118TH CONGRESS
2D SESSION

S. 4728

To amend the Federal Food, Drug, and Cosmetic Act to ensure the safety of food and limit the presence of contaminants in infant and toddler food, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 11 (legislative day, JULY 10), 2024

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 ensure the safety of food and limit the presence of contaminants in 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 2024''.

SEC. 2. DEFINITION OF INFANT OR 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:

''(tt) The term 'infant or toddler food' means food that purports to be, or is represented as being, for infants or children up to the age of 24 months. Such term does not include infant formula.''.

SEC. 3. CONTAMINANTS IN FOOD, INCLUDING INFANT OR TODDLER FOOD.

(a) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

''SEC. 425. CONTAMINANTS IN FOOD, INCLUDING INFANT OR TODDLER FOOD.

''(a) ADMINISTRATIVE ORDERS FOR CONTAMINANTS, INCLUDING TOXIC ELEMENTS, IN FOOD.—

''(1) IN GENERAL.—

''(A) REQUIRED LIMITS.—The Secretary, by administrative order, shall establish limits on the toxic elements of lead, cadmium, mercury, and arsenic (or a species of any such toxic element) in—

''(i) any infant or toddler food; and

''(ii) food predominantly composed of a fruit or vegetable puree or juice;

"(B) ADDITIONAL LIMITS.—If the Secretary determines appropriate upon review of relevant health data and other relevant available information, the Secretary, by administrative order, may—

"(i) establish limits for contaminants, including toxic elements, in infant or toddler food, in addition to the limits for toxic elements described in subparagraph (A); and

"(ii) establish limits for contaminants, including toxic elements, in food predominantly composed of a fruit or vegetable puree or juice, in addition to the limits for toxic elements described in subparagraph (A); and

"(2) PROCEDURE.—In establishing or revising any limit under paragraph (1), the Secretary shall—

"(A) evaluate relevant health data and assessments, data from State and local health departments, and other information the Secretary considers relevant;

"(B) take into account relevant differences among food types, groups, and categories, as appropriate, including the extent to which the

use of such substances cannot be avoided in the production of the applicable food and its ingredients, based on an evaluation of alternative ingredients, use of best manufacturing and agricultural practices, and full compliance with section 418; and

''(C) notwithstanding the requirements of subchapter II of chapter 5 of title 5, United States Code, and chapter 6 of title 5, United States Code—

''(i) publish any administrative order under paragraph (1) in the Federal Register following—

''(I) publication of a proposed order in the Federal Register; and

''(II) consideration of comments to a public docket open for not fewer than 45 calendar days; and

''(ii) set forth in any proposed or final administrative order under paragraph (1) a substantive summary of the valid scientific evidence concerning the proposed or final limit.

''(3) CHANGES TO LIMITS.—If the Secretary determines appropriate after review of relevant data

and assessments and other available and relevant health information, the Secretary may revise any limit established under this subsection by administrative order published in the Federal Register in accordance with paragraph (2).

''(4) TIMEFRAME FOR INITIAL LIMITS.—

''(A) PROPOSED ORDERS.—Subject to the requirements of paragraph (2), the Secretary shall issue proposed orders for limits under paragraph (1)(A) as follows:

''(i) For lead, not later than December 31, 2025.

''(ii) For arsenic, not later than December 31, 2025.

''(iii) For cadmium, not later than April 30, 2026.

''(iv) For mercury, not later than April 30, 2028.

''(B) FINAL ORDERS.—The Secretary shall issue each final administrative order for a limit established pursuant to subparagraph (A) or (B) of paragraph (1) not later than 18 months after issuance of the respective proposed order.

''(5) CRITERIA.—The limits established under this section shall represent the level at which the

contaminant may render the infant or toddler food injurious to health. In determining such limits the Secretary shall take into account the extent to which the use of such substance cannot be avoided in the production of each such food and its ingredients, based on an evaluation of alternative ingredients, use of best manufacturing and agricultural practices, and compliance with section 418.

''(6) ADULTERATED FOOD.—A food may be determined adulterated, at the final product form, under section 402(j), if such food bears or contains any contaminant (including any toxic element) in excess of a limit established under this subsection.

''(7) PERIODIC REVIEW.—The Secretary shall review, not less frequently than every 4 years, the limits established under this subsection, taking into consideration relevant information and available data to consider whether such limits should be revised, following the procedure described in paragraph (2), in accordance with the criteria specified in paragraph (5).

''(b) SAMPLING AND TESTING FOR TOXIC ELEMENTS AND CONTAMINANTS IN FOOD, INCLUDING INFANT AND TODDLER FOOD.—

"(1) IN GENERAL.—Beginning not later than 180 days after the date of enactment of the Baby Food Safety Act of 2024, the owner, operator, or agent in charge of a facility engaged in manufacturing or processing infant or toddler food; food predominantly composed of a fruit or vegetable puree or juice; or such other food as the Secretary may specify by regulation, for consumption in the United States, shall—

"(A) have a control program in place for toxic elements and contaminants subject to limits under subsection (a)(1);

"(B) collect representative samples of each such food in final product form in accordance with a sampling plan described in paragraph (2); and

"(C) conduct testing of the samples collected from the final food product for toxic elements and contaminants, in accordance with a sampling plan described in paragraph (2).

"(2) REQUIREMENTS FOR SAMPLING AND TESTING PLAN.—

"(A) IN GENERAL.—The owner, operator, or agent in charge of a facility described in paragraph (1) shall—

''(i) prepare a written plan for all sampling and testing required under this subsection; and

''(ii) ensure that all sampling and testing conducted under this subsection is conducted in accordance with the plan described in clause (i).

''(B) SAMPLING PLAN.—A sampling and testing plan required by subparagraph (A) shall identify—

''(i) the number of sampling units and sample unit size based upon appropriate criteria for identifying, in a representative fashion, the levels of toxic elements and contaminants in each food;

''(ii) one or more appropriate test methods and procedures to be used to analyze the samples; and

''(iii) appropriate testing frequencies not less frequently than every quarter and whenever a significant change in the product or process necessitates such testing.

''(C) GUIDANCE.—Not later than 18 months after the date of enactment of the Baby Food Safety Act of 2024, the Secretary shall

issue guidance to assist facilities described under paragraph (1) with developing sampling and testing plans. Such guidance shall address the standards for adequate and appropriate sampling and testing of each toxic element and contaminant as required by the Secretary, the minimum frequency at which samples should be tested for toxic elements and contaminants or specific species of toxic elements or contaminants, and standards for compliance.

''(3) CONTAMINANTS TO BE TESTED.—In carrying out the sampling and testing under this subsection, the owner, operator, or agent in charge of a facility described in paragraph (1) shall ensure that each sample is tested for levels of—

''(A) lead, cadmium, mercury, and arsenic; and

''(B) any other contaminant that the Secretary may specify, in accordance with the sampling plan under paragraph (2).

''(4) FOODS TO BE TESTED.—The sampling and testing conducted under this subsection shall be conducted for—

''(A) infant and toddler foods, in final product form;

''(B) foods predominantly composed of a fruit or vegetable puree or juice; and

''(C) such other foods in final product form as the Secretary has specified, as appropriate for the protection of public health.

''(5) RECORDKEEPING.—

''(A) IN GENERAL.—The owner, operator, or agent in charge of a facility described in paragraph (1) shall maintain, for not less than 2 years or the shelf life of each food product manufactured or processed by the facility, whichever is longer, records documenting the sampling plan and results of testing conducted under this subsection with respect to the food. The owner, operator, or agent in charge of such a facility shall make such records available for inspection and copying by the Secretary upon request by the Secretary.

''(B) REQUIREMENTS.—The records maintained as required under subparagraph (A) shall include—

''(i) a detailed description of the foods sampled and tested;

''(ii) the number of samples and tests performed;

''(iii) the size and number of items in each sample unit;

''(iv) a copy of the sampling plan required under paragraph (2);

''(v) identification of the entity conducting the sampling;

''(vi) identification of the entity conducting the testing;

''(vii) identification of the analytical methods used to perform the sampling and testing;

''(viii) analytical findings of the sampling and testing; and

''(ix) such other data and information as the Secretary may require.

''(C) APPLICABILITY.—The requirements of this paragraph shall apply to all records of sampling and testing conducted pursuant to this subsection, regardless of the findings.

''(6) LABORATORY ACCREDITATION.—The owner, operator, or agent in charge of a facility described in paragraph (1) shall ensure that testing required pursuant to this subsection is performed in accordance with international standards by a laboratory that—

"(A) is in compliance with the requirements regarding laboratory accreditation described in section 422; or

"(B) if the requirements described in subparagraph (A) do not apply to the laboratory, is accredited by an accreditation body that conforms to international accreditation standards.

"(7) SAMPLING AND TESTING PROGRAM.—The Secretary shall develop and implement a sampling and testing program for infant and toddler food that is sufficient to—

"(A) support the periodic review under subsection (a)(7) of limits on toxic elements in infant and toddler food; and

"(B) independently verify that products are compliant with the limits proscribed pursuant to this subsection.

"(c) RECORD AVAILABILITY.—

"(1) IN GENERAL.—Upon request by the Secretary, the owner, operator, or agent in charge of a facility described in subsection (b)(1) shall—

"(A) make all records required under this section available promptly to the Secretary for inspection and copying; and

''(B) provide within a reasonable time an English translation of such records maintained in a language other than English.

''(2) RECORD AVAILABILITY.—Any records that the Secretary may inspect under this section shall, upon the request of the Secretary, be provided to the Secretary by the owner, operator, or agent in charge of a facility described in subsection (b)(1), in advance of or in lieu of an inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, and in either electronic or physical form, at the expense of such owner, operator, or agent. The Secretary's request shall include a sufficient description of the records requested.

''(3) CONFIRMATION.—Upon receipt of records requested under paragraph (1) or (2), the Secretary shall provide to the owner, operator, or agent described in paragraph (2) confirmation of the receipt.

''(4) AUTHORITY OF THE SECRETARY.—Nothing in this subsection supplants the authority of the Secretary to conduct sampling, testing, or inspections otherwise permitted under this Act in order to ensure compliance with this Act.

''(d) DELAYED APPLICABILITY.—The requirements for sampling and testing under this section shall apply be-

ginning on the date that is 2 years after the date of enactment of this subsection.''.

(b) IMPORTER REQUIREMENTS.—Section 805(c)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384a(c)(4)) is amended, by inserting ''monitoring and verifying the accuracy of records described in section 425(b)'' after ''for shipments,''.

(c) ENFORCEMENT.—

(1) ADULTERATION.—Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by adding at the end the following:

''(j) If it is an article of food in final product form that is an infant and toddler food, a food predominantly composed of a fruit or vegetable puree or juice, or such other food as the Secretary may specify and—

''(1) such food bears or contains any toxic element or contaminant in excess of a limit established under section 425(a); or

''(2) the owner, operator, or agent in charge of a facility that manufactures or processes the food is not in compliance with subsection (b) or (c) of section 425.''.

(2) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(jjj) The failure of an owner, operator, or agent in charge of a facility that manufactures or processes food to comply with applicable requirements under subsection (b) or (c) of section 425.''.

SEC. 4. IMPLEMENTATION OF FOOD TRACEABILITY PLAN; STUDY ON INSPECTIONS; REPORTING ON INSPECTIONS.

(a) IMPLEMENTATION PLAN.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, in coordination with the FDA Human Foods Program and the Center for Food Safety and Applied Nutrition, shall finalize an implementation plan for the Food and Drug Administration to achieve its goal of compliance, not later than January 20, 2026, with the rule issued by the Food and Drug Administration titled, ''Requirements for Additional Traceability Records for Certain Foods'' (87 Fed. Reg. 70910 (November 21, 2022)) (or any successor rule). Such plan shall include a description of—

(1) any resource needs of the Food and Drug Administration;

(2) strategies for facilitating compliance with the rule; and

(3) detailed plans for communicating with and educating regulated entities, non-Federal regulatory partners, and regulatory staff of the Food and Drug Administration about the requirements under the rule.

(b) STUDY ON INSPECTIONS.—The Secretary shall—

(1) conduct a study to—

(A) determine the annual number of facility inspections that is sufficient to determine that imported foods are held to the same safety standards as domestic food; and

(B) identify whether such inspection targets are consistent with the targets in the most recent annual report regarding food conducted under section 1003(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(h)); and

(2) not later than 1 year after the date of enactment of this Act, submit a report to Congress on the findings of such study, and, if applicable, any factors preventing the Secretary from meeting its goal for the number of inspections and a plan to ensure that such goal is met in the next 2 years.

(c) ANNUAL REPORT REGARDING FOOD.—Section 1003(h)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(h)(1)) is amended—

(1) in subparagraph (E), by striking ''and'' at the end;

(2) in subparagraph (F), by striking the period and inserting ''; and''; and

(3) by adding at the end the following:

''(G) the nature of domestic facility and foreign facility inspections described in subparagraph (C), the aggregate inspection findings of such inspections, and the compliance rate of foreign food importers with certification standards;''.

SEC. 5. RECORDS FOR OR IN LIEU OF CERTAIN INSPECTIONS.

Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(4)) is amended—

(1) by redesignating subparagraphs (B) through (D) as subparagraphs (C) through (E), respectively;

(2) by inserting after subparagraph (A) the following new subparagraph:

''(B)(i) Any records or other information that the Secretary may remotely inspect or copy under authority

of this Act from a person that owns or operates, or is an agent in charge of, an establishment that is engaged in any of the activities described in clause (ii) shall, upon the request of the Secretary, be provided to the Secretary by such person, in advance of, at the time of, or in the case in which an in-person inspection would be unsafe, in lieu of, an in-person, on-site inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, and in either electronic or physical form, at the expense of such person. The Secretary's request shall include a sufficient description of the records or other information requested.

''(ii) The activities described in this clause are records relating to—

''(I) the manufacturing, processing, sampling, testing, packing, transporting, distributing, receiving, holding, or importing of an article of food; or

''(II) the distribution or use of animal feed bearing or containing a veterinary feed directive drug, or the issuance of a veterinary feed directive.''; and

(3) by adding at the end the following:

''(F) Section 703 does not apply to records obtained or copied, or other information obtained or copied pursuant to a request made under this section.''.

SEC. 6. MANDATORY RECALL AUTHORITY.

Section 423(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350l(a)) is amended by inserting after ''animals,'' the following: ''or that an article of food is adulterated under paragraph (a)(1) or (j) of section 402,''.

SEC. 7. ENVIRONMENTAL MONITORING.

Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.), as amended by section 3, is further amended by adding the following:

''SEC. 426. ENVIRONMENTAL MONITORING OF INFANT AND TODDLER FOOD.

''(a) IN GENERAL.—A manufacturer of infant and toddler food (other than infant formula) shall establish and implement an environmental monitoring program to verify the effectiveness of sanitation and hygiene controls during the manufacturing and packaging process where the food has the potential to be exposed to pathogens. The environmental monitoring program shall be written and include procedures for determining sample location, number of samples to be taken, and timing and frequency of sample collection and testing.

''(b) ORGANISMS SAMPLED.—The environmental monitoring program under subsection (a) shall include testing for environmental pathogens or a reliable indicator organism.

''(c) SAMPLING LOCATION AND NUMBER OF SAMPLES.—A manufacturer of infant and toddler food shall ensure that the sampling locations from which samples will be taken, and the number of sites to be tested during routine environmental monitoring are adequate to determine whether sanitation and hygiene controls are effective.

''(d) TIMING AND FREQUENCY.—The timing and frequency for collecting and testing samples shall be adequate to determine whether sanitation and hygiene controls are effective, and shall occur not less frequently than every 3 years.

''(e) RECORDS.—

''(1) AVAILABILITY TO THE SECRETARY.—A manufacturer of infant and toddler food shall make all the records required under this section available promptly to the Secretary, upon request by the Secretary, for inspection and copying.

''(2) MAINTENANCE OF RECORDS PERTAINING TO ENVIRONMENTAL MONITORING.—Records of environmental sampling, testing, and monitoring conducted pursuant to this section shall be established and maintained by the manufacturer for not less than 2 years or the shelf life of the food, whichever is longer.

''(3) CONDITIONS OF INSPECTION.—Any records or other information that the Secretary may inspect under this section shall, upon the request of the Secretary, be provided to the Secretary by the manufacturer, in advance of, at the time of, or in the case in which an in-person inspection would be unsafe, in lieu of, an in-person, on-site inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, and in either electronic or physical form, at the expense of such manufacturer. The Secretary's request shall include a sufficient description of the records requested.

''(4) CONFIRMATION OF RECEIPT.—Upon receipt of the records requested under paragraph (3), the Secretary shall provide to the manufacturer confirmation of receipt.

''(f) AUTHORITY OF THE SECRETARY.—Nothing in this section supplants the authority of the Secretary to conduct inspections otherwise permitted under this Act in order to ensure compliance with this Act.

''(g) EFFECTIVE DATE.—The requirements of this section shall apply beginning on the date that is 2 years after the date of enactment of the Baby Food Safety Act of 2024.

"(h) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to exempt any manufacturer from the requirements of this Act, including the requirements under section 418.".

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