

119TH CONGRESS
2D SESSION

H. R. 7867

To amend the Federal Food, Drug, and Cosmetic Act to establish standardized pathogen and microorganism testing of infant formula products and manufacturing facilities, to mandate notification of specific positive tests and inspection classifications, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 9, 2026

Ms. DELAURO (for herself, Mrs. GRIJALVA, Mr. PANETTA, Ms. JACOBS, Ms. NORTON, Ms. WILSON of Florida, Mr. BISHOP, Ms. WILLIAMS of Georgia, Mr. PAPPAS, Mr. QUIGLEY, Mr. KRISHNAMOORTHY, Ms. SCHAKOWSKY, Ms. TLAIB, Mr. THANEDAR, Ms. ROSS, Mr. VAN DREW, Ms. DEAN of Pennsylvania, and Mr. COHEN) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish standardized pathogen and microorganism testing of infant formula products and manufacturing facilities, to mandate notification of specific positive tests and inspection classifications, 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 “Infant Formula Safety
5 Modernization Act of 2026”.

1 **SEC. 2. MEASURES TO ENHANCE THE SAFETY OF INFANT**
2 **FORMULA.**

3 (a) GOOD MANUFACTURING PRACTICES.—

4 (1) IN GENERAL.—Section 412(b) of the Fed-
5 eral Food, Drug, and Cosmetic Act (21 U.S.C.
6 350a(b)) is amended by adding at the end the fol-
7 lowing:

8 “(5)(A) The Secretary shall by regulation update the
9 good manufacturing practices for infant formulas estab-
10 lished under this subsection to require the manufacturer
11 of an infant formula to conduct pathogen and microorga-
12 nism testing of—

13 “(i) the infant formula manufacturing facilities
14 of the manufacturer; and

15 “(ii) in addition to other applicable testing re-
16 quirements under this Act, the finished infant for-
17 mula product of the manufacturer.

18 “(B) The regulations issued under subparagraph (A)
19 shall—

20 “(i) require the Commissioner of Food and
21 Drugs to develop a list of pathogens and microorga-
22 nisms that infant formula manufacturers must test
23 for in infant formula manufacturing facilities and
24 finished infant formula products, which list shall in-
25 clude clostridium botulinum and such other patho-

1 gens and microorganisms as the Secretary des-
2 ignates;

3 “(ii) specify the recommended frequency of en-
4 vironmental testing, including requirements for test-
5 ing in Zones 2 and 3 of an infant formula manufac-
6 turing facility;

7 “(iii) require the manufacturer of an infant for-
8 mula to submit to the Secretary a written notifica-
9 tion of any positive test result for a pathogen or
10 microorganism referred to in clause (i) in infant for-
11 mula, not later than one business day following the
12 date of the result, even if the formula has not left
13 the control of the manufacturer;

14 “(iv) for the purposes of inspections conducted
15 under this Act, require the manufacturer of an in-
16 fant formula to retain records of any positive test re-
17 sult for a pathogen or microorganism referred to in
18 clause (i)—

19 “(I) in infant formula; or

20 “(II) in the infant formula manufacturing
21 facility of the manufacturer; and

22 “(v) require Commissioner of Food and Drugs
23 to establish and enforce clear, consistent inspection
24 and compliance standards for all infant formula
25 products, regardless of their country of origin.

1 “(C) In this paragraph:

2 “(i) The term ‘Zone 2’, with respect to an in-
3 fant formula manufacturing facility, means areas di-
4 rectly adjacent to locations where infant formula
5 could be exposed during manufacturing, but that are
6 not food-contact surfaces.

7 “(ii) The term ‘Zone 3’, with respect to an in-
8 fant formula manufacturing facility, means areas
9 further away from direct infant formula exposure
10 than Zone 2, yet still within the processing environ-
11 ment; contamination in Zone 3 could reach Zone 2
12 (and thus the infant formula) through movement of
13 people, equipment, or airflow.”.

14 (2) DEADLINE.—Not later than 90 days after
15 the date of enactment of this Act, the Secretary
16 shall issue final regulations under section
17 412(b)(5)(A) of the Federal Food, Drug, and Cos-
18 metic Act (as added by paragraph (1) of this sub-
19 section).

20 (b) CONGRESSIONAL NOTIFICATION REQUIRE-
21 MENTS.—Section 412 of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 350a) is amended by adding at
23 the end the following:

24 “(n) CONGRESSIONAL NOTIFICATION REQUIRE-
25 MENTS.—(1) If the Secretary receives from a manufac-

1 turer a written notification of any test result that is a posi-
2 tive analytical result for a pathogen or microorganism in
3 finished infant formula pursuant to subsection
4 (b)(5)(B)(iii), the Secretary shall, not later than one busi-
5 ness day following the date of such receipt, provide a writ-
6 ten notice of such receipt to the appropriate committees
7 of Congress.

8 “(2) If the Food and Drug Administration issues an
9 ‘official action indicated’ classification (or an equivalent
10 classification) following an inspection of an infant formula
11 manufacturing facility, the Secretary shall, not later than
12 one business day following the date of such issuance, pro-
13 vide a written notice of such issuance to the appropriate
14 committees of Congress.

15 “(3) In this subsection, the term ‘appropriate com-
16 mittees of Congress’ means—

17 “(A) the Committee on Appropriations and the
18 Committee on Energy and Commerce of the House
19 of Representatives; and

20 “(B) the Committee on Appropriations and the
21 Committee on Health, Education, Labor, and Pen-
22 sions of the Senate.”.

23 (c) CONFORMING AMENDMENT.—Section
24 412(b)(4)(A)(i) of the Federal Food, Drug, and Cosmetic
25 Act (21 U.S.C. 350a(b)(4)(A)(i)) is amended by striking

- 1 “paragraph (2)(B)” and inserting “paragraphs (2)(B)
- 2 and (5)(A)”.

