Calendar No. 372

117TH CONGRESS
2D SESSION

S. 4261

To suspend duties and other restrictions on the importation of infant formula to address the shortage of infant formula in the United States, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 19 (legislative day, MAY 17), 2022

Mr. LEE (for himself, Mr. WICKER, Mr. DAINES, Mr. CASSIDY, and Mr. GRASSLEY) introduced the following bill; which was read the first time

MAY 19, 2022

Read the second time and placed on the calendar

A BILL

To suspend duties and other restrictions on the importation of infant formula to address the shortage of infant formula in the United States, 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 ''Fixing Our Regulatory Mayhem Upsetting Little Americans Act'' or the ''FORMULA Act''.

SEC. 2. SUSPENSION OF RESTRICTIONS ON IMPORTATION OF INFANT FORMULA TO ADDRESS SHORTAGE.

(a) DUTY-FREE TREATMENT OF INFANT FORMULA IMPORTED FROM CERTAIN COUNTRIES.—

(1) IN GENERAL.—During the 180-day period beginning on the date of the enactment of this Act, infant formula described in paragraph (2) shall enter the United States free of duty and free of quantitative limitation.

(2) INFANT FORMULA DESCRIBED.—Infant formula is described in this paragraph if the infant formula—

(A) is classified under heading 1901.10 of the Harmonized Tariff Schedule of the United States;

(B) is imported from a country described in paragraph (3); and

(C) was approved by the agency of the government of that country that regulates infant formula.

(3) COUNTRIES DESCRIBED.—A country described in this paragraph is any of the following:

(A) Australia.

(B) Israel.

(C) Japan.

(D) New Zealand.

(E) Switzerland.

(F) South Africa.

(G) The United Kingdom.

(H) A member country of the European Union.

(I) A member country of the European Economic Area.

(b) TEMPORARY EXEMPTIONS FROM FDA REQUIREMENTS.—

(1) IN GENERAL.—With respect to any infant formula introduced or delivered for introduction into interstate commerce pursuant to subsection (a) during the 180-day period beginning on the date of the enactment of this Act—

(A) the requirements under section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) shall not apply;

(B) such infant formula may be manufactured, processed, packed, or held in a domestic or foreign facility that is not registered under section 415 of such Act (21 U.S.C. 350d);

(C) the requirements under parts 106 and 107 of title 21, Code of Federal Regulations, shall not apply; and

(D) such infant formula shall not be considered to be misbranded or adulterated solely on the basis of not being in compliance with the requirements of such section 412 or 415, or such part 106 or 107.

(2) NOTIFICATION REQUIREMENT.—

(A) IN GENERAL.—A person who introduces or delivers for introduction into interstate commerce an infant formula pursuant to subsection (a) shall notify the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') if such person has knowledge which reasonably supports the conclusion that such infant formula—

(i) may not provide the nutrients required by section 412(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(i)); or

(ii) is a product that meets any criterion under section 402(a) of such Act (21 U.S.C. 342(a)), or which otherwise may be unsafe for infant consumption.

(B) KNOWLEDGE DEFINED.—For purposes of subparagraph (A), the term ''knowledge'' as

applied to a person subject to such subparagraph means—

(i) the actual knowledge that the manufacturer had; or

(ii) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

(3) RECALL AUTHORITY.—If the Secretary determines that infant formula introduced or delivered for introduction into interstate commerce pursuant to subsection (a) is a product described in paragraph (2)(A)(ii), the manufacturer or importer shall immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary.

(4) CLARIFICATION.—Section 801(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(j)) shall apply with respect to any infant formula introduced or delivered for introduction into interstate commerce pursuant to subsection (a) during the 180-day period beginning on the date of the enactment of this Act.

(c) SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS, AND CHILDREN.—

(1) ACCESS FOR WIC BENEFICIARIES.—Notwithstanding any other provision of law, any infant formula introduced or delivered for introduction into interstate commerce pursuant to subsection (a) during the 180-day period beginning on the date of enactment of this Act is eligible for purchase using benefits received under the special supplemental nutrition program for women, infants, and children established by section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786).

(2) WAIVERS.—

(A) DEFINITION OF COVERED DOCUMENT.—In this paragraph, the term ''covered document'' means the attachment entitled ''Process for State Agency Waiver Requests Related to Shortages'' to the letter of the Secretary of Agriculture dated February 18, 2022, entitled ''Voluntary Recall of Certain Abbott Powder Formulas, including Similac, Alimentum and EleCare''.

(B) WAIVERS.—During the 180-day period beginning on the date of enactment of this Act, the Secretary of Agriculture may grant any

waiver described in the covered document, including with respect to the exchange or issuance, as applicable, of infant formula introduced or delivered for introduction into interstate commerce pursuant to subsection (a).

(d) LIST OF IMPORTED INFANT FORMULA.—The Secretary of Agriculture, in conjunction with the Secretary of Health and Human Services, shall—

(1) maintain a list of all infant formula introduced or delivered for introduction into interstate commerce pursuant to subsection (a) during the 180-day period beginning on the date of enactment of this Act, which shall include, for each infant formula—

(A) the country of origin;

(B) the recommended measurements for mixing or otherwise preparing the infant formula; and

(C) the approved use and marketing status of the infant formula in the country of origin according to the applicable government entity that regulates infant formula in that country; and

(2) make the list maintained under paragraph (1) publicly available on the websites of each of the

Department of Agriculture and the Food and Drug Administration.

(e) INFANT FORMULA DEFINED.—In this section, the term ''infant formula'' has the meaning given that term in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)).

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