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(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

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

Ms. DELAURO introduced the following bill; which was referred to the Committee on _____

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Infant Formula Safety Modernization Act of 2026''.

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

(a) GOOD MANUFACTURING PRACTICES.—

(1) IN GENERAL.—Section 412(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(b)) is amended by adding at the end the following:

''(5)(A) The Secretary shall by regulation update the good manufacturing practices for infant formulas established under this subsection to require the manufacturer of an infant formula to conduct pathogen and microorganism testing of—

''(i) the infant formula manufacturing facilities of the manufacturer; and

''(ii) in addition to other applicable testing requirements under this Act, the finished infant formula product of the manufacturer.

''(B) The regulations issued under subparagraph (A) shall—

''(i) require the Commissioner of Food and Drugs to develop a list of pathogens and microorganisms that infant formula manufacturers must test for in infant formula manufacturing facilities and finished infant formula products, which list shall include clostridium botulinum and such other patho-

gens and microorganisms as the Secretary designates;

''(ii) specify the recommended frequency of environmental testing, including requirements for testing in Zones 2 and 3 of an infant formula manufacturing facility;

''(iii) require the manufacturer of an infant formula to submit to the Secretary a written notification of any positive test result for a pathogen or microorganism referred to in clause (i) in infant formula, not later than one business day following the date of the result, even if the formula has not left the control of the manufacturer;

''(iv) for the purposes of inspections conducted under this Act, require the manufacturer of an infant formula to retain records of any positive test result for a pathogen or microorganism referred to in clause (i)—

''(I) in infant formula; or

''(II) in the infant formula manufacturing facility of the manufacturer; and

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

''(C) In this paragraph:

''(i) The term 'Zone 2', with respect to an infant formula manufacturing facility, means areas directly adjacent to locations where infant formula could be exposed during manufacturing, but that are not food-contact surfaces.

''(ii) The term 'Zone 3', with respect to an infant formula manufacturing facility, means areas further away from direct infant formula exposure than Zone 2, yet still within the processing environment; contamination in Zone 3 could reach Zone 2 (and thus the infant formula) through movement of people, equipment, or airflow.''.

(2) DEADLINE.—Not later than 90 days after the date of enactment of this Act, the Secretary shall issued final regulations under section 412(b)(5)(A) of the Federal Food, Drug, and Cosmetic Act (as added by paragraph (1) of this subsection).

(b) CONGRESSIONAL NOTIFICATION REQUIREMENTS.—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) CONGRESSIONAL NOTIFICATION REQUIREMENTS.—(1) If the Secretary receives from a manufac-

turer a written notification of any test result that is a positive analytical result for a pathogen or microorganism in finished infant formula pursuant to subsection (b)(5)(B)(iii), the Secretary shall, not later than one business day following the date of such receipt, provide a written notice of such receipt to the appropriate committees of Congress.

''(2) If the Food and Drug Administration issues an 'official action indicated' classification (or an equivalent classification) following an inspection of an infant formula manufacturing facility, the Secretary shall, not later than one business day following the date of such issuance, provide a written notice of such issuance to the appropriate committees of Congress.

''(3) In this subsection, the term 'appropriate committees of Congress' means—

''(A) the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives; and

''(B) the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate.''.

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

"paragraph (2)(B)" and inserting "paragraphs (2)(B) and (5)(A)".