II

118TH CONGRESS
2D SESSION

S. 4436

To improve the safety of infant formula through testing of infant formula for microorganisms and toxic elements, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 3, 2024

Mr. PETERS (for himself and Mr. HOEVEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To improve the safety of infant formula through testing of infant formula for microorganisms and toxic elements, 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 ''Protect Infant Formula from Contamination Act''.

SEC. 2. MANDATING TESTING OF INFANT FORMULA.

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(e)) is amended—

(1) in paragraph (1), in the matter following subparagraph (B)—

(A) by striking ''promptly'';

(B) by inserting '', within 24 hours of acquiring such knowledge'' after ''such knowledge''; and

(C) by striking ''the infant formula'' and inserting ''an infant formula'';

(2) by redesignating paragraph (2) as paragraph (5);

(3) in paragraph (5), as so redesignated, by striking ''paragraph (1)'' and inserting ''paragraphs (1) and (2)''; and

(4) by inserting after paragraph (1) the following:

''(2) If the result of any testing of a sample from any production aggregate of finished infant formula product is confirmed as a positive analytical result for any microorganism for which finished product testing is required under section 106.55(e) of title 21, Code of Federal Regulations (or any successor regulation), the manufacturer shall—

''(A) within 24 hours of acquiring a confirmed positive analytical result, notify the Secretary of such knowledge, regardless of whether such product

has left an establishment subject to the control of the manufacturer;

''(B) promptly consult with the Secretary for proper isolation of the affected product, and, as the Secretary may require, cease distribution and properly dispose of the affected product; and

''(C) promptly provide to the Secretary results and isolates from a positive sample of such product.

''(3) Not later than 72 hours after receipt by the Secretary of a notification under paragraph (2)(A), the Secretary shall respond to the manufacturer of the infant formula to begin discussions regarding investigation and corrective action, and, as appropriate, share the findings of the Secretary with the manufacturer.

''(4) Not later than 90 days after receipt of a notification under paragraph (1) or (2), the Secretary shall confirm, including through the collection of documentation, that the manufacturer submitting the notification performed, or is performing, an appropriate investigation and corrective action, if applicable. The Secretary shall consider, as part of the review of the root cause investigation, the analytical method used to conduct laboratory testing and, as appropriate, the potential for cross contamination of the sample by handling and testing. The manufacturer shall make such documentation available to the Secretary

electronically or by other means, if requested by the Secretary.''.

SEC. 3. REPORTING TO IMPROVE THE SAFETY AND SUPPLY OF INFANT FORMULA.

Section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) is amended by adding at the end the following:

''(n) REPORTING TO IMPROVE THE SAFETY AND SUPPLY OF INFANT FORMULA.—

''(1) PROGRESS REPORT.—Not later than 180 days after the date of enactment of the Protect Infant Formula from Contamination Act, the Secretary shall issue a progress report on implementation of the recommendations to improve the safety and supply of infant formula contained in the report titled, 'Immediate National Strategy to Increase the Resiliency of the U.S. Infant Formula Market', issued by the Food and Drug Administration in March 2023. Such progress report shall include additional authorities or resources that the Secretary may require for purposes of improving the safety and supply of infant formula.

''(2) QUARTERLY REPORTS ON SUPPLY CHAIN.—Not later than 270 days after the date of enactment of the Protect Infant Formula from Con-

tamination Act, and not less frequently than quarterly for the 5-year period thereafter, the Secretary shall submit a report on the most current, critical supply chain data for infant formula, including in-stock rates, to—

"(A) the Committee on Health, Education, Labor, and Pensions; the Committee on Agriculture, Nutrition, and Forestry; and the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the Committee on Appropriations of the Senate; and

"(B) the Committee on Energy and Commerce; the Committee on Agriculture; and the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the Committee on Appropriations of the House of Representatives.

"(3) CONSULTATION.—The Secretary, in accordance with the National Strategy set forth in the report described in paragraph (1), shall engage with the Department of Agriculture and other relevant agencies of the Federal Government regarding ongoing efforts to address immediate formula needs and

build long-term resiliency into the infant formula market.

''(4) ANNUAL REPORTS ON ADEQUACY OF SUPPLY.—Not later than 270 days after the date of enactment of the Protect Infant Formula from Contamination Act, and not less frequently than annually for the 5-year period thereafter, the Secretary shall—

''(A) engage with infant formula manufacturers to determine evidence-based practices that can be implemented to maximize infant formula supply and infant safety, including the value of high frequency testing in identifying contamination events and bracketing potentially contaminated product, the impact of corrective action on contamination events, and evidence-based recommendations for enhancing infant formula supply and safety; and

''(B) submit a report to the committees described in subparagraphs (A) and (B) of paragraph (2) that identifies the modifications to manufacturer practices and actions described in subparagraph (A), if any, that could be imple-

mented to improve infant formula supply and safety.''.

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