SB 723

Department of Legislative Services

Maryland General Assembly
2024 Session

FISCAL AND POLICY NOTE
Enrolled - Revised

Senate Bill 723 (Senator Benson)
Finance Health and Government Operations

Baby Food - Toxic Heavy Metals - Testing and Labeling (Rudy's Law)

This bill prohibits a person, beginning January 1, 2025, from selling, distributing, or offering for sale "baby food" that contains "toxic heavy metals" that exceed the limits established by the U.S. Food and Drug Administration (FDA). A person may sell, distribute, or offer for sale baby food manufactured before January 1, 2026. Beginning January 1, 2025, each "manufacturer" of baby food must test a "representative sample" of each "production aggregate" of the manufacturer's final baby food product for each toxic heavy metal. On request of the Maryland Department of Health (MDH), a manufacturer of baby food must provide the laboratory test results to an authorized agent of the department. Beginning January 1, 2026, each manufacturer of baby food must make specified information publicly available on their website and the baby food product label.

Fiscal Summary

State Effect: General fund expenditures increase by $27,700 in FY 2025. Future years reflect annualization and ongoing costs. Revenues are not affected.

(in dollars)	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
Revenues	$0	$0	$0	$0	$0
GF Expenditure	27,700	25,500	26,500	27,500	28,600
Net Effect	($27,700)	($25,500)	($26,500)	($27,500)	($28,600)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

Local Effect: The bill is not anticipated to have a material impact on local governments. To the extent that local health departments must inspect baby food products sold in licensed food establishments such as grocery stores, expenditures may increase beginning in FY 2025. Revenues are not likely affected.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary:

Definitions

"Baby food" means food packaged in a jar, pouch, tub, or box sold specifically for babies and children younger than age two. "Baby food" does not include infant formula. "Manufacturer" includes a food manufacturer, food processor, and food packer. "Production aggregate" means a quantity of product that is intended to have uniform composition, character, and quality and is produced according to a master manufacturing order. "Proficient laboratory" means a laboratory that (1) is accredited under the standards of the International Organization for Standardization/International Electrotechnical Commission 17025:2017; (2) uses an analytical method at least as sensitive as the analytical method described in Section 4.7 of the FDA *Elemental Analysis Manual for Food and Related Products*; and (3) demonstrates proficiency in quantifying each toxic element to at least 6 micrograms of the toxic element to kilogram of food through an independent proficiency test by achieving a z-score that is less than or equal to plus or minus two. "Representative sample" means a sample that consists of a number of units that are drawn based on rational criteria, such as random sampling, and intended to ensure that the sample accurately portrays the material being sampled. "Toxic heavy metal" means arsenic, cadmium, lead, or mercury.

Baby Food Manufacturer Requirements

Baby food testing must be conducted by a proficient laboratory at least once per month. A manufacturer *may* test the final baby food product before packaging individual units of baby food for sale or distribution.

Beginning January 1, 2026, each manufacturer of baby food must:

- make publicly available on their website for each baby food product sold, manufactured, delivered, held, or offered for sale in the State (1) the name and level of each toxic heavy metal present in the final baby food product; (2) sufficient information, such as the product name, universal product code, or lot or batch number, to enable consumers to identify the final baby food product; and (3) a link to the FDA website that includes the most recent guidance and information about the health effects of toxic heavy metals on children; and
- if the baby food is tested for a toxic heavy metal subject to an action level, regulatory limit, or tolerance established by FDA under 21 CFR § 109, include on the baby food product label a (1) Quick Response (QR) Code or other machine-readable code that allows consumers to access on the manufacturer's website of the

baby food product information page, the test results for the toxic heavy metals and a link to the webpage on the FDA website that includes the most recent guidance and information about the health effects of the toxic heavy metal on children and (2) specified statement regarding the QR Code.

Consumer Complaints

If a consumer believes, based on information gathered through the use of the QR Code included on the baby food product label, that the baby food is being sold in the State with toxic heavy metals that exceed limits established by FDA, the consumer must report the baby food product to MDH.

Current Law: MDH's Center for Food Processing is responsible for licensing and inspecting facilities that make, process, store, hold, or distribute food to sell wholesale to other businesses in Maryland. The Center for Facility and Process Review conducts a plan and process review for all food processing plants and prototypical food service facilities. Food processing plans are inspected to ensure compliance with applicable State and federal laws and regulations. Facilities that manufacture, process, pack, and hold food and operate (receive or distribute) across state lines fall under FDA jurisdiction and must comply with federal regulations.

The federal Food, Drug, and Cosmetics Act prohibits the manufacture or sale of any food that is adulterated or misbranded. The Food Additives Amendment to the Act authorizes FDA to regulate food ingredients. MDH implements the Maryland Food, Drug, and Cosmetic Act, which conforms to the federal Act.

Under the federal Food, Drug, and Cosmetics Act, a substance added to food is considered unsafe unless the substance confirms to the terms of an exemption for investigational use, or unless the substance is in conformance with a regulation describing the conditions under which the substance may be safely used. Pursuant to federal regulations (21 CFR § 109), a tolerance, regulatory limit, or action level may be established when a food additive cannot be controlled by regulation. A tolerance for an added substance in any food may be established when (1) the substance cannot be avoided by good manufacturing practice; (2) the tolerance is sufficient for the protection of the public health; and (3) no technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established.

A regulatory limit for an added substance in any food may be established when (1) the substance cannot be avoided by good manufacturing practice; (2) there is no tolerance established for the substance in the particular food; and (3) there is insufficient information by which a tolerance may be established, or technological changes appear reasonably possible that may affect the appropriateness of a tolerance. An action level for an added

substance in any food may be established when the criteria for a tolerance may be established, except that technological or other changes might affect the appropriateness of a tolerance in the foreseeable near future.

Pursuant to 21 U.S.C. § 321, "infant formula" means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

There is currently no State or federal requirement for manufacturers to test baby food for toxic heavy metals.

State Expenditures: General fund expenditures increase by $27,655 in fiscal 2025, which accounts for the bill's October 1, 2024 effective date. This estimate reflects the cost of hiring one part-time contractual administrative specialist to review heavy metal test results for baby food manufactured for sale in the State, review manufacturer's compliance with the bill's information sharing requirements, and respond to consumer complaints. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Contractual Position	0.5
Salary and Fringe Benefits	$17,050
Operating Expenses	10,605
Total FY 2025 State Expenditures	**$27,655**

This estimate does not include any health insurance costs that could be incurred for specified contractual employees under the State's implementation of the federal Patient Protection and Affordable Care Act.

Future year expenditures reflect a full salary with annual increases and employee turnover as well as annual increases in ongoing operating expenses.

Small Business Effect: To the extent a small business baby food manufacturer does not currently test for heavy metals, expenditures for the business increase by a potentially significant amount. Small businesses must also make specified information available to consumers on baby food packaging, which further increase expenditures. Revenues for small businesses food establishments may decrease if the facility is no longer able to sell baby food products that do not comply with the bill's requirements.

Additional Comments: According to the FDA, the level of toxic heavy metals in the environment used to grow crops, process foods, and raise animals can vary depending on natural geographic differences, human activity, and proximity to pollutants. Babies and young children are more vulnerable to the harmful effects of toxic heavy metals in food because of their small body sizes and metabolism. In 2021, following a congressional

investigation, the FDA launched the Closer to Zero campaign to reduce dietary exposure to contaminants as low as possible, while also maintaining access to nutritious foods. In January 2023, the FDA released draft guidance for lead in food intended for babies and children. Guidelines are expected to be finalized in 2025.

Additional Information

Recent Prior Introductions: Similar legislation has not been introduced within the last three years.

Designated Cross File: HB 97 (Delegate Taveras, *et al.*) - Health and Government Operations.

Information Source(s): Maryland Association of County Health Officers; Maryland Department of Health; U.S. Food and Drug Administration; Department of Legislative Services

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Analysis by: Amberly E. Holcomb

Direct Inquiries to:
(410) 946-5510
(301) 970-5510