117TH CONGRESS
1ST SESSION

S. 1019

To amend the Federal Food, Drug, and Cosmetic Act to limit the presence of toxic elements in, and otherwise regulate, infant and toddler food, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 25, 2021

Ms. KLOBUCHAR (for herself and Ms. DUCKWORTH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to limit the presence of toxic elements in, and otherwise regulate, infant and toddler food, 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 ''Baby Food Safety Act of 2021''.

SEC. 2. DEFINITION OF INFANT AND TODDLER FOOD.

Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(ss) The term 'infant and toddler food' means food intended for sale to children up to 36 months of age, including infant formula.''.

SEC. 3. INFANT AND TODDLER FOOD HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.

(a) PREVENTIVE CONTROLS.—Section 418(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g(c)) is amended—

(1) in paragraph (2), by striking ''and'' at the end;

(2) in paragraph (3), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(4) the infant and toddler foods manufactured, processed, packed, or held by such facility will comply with the performance standards and action levels for toxic elements in infant and toddler foods required under section 104 of the FDA Food Safety Modernization Act.''.

(b) VERIFICATION.—Paragraph (4) of section 418(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g(f)) is amended to read as follows:

''(4) the preventive controls implemented under subsection (c) are effectively and significantly minimizing or preventing the occurrence of identified

hazards, including through the use of environmental and product testing programs and other appropriate means, including representative testing by manufacturers of infant and toddler foods that are finished products; and''.

(c) BIANNUAL REPORTING.—Section 418(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g(h)) is amended by adding at the end the following: ''The owner, operator, or agent in charge of a facility that manufactures infant and toddler foods shall make publicly available on a web page a biannual report summarizing the results of monitoring under subsection (d), and verification results under subsection (f), with respect to such facility and infant and toddler foods.''.

SEC. 4. INFANT AND TODDLER FOOD ACTION LEVELS.

(a) PERFORMANCE STANDARD GUIDANCE DOCUMENTS AND REGULATIONS.—Section 104(b) of the FDA Food Safety Modernization Act (21 U.S.C. 2201(b)) is amended—

(1) in the matter preceding paragraph (1), by striking ''reduce the risk of serious illness or death'' and inserting ''reduce the risk of serious illness, including neurological impairment, or death''; and

(2) in paragraph (1), by inserting ''and toxic elements in infant and toddler foods'' before the semicolon.

(b) ACTION LEVELS.—Section 104 of the FDA Food Safety Modernization Act (21 U.S.C. 2201) is amended by adding at the end the following:

''(e) ACTION LEVELS.—

''(1) IN GENERAL.—Beginning not later than 1 year after the date of enactment of the Baby Food Safety Act of 2021, infant and toddler food is deemed to be adulterated if it meets or exceeds the action level or regulatory limit that is applicable with respect to such food under this subsection.

''(2) INITIAL LEVELS.—The initial action levels under this subsection are the following:

''Toxic Element	**Action Level**
Inorganic arsenic	10 ppb for infant and toddler food (except cereal) and 15 ppb for infant and toddler food that is cereal
Cadmium	5 ppb for infant and toddler food (except cereal) and 10 ppb for infant and toddler food that is cereal
Lead	5 ppb for infant and toddler food (except cereal) and 10 ppb for infant and toddler food that is cereal
Mercury	2 ppb

''(3) INTERIM ACTION LEVELS.—Not later than 2 years after the date of enactment of the Baby Food Safety Act of 2021, the Secretary shall—

''(A) review relevant health and dietary data; and

''(B) by guidance, lower the initial action levels established by paragraph (2) to further minimize exposure to toxic elements in infant and toddler food to further reduce potential clinical or population-level health effects as indicated by the Secretary's review of relevant health and dietary data.

''(4) FINAL REGULATORY LIMITS; PERIODIC REVIEW.—The Secretary shall—

''(A) not later than 3 years after the date of enactment of the Baby Food Safety Act of 2021, by regulation set regulatory limits lower than the action levels established by paragraphs (2) and (3) to levels protective of infant and toddler neurological development, taking into account the most sensitive testing available; and

''(B) every 5 years thereafter—

''(i) review the levels established under this subsection to consider whether such levels should be lowered further con-

sistent with the standard described in subparagraph (A); and

''(ii) if so, by regulation so lower such levels.

''(5) TOXIC ELEMENTS.—The Secretary may by guidance or regulation, as applicable, establish interim action levels and regulatory limits for toxic elements in infant and toddler food in addition to the toxic elements specified in the table in paragraph (2) if determined by the Secretary to be appropriate upon review of relevant health and dietary data.

''(6) PROGRESS REPORTS.—Not later than 1 year, 2 years, and 3 years after the date of enactment of the Baby Food Safety Act of 2021, the Secretary shall submit a report to the Congress containing—

''(A) a summary of progress towards establishing the required levels under this subsection;

''(B) an evaluation of the effectiveness of preventive controls for infant and toddler food based on monitoring results and verification results under section 418 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g) compared to levels under this subsection; and

''(C) an estimate of progress in reducing the cumulative exposure of children to toxic elements in infant and toddler food.''.

(c) DEFINITION.—Section 104 of the FDA Food Safety Modernization Act (21 U.S.C. 2201(b)), as amended by subsections (a) and (b), is further amended by adding at the end the following:

''(f) INFANT AND TODDLER FOOD DEFINED.—In this section, the term 'infant and toddler food' has the meaning given to such term in section 201(ss) of the Federal Food, Drug, and Cosmetic Act.''.

(d) MANDATORY RECALL AUTHORITY.—Section 423(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350l(a)) is amended—

(1) by striking ''(other than infant formula)''; and

(2) by inserting after ''animals,'' the following: ''or the Secretary determines that an article of infant and toddler food contains a toxic element that meets or exceeds the action level applicable under subsection (e) of section 104 of the FDA Food Safety Modernization Act,''.

(e) PUBLIC AWARENESS CAMPAIGN.—Section 1009 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399) is amended—

(1) by redesignating subsection (h) as subsection (i); and

(2) after executing the amendment made by paragraph (1), by inserting after subsection (g) the following:

''(h) BABY FOOD PUBLIC AWARENESS CAMPAIGN.—The Secretary, acting through the Director of the Centers for Disease Control, shall carry out a public awareness campaign to highlight the risks posed by toxic elements in infant and toddler food and make recommendations to the public with respect to such toxic elements and food.''.

(f) GRANTS FOR FARMING RESEARCH.—Section 401 of the FDA Food Safety Modernization Act (Public Law 111–353; 124 Stat. 3967) is amended by adding the end the following:

''(c) GRANTS FOR FARMING RESEARCH.—

''(1) IN GENERAL.—The Commissioner of Food and Drugs shall commission the National Academy of Sciences (or, if the National Academy declines, another appropriate entity) to conduct research on agricultural methods of minimizing levels of toxic heavy metals in crops.

''(2) AUTHORIZATION OF APPROPRIATIONS.—To carry out this subsection, there is authorized to be appropriated $50,000,000.''.

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