

The Baby Food Safety Act of 2021
Section-by-Section Summary

Section 1 – Short Title

This Act may be cited as the “Baby Food Safety Act of 2021.”

Section 2 – Definition of Infant and Toddler Food

Defines “infant and toddler food” as food intended for sale to children up to 36 months of age, including infant formula.

Section 3 – Infant and Toddler Food Hazard Analysis and Risk-Based Preventive Controls

Amends Section 418 of the Federal Food, Drug, and Cosmetic Act (FFDCA) to

- Require manufacturers of infant and toddler food to implement preventive controls to comply with performance standards under Section 104 of the FDA Food Safety Modernization Act (FSMA) and with maximum levels of toxic heavy metals set in Section 4 below.
- Require manufacturers to conduct representative testing of final products for toxic heavy metals as part of their hazard preventive control efforts.
- Require manufacturers to make publicly available online, twice per year, reports summarizing the results of their product testing and their efforts to monitor and verify the effectiveness of hazard preventive controls.

Section 4 – Infant and Toddler Food Action Levels

Amends Section 104 of FSMA to

- Clarify that neurological impairment is included in “serious illness” for the purposes of issuing guidance documents or regulations when appropriate to reduce the risk of serious illness or death from foodborne contaminants.
- Require such guidance documents or regulations to apply to toxic elements in infant and toddler foods.
- Establish initial action levels, effective one year after enactment, setting the maximum allowable limit of toxic heavy metals in infant and toddler foods as follows:
 - 10 parts per billion (ppb) inorganic arsenic (15 ppb for cereal)
 - 5 ppb cadmium (10 ppb for cereal)
 - 5 ppb lead (10 ppb for cereal)
 - 2 ppb mercury
- Establish that if an infant or toddler food fails to meet the levels, it will be deemed adulterated.
- Require the Secretary of Health and Human Services (Secretary) to lower the action levels above by guidance to further minimize exposure to toxic elements in infant and toddler foods within two years.
- Require the Secretary to set regulatory limits lower than the action levels above to levels protective of infant and toddler neurological development, taking into account the most sensitive testing available, within three years.
- Require the Secretary to review the regulatory limits every five years thereafter to consider whether they should be lowered further, and if so, to lower them by regulation.
- Establish that the Secretary may establish action levels and regulatory limits for toxic elements in infant and toddler foods other than inorganic arsenic, cadmium, lead, or mercury.
- Require the Secretary to submit reports to Congress after not later than one, two, and three years summarizing progress toward establishing the levels above, the effectiveness of manufacturers’ preventive controls for meeting the levels, and progress towards reducing children’s cumulative exposure to toxic elements in food.

Amends Section 423 of FFDCA to allow the Secretary to recall infant and toddler food if it is determined to contain toxic heavy metals exceeding the levels above and removes restrictions on the Secretary recalling infant formula generally.

Requires the Centers for Disease Control and Prevention to carry out a public awareness campaign to highlight the risks posed by toxic heavy metals in infant and toddler food.

Authorizes \$50 million for the FDA Commissioner to commission the National Academy of Sciences to conduct research on agricultural methods of minimizing levels of toxic heavy metals in crops.