

119TH CONGRESS  
2D SESSION

# S. 272

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## AN ACT

To improve the safety of infant formula through testing of infant formula for microorganisms, 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,*

1 **SECTION 1. SHORT TITLE.**

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

4 **SEC. 2. NOTIFICATIONS FOR TESTING OF INFANT FOR-**  
5 **MULA.**

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

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

10 (A) by striking “promptly”;

11 (B) by inserting “, within 1 business day  
12 of acquiring such knowledge” after “such  
13 knowledge”; and

14 (C) by striking “the infant formula” and  
15 inserting “an infant formula”;

16 (2) by redesignating paragraph (2) as para-  
17 graph (5); and

18 (3) by inserting after paragraph (1) the fol-  
19 lowing:

20 “(2) If the result of any testing of a sample from  
21 any production aggregate of finished infant formula prod-  
22 uct is confirmed as a positive analytical result for any  
23 microorganism for which finished product testing is re-  
24 quired under section 106.55(e) of title 21, Code of Federal  
25 Regulations (or any successor regulation), the manufac-  
26 turer shall—

1           “(A) within 1 business day of acquiring a con-  
2           firmed positive analytical result, notify the Secretary  
3           of such result, regardless of whether such product  
4           has left an establishment subject to the control of  
5           the manufacturer;

6           “(B) promptly consult with the Secretary for  
7           proper isolation of the affected product, and, as the  
8           Secretary may require, cease distribution and prop-  
9           erly dispose of the affected product; and

10          “(C) promptly provide to the Secretary results  
11          and isolates from a positive sample of such product  
12          or the whole genome sequence data from any con-  
13          firmed positive analytical result.

14          “(3) Not later than 1 business day after receipt by  
15          the Secretary of a notification under paragraph (2)(A),  
16          the Secretary shall respond to the manufacturer of the in-  
17          fant formula to begin discussions regarding investigation  
18          and corrective action, and, as appropriate, share the find-  
19          ings of the Secretary with the manufacturer.

20          “(4) Not later than 90 days after receipt of a notifi-  
21          cation under paragraph (1) or (2), the Secretary shall con-  
22          firm, including through the collection of documentation,  
23          that the manufacturer submitting the notification per-  
24          formed, or is performing, an appropriate investigation and  
25          corrective action, if applicable. The Secretary shall con-

1 sider, as part of the review of the root cause investigation,  
2 the analytical method used to conduct laboratory testing  
3 and, as appropriate, the potential for cross contamination  
4 of the sample by handling and testing. The manufacturer  
5 shall make such documentation available to the Secretary  
6 electronically and for inspection under section 704.”.

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

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

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

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

1 and supply of infant formula and any revisions to  
2 the recommendations as a result of any infant for-  
3 mula recalls since the publication of the report, as  
4 appropriate.

5 “(2) QUARTERLY REPORTS ON SUPPLY  
6 CHAIN.—Not later than 270 days after the date of  
7 enactment of the Protect Infant Formula from Con-  
8 tamination Act, and not less frequently than quar-  
9 terly for the 5-year period thereafter, the Secretary  
10 shall submit a report on the most current critical  
11 supply chain data for infant formula, including in-  
12 stock rates, to—

13 “(A) the Committee on Health, Education,  
14 Labor, and Pensions; the Committee on Agri-  
15 culture, Nutrition, and Forestry; and the Sub-  
16 committee on Agriculture, Rural Development,  
17 Food and Drug Administration, and Related  
18 Agencies of the Committee on Appropriations of  
19 the Senate; and

20 “(B) the Committee on Energy and Com-  
21 merce; the Committee on Agriculture; and the  
22 Subcommittee on Agriculture, Rural Develop-  
23 ment, Food and Drug Administration, and Re-  
24 lated Agencies of the Committee on Appropria-  
25 tions of the House of Representatives.

1           “(3) CONSULTATION.—The Secretary shall en-  
2           gage with the Department of Agriculture and other  
3           relevant agencies of the Federal Government regard-  
4           ing ongoing efforts to address immediate formula  
5           needs and build long-term resiliency into the infant  
6           formula market.

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

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

1           “(B) submit a report to the committees de-  
2           scribed in subparagraphs (A) and (B) of para-  
3           graph (2) that identifies the modifications to  
4           manufacturer practices and actions described in  
5           subparagraph (A), if any, that could be imple-  
6           mented to improve infant formula supply and  
7           safety.”.

Passed the Senate April 28, 2026.

Attest:

*Secretary.*

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