

117TH CONGRESS
2D SESSION

S. 4256

To amend the Federal Food, Drug, and Cosmetic Act to prevent food shortages, including shortages of infant formula and certain medical foods.

IN THE SENATE OF THE UNITED STATES

MAY 18 (legislative day, MAY 17), 2022

Mr. CASEY (for himself, Mr. BROWN, Ms. DUCKWORTH, Mrs. GILLIBRAND, and Ms. WARREN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to prevent food shortages, including shortages of infant formula and certain medical foods.

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 “Protecting Infants
5 from Formula Shortages Act of 2022”.

1 **SEC. 2. DISCONTINUANCE OR INTERRUPTION IN THE PRO-**
2 **DUCTION OF ESSENTIAL SOURCES OF NUTRI-**
3 **TION.**

4 (a) DISCONTINUANCE OR INTERRUPTION IN THE
5 PRODUCTION OF ESSENTIAL FOOD.—The Federal Food,
6 Drug, and Cosmetic Act is amended by inserting after sec-
7 tion 412 (21 U.S.C. 350a) the following new section:

8 **“SEC. 412A. DISCONTINUANCE OR INTERRUPTION IN THE**
9 **PRODUCTION OF FOOD, INCLUDING INFANT**
10 **FORMULA AND CERTAIN MEDICAL FOODS**
11 **FOR INBORN ERRORS OF METABOLISM.**

12 “(a) IN GENERAL.—A manufacturer of an essential
13 source of nutrition shall notify the Secretary, in accord-
14 ance with subsection (b), of a permanent discontinuance
15 in the manufacture of such food or an interruption of the
16 manufacture of an essential source of nutrition or any
17 other circumstance that is likely to lead to a meaningful
18 disruption in the supply of such food in the United States,
19 and the reasons for such discontinuance or interruption.

20 “(b) TIMING.—Except as provided in subsection (g),
21 a notice required under subsection (a) shall be submitted
22 to the Secretary—

23 “(1) at least 6 months prior to the date of the
24 discontinuance or interruption; or

25 “(2) if compliance with paragraph (1) is not
26 possible, as soon as practicable.

1 “(c) DISTRIBUTION.—To the maximum extent prac-
2 ticable, the Secretary shall distribute, to the Secretary of
3 Agriculture and to appropriate organizations, as deter-
4 mined by the Secretary, through such means as the Sec-
5 retary determines appropriate, information on the dis-
6 continuance or interruption of the manufacture of an es-
7 sential source of nutrition, or other circumstance, reported
8 under subsection (a).

9 “(d) CONFIDENTIALITY.—Nothing in this section au-
10 thorizes the Secretary to disclose any information that is
11 a trade secret or confidential information subject to sec-
12 tion 552(b)(4) of title 5, United States Code, or section
13 1905 of title 18, United States Code.

14 “(e) FAILURE TO MEET REQUIREMENTS.—If a per-
15 son fails to submit information required under subsection
16 (a) in accordance with subsection (b)—

17 “(1) the Secretary shall issue to such person a
18 letter that—

19 “(A) informs such person of the failure to
20 comply;

21 “(B) describes the basis for noncompli-
22 ance; and

23 “(C) requires the person to comply not
24 later than 30 calendar days after the date on
25 which the letter was issued;

1 “(2) not later than 30 calendar days after the
2 issuance of a letter under paragraph (1), the person
3 who receives such letter shall submit to the Sec-
4 retary a written response to such letter that provides
5 the information required under subsection (a); and

6 “(3) not later than 45 calendar days after the
7 issuance of a letter under paragraph (1), the Sec-
8 retary shall make such letter and any response to
9 such letter under paragraph (2) available to the pub-
10 lic on the website of the Food and Drug Administra-
11 tion, with appropriate redactions made to protect in-
12 formation described in subsection (d), except that, if
13 the Secretary determines that the letter under para-
14 graph (1) was issued in error or, after review of
15 such response, the person had a reasonable basis for
16 not notifying as required under subsection (a), the
17 requirements of this paragraph shall not apply.

18 “(f) REGULATIONS.—

19 “(1) IN GENERAL.—Not later than 1 year after
20 the date of enactment of the Protecting Infants from
21 Formula Shortages Act of 2022, the Secretary shall
22 promulgate regulations regarding the requirements
23 under this section.

24 “(2) CONTENTS.—Such regulations—

1 “(A) shall include a list of each category of
2 food for which a manufacturer is required to
3 notify the Secretary in accordance with sub-
4 section (a); and

5 “(B) may—

6 “(i) designate foods not otherwise de-
7 fined as an essential source of nutrition,
8 giving special consideration to foods—

9 “(I) upon which individuals with
10 certain diseases or conditions may be
11 particularly reliant; or

12 “(II) that are administered under
13 medical supervision;

14 “(ii) designate additional categories of
15 foods for which the Secretary determines
16 notification described in subsection (a) is
17 appropriate during a public health emer-
18 gency declared under section 319 of the
19 Public Health Service Act; and

20 “(iii) prescribe additional conditions
21 on the timing and manner of such notifica-
22 tions as are reasonable and appropriate
23 during such a public health emergency.

24 “(g) ORDER.—During a public health emergency de-
25 clared under section 319 of the Public Health Service Act,

1 the Secretary may order any manufacturer of an essential
2 source of nutrition to provide notification required by this
3 section. Such order may—

4 “(1) impose additional conditions on the timing
5 and manner of notification as are reasonable and ap-
6 propriate in light of the circumstances of the public
7 health emergency; and

8 “(2) designate additional categories of food for
9 which the Secretary determines notification is appro-
10 priate during the public health emergency.

11 “(h) RISK MANAGEMENT PLANS.—Each manufac-
12 turer of an essential source of nutrition shall develop,
13 maintain, and, as appropriate, implement a redundancy
14 risk management plan that identifies and evaluates risks
15 to the supply of the food, as applicable, for each establish-
16 ment in which such food is manufactured. A risk manage-
17 ment plan under this subsection—

18 “(1) may identify and evaluate risks to the sup-
19 ply of more than one food, or food category, manu-
20 factured at the same establishment; and

21 “(2) shall be subject to inspection and copying
22 by the Secretary pursuant to section 704 or at the
23 request of the Secretary.

24 “(i) DEFINITIONS.—In this section:

1 “(1) ESSENTIAL SOURCE OF NUTRITION.—The
2 term ‘essential source of nutrition’ means—

3 “(A) an infant formula;

4 “(B) a food that—

5 “(i) meets the definition of ‘medical
6 food’ in section 5(b) of the Orphan Drug
7 Act; and

8 “(ii) is intended for use by individuals
9 with—

10 “(I) certain inborn errors of me-
11 tabolism; or

12 “(II) other conditions requiring a
13 medical food, as determined by the
14 Secretary in guidance issued under
15 subsection (f); or

16 “(C) a food so designated pursuant to sub-
17 section (f).

18 “(2) MEANINGFUL DISRUPTION.—The term
19 ‘meaningful disruption’—

20 “(A) means a change in production that is
21 reasonably likely to lead to a reduction in the
22 supply of an essential source of nutrition by a
23 manufacturer that is more than negligible and
24 affects the ability of the manufacturer to fulfill

contractual obligations or meet expected demand for its product; and

“(B) does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.”.

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following new subsection:

“(fff) The failure to provide information as required under section 412A after receipt of a letter from the Secretary under subsection (e) of such section.”.

SEC. 3. REMOTE RECORDS ASSESSMENT FOR ESSENTIAL SOURCES OF NUTRITION.

(a) FACTORY INSPECTION.—Section 704(a)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(4)(A)) is amended in the first sentence by inserting “or the manufacturing, processing, packing, or holding of an essential source of nutrition (as defined in section 412A)” after “processing of a drug”.

(b) REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the “Sec-

1 retary”) shall promulgate regulations describing cir-
2 cumstances in which the Secretary may issue requests for
3 records or other information in advance of, or in lieu of,
4 an inspection pursuant to section 704(a)(4)(A) of the Fed-
5 eral Food, Drug, and Cosmetic Act, as amended by sub-
6 section (a), processes for responding to such requests elec-
7 tronically or in physical form, and factors the Secretary
8 may consider in evaluating whether such records are pro-
9 vided within a reasonable timeframe, within reasonable
10 limits, and in a reasonable manner, accounting for re-
11 source and other limitations that may exist, including for
12 small businesses.

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