AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—118th Cong., 2d Sess.

S. 4436

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Protect Infant Formula from Contamination Act''.

SEC. 2. NOTIFICATIONS FOR 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 1 business day 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); and

(3) 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 1 business day of acquiring a confirmed positive analytical result, notify the Secretary of such result, 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 or the whole genetic sequence from any confirmed positive analytical result.

''(3) Not later than 1 business day 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 and for inspection under section 704.''.

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 Contamination 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 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) REPORTS ON ADEQUACY OF SUPPLY.—Not later than 1 year, 3 years, and 5 years after the date of enactment of the Protect Infant Formula from Contamination Act, the Secretary shall—

"(A) engage with public stakeholders, infant formula manufacturers, and other stakeholders, as determined by the Secretary, to determine evidence-based practices that can be implemented to maximize infant formula supply and infant safety, which may include the value of high frequency testing for purposes of 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 implemented to improve infant formula supply and safety.".