

Calendar No. 306

119TH CONGRESS
2D SESSION

S. 272

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

JANUARY 28, 2025

Mr. PETERS (for himself, Mr. HOEVEN, Ms. COLLINS, Ms. SMITH, Mrs. SHAHEEN, Ms. HASSAN, Mr. KAINE, and Ms. BALDWIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JANUARY 28, 2026

Reported by Mr. CASSIDY, with an amendment and an amendment to the title
[Strike out all after the enacting clause and insert the part printed in *italic*]

A BILL

To improve the safety of infant formula through testing of infant formula for microorganisms and toxic elements, 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 “Protect Infant For-
5 mula from Contamination Act”.

1 **SEC. 2. NOTIFICATIONS FOR TESTING OF INFANT FOR-**
 2 **MULA.**

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

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

7 (A) by striking “promptly”;

8 (B) by inserting “, within 1 business day
 9 of acquiring such knowledge” after “such
 10 knowledge”; and

11 (C) by striking “the infant formula” and
 12 inserting “an infant formula”;

13 (2) by redesignating paragraph (2) as para-
 14 graph (5); and

15 (3) by inserting after paragraph (1) the fol-
 16 lowing:

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

24 “(A) within 1 business day of acquiring a con-
 25 firmed positive analytical result, notify the Secretary
 26 of such result, regardless of whether such product

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

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

7 “(C) promptly provide to the Secretary results
8 and isolates from a positive sample of such product
9 or the whole genetic sequence from any confirmed
10 positive analytical result.

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

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

1 of the sample by handling and testing. The manufacturer
 2 shall make such documentation available to the Secretary
 3 electronically and for inspection under section 704.”.

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

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

9 “(n) **REPORTING TO IMPROVE THE SAFETY AND**
 10 **SUPPLY OF INFANT FORMULA.—**

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

24 “(2) **QUARTERLY REPORTS ON SUPPLY**
 25 **CHAIN.—**Not later than 270 days after the date of

1 enactment of the Protect Infant Formula from Con-
2 tamination Act, and not less frequently than quar-
3 terly for the 5-year period thereafter, the Secretary
4 shall submit a report on the most current, critical
5 supply chain data for infant formula, including in-
6 stock rates, to—

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

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

20 “(3) CONSULTATION.—The Secretary shall en-
21 gage with the Department of Agriculture and other
22 relevant agencies of the Federal Government regard-
23 ing ongoing efforts to address immediate formula
24 needs and build long-term resiliency into the infant
25 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 and bracketing po-
13 tentially contaminated product, the impact of
14 corrective action on contamination events, and
15 evidence-based recommendations for enhancing
16 infant formula supply and safety; and

17 “(B) submit a report to the committees de-
18 scribed in subparagraphs (A) and (B) of para-
19 graph (2) that identifies the modifications to
20 manufacturer practices and actions described in
21 subparagraph (A), if any, that could be imple-
22 mented to improve infant formula supply and
23 safety.”.

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “Protect Infant Formula*
 3 *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 of*
 12 *acquiring such knowledge” after “such knowl-*
 13 *edge”; 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 any*
 21 *production aggregate of finished infant formula product is*
 22 *confirmed as a positive analytical result for any microorga-*
 23 *nism for which finished product testing is required under*
 24 *section 106.55(e) of title 21, Code of Federal Regulations*
 25 *(or any successor regulation), the manufacturer 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 has*
4 *left an establishment subject to the control of the man-*
5 *ufacturer;*

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 the*
15 *Secretary of a notification under paragraph (2)(A), the*
16 *Secretary shall respond to the manufacturer of the infant*
17 *formula to begin discussions regarding investigation and*
18 *corrective action, and, as appropriate, share the findings*
19 *of the Secretary with the manufacturer.*

20 “(4) *Not later than 90 days after receipt of a notifica-*
21 *tion 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 the*
 11 *following:*

12 *“(n) REPORTING TO IMPROVE THE SAFETY AND SUP-*
 13 *PLY OF INFANT FORMULA.—*

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

1 *and any revisions to the recommendations as a result*
2 *of any infant formula recalls since the publication of*
3 *the report, as appropriate.*

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

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

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

24 “(3) *CONSULTATION.—The Secretary shall en-*
25 *gage with the Department of Agriculture and other*

1 *relevant agencies of the Federal Government regard-*
2 *ing ongoing efforts to address immediate formula*
3 *needs and build long-term resiliency into the infant*
4 *formula market.*

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

9 *“(A) engage with public stakeholders, infant*
10 *formula manufacturers, and other stakeholders,*
11 *as determined by the Secretary, to determine evi-*
12 *dence-based practices that can be implemented to*
13 *maximize infant formula supply and infant*
14 *safety, which may include the value of high fre-*
15 *quency testing for purposes of identifying con-*
16 *tamination events, including events associated*
17 *with botulism or other contaminants, and brack-*
18 *eting potentially contaminated product, the im-*
19 *port of corrective action on contamination*
20 *events, including events associated with botulism*
21 *or other contaminants, and evidence-based rec-*
22 *ommendations for enhancing infant formula*
23 *supply and safety; and*

24 *“(B) submit a report to the committees de-*
25 *scribed in subparagraphs (A) and (B) of para-*

1 *graph (2) that identifies the modifications to*
2 *manufacturer practices and actions described in*
3 *subparagraph (A), if any, that could be imple-*
4 *mented to improve infant formula supply and*
5 *safety.”.*

Amend the title so as to read: “A bill to improve the safety of infant formula through testing of infant formula for microorganisms, and for other purposes.”.

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