

117TH CONGRESS
2D SESSION

S. 4262

To temporarily allow the importation of infant formula free of duty and free of quantitative limitation, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 19 (legislative day, MAY 17), 2022

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

A BILL

To temporarily allow the importation of infant formula free of duty and free of quantitative limitation, 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 “Formula Act of 2022”.

5 **SEC. 2. INCREASING THE SUPPLY OF INFANT FORMULA.**

6 (a) IN GENERAL.—During the 180 day period begin-
7 ning on the date of the enactment of this Act, infant for-
8 mula classified under heading 1901.10 of the Harmonized
9 Tariff Schedule of the United States shall enter the

1 United States free of duty and free of quantitative limita-
 2 tion, if such formula—

3 (1) is imported from a country on the list pub-
 4 lished by the Secretary of Health and Human Serv-
 5 ices under subsection (c)(1) or a member country of
 6 the European Union; and

7 (2) is lawfully marketed in the country of ori-
 8 gin.

9 (b) GUIDANCE.—

10 (1) IN GENERAL.—The Secretary of Health and
 11 Human Services (referred to in this subsection and
 12 in subsection (c) as the “Secretary”) shall, not later
 13 than 7 days after the date of enactment of this Act,
 14 issue, and periodically update, as appropriate, guid-
 15 ance for domestic and foreign manufacturers of in-
 16 fant formula in order to increase availability of such
 17 formula in the United States that is safe and nutri-
 18 tionally adequate.

19 (2) ELEMENTS OF THE GUIDANCE.—The guid-
 20 ance under paragraph (1) shall address the fol-
 21 lowing:

22 (A) Information to be submitted to the
 23 Secretary by foreign and domestic manufactur-
 24 ers of infant formula for consideration with re-
 25 gard to the introduction into interstate com-

merce (including importation) of infant formula that is safe and nutritionally adequate but that may not comply with all applicable statutory and regulatory requirements. Such information shall include—

(i) safety and nutritional adequacy of the infant formula;

(ii) product identification information;

(iii) the quantity of the infant formula intended for introduction into interstate commerce;

(iv) a copy of the label for the infant formula (with information on any allergens present on the product label and adequate instructions for safe product preparation and use) and description of the packaging of the infant formula; and

(v) manufacturing information, including test results, and facility compliance and inspection history.

(B) Information for manufacturers planning to increase domestic production of infant formula for purposes of addressing the ongoing shortage.

1 (3) PRIORITY.—The guidance under paragraph
2 (1) shall provide for priority consideration for manu-
3 facturers that are able to produce large volumes of
4 such infant formula quickly.

5 (c) IMPORTATION FROM COUNTRIES MEETING CER-
6 TAIN STANDARDS.—

7 (1) IN GENERAL.—Not later than 7 days after
8 the date of enactment of this Act, the Secretary
9 shall publish a list of countries the Secretary deter-
10 mines to have manufacturing and safety standards
11 for infant formula that are similar, equivalent, or
12 otherwise suitable, as compared to United States
13 standards.

14 (2) PERSONAL AND COMMERCIAL IMPORTA-
15 TION.—Beginning on the date on which the list of
16 countries is published under paragraph (1), for a pe-
17 riod not to exceed 180 days, the Secretary shall
18 allow personal and commercial importation of infant
19 formula from any country on such list, as well as
20 from any member country of the European Union,
21 without regard to the guidance under subsection
22 (b)(2) and the requirements of section 412 of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 350a), section 415 of such Act (21 U.S.C. 350d),

1 and parts 106 and 107 of title 21, Code of Federal
2 Regulations.

3 (d) DEFINITION.—In this section, the term “infant
4 formula” has the meaning given such term in section
5 201(z) of the Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 321(z)).

7 **SEC. 3. SPECIAL SUPPLEMENTAL NUTRITION PROGRAM**
8 **FOR WOMEN, INFANTS, AND CHILDREN.**

9 (a) ACCESS FOR WIC BENEFICIARIES.—Notwith-
10 standing any other provision of law, any infant formula
11 (as defined in section 2(d)) imported into the United
12 States pursuant to section 2(c)(2) is eligible for purchase
13 using benefits received under the special supplemental nu-
14 trition program for women, infants, and children estab-
15 lished by section 17 of the Child Nutrition Act of 1966
16 (42 U.S.C. 1786).

17 (b) PRODUCT RECALLS AND SUPPLY CHAIN DISRUP-
18 TIONS.—Section 17 of the Child Nutrition Act of 1966
19 (42 U.S.C. 1786) is amended—

20 (1) in subsection (b), by adding at the end the
21 following:

22 “(24) SUPPLY CHAIN DISRUPTION.—The term
23 ‘supply chain disruption’ means a shortage of sup-
24 plemental foods that impedes the redemption of food
25 instruments, as determined by the Secretary.”; and

1 (2) by adding at the end the following:

2 “(r) PRODUCT RECALLS AND SUPPLY CHAIN DIS-
3 RUPTIONS.—

4 “(1) DEFINITION OF QUALIFIED ADMINISTRA-
5 TIVE REQUIREMENT.—In this subsection, the term
6 ‘qualified administrative requirement’ means—

7 “(A) a requirement under this section; and

8 “(B) any regulatory requirement promul-
9 gated pursuant to this section.

10 “(2) MODIFICATION OR WAIVER OF REQUIRE-
11 MENTS.—Notwithstanding any other provision of
12 law, the Secretary shall modify or waive a qualified
13 administrative requirement to allow 1 or more State
14 agencies—

15 “(A) to permit vendors authorized to par-
16 ticipate in the program under this section to ex-
17 change or substitute authorized supplemental
18 foods obtained with food instruments with food
19 items that are not identical (including in brand
20 and size);

21 “(B) to modify or waive any requirement
22 with respect to medical documentation for the
23 issuance of noncontract brand infant formula,
24 except the requirements for participants receiv-
25 ing Food Package III (as defined in section

1 246.10(e)(3) of title 7, Code of Federal Regula-
2 tions (as in effect on the date of enactment of
3 this subsection));

4 “(C) to modify or waive the maximum
5 monthly allowance for infant formula;

6 “(D) to modify or waive any additional re-
7 quirement with respect to supplemental food
8 products provided under the program under
9 this section if the modification or waiver—

10 “(i) may facilitate increased access to
11 those products;

12 “(ii) does not substantially weaken the
13 nutritional quality of those products; and

14 “(iii) is in accordance with any appli-
15 cable guidance or directive from the Ad-
16 ministrator of Food and Drugs determined
17 to be applicable by the Secretary.

18 “(3) DURATION.—A modification or waiver
19 under paragraph (2)—

20 “(A) shall be available for a period of not
21 more than 180 days beginning on the date of
22 enactment of this subsection; and

23 “(B) may be renewed, subject to the condi-
24 tion that the Secretary shall provide notice of

- 1 the renewal not less than 15 days before the re-
- 2 newal shall take effect.”.

