Administrator of Food
12 Safety, who shall have food safety expertise, and be
13 appointed by the President, by and with the advice
14 and consent of the Senate.

15 (3) EFFECT.—The Federal Food and Drug Ad-
16 ministration shall be renamed “Federal Drug Ad-
17 ministration” and retain responsibility for carrying
18 out its responsibilities related to drugs, cosmetics,
19 devices, biological products, color additives, and to-
20 bacco. The Commissioner of Food and Drugs shall
21 be renamed the “Commissioner of Drugs”, and shall
22 retain the responsibilities of the Commissioner of
23 Food and Drugs, except such responsibilities that re-
24 late to food, which shall be assumed by the Adminis-
25 trator of Food Safety. Each reference in statute to

1 the “Food and Drug Administration” shall be
2 deemed a reference to the “Federal Drug Adminis-
3 tration”, and each reference in statute to the “Com-
4 missioner of Food and Drugs” shall be deemed a
5 reference to the “Commissioner of Drugs”.

6 (b) DUTIES OF THE ADMINISTRATOR.—The Adminis-
7 trator shall—

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

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

13 (3) promulgate and enforce regulations to en-
14 sure the security of the food supply from all forms
15 of contamination, including intentional contamina-
16 tion; and

17 (4) oversee—

18 (A) implementation of Federal food safety;

19 (B) inspection, labeling, enforcement, and
20 research efforts to protect the public health;

21 (C) development of consistent and science-
22 based standards for safe food;

23 (D) safety reviews and reassessments of
24 food additives;

1 (E) establishment and enforcement of tol-
2 erances for poisonous or deleterious substances;

3 (F) monitoring and enforcement of pes-
4 ticide residue tolerances in or on foods;

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

8 (H) prioritization of Federal food safety
9 efforts and deployment of Federal food safety
10 resources to achieve the greatest benefit in re-
11 ducing foodborne illness;

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

15 (J) integration of Federal food safety ac-
16 tivities with State and local agencies; and

17 (K) assignment of tolerances for animal
18 drugs used in food-producing animals.

19 **SEC. 102. TRANSFER OF AUTHORITY, FUNCTIONS, AND**
20 **AGENCIES.**

21 (a) **TRANSFER OF AUTHORITY.**—The Agency shall
22 assume responsibility for carrying out chapter IV of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341
24 et seq.) and maintain all enforcement authorities with re-

1 spect to food held by the Food and Drug Administration
2 on the date of enactment of this Act.

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

11 (c) TRANSFERRED AGENCIES.—The Federal agencies
12 referred to in subsection (b) are—

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

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

22 (3) the resources and facilities of the Center for
23 Veterinary Medicine of the Food and Drug Adminis-
24 tration that administer chapter IV of the Federal

1 Food, Drug, and Cosmetics Act (21 U.S.C. 341 et
2 seq.);

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

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

8 (d) CONFORMING AMENDMENT.—Subchapter A of
9 chapter VII of the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 371 et seq.) is amended by adding at the end
11 the following:

12 **“SEC. 703. REGULATION OF FOOD.**

13 “Notwithstanding any other provision of this Act, be-
14 ginning on the date that is 180 days after the date of
15 enactment of the Food Safety Administration Act of 2022,
16 any authority under this Act that relates to food shall be
17 under the authority of the Food Safety Administration,
18 and shall be carried out by the Administrator of Food
19 Safety. Any reference in this Act to authorities related to
20 food held by the Secretary shall be deemed to be references
21 to authorities held by the Administrator of Food Safety.”.

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

23 (a) OFFICERS AND EMPLOYEES.—The Administrator
24 may—

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

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

9 (b) EXPERTS AND CONSULTANTS.—The Administra-
10 tion may—

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

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

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

25 (d) ADVISORY COMMITTEES.—

1 (1) IN GENERAL.—The Administrator shall es-
 2 tablish advisory committees that consist of rep-
 3 resentative of scientific expert bodies, academics, in-
 4 dustry specialists, and consumers.

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

11 **TITLE II—ADMINISTRATION OF** 12 **FOOD SAFETY PROGRAM**

13 **SEC. 201. ESTABLISHMENT OF INSPECTION PROGRAM.**

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

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

23 (c) INSPECTION FREQUENCIES.—Frequency of in-
 24 spections of food facilities under this Act shall be based

1 on the categories defined pursuant to subsection (b) and
2 in accordance with section 202.

3 **SEC. 202. INSPECTIONS OF FOOD FACILITIES.**

4 (a) FREQUENCY OF INSPECTIONS.—

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

8 (2) INTERMEDIATE-RISK FACILITIES.—The Ad-
9 ministrator shall inspect intermediate-risk facilities
10 not less than once every 2 years.

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

16 (b) INFANT FORMULA MANUFACTURING FACILI-
17 TIES.—The Administrator shall inspect the facilities of
18 each manufacturer of infant formula not less than every
19 6 months.

20 (c) FEDERAL AND STATE COOPERATION.—The Ad-
21 ministrator shall contract with State officials to carry out
22 half of the safety inspections required under this section.

23 **SEC. 203. COMPLIANCE CHECKS.**

24 Not later than 30 days after issuing a form that is
25 equivalent to an FDA Form 483 to a facility, pursuant

1 to an inspection under section 704 of Federal Food, Drug,
2 and Cosmetic Act (21 U.S.C. 374), the Administrator
3 shall conduct a follow-up compliance check with the facil-
4 ity.

5 **SEC. 204. TRACEABILITY RULE.**

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

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

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

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

18 “(a) NOTICE REQUIREMENT.—Not later than 5 busi-
19 ness days after a manufacturer of infant formula or essen-
20 tial medical food becomes aware of circumstances that
21 could lead to a shortage of infant formula or essential
22 medical food in the United States, such manufacturer
23 shall give written notice of such circumstances to the Ad-
24 ministrator.

1 “(b) FINES.—If the Administrator finds that a man-
 2 ufacturer of infant formula or essential medical food is
 3 in violation of the requirement of this section to give writ-
 4 ten notice, such violation shall be treated as an infraction
 5 for purposes of imposing a fine in accordance with title
 6 18, United States Code.

7 “(c) DEFINITIONS.—In this section:

8 “(1) The term ‘Administrator’ means the Ad-
 9 ministrator of Food Safety.

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

12 “(A) is formulated to be consumed or ad-
 13 ministered enterally under the supervision of a
 14 physician;

15 “(B) is intended for the specific dietary
 16 management of a disease or condition for which
 17 distinctive nutritional requirements, based on
 18 recognized scientific principles, are established
 19 by medical evaluation; and

20 “(C) is identified by the Administrator as
 21 being essential for any urgent medical condi-
 22 tion.”.

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