

118TH CONGRESS  
2D SESSION

# H. R. 8385

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.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 14, 2024

Mr. KRISHNAMOORTHY (for himself and Mr. CÁRDENAS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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.

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 AND 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 and toddler food’ means food  
6 that purports to be, or is represented as being, specifically  
7 for infants or children up to the age of 24 months.”.

8 **SEC. 3. CONTAMINANTS IN FOOD, INCLUDING INFANT AND**  
9 **TODDLER FOOD.**

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

13 **“SEC. 425. CONTAMINANTS IN FOOD, INCLUDING INFANT**  
14 **AND TODDLER FOOD.**

15 “(a) ADMINISTRATIVE ORDERS FOR CONTAMINANTS  
16 IN FOOD.—

17 “(1) IN GENERAL.—Within the applicable time-  
18 frame specified in paragraph (4), the Secretary, by  
19 administrative order—

20 “(A) shall establish limits on—

21 “(i) lead, cadmium, mercury, and  
22 total arsenic in infant and toddler food;

23 “(ii) lead, cadmium, mercury, and  
24 total arsenic in food pouches made with  
25 fruit or vegetable puree or juice; and

26 “(iii) lead and arsenic in juice; and

1           “(B) if the Secretary determines appro-  
2           priate upon review of relevant health data and  
3           other relevant available information, may—

4                   “(i) establish limits for additional con-  
5                   taminants in infant and toddler food;

6                   “(ii) establish limits for additional  
7                   contaminants in juice;

8                   “(iii) establish limits for additional  
9                   contaminants in food pouches made with  
10                  fruit or vegetable puree or juice; and

11                  “(iv) revise limits established pursu-  
12                  ant to subparagraph (A).

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

15                   “(A) evaluate relevant health data and  
16                   other information the Secretary considers rel-  
17                   evant;

18                   “(B) take into account relevant differences  
19                   among food types, groups, and categories, as  
20                   appropriate, including the extent to which the  
21                   presence of a contaminant cannot be avoided;  
22                   and

23                   “(C) notwithstanding the requirements of  
24                   subchapter II of chapter 5 of title 5, United

1 States Code, and chapter 6 of title 5, United  
2 States Code—

3 “(i) publish any administrative order  
4 under paragraph (1) in the Federal Reg-  
5 ister following—

6 “(I) publication of a proposed  
7 order in the Federal Register; and

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

11 “(ii) set forth in any proposed or final  
12 administrative order under paragraph (1)  
13 a substantive summary of the valid sci-  
14 entific evidence concerning the proposed or  
15 final limit.

16 “(3) ADDITIONAL CONTAMINANTS; CHANGES TO  
17 LIMITS.—If the Secretary determines appropriate  
18 after review of relevant data and available health in-  
19 formation, the Secretary may revise any limit estab-  
20 lished under this subsection by administrative order  
21 published in the Federal Register in accordance with  
22 paragraph (2)(C).

23 “(4) TIMEFRAME FOR INITIAL LIMITS.—

24 “(A) PROPOSED ORDERS.—Subject to the  
25 requirements of paragraph (2)(C), the Sec-

1           retary shall issue proposed orders for limits  
2           under paragraph (1)(A) as follows:

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

5                   “(ii) For total arsenic, not later than  
6                   December 31, 2025.

7                   “(iii) For cadmium, not later than  
8                   April 30, 2026.

9                   “(iv) For mercury, not later than  
10                  April 30, 2028.

11                  “(B) FINAL ORDERS.—The Secretary shall  
12                  issue each final administrative order for a limit  
13                  established pursuant to paragraph (1)(A) not  
14                  later than the earlier of—

15                       “(i) the applicable deadline for a final  
16                       order specified in paragraph (1); or

17                       “(ii) 18 months after issuance of the  
18                       respective proposed order.

19                  “(5) CRITERIA.—The limits established under  
20                  this section shall represent the level at which the  
21                  Secretary finds necessary for the protection of public  
22                  health. In determining such limits the Secretary  
23                  shall take into account the extent to which the use  
24                  of such substance is required or cannot be avoided  
25                  in the production of each such article, and the other

1 ways in which a consumer may be affected by the  
2 same or other contaminants, taking into consider-  
3 ation relevant information and data that has been  
4 made available.

5 “(6) ADULTERATED FOOD.—A food may be de-  
6 termined adulterated, at the final product stage,  
7 under section 402(j), if such food bears or contains  
8 any contaminant in excess of a limit established  
9 under this subsection when considering variability of  
10 the validated method of analysis.

11 “(7) PERIODIC REVIEW.—The Secretary shall  
12 periodically review the limits established under this  
13 subsection, taking into consideration relevant infor-  
14 mation and available data to consider whether such  
15 limits should be revised, following the procedure de-  
16 scribed in paragraph (2), in accordance with the cri-  
17 teria specified in paragraph (5).

18 “(b) SAMPLING AND TESTING FOR CONTAMINANTS  
19 IN FOOD, INCLUDING INFANT AND TODDLER FOOD.—

20 “(1) IN GENERAL.—Beginning not later than  
21 180 days after the date of enactment of the Baby  
22 Food Safety Act of 2024, the owner, operator, or  
23 agent in charge of a facility engaged in manufac-  
24 turing or processing infant and toddler food, food  
25 pouches made with fruit or vegetable puree or juice,

1 or juice for consumption in the United States  
2 shall—

3 “(A) have a control program pursuant to  
4 section 418 in place for contaminants subject to  
5 ordered limits under subsection (a), or be in  
6 compliance with the Juice Hazard Analysis  
7 Critical Control Points Program of the Food  
8 and Drug Administration, as applicable;

9 “(B) be in compliance with regulations  
10 promulgated under section 420(b);

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

15 “(D) conduct testing of the samples col-  
16 lected from the final food product for contami-  
17 nants, in accordance with such sampling plan.

18 “(2) REQUIREMENTS FOR SAMPLING PLAN.—

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

22 “(i) prepare a written sampling plan  
23 for all sampling and testing required under  
24 this subsection; and

1           “(ii) ensure that all sampling and  
2           testing conducted under this subsection is  
3           conducted in accordance with the sampling  
4           plan.

5           “(B) SAMPLING PLAN.—A sampling plan  
6           required by subparagraph (A) shall identify—

7                   “(i) the number of sampling units and  
8                   sample unit size based upon appropriate  
9                   criteria for identifying, in a representative  
10                  fashion, the levels of contaminants in each  
11                  food; and

12                   “(ii) one or more appropriate test  
13                   methods and procedures to be used to ana-  
14                   lyze the samples.

15           “(C) GUIDANCE.—Not later than 18  
16           months after the date of enactment of the Baby  
17           Food Safety Act of 2024, the Secretary shall  
18           issue guidance to assist facilities described  
19           under paragraph (1) with developing sampling  
20           plans. Such guidance may, as the Secretary de-  
21           termines appropriate, address when samples  
22           should be tested for specific species of contami-  
23           nants.

24           “(3) CONTAMINANTS TO BE TESTED.—In car-  
25           rying out the sampling and testing under this sub-



1 section, the owner, operator, or agent in charge of  
2 a facility described in paragraph (1) shall ensure  
3 that each sample is tested for levels of—

4 “(A) lead, cadmium, mercury, and total ar-  
5 senic; and

6 “(B) any other contaminant that the Sec-  
7 retary may specify by regulation, and in accord-  
8 ance with the sampling plan under paragraph  
9 (2).

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

13 “(A) infant and toddler foods, in final  
14 product form;

15 “(B) pouches made with fruit and vege-  
16 table puree or juice;

17 “(C) juice; and

18 “(D) such other foods in final product  
19 form as the Secretary may specify, by regula-  
20 tion, as appropriate to protect the public health.

21 “(5) RECORDKEEPING.—

22 “(A) IN GENERAL.—The owner, operator,  
23 or agent in charge of a facility described in  
24 paragraph (1) shall maintain, for not less than  
25 2 years or the shelf-life of each food product

1 manufactured or processed by the facility,  
2 whichever is longer, records documenting the  
3 sampling plan and results of testing conducted  
4 under this subsection with respect to the food.  
5 The owner, operator, or agent in charge of such  
6 a facility shall make such records available for  
7 inspection by the Secretary upon request by the  
8 Secretary.

9 “(B) REQUIREMENTS.—The records main-  
10 tained as required under subparagraph (A)  
11 shall include—

12 “(i) a detailed description of the foods  
13 sampled and tested;

14 “(ii) the number of samples and tests  
15 performed;

16 “(iii) the size and number of items in  
17 each sample unit;

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

20 “(v) identification of the entity con-  
21 ducting the sampling;

22 “(vi) identification of the entity con-  
23 ducting the testing; and

1                   “(vii) identification of the analytical  
2                   methods used to perform the sampling and  
3                   testing.

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

8                   “(6) LABORATORY ACCREDITATION.—The  
9                   owner, operator, or agent in charge of a facility de-  
10                  scribed in paragraph (1) shall ensure that testing re-  
11                  quired pursuant to this subsection is performed in  
12                  accordance with international standards by a labora-  
13                  tory that is accredited by an accreditation body that  
14                  conforms to international accreditation standards.  
15                  Testing conducted under this subsection is not sub-  
16                  ject to the requirements regarding laboratory accred-  
17                  itation described in section 422.

18                  “(7) SAMPLING AND TESTING PROGRAM.—The  
19                  Secretary shall develop and implement a sampling  
20                  and testing program for infant and toddler food for  
21                  sale to consumers that is sufficient to—

22                         “(A) support the periodic review under  
23                         subsection (a)(7) of limits on lead, cadmium,  
24                         mercury, and arsenic in infant and toddler food;  
25                         and

1           “(B) independently verify the effectiveness  
2           of the sampling and testing conducted pursuant  
3           to this subsection by the owner, operator, or  
4           agent in charge of a food facility.

5           “(8) GUIDANCE.—The Secretary shall issue  
6           guidance to assist food facilities in complying with  
7           this subsection.

8           “(c) RECORD AVAILABILITY.—

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

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

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

18           “(2) RECORD AVAILABILITY IN LIEU OF AN IN-  
19          SPECTION.—Any records that the Secretary may in-  
20          spect under this section shall, upon the request of  
21          the Secretary, be provided to the Secretary by the  
22          owner, operator, or agent in charge of a facility de-  
23          scribed in subsection (b)(1), in advance of or in lieu  
24          of an inspection, within a reasonable timeframe,  
25          within reasonable limits, and in a reasonable man-

1 ner, and in either electronic or physical form, at the  
2 expense of such owner, operator, or agent. The Sec-  
3 retary's request shall include a sufficient description  
4 of the records requested.

5 “(3) CONFIRMATION.—Upon receipt of records  
6 requested under paragraph (1) or (2), the Secretary  
7 shall provide to the owner, operator, or agent de-  
8 scribed in paragraph (2) confirmation of the receipt.

9 “(4) AUTHORITY OF THE SECRETARY.—Noth-  
10 ing in this subsection supplants the authority of the  
11 Secretary to conduct sampling, testing, or inspec-  
12 tions otherwise permitted under this Act in order to  
13 ensure compliance with this Act.

14 “(d) DELAYED APPLICABILITY.—The requirements  
15 for sampling and testing under this section shall apply be-  
16 ginning on the date that is 2 years after the date of enact-  
17 ment of this subsection.

18 “(e) PREEMPTION OF STATE AND LOCAL REQUIRE-  
19 MENTS REGARDING FOOD INGREDIENTS AND CONTAMI-  
20 NANTS IN FOOD, INCLUDING INFANT AND TODDLER  
21 FOOD.—No State or political subdivision of a State may  
22 establish or continue in effect with respect to contami-  
23 nants in food, including infant and toddler food, food  
24 pouches made with fruit or vegetable puree or juice, and  
25 juice, any requirement that is different from, or in addi-

1 tion to, or not identical with any requirement under this  
2 section, and relates to contaminant sampling and testing,  
3 contaminant limits, disclosure of contaminant test results,  
4 contaminant labeling, contaminant warnings, or any other  
5 matter related to contaminants in food.”.

6 (b) IMPORTER REQUIREMENTS.—Section 805(c)(4)  
7 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
8 384a(c)(4)) is amended, by inserting “, including as de-  
9 scribed in section 425(b)” before the period at the end.

10 (c) ENFORCEMENT.—

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

14 “(j) If it is an article of food in final product form  
15 that is an infant and toddler food, a food pouch made with  
16 fruit or vegetable puree or juice, or juice and—

17 “(1) such food bears or contains any contami-  
18 nant in excess of limits established under section  
19 425(a); or

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

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

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

8           **SEC. 4. IMPLEMENTATION OF FOOD TRACEABILITY PLAN;**  
9                           **STUDY ON INSPECTIONS; REPORTING ON IN-**  
10                           **SPECTIONS.**

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

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

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

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

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

9           (1) conduct a study to—

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

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

20           (2) not later than 1 year after the date of en-  
21 actment of this Act, submit a report to Congress on  
22 the findings of such study, and, if applicable, any  
23 factors preventing the Secretary from meeting its  
24 goal for the number of inspections and a plan to en-  
25 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 inspect under authority of this Act from

1 a person that owns or operates, or is an agent in charge  
2 of, an establishment that is engaged in any of the activi-  
3 ties described in clause (ii) shall, upon the request of the  
4 Secretary, be provided to the Secretary by such person,  
5 in advance of or in lieu of an inspection, within a reason-  
6 able timeframe, within reasonable limits, and in a reason-  
7 able manner, and in either electronic or physical form, at  
8 the expense of such person. The Secretary’s request shall  
9 include a sufficient description of the records requested.

10 “(ii) The activities described in this clause are  
11 records relating to—

12 “(I) the manufacturing, processing, packing,  
13 transporting, distributing, receiving, holding, or im-  
14 porting of an article of food; or

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

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

20 “(F) Section 703 does not apply to records or other  
21 information obtained pursuant to a request made under  
22 this section.”.

23 **SEC. 6. MANDATORY RECALL AUTHORITY.**

24 Section 423(a) of the Federal Food, Drug, and Cos-  
25 metic Act (21 U.S.C. 350l(a)) is amended by inserting

1 after “animals,” the following: “or if the Secretary deter-  
2 mines through any means that an article of infant and  
3 toddler food (other than infant formula) bears or contains  
4 a contaminant that renders the product adulterated under  
5 section 402(a)(1),”.

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

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

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

12 “(a) IN GENERAL.—A manufacturer of infant and  
13 toddler food shall establish and implement an environ-  
14 mental monitoring program to verify the effectiveness of  
15 sanitation and hygiene controls where the food has the po-  
16 tential to be exposed to environment pathogens during the  
17 manufacturing and packing process. The environmental  
18 monitoring program shall be written and include proce-  
19 dures for determining sample location, number of samples  
20 to be taken, and timing and frequency of sample collection  
21 and testing.

22 “(b) ORGANISMS SAMPLED.—The environmental  
23 monitoring program under subsection (a) shall include  
24 testing for environmental pathogens, lead, arsenic, mer-  
25 cury, or a reliable indicator 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.

11       “(e) RECORDS.—

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

16               “(2) MAINTENANCE.—Records of environmental  
17 monitoring conducted pursuant to this section shall  
18 be established and maintained by the manufacturer  
19 for not less than 2 years or the shelf-life of the food,  
20 whichever is longer.

21               “(3) CONDITIONS OF INSPECTION.—Any  
22 records that the Secretary may inspect under this  
23 section shall, upon the request of the Secretary, be  
24 provided to the Secretary by the manufacturer, in  
25 advance of or in lieu of an inspection, within a rea-

1       sonable timeframe, within reasonable limits, and in  
2       a reasonable manner, and in either electronic or  
3       physical form, at the expense of such manufacturer.  
4       The Secretary’s request shall include a sufficient de-  
5       scription of the records requested.

6               “(4) CONFIRMATION OF RECEIPT.—Upon re-  
7       ceipt of the records requested under paragraph (3),  
8       the Secretary shall provide to the manufacturer con-  
9       firmation of receipt.

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

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

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

○