

#### 117TH CONGRESS 2D SESSION

# H. R. 7808

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 HOUSE OF REPRESENTATIVES

May 17, 2022

Mr. Stewart introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, and Education and Labor, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

## 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.

- 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 "Fixing Our Regulatory
- 5 Mayhem Upsetting Little Americans Act" or the "FOR-
- 6 MULA Act".

1	SEC. 2. SUSPENSION OF RESTRICTIONS ON IMPORTATION
2	OF INFANT FORMULA TO ADDRESS SHORT-
3	AGE.
4	(a) DUTY-FREE TREATMENT OF INFANT FORMULA
5	IMPORTED FROM CERTAIN COUNTRIES.—
6	(1) In general.—During the 180-day period
7	beginning on the date of the enactment of this Act,
8	infant formula described in paragraph (2) shall
9	enter the United States free of duty and free of
10	quantitative limitation.
11	(2) Infant formula described.—Infant for-
12	mula is described in this paragraph if the infant for-
13	mula—
14	(A) is classified under heading 1901.10 of
15	the Harmonized Tariff Schedule of the United
16	States;
17	(B) is imported from a country described
18	in paragraph (3); and
19	(C) was approved by the agency of the gov-
20	ernment of that country that regulates infant
21	formula.
22	(3) Countries described.—A country de-
23	scribed in this paragraph is any of the following:
24	(A) Australia.
25	(B) Israel.
26	(C) Japan.

1	(D) New Zealand.
2	(E) Switzerland.
3	(F) South Africa.
4	(G) The United Kingdom.
5	(H) A member country of the European
6	Union.
7	(I) A member country of the European
8	Economic Area.
9	(b) Temporary Exemptions From FDA Require-
10	MENTS.—
11	(1) In general.—With respect to any infant
12	formula introduced or delivered for introduction into
13	interstate commerce pursuant to subsection (a) dur-
14	ing the 180-day period beginning on the date of the
15	enactment of this Act—
16	(A) the requirements under section 412 of
17	the Federal Food, Drug, and Cosmetic Act (21
18	U.S.C. 350a) shall not apply;
19	(B) such infant formula may be manufac-
20	tured, processed, packed, or held in a domestic
21	or foreign facility that is not registered under
22	section 415 of such Act (21 U.S.C. 350d);
23	(C) the requirements under parts 106 and
24	107 of title 21, Code of Federal Regulations,
25	shall not apply; and

1	(D) such infant formula shall not be con-
2	sidered to be misbranded or adulterated solely
3	on the basis of not being in compliance with the
4	requirements of such section 412 or 415, or
5	such part 106 or 107.
6	(2) Notification requirement.—
7	(A) In general.—A person who intro-
8	duces or delivers for introduction into interstate
9	commerce an infant formula pursuant to sub-
10	section (a) shall notify the Secretary of Health
11	and Human Services (referred to in this sub-
12	section as the "Secretary") if such person has
13	knowledge which reasonably supports the con-
14	clusion that such infant formula—
15	(i) may not provide the nutrients re-
16	quired by section 412(i) of the Federal
17	Food, Drug, and Cosmetic Act (21 U.S.C.
18	350a(i)); or
19	(ii) is a product that meets any cri-
20	terion under section 402(a) of such Act
21	(21 U.S.C. 342(a)), or which otherwise
22	may be unsafe for infant consumption.
23	(B) Knowledge defined.—For purposes
24	of subparagraph (A), the term "knowledge" as

1	applied to a person subject to such subpara-
2	graph means—
3	(i) the actual knowledge that the man-
4	ufacturer had; or
5	(ii) the knowledge which a reasonable
6	person would have had under like cir-
7	cumstances or which would have been ob-
8	tained upon the exercise of due care.
9	(3) Recall Authority.—If the Secretary de-
10	termines that infant formula introduced or delivered
11	for introduction into interstate commerce pursuant
12	to subsection (a) is a product described in paragraph
13	(2)(A)(ii), the manufacturer or importer shall imme-
14	diately take all actions necessary to recall shipments
15	of such infant formula from all wholesale and retail
16	establishments, consistent with recall regulations
17	and guidelines issued by the Secretary.
18	(4) Clarification.—Section 801(j) of the
19	Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20	381(j)) shall apply with respect to any infant for-
21	mula introduced or delivered for introduction into

interstate commerce pursuant to subsection (a) dur-

ing the 180-day period beginning on the date of the

enactment of this Act.

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1 (c) Special Supplemental Nutrition Program
2 for Women, Infants, and Children.—
3 (1) Access for wic beneficiaries.—Not4 withstanding 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 es-

tablished by section 17 of the Child Nutrition Act of 12 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

1	waiver described in the covered document, in-
2	cluding with respect to the exchange or
3	issuance, as applicable, of infant formula intro-
4	duced or delivered for introduction into inter-
5	state commerce pursuant to subsection (a).
6	(d) List of Imported Infant Formula.—The
7	Secretary of Agriculture shall—
8	(1) maintain a list of all infant formula intro-
9	duced or delivered for introduction into interstate
10	commerce pursuant to subsection (a) during the
11	180-day period beginning on the date of enactment
12	of this Act, which shall include, for each infant for-
13	mula—
14	(A) the country of origin;
14 15	<ul><li>(A) the country of origin;</li><li>(B) the recommended measurements for</li></ul>
	· · · · · · · · · · · · · · · · · · ·
15	(B) the recommended measurements for
15 16	(B) the recommended measurements for mixing or otherwise preparing the infant for-
15 16 17	(B) the recommended measurements for mixing or otherwise preparing the infant formula; and
15 16 17 18	<ul><li>(B) the recommended measurements for mixing or otherwise preparing the infant formula; and</li><li>(C) the approved use and marketing status</li></ul>
15 16 17 18	<ul> <li>(B) the recommended measurements for mixing or otherwise preparing the infant formula; and</li> <li>(C) the approved use and marketing status of the infant formula in the country of origin</li> </ul>
115 116 117 118 119 220	<ul> <li>(B) the recommended measurements for mixing or otherwise preparing the infant formula; and</li> <li>(C) the approved use and marketing status of the infant formula in the country of origin according to the applicable government entity</li> </ul>
115 116 117 118 119 220 221	<ul> <li>(B) the recommended measurements for mixing or otherwise preparing the infant formula; and</li> <li>(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;</li> </ul>

- 1 Department of Agriculture and the Food and Drug
- 2 Administration.
- 3 (e) Infant Formula Defined.—In this section,
- 4 the term "infant formula" has the meaning given that
- 5 term in section 201(z) of the Federal Food, Drug, and
- 6 Cosmetic Act (21 U.S.C. 321(z)).

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