

119TH CONGRESS
2D SESSION

H. R. 9788

To amend the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services to establish maximum permissible levels for contaminants in infant formulas, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 20, 2026

Mr. MAST (for himself and Mr. CARTER of Georgia) 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 direct the Secretary of Health and Human Services to establish maximum permissible levels for contaminants in infant formulas, 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 “Formula Oversight,
5 Regulation, and Manufacturing Uniformity for Life-sus-
6 taining Assurance Act of 2026” or the “FORMULA Act
7 of 2026”.

1 **SEC. 2. REQUIREMENTS FOR INFANT FORMULAS.**

2 (a) CRITERIA FOR DETERMINING IF AN INFANT FOR-
3 MULA IS ADULTERATED.—Section 412(a) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 350a(a)) is
5 amended—

6 (1) in paragraph (2), by striking “or” at the
7 end;

8 (2) in paragraph (3), by striking the period at
9 the end and inserting “, or”; and

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

11 “(4) such infant formula does not comply with
12 the maximum permissible levels for contaminants in
13 infant formula established by the Secretary under
14 subsection (n).”.

15 (b) MAXIMUM PERMISSIBLE LEVELS FOR CONTAMI-
16 NANTS IN INFANT FORMULA.—Section 412 of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 350a) is
18 amended by adding at the end the following:

19 “(n) MAXIMUM PERMISSIBLE LEVELS FOR CONTAMI-
20 NANTS IN INFANT FORMULA.—

21 “(1) ESTABLISHMENT.—The Secretary shall by
22 regulation establish maximum permissible levels for
23 contaminants in infant formula.

24 “(2) MAXIMUM CONTAMINANT LEVELS.—In
25 prescribing regulations under paragraph (1), the
26 Secretary shall ensure that the level of any contami-

1 nant in infant formula is as close to the maximum
2 contaminant level goal as is feasible with the use of
3 the best available technology, treatment techniques,
4 and other means which the Secretary finds are avail-
5 able, taking cost into consideration.

6 “(3) FACTORS TO CONSIDER.—In establishing
7 the maximum permissible level for a contaminant
8 under paragraph (1), the Secretary shall consider—

9 “(A) the cumulative health impacts of low-
10 level exposure of the contaminant on infant
11 neurodevelopment;

12 “(B) the prevalence of the contaminant in
13 agricultural soil and manufacturing source-
14 water; and

15 “(C) the bioaccumulative nature of the
16 contaminant in the human body.

17 “(4) TESTING AND RECORDS.—In prescribing
18 regulations under paragraph (1), the Secretary shall
19 require a manufacturer of infant formula—

20 “(A) to conduct testing to ensure compli-
21 ance with the maximum permissible contami-
22 nant levels established by the Secretary under
23 paragraph (1);

24 “(B) to maintain records relating to such
25 testing for not fewer than 2 years after the ex-

1 piration of the shelf life of such infant formula;
2 and

3 “(C) to make such records available to the
4 Secretary upon request.

5 “(5) CONTAMINANT DEFINED.—In this sub-
6 section, the term ‘contaminant’ means any physical,
7 chemical, biological, or radiological substance or
8 matter that is man-made or introduced into the en-
9 vironment via human activity, including heavy met-
10 als, per- and polyfluoroalkyl substances, phthalates,
11 microplastics, synthetic pesticides, and biological
12 toxins, including cyanotoxins associated with harm-
13 ful algal blooms.

14 “(6) ANNUAL REPORT TO CONGRESS.—As part
15 of the annual report required under subsection (l),
16 the Secretary shall include—

17 “(A) a list of any manufacturers found to
18 be in violation of the maximum permissible con-
19 taminant levels established by the Secretary
20 under paragraph (1);

21 “(B) the specific concentrations of con-
22 taminants, including microplastics and
23 cyanotoxins, detected in infant formula during
24 routine surveillance testing; and

1 “(C) an assessment of the progress made
2 toward achieving the lowest feasible levels for
3 contaminants in infant formula in the domestic
4 supply chain.”.

5 (c) REGULATIONS.—Not later than 180 days after
6 the date of enactment of this Act, the Secretary of Health
7 and Human Services shall issue regulations to implement
8 section 412(n) of the Federal Food, Drug, and Cosmetic
9 Act (as added by subsection (b) of this section). Such reg-
10 ulations shall apply to infant formula manufactured on or
11 after the date that is 180 days after the date of issuance
12 of the regulations.

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