

117TH CONGRESS
1ST SESSION

S. 1019

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.

IN THE SENATE OF THE UNITED STATES

MARCH 25, 2021

Ms. KLOBUCHAR (for herself and Ms. DUCKWORTH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 web page a biennial report summarizing
 12 the 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

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

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

“(e) ACTION LEVELS.—

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

“(2) INITIAL LEVELS.—The initial action levels 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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