

AMENDMENT NO._____

Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—119th Cong., 2d Sess.**S.272**

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:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Protect Infant For-
5 mula from Contamination Act”.

6 **SEC. 2. NOTIFICATIONS FOR TESTING OF INFANT FOR-
7 MULA.**

8 Section 412(e) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 350a(e)) is amended—

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

5 (C) by striking “the infant formula” and
6 inserting “an infant formula”;

7 (2) by redesignating paragraph (2) as para-
8 graph (5); and

11 “(2) If the result of any testing of a sample from
12 any production aggregate of finished infant formula prod-
13 uct is confirmed as a positive analytical result for any
14 microorganism for which finished product testing is re-
15 quired under section 106.55(e) of title 21, Code of Federal
16 Regulations (or any successor regulation), the manufac-
17 turer shall—

18 “(A) within 1 business day of acquiring a con-
19 firmed positive analytical result, notify the Secretary
20 of such result, regardless of whether such product
21 has left an establishment subject to the control of
22 the manufacturer;

23 “(B) promptly consult with the Secretary for
24 proper isolation of the affected product, and, as the

1 Secretary may require, cease distribution and prop-
2 erly dispose of the affected product; and

3 “(C) promptly provide to the Secretary results
4 and isolates from a positive sample of such product
5 or the whole genome sequence data from any con-
6 firmed positive analytical result.

7 “(3) Not later than 1 business day after receipt by
8 the Secretary of a notification under paragraph (2)(A),
9 the Secretary shall respond to the manufacturer of the in-
10 fant formula to begin discussions regarding investigation
11 and corrective action, and, as appropriate, share the find-
12 ings of the Secretary with the manufacturer.

13 “(4) Not later than 90 days after receipt of a notifi-
14 cation under paragraph (1) or (2), the Secretary shall con-
15 firm, including through the collection of documentation,
16 that the manufacturer submitting the notification per-
17 formed, or is performing, an appropriate investigation and
18 corrective action, if applicable. The Secretary shall con-
19 sider, as part of the review of the root cause investigation,
20 the analytical method used to conduct laboratory testing
21 and, as appropriate, the potential for cross contamination
22 of the sample by handling and testing. The manufacturer
23 shall make such documentation available to the Secretary
24 electronically and for inspection under section 704.”.

1 SEC. 3. REPORTING TO IMPROVE THE SAFETY AND SUPPLY**2 OF INFANT FORMULA.**

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

6 “(n) REPORTING TO IMPROVE THE SAFETY AND
7 SUPPLY OF INFANT FORMULA.—

8 “(1) PROGRESS REPORT.—Not later than 180
9 days after the date of enactment of the Protect In-
10 fant Formula from Contamination Act, the Sec-
11 retary shall issue a progress report on implemen-
12 tation of the recommendations to improve the safety
13 and supply of infant formula contained in the report
14 titled, ‘Long-Term National Strategy to Increase the
15 Resiliency of the U.S. Infant Formula Market’,
16 issued by the Food and Drug Administration in Jan-
17 uary 2025. Such progress report shall include addi-
18 tional authorities or resources that the Secretary
19 may require for purposes of improving the safety
20 and supply of infant formula and any revisions to
21 the recommendations as a result of any infant for-
22 mula recalls since the publication of the report, as
23 appropriate.

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

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

6 “(A) the Committee on Health, Education,
7 Labor, and Pensions; the Committee on Agriculture,
8 Nutrition, and Forestry; and the Sub-
9 committee on Agriculture, Rural Development,
10 Food and Drug Administration, and Related
11 Agencies of the Committee on Appropriations of
12 the Senate; and

13 “(B) the Committee on Energy and Com-
14 merce; the Committee on Agriculture; and the
15 Subcommittee on Agriculture, Rural Develop-
16 ment, Food and Drug Administration, and Re-
17 lated Agencies of the Committee on Appropria-
18 tions of the House of Representatives.

19 “(3) CONSULTATION.—The Secretary shall en-
20 gage with the Department of Agriculture and other
21 relevant agencies of the Federal Government regard-
22 ing ongoing efforts to address immediate formula
23 needs and build long-term resiliency into the infant
24 formula market.

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

5 “(A) engage with public stakeholders, in-
6 fant formula manufacturers, and other stake-
7 holders, as determined by the Secretary, to de-
8 termine evidence-based practices that can be
9 implemented to maximize infant formula supply
10 and infant safety, which may include the value
11 of high frequency testing for purposes of identi-
12 fying contamination events, including events as-
13 sociated with botulism or other contaminants,
14 and bracketing potentially contaminated prod-
15 uct, the impact of corrective action on contami-
16 nation events, including events associated with
17 botulism or other contaminants, and evidence-
18 based recommendations for enhancing infant
19 formula supply and safety; and

20 “(B) submit a report to the committees de-
21 scribed in subparagraphs (A) and (B) of para-
22 graph (2) that identifies the modifications to
23 manufacturer practices and actions described in
24 subparagraph (A), if any, that could be imple-

1 mented to improve infant formula supply and
2 safety.”.