

117TH CONGRESS
2D SESSION

S. 4257

To amend the Child Nutrition Act of 1966 to establish requirements for infant formula cost containment contracts, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 18 (legislative day, MAY 17), 2022

Ms. STABENOW (for herself, Mr. BOOZMAN, Mr. LEAHY, Mr. HOEVEN, Mr. BROWN, Mr. MARSHALL, Ms. KLOBUCHAR, Mrs. CAPITO, Mr. BENNET, Mr. TILLIS, Mrs. GILLIBRAND, Ms. COLLINS, Ms. SMITH, Mr. GRASSLEY, Mr. BOOKER, Mrs. FISCHER, Mr. WARNOCK, Mr. CORNYN, Mr. CASEY, Mr. LUJÁN, Mr. DURBIN, Ms. HASSAN, Ms. DUCKWORTH, and Mr. KELLY) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To amend the Child Nutrition Act of 1966 to establish requirements for infant formula cost containment contracts, 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 “Access to Baby For-
5 mula Act of 2022”.

1 **SEC. 2. INFANT FORMULA REQUIREMENTS.**

2 Section 17 of the Child Nutrition Act of 1966 (42
3 U.S.C. 1786) is amended—

4 (1) in subsection (b), by adding at the end the
5 following:

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

10 (2) in subsection (h)(8), by adding at the end
11 the following:

12 “(L) INFANT FORMULA COST CONTAIN-
13 MENT CONTRACT REQUIREMENTS.—

14 “(i) IN GENERAL.—Not later than
15 120 days after the date of enactment of
16 this subparagraph, the Secretary shall
17 issue an interim final rule to require that
18 each infant formula cost containment con-
19 tract entered into between a State and an
20 infant formula manufacturer on or after
21 the effective date of the interim final rule
22 includes remedies in the event of an infant
23 formula recall, including how an infant for-
24 mula manufacturer will protect against dis-
25 ruption to program participants in the
26 State.

1 “(ii) REBATES.—In the case of an in-
 2 fant formula recall, an infant formula
 3 manufacturer contracted to provide infant
 4 formula under this section shall comply
 5 with the contract requirements under
 6 clause (i).

7 “(iii) REGULATIONS.—The Secretary
 8 shall promulgate regulations to carry out
 9 this subparagraph—

10 “(I) pursuant to section 808(2)
 11 of title 5, United States Code; and

12 “(II) that shall be carried out
 13 without regard to chapter 35 of title
 14 44, United States Code (commonly
 15 known as the ‘Paperwork Reduction
 16 Act’).

17 “(M) MEMORANDUM OF UNDER-
 18 STANDING.—Not later than 30 days after the
 19 date of enactment of this subparagraph, the
 20 Secretary shall ensure that there is a memo-
 21 randum of understanding that establishes pro-
 22 cedures to promote coordination and informa-
 23 tion sharing between the Department of Agri-
 24 culture and the Department of Health and
 25 Human Services regarding any supply chain

1 disruption, including a supplemental food re-
 2 call.”; and

3 (3) by adding at the end the following:

4 “(r) EMERGENCIES AND DISASTERS.—

5 “(1) DEFINITIONS.—In this subsection:

6 “(A) EMERGENCY PERIOD.—The term
 7 ‘emergency period’ means a period during which
 8 there is—

9 “(i) a public health emergency de-
 10 clared by the Secretary of Health and
 11 Human Services under section 319 of the
 12 Public Health Service Act (42 U.S.C.
 13 247d);

14 “(ii) a renewal of a public health
 15 emergency described in clause (i) pursuant
 16 to section 319 of that Act (42 U.S.C.
 17 247d);

18 “(iii) a major disaster declared by the
 19 President under section 401 of the Robert
 20 T. Stafford Disaster Relief and Emergency
 21 Assistance Act (42 U.S.C. 5170); or

22 “(iv) an emergency declared by the
 23 President under section 501 of the Robert
 24 T. Stafford Disaster Relief and Emergency
 25 Assistance Act (42 U.S.C. 5191).

“(B) QUALIFIED ADMINISTRATIVE REQUIREMENT.—The term ‘qualified administrative requirement’ means—

“(i) a requirement under this section;
and

“(ii) any regulatory requirement promulgated pursuant to this section.

“(2) MODIFICATION OR WAIVER OF REQUIREMENTS.—Notwithstanding any other provision of law, during an emergency period, the Secretary may modify or waive any qualified administrative requirement for a State agency if—

“(A) the qualified administrative requirement cannot be met by the State agency during any portion of the emergency period due to the conditions that prompted the emergency period;
and

“(B) the modification or waiver of the qualified administrative requirement—

“(i) is necessary to provide assistance to participants of the program established by this section; and

“(ii) does not substantially weaken the nutritional quality of supplemental foods provided under the program.

1 “(3) DURATION.—A modification or waiver
 2 under paragraph (2) shall be in effect for a period
 3 determined by the Secretary, but not later than 60
 4 days after the end of the applicable emergency pe-
 5 riod.

6 “(s) PRODUCT RECALLS AND SUPPLY CHAIN DIS-
 7 RUPTIONS.—

8 “(1) DEFINITION OF QUALIFIED ADMINISTRA-
 9 TIVE REQUIREMENT.—In this subsection, the term
 10 ‘qualified administrative requirement’ has the mean-
 11 ing given the term in subsection (r)(1).

12 “(2) MODIFICATION OR WAIVER OF REQUIRE-
 13 MENTS.—Notwithstanding any other provision of
 14 law, in order to address a supplemental food product
 15 recall or supply chain disruption, the Secretary may
 16 modify or waive a qualified administrative require-
 17 ment to allow 1 or more State agencies—

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

24 “(B) to modify or waive any requirement
 25 with respect to medical documentation for the

1 issuance of noncontract brand infant formula,
 2 except the requirements for participants receiv-
 3 ing Food Package III (as defined in section
 4 246.10(e)(3) of title 7, Code of Federal Regula-
 5 tions (as in effect on the date of enactment of
 6 this subsection));

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

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

13 “(i) may facilitate increased access to
 14 those products;

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

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

21 “(3) DURATION.—A modification or waiver
 22 under paragraph (2)—

23 “(A) may be—

1 “(i) available for a period of not more
2 than 45 days, to begin on a date deter-
3 mined by the Secretary; and

4 “(ii) renewed, subject to the condition
5 that the Secretary shall provide notice of
6 the renewal not less than 15 days before
7 the renewal shall take effect; and

8 “(B) shall not be available after the date
9 that is 60 days after the supplemental food
10 product recall or supply chain disruption for
11 which the modification or waiver is established
12 ceases to exist.”.

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