

117TH CONGRESS  
1ST SESSION

# H. R. 2229

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.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 26, 2021

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 limit the presence of toxic elements in, and otherwise regulate, 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 2021”.

6 **SEC. 2. DEFINITION OF INFANT AND TODDLER FOOD.**

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

1 “(ss) The term ‘infant and toddler food’ means food  
2 intended for sale to children up to 36 months of age, in-  
3 cluding infant formula.”.

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

6 (a) PREVENTIVE CONTROLS.—Section 418(c) of the  
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
8 350g(c)) is amended—

9 (1) in paragraph (2), by striking “and” at the  
10 end;

11 (2) in paragraph (3), by striking the period at  
12 the end and inserting “; and”; and

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

14 “(4) the infant and toddler foods manufactured,  
15 processed, packed, or held by such facility will com-  
16 ply with the performance standards and action levels  
17 for toxic elements in infant and toddler foods re-  
18 quired under section 104 of the FDA Food Safety  
19 Modernization Act.”.

20 (b) VERIFICATION.—Paragraph (4) of section 418(f)  
21 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
22 350g(f)) is amended to read as follows:

23 “(4) the preventive controls implemented under  
24 subsection (c) are effectively and significantly mini-  
25 mizing or preventing the occurrence of identified

1 hazards, including through the use of environmental  
2 and product testing programs and other appropriate  
3 means, including representative testing by manufac-  
4 turers of infant and toddler foods that are finished  
5 products; and”.

6 (c) BIENNIAL REPORTING.—Section 418(h) of the  
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
8 350g(h)) is amended by adding at the end the following:  
9 “The owner, operator, or agent in charge of a facility that  
10 manufactures infant and toddler foods shall make publicly  
11 available on a webpage a biennial report summarizing the  
12 results of monitoring under subsection (d), and  
13 verification results under subsection (f), with respect to  
14 such facility and infant and toddler foods.”.

15 **SEC. 4. INFANT AND TODDLER FOOD ACTION LEVELS.**

16 (a) PERFORMANCE STANDARD GUIDANCE DOCU-  
17 MENTS AND REGULATIONS.—Section 104(b) of the FDA  
18 Food Safety Modernization Act (21 U.S.C. 2201(b)) is  
19 amended—

20 (1) in the matter preceding paragraph (1), by  
21 striking “reduce the risk of serious illness or death”  
22 and inserting “reduce the risk of serious illness, in-  
23 cluding neurological impairment, or death”; and

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

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

7           “(e) ACTION LEVELS.—

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

14                 “(2) INITIAL LEVELS.—The initial action levels  
15          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
Mereury .....	2 ppb

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

4                   “(A) review relevant health and dietary  
5                   data; and

6                   “(B) by guidance, lower the initial action  
7                   levels established by paragraph (2) to further  
8                   minimize exposure to toxic elements in infant  
9                   and toddler food to further reduce potential  
10                  clinical or population-level health effects as indi-  
11                  cated by the Secretary’s review of relevant  
12                  health and dietary data.

13           “(4) FINAL REGULATORY LIMITS; PERIODIC RE-  
14           VIEW.—The Secretary shall—

15                   “(A) not later than 3 years after the date  
16                   of enactment of the Baby Food Safety Act of  
17                   2021, by regulation set regulatory limits lower  
18                   than the action levels established by paragraphs  
19                   (2) and (3) to levels protective of infant and  
20                   toddler neurological development, taking into  
21                   account the most sensitive testing available; and

22                   “(B) every 5 years thereafter—

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

1                   sistent with the standard described in sub-  
2                   paragraph (A); and

3                   “(ii) if so, by regulation so lower such  
4                   levels.

5                   “(5) TOXIC ELEMENTS.—The Secretary may by  
6                   guidance or regulation, as applicable, establish in-  
7                   terim action levels and regulatory limits for toxic ele-  
8                   ments in infant and toddler food in addition to the  
9                   toxic elements specified in the table in paragraph (2)  
10                  if determined by the Secretary to be appropriate  
11                  upon review of relevant health and dietary data.

12                  “(6) PROGRESS REPORTS.—Not later than 1  
13                  year, 2 years, and 3 years after the date of enact-  
14                  ment of the Baby Food Safety Act of 2021, the Sec-  
15                  retary shall submit a report to the Congress con-  
16                  taining—

17                         “(A) a summary of progress towards es-  
18                         tablishing the required levels under this sub-  
19                         section;

20                         “(B) an evaluation of the effectiveness of  
21                         preventive controls for infant and toddler food  
22                         based on monitoring results and verification re-  
23                         sults under section 418 of the Federal Food,  
24                         Drug, and Cosmetic Act (21 U.S.C. 350g) com-  
25                         pared to levels under this subsection; and

1                   “(C) an estimate of progress in reducing  
2                   the cumulative exposure of children to toxic ele-  
3                   ments in infant and toddler food.”.

4           (c) DEFINITION.—Section 104 of the FDA Food  
5 Safety Modernization Act (21 U.S.C. 2201(b)), as amend-  
6 ed by subsections (a) and (b), is further amended by add-  
7 ing at the end the following:

8           “(f) INFANT AND TODDLER FOOD DEFINED.—In  
9 this section, the term ‘infant and toddler food’ has the  
10 meaning given to such term in section 201(ss) of the Fed-  
11 eral Food, Drug, and Cosmetic Act.”.

12          (d) MANDATORY RECALL AUTHORITY.—Section  
13 423(a) of the Federal Food, Drug, and Cosmetic Act (21  
14 U.S.C. 350l(a)) is amended—

15               (1) by striking “(other than infant formula)”;  
16               and

17               (2) by inserting after “animals,” the following:  
18               “or the Secretary determines that an article of in-  
19               fant and toddler food contains a toxic element that  
20               meets or exceeds the action level applicable under  
21               subsection (e) of section 104 of the FDA Food Safe-  
22               ty Modernization Act,”.

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

1           (1) by redesignating subsection (h) as sub-  
2           section (i); and

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

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

12          (f) GRANTS FOR FARMING RESEARCH.—Section 401  
13          of the FDA Food Safety Modernization Act (Public Law  
14          111–353; 124 Stat. 3967) is amended by adding the end  
15          the following:

16          “(c) GRANTS FOR FARMING RESEARCH.—

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

1           “(2) AUTHORIZATION OF APPROPRIATIONS.—  
2           To carry out this subsection, there is authorized to  
3           be appropriated \$50,000,000.”.

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