117TII CONGRESS 2D Session

> 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

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, and Mr. LUJÁN) introduced the following bill; which was read twice and referred to the Committee on ______

+ Durbin + Hassan + Duckworth

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 For5 mula Act of 2022".

6 SEC. 2. INFANT FORMULA REQUIREMENTS.

7 Section 17 of the Child Nutrition Act of 1966 (42

8 U.S.C. 1786) is amended—

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1	(1) in subsection (b), by adding at the end the
2	following:
3	"(24) SUPPLY CHAIN DISRUPTION.—The term
4	'supply chain disruption' means a shortage of sup-
5	plemental foods that impedes the redemption of food
6	instruments, as determined by the Secretary.";
7	(2) in subsection $(h)(8)$, by adding at the end
8	the following:
9	"(L) INFANT FORMULA COST CONTAIN-
10	MENT CONTRACT REQUIREMENTS.—
11	"(i) IN GENERALNot later than
12	120 days after the date of enactment of
13	this subparagraph, the Secretary shall
14	issue an interim final rule to require that
15	each infant formula cost containment con-
16	tract entered into between a State and an
17	infant formula manufacturer on or after
18	the effective date of the interim final rule
19	includes remedies in the event of an infant
20	formula recall, including how an infant for-
21	mula manufacturer will protect against dis-
22	ruption to program participants in the
23	State.
24	"(ii) REBATES.—In the case of an in-
25	fant formula recall, an infant formula

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1	manufacturer contracted to provide infant
2	formula under this section shall comply
3	with the contract requirements under
4	clause (i).
5	"(iii) REGULATIONS.—The Secretary
6	shall promulgate regulations to carry out
7	this subparagraph—
8	"(I) pursuant to section 808(2)
9	of title 5, United States Code; and
10	"(II) that shall be carried out
11	without regard to chapter 35 of title
12	44, United States Code (commonly
13	known as the 'Paperwork Reduction
14	Act').
15	"(M) MEMORANDUM OF UNDER-
16	STANDING.—Not later than 30 days after the
17	date of enactment of this subparagraph, the
18	Secretary shall ensure that there is a memo-
19	randum of understanding that establishes pro-
20	cedures to promote coordination and informa-
21	tion sharing between the Department of Agri-
22	culture and the Department of Health and
23	Human Services regarding any supply chain
24	disruption, including a supplemental food re-
25	call."; and

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1	(3) by adding at the end the following:
2	"(r) Emergencies and Disasters.—
3	"(1) DEFINITIONS.—In this subsection:
4	"(A) Emergency period.—The term
5	'emergency period' means a period during which
6	there is—
7	"(i) a public health emergency de-
8	clared by the Secretary of Health and
9	Human Services under section 319 of the
10	Public Health Service Act (42 U.S.C.
11	247d);
12	"(ii) a renewal of a public health
13	emergency described in clause (i) pursuant
14	to section 319 of that Act (42 U.S.C.
15	247d);
16	"(iii) a major disaster declared by the
17	President under section 401 of the Robert
18	T. Stafford Disaster Relief and Emergency
19	Assistance Act (42 U.S.C. 5170); or
20	"(iv) an emergency declared by the
21	President under section 501 of the Robert
22	T. Stafford Disaster Relief and Emergency
23	Assistance Act (42 U.S.C. 5191).

ELT22283 3D2

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1	"(B) QUALIFIED ADMINISTRATIVE RE-
2	QUIREMENT.—The term 'qualified administra-
3	tive requirement' means—
4	"(i) a requirement under this section;
5	and
6	"(ii) any regulatory requirement pro-
7	mulgated pursuant to this section.
8	"(2) MODIFICATION OR WAIVER OF REQUIRE-
9	MENTS.—Notwithstanding any other provision of
10	law, during an emergency period, the Secretary may
11	modify or waive any qualified administrative require-
12	ment for a State agency if—
13	"(A) the qualified administrative require-
14	ment cannot be met by the State agency during
15	any portion of the emergency period due to the
16	conditions that prompted the emergency period;
17	and
18	"(B) the modification or waiver of the
19	qualified administrative requirement—
20	"(i) is necessary to provide assistance
21	to participants of the program established
22	by this section; and
23	"(ii) does not substantially weaken the
24	nutritional quality of supplemental foods
25	provided under the program.

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

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

8 "(1) DEFINITION OF QUALIFIED ADMINISTRA9 TIVE REQUIREMENT.—In this subsection, the term
10 'qualified administrative requirement' has the mean11 ing given the term in subsection (r)(1).

12 "(2) MODIFICATION OR WAIVER OF REQUIRE13 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 require17 ment to allow 1 or more State agencies—

18 "(A) to permit vendors authorized to par19 ticipate in the program under this section to ex20 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 requirement25 with respect to medical documentation for the

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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—

ELT22283 3D2

8

"(i) available for a period of not more 1 2 than 45 days, to begin on a date deter-3 mined by the Secretary; and "(ii) renewed, subject to the condition 4 5 that the Secretary shall provide notice of 6 the renewal not less than 15 days before 7 the renewal shall take effect; and "(B) shall not be available after the date 8 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.".