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.

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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

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# 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.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Emergency Infant Formula Act''.

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

(a) AUTHORIZATION FOR IMPORTATION AND SALE.—

(1) DECLARATION OF SHORTAGE.—The President may declare, in consultation with the Commissioner of Food and Drugs and through Executive order, that a shortage exists in the United States of infant formula with respect to any period specified in such order.

(2) AUTHORIZATION FOR IMPORTATION AND SALE.—The President, in consultation with the Commissioner of Food and Drugs, may authorize the importation, distribution, and sale of any covered infant formula, notwithstanding the provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), if the applicable brand, manufacturer, or manufacturing plant, or the specific infant formula product, is included in the Executive order promulgated pursuant to the authority provided by paragraph (1). Such Executive order may further specify, with respect to such authorized products, specific requirements with respect to the labeling or usage guidance to be eligible for importation, distribution, and sale pursuant to the authority provided by this paragraph.

(3) LABELING REQUIREMENTS.—

(A) EXEMPTION FROM UNITED STATES LABELING REQUIREMENTS.—Any provision of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) relating to labeling requirements for infant formula products imported into the United States shall not apply with respect to such products imported pursuant to the authority provided by paragraph (2).

(B) REQUIREMENT WITH RESPECT TO FOREIGN MARKETING ELIGIBILITY.—Notwithstanding subparagraph (A), the Commissioner of Food and Drugs shall require any retailer of covered infant formula imported subject to the authority provided by paragraph (2), including an online retailer, to include in an appropriate and conspicuous place next to the product or description of the product, as applicable, a label—

(i) that indicates that such product has not been approved for importation, distribution, or sale by the Commissioner of Food and Drugs and is authorized for sale only subject to the provisions of this Act; and

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

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

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

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

(2) with respect to any other article used in the production of infant formula that the importer certifies is being imported for such production.

(c) PRIORITY HANDLING OF ENTRIES.—During any period in which an infant formula shortage is declared in accordance with subsection (a)(1), the Commissioner of U.S. Customs and Border Patrol shall give the highest priority and take any steps as may be necessary to expedite the processing of all entries of covered infant formula and articles used in the production of infant formula (as described in subsection (b)(2)).

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

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

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

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

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