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2D SESSION

S. 4745

To establish the Federal Food Administration to protect the public health by ensuring the safety of food, preventing foodborne illness, maintaining safety reviews and reassessments of food additives, reducing the prevalence of diet-related chronic diseases, enforcing pesticide residue tolerances, improving the surveillance of foodborne pathogens, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 23, 2024

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 Federal Food Administration to protect the public health by ensuring the safety of food, preventing foodborne illness, maintaining safety reviews and reassessments of food additives, reducing the prevalence of diet-related chronic diseases, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Federal Food Adminis-
3 tration Act of 2024”.

4 **SEC. 2. DEFINITIONS.**

5 In this Act:

6 (1) **ADMINISTRATION.**—The term “Administra-
7 tion”, except as otherwise provided, means the Fed-
8 eral Food Administration established under section
9 101(a)(1).

10 (2) **COMMISSIONER.**—The term “Commis-
11 sioner”, except as otherwise provided, means the
12 Commissioner of Foods appointed under section
13 101(a)(2).

14 (3) **FACILITY.**—The term “facility” means any
15 factory, warehouse, or establishment that is subject
16 to the requirements of section 415 or 419 of the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 350d; 350h).

19 **SEC. 3. EFFECTIVE DATE.**

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

23 **SEC. 4. FUNDING.**

24 (a) **TRANSFER OF FUNDS.**—The appropriations, allo-
25 cations, and other funds that relate to the authorities,

1 functions and agencies transferred under section 102 shall
2 be transferred to the Administration.

3 (b) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated to carry out this section,
5 such sums as may be necessary for fiscal year 2025 and
6 each fiscal year thereafter.

7 **TITLE I—ESTABLISHMENT OF**
8 **FEDERAL FOOD ADMINISTRA-**
9 **TION**

10 **SEC. 101. ESTABLISHMENT OF FEDERAL FOOD ADMINIS-**
11 **TRATION.**

12 (a) ESTABLISHMENT.—

13 (1) IN GENERAL.—There is established within
14 the Department of Health and Human Services an
15 agency to be known as the “Federal Food Adminis-
16 tration”.

17 (2) HEAD OF ADMINISTRATION.—The Adminis-
18 tration shall be headed by the Commissioner of
19 Foods, who shall have food safety expertise, and be
20 appointed by the President, by and with the advice
21 and consent of the Senate.

22 (3) EFFECT.—The Federal Food and Drug Ad-
23 ministration shall be renamed the “Federal Drug
24 Administration” and retain responsibility for car-
25 rying out its responsibilities related to drugs, cos-

1 metics, devices, biological products, color additives,
2 and tobacco. The Commissioner of Food and Drugs
3 shall be renamed the “Commissioner of Drugs”, and
4 shall retain the responsibilities of the Commissioner
5 of Food and Drugs, as of the day before the date
6 of enactment of this Act, except such responsibilities
7 that relate to food, which shall be assumed by the
8 Commissioner of Food. Each reference in law, regu-
9 lation, document, paper, or other record of the
10 United States to the “Food and Drug Administra-
11 tion” shall be deemed a reference to the “Federal
12 Drug Administration”, and each reference in law,
13 regulation, document, paper, or other record of the
14 United States to the “Commissioner of Food and
15 Drugs” shall be deemed a reference to the “Commis-
16 sioner of Drugs”.

17 (b) DUTIES OF THE COMMISSIONER.—The Commis-
18 sioner shall—

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

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

24 (3) promulgate and enforce regulations to en-
25 sure the security of the food supply from all forms

1 of contamination, including intentional contamina-
2 tion; and

3 (4) oversee—

4 (A) implementation of Federal food efforts;

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

7 (C) development of consistent and science-
8 based standards for safe food;

9 (D) safety reviews and reassessments of
10 food additives;

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

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

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

18 (H) prioritization of Federal food efforts
19 and deployment of Federal food resources to
20 achieve the greatest benefit in reducing
21 foodborne illness and diet-related chronic dis-
22 eases;

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

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

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

5 **SEC. 102. TRANSFER OF AUTHORITY, FUNCTIONS AND**
6 **AGENCIES.**

7 (a) TRANSFER OF AUTHORITY.—The Administration
8 shall assume responsibility for carrying out chapter IV of
9 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341
10 et seq.) and maintain all enforcement authorities with re-
11 spect to food held by the Food and Drug Administration
12 on the date of enactment of this Act.

13 (b) TRANSFER OF FUNCTIONS.—For each Federal
14 agency, office, and center specified in subsection (c), there
15 are transferred to the Administration all functions that
16 the head of the Federal agency exercised on the day before
17 the date of enactment of this Act (including all related
18 functions of any officer or employee of the Federal agency)
19 that relate to administration or enforcement of the food
20 law, as determined by the President.

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

23 (1) the resources and facilities of the Center for
24 Food Safety and Applied Nutrition of the Food and
25 Drug Administration that administer chapter IV of

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

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

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

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

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

17 (d) CONFORMING AMENDMENT.—Subchapter A of
18 chapter VII of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 371 et seq.) is amended by adding at the end
20 the following:

21 **“SEC. 716. REGULATION OF FOOD.**

22 “Notwithstanding any other provision of this Act, be-
23 ginning on the date that is 180 days after the date of
24 enactment of the Federal Food Administration Act of
25 2024, any authority under this Act that relates to food

1 shall be under the authority of the Federal Food Adminis-
 2 tration, and shall be carried out by the Commissioner of
 3 Food. Any reference in this Act to authorities related to
 4 food held by the Secretary shall be deemed to be a ref-
 5 erence to authorities held by the Commissioner of Food.”.

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

7 (a) OFFICERS AND EMPLOYEES.—The Commissioner
 8 may—

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

13 (2) fix the compensation of those officers and
 14 employees in accordance with chapter 51 and with
 15 subchapter III of chapter 53 of that title, relating to
 16 classification and General Schedule pay rates.

17 (b) EXPERTS AND CONSULTANTS.—The Administra-
 18 tion may—

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

22 (2) pay in connection with those services the
 23 travel expenses of the experts and consultants, in-
 24 cluding transportation and per diem in lieu of sub-
 25 sistence while away from the homes or regular

1 places of business of the individuals, as authorized
2 by section 5703 of that title.

3 (c) BUREAUS, OFFICES, AND DIVISIONS.—The Com-
4 missioner may establish within the Administration such
5 bureaus, offices, and divisions as the Commissioner deter-
6 mines are necessary to perform the duties of the Commis-
7 sioner.

8 (d) ADVISORY COMMITTEES.—

9 (1) IN GENERAL.—The Commissioner shall es-
10 tablish advisory committees that consist of rep-
11 resentative of scientific expert bodies, academics, in-
12 dustry specialists, and consumers.

13 (2) DUTIES.—The duties of an advisory com-
14 mittee established under paragraph (1) may include
15 developing recommendations with respect to the de-
16 velopment of regulatory science and processes, re-
17 search, communications, performance standards, and
18 inspection.

19 **TITLE II—ADMINISTRATION OF** 20 **FOODS PROGRAM**

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

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

1 (b) FACILITY CATEGORIES.—Not later than 6
 2 months after the date of enactment of this Act, the Com-
 3 missioner shall issue formal guidance defining the criteria
 4 by which food facilities will be divided into “high-risk,”
 5 “intermediate risk,” and “low-risk” facilities.

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

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

11 (a) FREQUENCY OF INSPECTIONS.—

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

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

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

23 (b) INFANT FORMULA MANUFACTURING FACILI-
 24 TIES.—The Commissioner shall inspect the facilities of

1 each manufacturer of infant formula not less than every
2 6 months.

3 (c) FEDERAL AND STATE COOPERATION.—The Com-
4 missioner shall contract with State officials to carry out
5 half of the safety inspections required under this section.

6 **SEC. 203. COMPLIANCE CHECKS.**

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

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