

117TH CONGRESS
2D SESSION

S. 4350

To provide for the expedited and duty-free importation of infant formula that may be lawfully marketed in the European Union, Canada, Japan, or the United Kingdom, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 6, 2022

Mrs. GILLIBRAND introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide for the expedited and duty-free importation of infant formula that may be lawfully marketed in the European Union, Canada, Japan, or the United Kingdom, 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 “Emergency Infant For-
5 mula Act”.

6 **SEC. 2. EXPEDITED IMPORTATION OF INFANT FORMULA.**

7 (a) AUTHORIZATION FOR IMPORTATION AND SALE.—

1 (1) DECLARATION OF SHORTAGE.—The Presi-
2 dent may declare, in consultation with the Commis-
3 sioner of Food and Drugs and through Executive
4 order, that a shortage exists in the United States of
5 infant formula with respect to any period specified
6 in such order.

7 (2) AUTHORIZATION FOR IMPORTATION AND
8 SALE.—The President, in consultation with the
9 Commissioner of Food and Drugs, may authorize
10 the importation, distribution, and sale of any cov-
11 ered infant formula, notwithstanding the provisions
12 of the Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 301 et seq.), if the applicable brand, manu-
14 facturer, or manufacturing plant, or the specific in-
15 fant formula product, is included in the Executive
16 order promulgated pursuant to the authority pro-
17 vided by paragraph (1). Such Executive order may
18 further specify, with respect to such authorized
19 products, specific requirements with respect to the
20 labeling or usage guidance to be eligible for importa-
21 tion, distribution, and sale pursuant to the authority
22 provided by this paragraph.

23 (3) LABELING REQUIREMENTS.—

24 (A) EXEMPTION FROM UNITED STATES LA-
25 BELING REQUIREMENTS.—Any provision of the

1 Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 301 et seq.) relating to labeling require-
3 ments for infant formula products imported
4 into the United States shall not apply with re-
5 spect to such products imported pursuant to
6 the authority provided by paragraph (2).

7 (B) REQUIREMENT WITH RESPECT TO
8 FOREIGN MARKETING ELIGIBILITY.—Notwith-
9 standing subparagraph (A), the Commissioner
10 of Food and Drugs shall require any retailer of
11 covered infant formula imported subject to the
12 authority provided by paragraph (2), including
13 an online retailer, to include in an appropriate
14 and conspicuous place next to the product or
15 description of the product, as applicable, a
16 label—

17 (i) that indicates that such product
18 has not been approved for importation, dis-
19 tribution, or sale by the Commissioner of
20 Food and Drugs and is authorized for sale
21 only subject to the provisions of this Act;
22 and

23 (ii) that may additionally indicate the
24 foreign country or countries where such
25 product may be lawfully marketed.

1 (4) TERMINATION OF SHORTAGE.—The Presi-
 2 dent may, upon determining that a shortage no
 3 longer exists in the United States of infant formula,
 4 terminate a declaration described in paragraph (1).

5 (b) DUTY-FREE TREATMENT.—Notwithstanding any
 6 other provision of law, the President may, during any pe-
 7 riod in which an infant formula shortage is declared in
 8 accordance with subsection (a)(1), reduce or suspend any
 9 duties imposed—

10 (1) with respect to the importation of covered
 11 infant formula; or

12 (2) with respect to any other article used in the
 13 production of infant formula that the importer cer-
 14 tifies is being imported for such production.

15 (c) PRIORITY HANDLING OF ENTRIES.—During any
 16 period in which an infant formula shortage is declared in
 17 accordance with subsection (a)(1), the Commissioner of
 18 U.S. Customs and Border Patrol shall give the highest pri-
 19 ority and take any steps as may be necessary to expedite
 20 the processing of all entries of covered infant formula and
 21 articles used in the production of infant formula (as de-
 22 scribed in subsection (b)(2)).

23 (d) COVERED INFANT FORMULA.—In this Act:

24 (1) COVERED INFANT FORMULA.—

(A) IN GENERAL.—Subject to subparagraph (B), the term “covered infant formula” means any infant formula that is lawfully marketed in the European Union, Canada, Japan, the United Kingdom, and any country the President determines to have sufficient health and safety standards with respect to infant formula.

(B) EXCEPTION.—The President may exclude from the definition of “covered infant formula” products that—

(i) are not labeled in English or another language specified by the President;

(ii) do not include instructions for the use of the product which incorporate the imperial system of measurement; or

(iii) include any potential allergen identified by the President.

(2) INFANT FORMULA.—In paragraph (1), the term “infant formula” has the meaning given to such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(e) USE OF DEFENSE PRODUCTION ACT AUTHORITIES.—During any period in which an infant formula shortage is declared in accordance with subsection (a)(1);

1 (1) the President may use authorities provided
2 by the Defense Production Act of 1950 (50 U.S.C.
3 4501 et seq.) in the production of infant formula;
4 and

5 (2) infant formula shall be deemed to meet the
6 criteria specified in section 101(b) of such Act.

7 (f) SUNSET.—This Act shall cease to be effective on
8 the date that is 5 years after the date of enactment of
9 this Act.

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