

117TH CONGRESS
2D SESSION

H. R. 7933

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety and supply of infant formula, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 3, 2022

Ms. DELAURO (for herself, Mr. BISHOP of Georgia, Ms. BARRAGÁN, Ms. PRESSLEY, Mr. SAN NICOLAS, Mr. LARSON of Connecticut, Mr. THOMPSON of California, Ms. WILD, Ms. NORTON, Mr. NADLER, Mr. LAWSON of Florida, Mr. SARBANES, Mrs. BUSTOS, Ms. TLAIB, Mrs. NAPOLITANO, Ms. WILSON of Florida, Mr. COOPER, Mr. BLUMENAUER, Mr. CARBAJAL, Mr. EVANS, Mrs. TRAHAN, Mr. POCAN, Mr. TRONE, Mr. TORRES of New York, Mr. CICILLINE, Mr. DANNY K. DAVIS of Illinois, Ms. SPEIER, Ms. UNDERWOOD, Mr. DESAULNIER, Mrs. CAROLYN B. MALONEY of New York, Mr. CARSON, Mrs. HAYES, Ms. PINGREE, Ms. BONAMICI, Mr. LEVIN of California, Mr. COURTNEY, Ms. MENG, Mr. PERLMUTTER, Ms. CHU, Mr. BOWMAN, Ms. TITUS, Ms. DEAN, Ms. SCHAKOWSKY, Ms. BASS, Ms. LEE of California, Mrs. DEMINGS, Mr. KRISHNAMOORTHY, Mr. RASKIN, Ms. SCHRIER, Mr. PAPPAS, Ms. BLUNT ROCHESTER, Mr. KILMER, Mr. CASTEN, Ms. ROSS, Ms. STEVENS, Mrs. LAWRENCE, Ms. SPANBERGER, Mr. COHEN, Mr. PANETTA, Ms. PORTER, Mrs. WATSON COLEMAN, Mr. MICHAEL F. DOYLE of Pennsylvania, Mr. CONNOLLY, Ms. CASTOR of Florida, Mr. HIMES, Ms. MCCOLLUM, Mr. CROW, Mr. GALLEGO, Mr. SWALWELL, Ms. SCANLON, Mr. WELCH, Ms. CLARK of Massachusetts, Ms. ROYBAL-ALLARD, Mr. SOTO, Mr. CASE, Mr. CÁRDENAS, Ms. JACKSON LEE, Ms. KUSTER, Mr. LANGEVIN, and Ms. LOIS FRANKEL of Florida) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Financial Services, Education and Labor, and Agriculture, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety and supply of infant formula, 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 “Keep Infant Formula
5 Safe and On the Shelves Act of 2022”.

6 **SEC. 2. PRODUCT SAFETY.**

7 (a) INSPECTIONS AND AUDITS.—Section 412 of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a)
9 is amended by adding at the end the following:

10 “(j) INSPECTIONS AND AUDITS.—

11 “(1) IN GENERAL.—Not less than every 6
12 months, the Secretary shall inspect the facilities of
13 each manufacturer of infant formula registered
14 under subsection (c).

15 “(2) UNANNOUNCED INSPECTIONS.—Not later
16 than 6 months after the date of enactment of the
17 Keep Infant Formula Safe and On the Shelves Act
18 of 2022, and not less than once per calendar year
19 thereafter, the Secretary shall conduct unannounced
20 inspections of the facilities of each manufacturer of
21 infant formula registered under subsection (c), in-

1 including such facilities with no history of notable reg-
2 ulatory findings.

3 “(3) AUTOMATIC COMPREHENSIVE FOOD SAFE-
4 TY AUDIT.—If the Secretary makes a notable regu-
5 latory finding at any facility of a manufacturer of
6 infant formula during an inspection or audit, the
7 Secretary shall require such facility to undergo a
8 comprehensive food safety audit that includes—

9 “(A) a root cause analysis;

10 “(B) enhanced testing; and

11 “(C) comprehensive environmental samples
12 throughout the facility.

13 “(4) AUDITS.—The Secretary shall increase the
14 frequency of comprehensive food safety audits of a
15 facility of a manufacturer of infant formula reg-
16 istered under subsection (c) if there are persistent
17 notable regulatory findings at such facility.

18 “(5) MICROBIAL TEST RESULTS.—

19 “(A) IN GENERAL.—During any inspection
20 or audit by the Secretary of a facility of a man-
21 ufacturer of infant formula, the manufacturer
22 shall provide to the Secretary the results of all
23 microbial tests conducted by or for the facility
24 during the period of 15 years preceding the
25 date of the inspection or audit.

1 “(B) FINES.—If the Secretary finds that a
2 facility is in violation of subparagraph (A), such
3 violation shall be treated as an infraction for
4 purposes of imposing a fine in accordance with
5 title 18, United States Code.”.

6 (b) CRONOBACTER SAKAZAKII.—The Secretary of
7 Health and Human Services, acting through the Director
8 of the Centers for Disease Control and Prevention, and
9 in consultation with the Council of State and Territorial
10 Epidemiologists, shall consider adding cronobacter
11 sakazakii to the list of nationally notifiable diseases and
12 conditions under the National Notifiable Diseases Surveil-
13 lance System.

14 **SEC. 3. SUPPLY.**

15 (a) STRATEGIC NATIONAL STOCKPILE.—Not later
16 than 90 days after the date of enactment of this Act, the
17 Secretary of Agriculture, in consultation with the Assist-
18 ant Secretary for Preparedness and Response of the De-
19 partment of Health and Human Services and the Adminis-
20 trator of the Federal Emergency Management Agency,
21 shall—

22 (1) perform an assessment of—

23 (A) short- and long-term storage of infant
24 formula, including the possibility of storage of
25 infant formula in a Federal stockpile; and

1 (B) models for distribution of infant for-
 2 mula during shortages; and

3 (2) submit a report to the Congress on the re-
 4 sults of such assessment.

5 (b) NOTIFICATION BY MANUFACTURERS OF CIR-
 6 CUMSTANCES THAT COULD LEAD TO A SHORTAGE OF IN-
 7 FANT FORMULA OR ESSENTIAL MEDICAL FOOD.—

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

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

13 “(a) NOTICE REQUIREMENT.—Not later than 5 busi-
 14 ness days after a manufacturer of infant formula or essen-
 15 tial medical food becomes aware of circumstances that
 16 could lead to a shortage of infant formula or essential
 17 medical food in the United States, such manufacturer
 18 shall give written notice of such circumstances to the Sec-
 19 retary.

20 “(b) DEFINITION.—In this section, the term ‘essen-
 21 tial medical food’ means a food that—

22 “(1) is formulated to be consumed or adminis-
 23 tered enterally under the supervision of a physician;

24 “(2) is intended for the specific dietary man-
 25 agement of a disease or condition for which distine-

1 tive nutritional requirements, based on recognized
2 scientific principles, are established by medical eval-
3 uation; and

4 “(3) is identified by the Secretary as being es-
5 sential for any urgent medical condition.

6 “(c) FINES.—If the Secretary finds that a manufac-
7 turer of infant formula or essential medical food is in vio-
8 lation of the requirement of this section to give written
9 notice, such violation shall be treated as an infraction for
10 purposes of imposing a fine in accordance with title 18,
11 United States Code.”.

12 (c) LIST OF FACILITIES THAT COULD BE CON-
13 VERTED TO MANUFACTURE INFANT FORMULA.—Section
14 412 of the Federal Food, Drug, and Cosmetic Act (21
15 U.S.C. 350a), as amended by section 2(a), is further
16 amended by adding at the end the following:

17 “(k) LIST OF FACILITIES THAT COULD BE CON-
18 VERTED.—The Secretary shall—

19 “(1) not later than 90 days after the date of
20 enactment of this subsection, identify and compile a
21 list of all manufacturing facilities in the United
22 States that could be converted to manufacture infant
23 formula in the event of a shortage;

24 “(2) on an annual basis, update such list; and

1 “(3) post such up-to-date list on the public
2 website of the Food and Drug Administration.”.

3 (d) REPORTING BY MANUFACTURERS DURING A
4 SHORTAGE.—Section 412 of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 350a), as amended by subsection
6 (c), is further amended by adding at the end the following:

7 “(1) REPORTING BY MANUFACTURERS DURING A
8 SHORTAGE.—In the event of a shortage of infant formula
9 in the United States, the Secretary may require manufac-
10 turers of infant formula to report to the Secretary—

11 “(1) the quantity of infant formula in the in-
12 ventories of such manufacturers and their distribu-
13 tors;

14 “(2) the location of recent or upcoming ship-
15 ments of infant formula by such manufacturers and
16 their distributors;

17 “(3) the capacity of such manufacturers and
18 their distributors to redistribute their inventories of
19 infant formula based on geographical needs; and

20 “(4) the quantity by which such manufacturers
21 could increase their output of infant formula.”.

1 **SEC. 4. USE OF AUTHORITIES UNDER THE DEFENSE PRO-**
2 **DUCTION ACT OF 1950 FOR FOOD.**

3 Section 101 of the Defense Production Act of 1950
4 (50 U.S.C. 4511) is amended by adding at the end the
5 following:

6 “(e) TREATMENT OF FOOD.—For purposes of this
7 title, title III, and title VII, food (including infant formula
8 and the ingredients necessary to produce infant formula)
9 is a critical material essential to the national defense.”.

10 **SEC. 5. ENSURING WORKER SAFETY AND HEALTH.**

11 The Assistant Secretary of Labor for Occupational
12 Safety and Health shall issue a fact sheet and provide
13 technical assistance to each manufacturer of infant for-
14 mula registered under section 412(c) of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 350a(c)) to promote
16 compliance with occupational safety and health standards
17 promulgated under section 6 of the Occupational Safety
18 and Health Act of 1970. Such fact sheet and technical
19 assistance shall include information on recognized hazards
20 and on the specific occupational safety and health stand-
21 ards, and any other legal requirements under the Occupa-
22 tional Safety and Health Act of 1970, that apply to such
23 manufacturer.

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