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H. R. 9105

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 HOUSE OF REPRESENTATIVES

JULY 23, 2024

Mr. KRISHNAMOORTHY (for himself and Mr. CÁRDENAS) 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 ensure the safety of food and limit the presence of contaminants in infant and toddler food, 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 “Baby Food Safety Act
5 of 2024”.

1 **SEC. 2. DEFINITION OF INFANT OR TODDLER FOOD.**

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

5 “(tt) The term ‘infant or toddler food’ means food
6 that purports to be, or is represented as being, for infants
7 or children up to the age of 24 months. Such term does
8 not include infant formula.”.

9 **SEC. 3. CONTAMINANTS IN FOOD, INCLUDING INFANT OR**
10 **TODDLER FOOD.**

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

14 **“SEC. 425. CONTAMINANTS IN FOOD, INCLUDING INFANT**
15 **OR TODDLER FOOD.**

16 “(a) ADMINISTRATIVE ORDERS FOR CONTAMINANTS,
17 INCLUDING TOXIC ELEMENTS, IN FOOD.—

18 “(1) IN GENERAL.—

19 “(A) REQUIRED LIMITS.—The Secretary,
20 by administrative order, shall establish limits on
21 the toxic elements of lead, cadmium, mercury,
22 and arsenic (or a species of any such toxic ele-
23 ment) in—

24 “(i) any infant or toddler food; and

25 “(ii) food predominantly composed of
26 a fruit or vegetable puree or juice;

1 “(B) ADDITIONAL LIMITS.—If the Sec-
2 retary determines appropriate upon review of
3 relevant health data and other relevant avail-
4 able information, the Secretary, by administra-
5 tive order, may—

6 “(i) establish limits for contaminants,
7 including toxic elements, in infant or tod-
8 dler food, in addition to the limits for toxic
9 elements described in subparagraph (A);
10 and

11 “(ii) establish limits for contaminants,
12 including toxic elements, in food predomi-
13 nantly composed of a fruit or vegetable
14 puree or juice, in addition to the limits for
15 toxic elements described in subparagraph
16 (A).

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

19 “(A) evaluate relevant health data and as-
20 sessments, data from State and local health de-
21 partments, and other information the Secretary
22 considers relevant;

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

1 use of such substances cannot be avoided in the
2 production of the applicable food and its ingre-
3 dients, based on an evaluation of alternative in-
4 gredients, use of best manufacturing and agri-
5 cultural practices, and full compliance with sec-
6 tion 418; and

7 “(C) notwithstanding the requirements of
8 subchapter II of chapter 5 of title 5, United
9 States Code, and chapter 6 of title 5, United
10 States Code—

11 “(i) publish any administrative order
12 under paragraph (1) in the Federal Reg-
13 ister following—

14 “(I) publication of a proposed
15 order in the Federal Register; and

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

19 “(ii) set forth in any proposed or final
20 administrative order under paragraph (1)
21 a substantive summary of the valid sci-
22 entific evidence concerning the proposed or
23 final limit.

24 “(3) CHANGES TO LIMITS.—If the Secretary de-
25 termines appropriate after review of relevant data

1 and assessments and other available and relevant
2 health information, the Secretary may revise any
3 limit established under this subsection by adminis-
4 trative order published in the Federal Register in ac-
5 cordance with paragraph (2).

6 “(4) TIMEFRAME FOR INITIAL LIMITS.—

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

11 “(i) For lead, not later than Decem-
12 ber 31, 2025.

13 “(ii) For arsenic, not later than De-
14 cember 31, 2025.

15 “(iii) For cadmium, not later than
16 April 30, 2026.

17 “(iv) For mercury, not later than
18 April 30, 2028.

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

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

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

9 “(6) ADULTERATED FOOD.—A food may be de-
10 termined adulterated, at the final product form,
11 under section 402(j), if such food bears or contains
12 any contaminant (including any toxic element) in ex-
13 cess of a limit established under this subsection.

14 “(7) PERIODIC REVIEW.—The Secretary shall
15 review, not less frequently than every 4 years, the
16 limits established under this subsection, taking into
17 consideration relevant information and available
18 data to consider whether such limits should be re-
19 vised, following the procedure described in para-
20 graph (2), in accordance with the criteria specified
21 in paragraph (5).

22 “(b) SAMPLING AND TESTING FOR TOXIC ELEMENTS
23 AND CONTAMINANTS IN FOOD, INCLUDING INFANT AND
24 TODDLER FOOD.—

1 “(1) IN GENERAL.—Beginning not later than
2 180 days after the date of enactment of the Baby
3 Food Safety Act of 2024, the owner, operator, or
4 agent in charge of a facility engaged in manufac-
5 turing or processing infant or toddler food; food pre-
6 dominantly composed of a fruit or vegetable puree or
7 juice; or such other food as the Secretary may speci-
8 fy by regulation, for consumption in the United
9 States, shall—

10 “(A) have a control program in place for
11 toxic elements and contaminants subject to lim-
12 its under subsection (a)(1);

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

17 “(C) conduct testing of the samples col-
18 lected from the final food product for toxic ele-
19 ments and contaminants, in accordance with a
20 sampling plan described in paragraph (2).

21 “(2) REQUIREMENTS FOR SAMPLING AND TEST-
22 ING PLAN.—

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

1 “(i) prepare a written plan for all
2 sampling and testing required under this
3 subsection; and

4 “(ii) ensure that all sampling and
5 testing conducted under this subsection is
6 conducted in accordance with the plan de-
7 scribed in clause (i).

8 “(B) SAMPLING PLAN.—A sampling and
9 testing plan required by subparagraph (A) shall
10 identify—

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

16 “(ii) one or more appropriate test
17 methods and procedures to be used to ana-
18 lyze the samples; and

19 “(iii) appropriate testing frequencies
20 not less frequently than every quarter and
21 whenever a significant change in the prod-
22 uct or process necessitates such testing.

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

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

11 “(3) CONTAMINANTS TO BE TESTED.—In car-
12 rying out the sampling and testing under this sub-
13 section, the owner, operator, or agent in charge of
14 a facility described in paragraph (1) shall ensure
15 that each sample is tested for levels of—

16 “(A) lead, cadmium, mercury, and arsenic;
17 and

18 “(B) any other contaminant that the Sec-
19 retary may specify, in accordance with the sam-
20 pling plan under paragraph (2).

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

24 “(A) infant and toddler foods, in final
25 product form;

1 “(B) foods predominantly composed of a
2 fruit or vegetable puree or juice; and

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

5
6 “(5) RECORDKEEPING.—

7 “(A) IN GENERAL.—The owner, operator,
8 or agent in charge of a facility described in
9 paragraph (1) shall maintain, for not less than
10 2 years or the shelf life of each food product
11 manufactured or processed by the facility,
12 whichever is longer, records documenting the
13 sampling plan and results of testing conducted
14 under this subsection with respect to the food.
15 The owner, operator, or agent in charge of such
16 a facility shall make such records available for
17 inspection and copying by the Secretary upon
18 request by the Secretary.

19 “(B) REQUIREMENTS.—The records main-
20 tained as required under subparagraph (A)
21 shall include—

22 “(i) a detailed description of the foods
23 sampled and tested;

24 “(ii) the number of samples and tests
25 performed;

1 “(iii) the size and number of items in
2 each sample unit;

3 “(iv) a copy of the sampling plan re-
4 quired under paragraph (2);

5 “(v) identification of the entity con-
6 ducting the sampling;

7 “(vi) identification of the entity con-
8 ducting the testing;

9 “(vii) identification of the analytical
10 methods used to perform the sampling and
11 testing;

12 “(viii) analytical findings of the sam-
13 pling and testing; and

14 “(ix) such other data and information
15 as the Secretary may require.

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

20 “(6) LABORATORY ACCREDITATION.—The
21 owner, operator, or agent in charge of a facility de-
22 scribed in paragraph (1) shall ensure that testing re-
23 quired pursuant to this subsection is performed in
24 accordance with international standards by a labora-
25 tory that—

1 “(A) is in compliance with the require-
2 ments regarding laboratory accreditation de-
3 scribed in section 422; or

4 “(B) if the requirements described in sub-
5 paragraph (A) do not apply to the laboratory,
6 is accredited by an accreditation body that con-
7 forms to international accreditation standards.

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

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

15 “(B) independently verify that products
16 are compliant with the limits proscribed pursu-
17 ant to this subsection.

18 “(c) RECORD AVAILABILITY.—

19 “(1) IN GENERAL.—Upon request by the Sec-
20 retary, the owner, operator, or agent in charge of a
21 facility described in subsection (b)(1) shall—

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

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

4 “(2) RECORD AVAILABILITY.—Any records that
5 the Secretary may inspect under this section shall,
6 upon the request of the Secretary, be provided to the
7 Secretary by the owner, operator, or agent in charge
8 of a facility described in subsection (b)(1), in ad-
9 vance of or in lieu of an inspection, within a reason-
10 able timeframe, within reasonable limits, and in a
11 reasonable manner, and in either electronic or phys-
12 ical form, at the expense of such owner, operator, or
13 agent. The Secretary’s request shall include a suffi-
14 cient description of the records requested.

15 “(3) CONFIRMATION.—Upon receipt of records
16 requested under paragraph (1) or (2), the Secretary
17 shall provide to the owner, operator, or agent de-
18 scribed in paragraph (2) confirmation of the receipt.

19 “(4) AUTHORITY OF THE SECRETARY.—Noth-
20 ing in this subsection supplants the authority of the
21 Secretary to conduct sampling, testing, or inspec-
22 tions otherwise permitted under this Act in order to
23 ensure compliance with this Act.

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

1 ginning on the date that is 2 years after the date of enact-
2 ment of this subsection.”.

3 (b) IMPORTER REQUIREMENTS.—Section 805(c)(4)
4 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 384a(c)(4)) is amended, by inserting “monitoring and
6 verifying the accuracy of records described in section
7 425(b)” after “for shipments,”.

8 (c) ENFORCEMENT.—

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

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

16 “(1) such food bears or contains any toxic ele-
17 ment or contaminant in excess of a limit established
18 under section 425(a); or

19 “(2) the owner, operator, or agent in charge of
20 a facility that manufactures or processes the food is
21 not in compliance with subsection (b) or (c) of sec-
22 tion 425.”.

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

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

5 **SEC. 4. IMPLEMENTATION OF FOOD TRACEABILITY PLAN;**
6 **STUDY ON INSPECTIONS; REPORTING ON IN-**
7 **SPECTIONS.**

8 (a) IMPLEMENTATION PLAN.—The Secretary of
9 Health and Human Services (referred to in this section
10 as the “Secretary”), acting through the Commissioner of
11 Food and Drugs, in coordination with the FDA Human
12 Foods Program and the Center for Food Safety and Ap-
13 plied Nutrition, shall finalize an implementation plan for
14 the Food and Drug Administration to achieve its goal of
15 compliance, not later than January 20, 2026, with the rule
16 issued by the Food and Drug Administration titled, “Re-
17 quirements for Additional Traceability Records for Cer-
18 tain Foods” (87 Fed. Reg. 70910 (November 21, 2022))
19 (or any successor rule). Such plan shall include a descrip-
20 tion of—

- 21 (1) any resource needs of the Food and Drug
22 Administration;
23 (2) strategies for facilitating compliance with
24 the rule; and

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

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

7 (1) conduct a study to—

8 (A) determine the annual number of facil-
9 ity inspections that is sufficient to determine
10 that imported foods are held to the same safety
11 standards as domestic food; and

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

18 (2) not later than 1 year after the date of en-
19 actment of this Act, submit a report to Congress on
20 the findings of such study, and, if applicable, any
21 factors preventing the Secretary from meeting its
22 goal for the number of inspections and a plan to en-
23 sure that such goal is met in the next 2 years.

1 (c) ANNUAL REPORT REGARDING FOOD.—Section
 2 1003(h)(1) of the Federal Food, Drug, and Cosmetic Act
 3 (21 U.S.C. 393(h)(1)) is amended—

4 (1) in subparagraph (E), by striking “and” at
 5 the end;

6 (2) in subparagraph (F), by striking the period
 7 and inserting “; and”; and

8 (3) by adding at the end the following:

9 “(G) the nature of domestic facility and
 10 foreign facility inspections described in subpara-
 11 graph (C), the aggregate inspection findings of
 12 such inspections, and the compliance rate of
 13 foreign food importers with certification stand-
 14 ards;”.

15 **SEC. 5. RECORDS FOR OR IN LIEU OF CERTAIN INSPEC-**
 16 **TIONS.**

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

19 (1) by redesignating subparagraphs (B)
 20 through (D) as subparagraphs (C) through (E), re-
 21 spectively;

22 (2) by inserting after subparagraph (A) the fol-
 23 lowing new subparagraph:

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

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

13 “(ii) The activities described in this clause are
14 records relating to—

15 “(I) the manufacturing, processing, sampling,
16 testing, packing, transporting, distributing, receiv-
17 ing, holding, or importing of an article of food; or

18 “(II) the distribution or use of animal feed
19 bearing or containing a veterinary feed directive
20 drug, or the issuance of a veterinary feed directive.”;
21 and

22 (3) by adding at the end the following:

23 “(F) Section 703 does not apply to records obtained
24 or copied, or other information obtained or copied pursu-
25 ant to a request made under this section.”.

1 **SEC. 6. MANDATORY RECALL AUTHORITY.**

2 Section 423(a) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 350l(a)) is amended by inserting
4 after “animals,” the following: “or that an article of food
5 is adulterated under paragraph (a)(1) or (j) of section
6 402,”.

7 **SEC. 7. ENVIRONMENTAL MONITORING.**

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

11 **“SEC. 426. ENVIRONMENTAL MONITORING OF INFANT AND**
12 **TODDLER FOOD.**

13 “(a) IN GENERAL.—A manufacturer of infant and
14 toddler food (other than infant formula) shall establish
15 and implement an environmental monitoring program to
16 verify the effectiveness of sanitation and hygiene controls
17 during the manufacturing and packaging process where
18 the food has the potential to be exposed to pathogens. The
19 environmental monitoring program shall be written and
20 include procedures for determining sample location, num-
21 ber of samples to be taken, and timing and frequency of
22 sample collection and testing.

23 “(b) ORGANISMS SAMPLED.—The environmental
24 monitoring program under subsection (a) shall include
25 testing for environmental pathogens or a reliable indicator
26 organism.

1 “(c) SAMPLING LOCATION AND NUMBER OF SAM-
2 PLES.—A manufacturer of infant and toddler food shall
3 ensure that the sampling locations from which samples
4 will be taken, and the number of sites to be tested during
5 routine environmental monitoring are adequate to deter-
6 mine whether sanitation and hygiene controls are effective.

7 “(d) TIMING AND FREQUENCY.—The timing and fre-
8 quency for collecting and testing samples shall be ade-
9 quate to determine whether sanitation and hygiene con-
10 trols are effective, and shall occur not less frequently than
11 every 3 years.

12 “(e) RECORDS.—

13 “(1) AVAILABILITY TO THE SECRETARY.—A
14 manufacturer of infant and toddler food shall make
15 all the records required under this section available
16 promptly to the Secretary, upon request by the Sec-
17 retary, for inspection and copying.

18 “(2) MAINTENANCE OF RECORDS PERTAINING
19 TO ENVIRONMENTAL MONITORING.—Records of envi-
20 ronmental sampling, testing, and monitoring con-
21 ducted pursuant to this section shall be established
22 and maintained by the manufacturer for not less
23 than 2 years or the shelf-life of the food, whichever
24 is longer.

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

13 “(4) CONFIRMATION OF RECEIPT.—Upon re-
14 ceipt of the records requested under paragraph (3),
15 the Secretary shall provide to the manufacturer con-
16 firmation of receipt.

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

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

1 “(h) RULE OF CONSTRUCTION.—Nothing in this sec-
2 tion shall be construed to exempt any manufacturer from
3 the requirements of this Act, including the requirements
4 under section 418.”.

○