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118TH CONGRESS
1ST SESSION

H. R. 5316

To amend section 412 of the Federal Food, Drug, and Cosmetic Act to enhance the safeguards applicable with respect to infant formula.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 29, 2023

Ms. PORTER (for herself and Mrs. MCCLAIN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend section 412 of the Federal Food, Drug, and Cosmetic Act to enhance the safeguards applicable with respect to infant formula.

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 ''Safeguarding Kids and Families from Critical Food Disruptions Act of 2023''.

SEC. 2. SAFEGUARDING KIDS AND FAMILIES FROM CRITICAL FOOD DISRUPTIONS.

(a) IN GENERAL.—Subsection (e) of section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) is amended to read as follows:

''(e)(1) If the manufacturer of an infant formula has knowledge which reasonably supports the conclusion that an infant formula which has been processed by the manufacturer and which has left an establishment subject to the control of the manufacturer—

''(A) may not provide the nutrients required by subsection (i); or

''(B) may be otherwise adulterated or misbranded,

the manufacturer shall, within 24 hours, notify the Secretary and the Director of the Office of Critical Foods of such knowledge.

''(2) If the manufacturer of an infant formula has knowledge which reasonably supports the conclusion that an infant formula which has been processed by the manufacturer may be adulterated due to pathogen contamination (such as confirmation of a positive analytical result from any in-process or finished product testing), the manufacturer shall—

''(A) within 24 hours, notify the Secretary and the Director of the Office of Critical Foods of such knowledge, regardless of whether such infant formula has left an establishment subject to the control of the manufacturer; and

''(B) provide to the Secretary, for the purpose of sequencing, results and isolates from a positive sample of such infant formula.

''(3) In submitting a notification under paragraph (1) or (2), a manufacturer shall adhere to any submission requirements or procedures specified by the Secretary.

''(4) If the Secretary determines that an infant formula presents a risk to human health, the manufacturer shall immediately take all actions necessary to cease distribution of such infant formula and recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary.

''(5)(A) Not later than 72 hours after receipt by the Director of the Office of Critical Foods of a notification under paragraph (1) or (2), the Director shall contact the manufacturer of the infant formula, or an affiliate thereof in the United States, to discuss corrective action.

''(B) If there is a failure of the Director of the Office of Critical Foods to act within 72 hours after receipt of a notification as required by subparagraph (A), the Secretary shall immediately notify the appropriate congressional committees what, if any, accountability mechanisms were, or will be, invoked for such failure.

''(6) The Director of the Office of Critical Foods—

''(A) not later than 90 days after receipt by the Director of a notification under paragraph (1) or (2), shall confirm that the manufacturer submitting the notification performed, or is performing, appropriate corrective action, including a root cause analysis;

''(B) in making such confirmation, may collect documentation during an inspection, electronically, or by other means; and

''(C) shall notify the appropriate congressional committees if the Director is unable to make such confirmation and what, if any, accountability mechanisms were, or will be, invoked for such failure.

''(7) Not later than the end of each of calendar years 2024, 2025, and 2026, the Secretary shall submit to the Congress a report containing—

''(A) the number of notifications received under paragraph (1) or (2) during the fiscal year ending in the respective calendar year;

''(B) the average number of hours it took the Director of the Office of Critical Foods to initiate contact, as required by paragraph (5), in response to such notifications;

''(C) the longest and shortest time it took the Director of the Office of Critical Foods to so initiate contact;

''(D) the average number of days it took the Director of the Office of Critical Foods to confirm corrective action, as required by paragraph (6), in response to such notifications; and

''(E) the longest and shortest number of days it took the Director of the Office of Critical Foods to so confirm corrective action.

''(8) For purposes of paragraphs (1) and (2), the term 'knowledge' as applied to a manufacturer means—

''(A) the actual knowledge that the manufacturer had; or

''(B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

''(9) For purposes of paragraph (2), the term 'pathogen' means a microorganism of public health significance.''.

(b) TIMING.—

(1) NOTIFICATION REQUIREMENTS.—Paragraphs (1), (2), (3), (4), (8), and (9) of subsection (e) of section 412 of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 350a), as amended by subsection (a), apply upon the enactment of this Act.

(2) RESPONSE BY SECRETARY.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the Office of Critical Foods, shall establish a process for carrying out paragraphs (5) and (6) of subsection (e) of section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a), as amended by subsection (a), and begin implementation of such process.

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