

118TH CONGRESS  
1ST SESSION

# H. R. 6770

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

---

## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 13, 2023

Mrs. SYKES (for herself, Mr. PALLONE, Mr. CÁRDENAS, and Mr. KRISHNAMOORTHY) 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 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 “Improving Newborns’  
5 Food and Nutrition Testing Safety Act of 2023” or the  
6 “INFANTS Act of 2023”.

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 which purports to be or is represented as food for children  
7 up to 24 months of age, including infant formula.”.

8 **SEC. 3. CONTAMINANTS IN FOOD.**

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

12 **“SEC. 425. SAMPLING AND TESTING FOR CONTAMINANTS IN**  
13 **FOOD.**

14 “(a) SAMPLING AND TESTING.—

15 “(1) IN GENERAL.—The owner, operator, or  
16 agent in charge of a food facility that manufactures  
17 or processes food, including infant and toddler food,  
18 in final product form intended for sale to consumers  
19 shall—

20 “(A) collect representative samples of each  
21 such food; and

22 “(B) conduct testing of the samples for  
23 contaminants, including toxic elements.

24 “(2) REQUIREMENT FOR SAMPLING PLAN.—

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

4           “(i) prepare a written sampling plan  
5 for all sampling and testing required under  
6 this section; and

7           “(ii) ensure that all sampling and  
8 testing conducted under this section is con-  
9 ducted in accordance with the sampling  
10 plan.

11           “(B) REQUIREMENTS.—A sampling plan  
12 under subparagraph (A) shall identify—

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

18           “(ii) one or more appropriate test  
19 methods and procedures to be used to ana-  
20 lyze the samples.

21           “(C) GUIDANCE.—Not later than 18  
22 months after the date of enactment of this sec-  
23 tion, the Secretary shall issue guidance to assist  
24 food facilities in developing sampling plans.  
25 Such guidance may, as determined appropriate

1           by the Secretary, address when samples should  
2           be tested for specific species of contaminants.

3           “(3) CONTAMINANTS TO BE TESTED.—Each  
4           sample taken pursuant to a sampling plan under  
5           this section shall be tested for levels of lead, cad-  
6           mium, mercury, arsenic, and any other contaminant,  
7           including other toxic elements, that the Secretary  
8           may specify by regulation.

9           “(4) FREQUENCY OF TESTING.—The sampling  
10          and testing conducted under this section shall be  
11          conducted at least once per quarter of each calendar  
12          year.

13          “(5) FOODS TO BE TESTED.—The sampling  
14          and testing conducted under this section shall be  
15          conducted for—

16                 “(A) infant and toddler foods, in final  
17                 package form; and

18                 “(B) such other foods as the Secretary  
19                 may specify, by regulation, as appropriate to  
20                 protect public health.

21          “(b) RECORDKEEPING.—

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

1 factured or processed at the facility, whichever is  
2 longer, records documenting the sampling and test-  
3 ing conducted under this section with respect to the  
4 food.

5 “(2) REQUIREMENTS.—Records required by  
6 paragraph (1) to be maintained shall include a de-  
7 tailed description of the foods sampled and tested,  
8 the number of samples and tests performed, the size  
9 and number of items in each sample unit, a copy of  
10 the facility’s sampling plan, identification of the en-  
11 tity conducting the sampling, identification of the  
12 entity conducting the testing, and the analytical  
13 methods used to perform the sampling and testing.

14 “(3) APPLICABILITY.—This subsection applies  
15 to all records of sampling and testing conducted  
16 under this section, regardless of the findings.

17 “(c) LABORATORY ACCREDITATION.—The owner, op-  
18 erator, or agent in charge of a food facility described in  
19 subsection (a)(1) shall ensure that testing conducted pur-  
20 suant to this section is performed in accordance with  
21 international standards by a laboratory that is accredited  
22 by an accreditation body that conforms to international  
23 accreditation standards. Testing conducted under this sec-  
24 tion is not subject to the requirements regarding labora-  
25 tory accreditation described in section 422.

1 “(d) RECORDS AVAILABILITY.—

2 “(1) IN GENERAL.—The owner, operator, or  
3 agent in charge of a food facility described in sub-  
4 section (a)(1) shall make all records required under  
5 this section available promptly to the Secretary,  
6 upon request, for inspection and copying. Upon re-  
7 quest of the Secretary, such an owner, operator, or  
8 agent in charge shall provide within a reasonable  
9 time an English translation of records maintained in  
10 a language other than English.

11 “(2) RECORDS AVAILABILITY IN LIEU OF AN IN-  
12 SPECTION.—Any records that the Secretary may in-  
13 spect under this section shall, upon the request of  
14 the Secretary, be provided to the Secretary by the  
15 owner, operator, or agent in charge of a food facility  
16 described in subsection (a)(1), in advance of or in  
17 lieu of an inspection, within a reasonable timeframe,  
18 within reasonable limits, and in a reasonable man-  
19 ner, and in either electronic or physical form, at the  
20 expense of such owner, operator, or agent. The Sec-  
21 retary’s request shall include a sufficient description  
22 of the records requested.

23 “(3) CONFIRMATION.—Upon receipt of records  
24 requested under paragraph (2), the Secretary shall  
25 provide to the person confirmation of receipt.

1           “(4) AUTHORITY OF THE SECRETARY.—Noth-  
2           ing in this subsection supplants the authority of the  
3           Secretary to conduct inspections otherwise permitted  
4           under this Act in order to ensure compliance with  
5           this Act.

6           “(e) DELAYED APPLICABILITY.—The requirements  
7           for sampling and testing under this section apply begin-  
8           ning on the date that is 180 days after the date on which  
9           the Secretary publishes the guidance required by sub-  
10          section (a)(2)(C).”.

11       **SEC. 4. ADULTERATION.**

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

15          “(j) If it is an article of food and the owner, operator,  
16          or agent in charge of a food facility that manufactures  
17          or processes such food—

18               “(1) is subject to the requirements of section  
19               425; and

20               “(2) fails to comply with the requirements of  
21               such section with regard to that article.”.

22       **SEC. 5. RECORDS FOR OR IN LIEU OF CERTAIN INSPEC-**  
23               **TIONS.**

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

1           (1) by redesignating subparagraphs (B), (C),  
2           and (D) as subparagraphs (C), (D), and (E), respec-  
3           tively;

4           (2) by inserting after subparagraph (A) the fol-  
5           lowing:

6           “(B)(i) Any records or other information that the  
7           Secretary may inspect under authority of this Act from  
8           a person that owns or operates an establishment that is  
9           engaged in any of the activities described in clause (ii)  
10          shall, upon the request of the Secretary, be provided to  
11          the Secretary by such person, in advance of or in lieu of  
12          an inspection, within a reasonable timeframe, within rea-  
13          sonable limits, and in a reasonable manner, and in either  
14          electronic or physical form, at the expense of such person.  
15          The Secretary’s request shall include a sufficient descrip-  
16          tion of the records requested.

17          “(ii) The activities described in this clause are the  
18          following:

19                 “(I) The manufacturing, processing, packing,  
20                 transporting, distributing, receiving, holding, or im-  
21                 porting of an article of food.

22                 “(II) The distribution or use of animal feed  
23                 bearing or containing a veterinary feed directive  
24                 drug, or the issuance of a veterinary feed directive.”;  
25                 and

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

2 “(F) Section 703 does not apply to requests for  
3 records or other information when those requests are  
4 made under this section.”.

5 **SEC. 6. MANDATORY RECALL AUTHORITY.**

6 Section 423(a) of the Federal Food, Drug, and Cos-  
7 metic Act (21 U.S.C. 350l(a)) is amended by inserting “or  
8 if the Secretary determines through any means that an  
9 article of infant and toddler food (other than infant for-  
10 mula) bears or contains a contaminant that renders the  
11 product adulterated under section 402(a)(1),” after “ani-  
12 mals,”.

13 **SEC. 7. REPORT FINAL PRODUCT POSITIVE TEST RESULTS**  
14 **FOR RELEVANT PATHOGENS IN INFANT FOR-**  
15 **MULA.**

16 Section 412 of the Federal Food, Drug, and Cosmetic  
17 Act (21 U.S.C. 350a) is amended—

18 (1) in subsection (e)—

19 (A) in paragraph (1)—

20 (i) in the first sentence, by striking  
21 “promptly” and inserting “, within 24  
22 hours of acquiring such knowledge,”; and

23 (ii) in the second sentence, by striking  
24 “the infant formula” and inserting “an in-  
25 fant formula”;

1 (B) by redesignating paragraph (2) as  
2 paragraph (4);

3 (C) in paragraph (4), as so redesignated,  
4 by striking “paragraph (1)” and inserting  
5 “paragraphs (1) and (2)”; and

6 (D) by inserting after paragraph (1) the  
7 following:

8 “(2) If the result of any in-process or finished prod-  
9 uct testing of an infant formula that has been processed  
10 by the manufacturer is confirmed as a positive analytical  
11 result for any environmental pathogen (as defined in sec-  
12 tion 117.3 of title 21, Code of Federal Regulations (or  
13 any successor regulation)), the manufacturer shall—

14 “(A) within 24 hours of acquiring such con-  
15 firmation, notify the Secretary of such confirmation  
16 regardless of whether such infant formula has left  
17 an establishment subject to the control of the manu-  
18 facturer;

19 “(B) consult with the Secretary for proper dis-  
20 posal and properly dispose of the affected product;  
21 and

22 “(C) provide to the Secretary results and iso-  
23 lates from a positive sample of such infant formula.

24 “(3) Not later than 90 days after receipt of a notifi-  
25 cation under paragraph (1) or (2), the Secretary shall con-

1 firm through the collection of documentation that the  
2 manufacturer submitting the notification performed, or is  
3 performing, appropriate corrective action. The manufac-  
4 turer shall make such documentation available to the Sec-  
5 retary during an inspection and, upon request of the Sec-  
6 retary, electronically or by other means.”.

7 **SEC. 8. ENVIRONMENTAL MONITORING.**

8 Section 412 of the Federal Food, Drug, and Cosmetic  
9 Act (21 U.S.C. 350a) is amended by adding at the end  
10 the following:

11 “(n) REQUIREMENTS FOR ENVIRONMENTAL MONI-  
12 TORING FOR CRONOBACTER SPP AND SALMONELLA.—

13 “(1) IN GENERAL.—A manufacturer of pow-  
14 dered infant formula shall establish and implement  
15 an environmental monitoring program to verify the  
16 effectiveness of sanitation and hygiene controls  
17 where the food has the potential to be exposed to  
18 Cronobacter spp. or Salmonella. The environmental  
19 monitoring program shall be written and include  
20 procedures for determining sampling location, num-  
21 ber of samples to be taken, and timing and fre-  
22 quency of sample collection and testing.

23 “(2) SAMPLING LOCATION AND NUMBER OF  
24 SAMPLES.—A manufacturer of powdered infant for-  
25 mula shall ensure that the sampling locations from

1       which samples will be taken, and the number of sites  
2       to be tested during routine environmental moni-  
3       toring pursuant to an environmental monitoring pro-  
4       gram under paragraph (1), are adequate to deter-  
5       mine whether sanitation and hygiene controls are ef-  
6       fective.

7               “(3) TIMING AND FREQUENCY.—A manufac-  
8       turer of powdered infant formula shall ensure that  
9       the timing and frequency for collecting ant testing  
10      samples pursuant to an environmental monitoring  
11      program under paragraph (1) are adequate to deter-  
12      mine whether sanitation and hygiene controls are ef-  
13      fective.

14              “(4) RECORDS.—

15                      “(A) AVAILABILITY TO THE SECRETARY.—  
16       A manufacturer of powdered infant formula  
17       shall make all records required under this sub-  
18       section available promptly to the Secretary,  
19       upon request, for inspection and copying.

20                      “(B) MAINTENANCE.—Records of environ-  
21       mental monitoring conducted pursuant to this  
22       subsection shall be maintained for not less than  
23       2 years or the shelf-life of the infant formula,  
24       whichever is longer.

1           “(C) CONDITIONS OF INSPECTION.—Any  
2 records that the Secretary may inspect under  
3 this subsection shall, upon the request of the  
4 Secretary, be provided to the Secretary by the  
5 manufacturer of powdered infant formula, in  
6 advance of or in lieu of an inspection, within a  
7 reasonable timeframe, within reasonable limits,  
8 and in a reasonable manner, and in either elec-  
9 tronic or physical form, at the expense of such  
10 manufacturer. The Secretary’s request shall in-  
11 clude a sufficient description of the records re-  
12 quested.

13           “(D) CONFIRMATION OF RECEIPT.—Upon  
14 receipt of records requested under subpara-  
15 graph (C), the Secretary shall provide to the  
16 person confirmation of receipt.

17           “(5) AUTHORITY OF THE SECRETARY.—Noth-  
18 ing in this subsection supplants the authority of the  
19 Secretary to conduct inspections otherwise permitted  
20 under this Act in order to ensure compliance with  
21 this Act.

22           “(6) DELAYED APPLICABILITY.—The require-  
23 ments of this subsection apply beginning on the date  
24 that is 180 days after the date of enactment of this  
25 subsection.

1           “(7) RULE OF CONSTRUCTION.—Nothing in  
2           this subsection shall be construed to exempt an in-  
3           fant formula manufacturer from the requirements of  
4           this Act, including the requirements of this section  
5           and section 418.”.

○