

118TH CONGRESS
1ST SESSION

H. R. 6756

To amend the Federal Food, Drug, and Cosmetic Act to establish limits on certain toxic elements in infant and toddler food, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 13, 2023

Mr. KRISHNAMOORTHY (for himself, Mr. CÁRDENAS, and Mrs. SYKES) 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 establish limits on certain toxic elements 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 2023”.

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 “(tt) The term ‘infant and toddler food’—

2 “(1) means foods intended for infants and chil-
3 dren less than two years of age; and

4 “(2) includes infant formula.”.

5 **SEC. 3. TOXIC ELEMENTS IN INFANT AND TODDLER FOOD.**

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

9 **“SEC. 425. TOXIC ELEMENTS IN INFANT AND TODDLER**
10 **FOOD.**

11 “(a) IN GENERAL.—The Secretary, by administrative
12 order—

13 “(1) shall establish limits for lead, cadmium,
14 mercury, and inorganic arsenic in infant and toddler
15 food; and

16 “(2) if determined by the Secretary to be ap-
17 propriate upon review of relevant health data and
18 other relevant information, may—

19 “(A) establish limits for additional toxic
20 elements in infant and toddler food; and

21 “(B) revise limits established pursuant to
22 paragraph (1) or subparagraph (A).

23 “(b) PROCEDURE.—In establishing or revising any
24 limit under subsection (a), the Secretary shall—

1 “(1) evaluate relevant health data and other
2 relevant information;

3 “(2) take into account relevant differences
4 among infant and toddler food types, groups, or cat-
5 egories, as appropriate, including—

6 “(A) the feasibility of achieving the limit
7 based on the food type, group, or category; and

8 “(B) the extent to which the level of a
9 toxic element in infant and toddler food is as
10 low as reasonably achievable; and

11 “(3) notwithstanding the requirements of sub-
12 chapter II of chapter 5 of title 5, United States
13 Code, and chapter 6 of title 5, United States Code—

14 “(A) publish any administrative order
15 under subsection (a) in the Federal Register
16 following—

17 “(i) publication of a proposed order in
18 the Federal Register; and

19 “(ii) consideration of comments to a
20 public docket open for no fewer than 45
21 calendar days; and

22 “(B) set forth in any proposed or final ad-
23 ministrative order under subsection (a) a sub-
24 stantive summary of the valid scientific evidence
25 concerning the proposed or final limit.

1 “(c) TIMEFRAME FOR INITIAL LIMITS.—

2 “(1) IN GENERAL.—Subject to the deadlines for
3 final orders under paragraph (2), the Secretary shall
4 issue orders for limits under subsection (a) as fol-
5 lows:

6 “(A) For each of lead, inorganic arsenic,
7 and cadmium, a proposed order not later than
8 December 31, 2025, and a final order not later
9 than June 30, 2027.

10 “(B) For mercury, a proposed order not
11 later than April 30, 2029, and a final order not
12 later than October 31, 2030.

13 “(2) FINAL ORDERS.—The Secretary shall issue
14 each final administrative order for a limit estab-
15 lished pursuant to subparagraph (a)(1) not later
16 than the earlier of—

17 “(A) the applicable deadline for a final
18 order specified in paragraph (1); and

19 “(B) 18 months after issuance of the re-
20 spective proposed order.

21 “(d) CRITERIA.—The limits established under this
22 section shall represent the level at which the toxic element
23 may render the infant and toddler food injurious to health,
24 taking into account—

25 “(1) the protection of the public health; and

1 “(2) the extent to which the level of the toxic
2 element is as low as reasonably achievable.

3 “(e) GUIDANCE.—Whenever the Secretary publishes
4 a new or revised limit for a toxic element under this sec-
5 tion, the Secretary shall publish, together with the admin-
6 istrative order establishing or revising such limit, guidance
7 concerning compliance with such limit.

8 “(f) PERIODIC REVIEW.—The Secretary shall peri-
9 odically, or as relevant data is made available, review the
10 limits and guidance established under this section to con-
11 sider whether such limits and guidance should be revised,
12 following the applicable procedures and criteria under this
13 section.”.

14 **SEC. 4. ADULTERATION.**

15 Section 402 of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S.C. 342) is amended by adding at the end the
17 following new subsection:

18 “(j) If it is an article of infant and toddler food in
19 final product form that bears or contains any toxic ele-
20 ment in excess of a limit established under section 425(a)
21 taking into consideration variability of the validated meth-
22 od of analysis.”.

23 **SEC. 5. 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 toxic element that renders the product adulterated under
5 section 402(a)(1) or 402(j),”.

○