



Testimony re: Maryland House Bill 196

INCA represents several of the leading domestic manufacturers of infant formula. For more than 50 years, INCA has advocated for optimal infant health and the critical role of infant nutrition, supported families in their feeding decisions, and provided evidence-based information to educate stakeholders on appropriate infant feeding options. Infant formula is the most highly regulated food in the U.S. food supply, and INCA members take the commitment to deliver safe formulas to the most vulnerable population very seriously. Safety and quality are our top priority.

Infant formula is produced under rigorously controlled conditions supported by robust, validated food safety management systems. Quality assurance activities are implemented throughout all production steps to ensure full compliance with applicable national and international regulations to maintain the highest standards of safety and quality. The comprehensive quality testing that infant formula goes through before release is the most extensive of any food category.

Our industry already tests for heavy metals as part of our longstanding commitment to provide safe, high quality infant formula products. As the results of those tests show, our products comply with heavy metals standards established by the European Food Safety Authority, the European Commission, Joint FAO/WHO Expert Committee on Food Additives, and Codex.

In addition to our testing under international standards, there are current FDA regulations that help guard against high levels of heavy metals in infant formula. The FDA's Infant Formula Good Manufacturing Practices (21 CFR Part 106) and regulations established under The Food Safety Modernization Act (promulgated in 21 CFR Part 117) requires that manufactures conduct a hazard analysis and establish risk-based preventive controls (including of raw material hazards such as potential for heavy metal contamination). As part of these obligations, infant formula manufacturers identify potential risks for heavy metals and monitor heavy metals across raw materials and finished product batches.

Heavy metals, in trace amounts, have always been a part of the human diet. They exist in the environment and may be absorbed or ingested by the plants and animals from which food ingredients (including formula ingredients) are sourced. Heavy metals are found in fruits, vegetables, meat, and seafood – even when organically grown or raised – and in human breast milk. This is why infant formula manufacturers have protocols in place to reduce the presence of these substances in ingredients to ensure that any trace levels in finished infant formula remain safe for consumption and satisfy all relevant regulatory requirements including the FDA, WHO, EU, and Codex.

INCA members recognize their obligation to provide products that are both safe and nutritious and can be used with utmost confidence. For these reasons, INCA would like to share our concerns with HB 196. HB 196 would alter the definition of “baby food” under Maryland’s recently enacted baby-food testing law (Maryland Code Ann. 21-330.4) “to include, rather than exclude, infant formula.”¹ If enacted, HB 196 would require infant formula manufacturers to post quantitative testing results for certain heavy metals on their public websites—as sellers of non-formula baby foods currently must do under that law.

¹ <https://mgaleg.maryland.gov/2026RS/bills/hb/hb0196f.pdf>.

While INCA appreciates the intent of HB 196, this proposal overlooks important differences between infant formula and the baby foods currently covered by HB 196. Infant formula is already highly regulated under federal law in a way that other baby foods are not. There have been no congressional reports asserting elevated levels of heavy metals in infant formulas, as there have been for certain non-formula baby foods. According to both FDA and industry testing, heavy metals are present in infant formula at trace levels that are far lower than those that have been reported in many non-formula baby foods. Indeed, the FDA stated in March 2025 that its recent testing “d[id] not indicate that [heavy metals] are present in infant formula at levels that would trigger a public health concern.”²

Moreover, the FDA is still in the process of determining action levels for heavy metals in infant formulas—unlike non-formula baby foods, for which certain action levels have already been established. For example, the FDA has already proposed or finalized action levels for lead in non-formula baby foods, and for arsenic in children’s juices and infant rice cereals, but infant formulas are expressly excluded from these guidances.³ The FDA announced its intent to set formula-specific action levels in March 2025 as part of its Operation Stork Speed—an effort we support. And just recently, the Department of Health and Human Services announced that it will publish a report in April 2026 addressing cadmium, mercury, and lead in infant formula—a precursor to setting federal action levels.

Requiring infant formula manufacturers to post quantitative testing results before the FDA has announced any action levels for formula is more likely to cause unwarranted confusion or alarm than to provide helpful information. Absent FDA guidance, a number like “1 part per billion cadmium” would not communicate anything meaningful to parents about the formula’s safety or compliance with FDA regulations. To date, all states that have adopted similar disclosure statutes for baby foods have chosen to exclude infant formula from those requirements, at least until the FDA issues action levels. California, for example, amended its bill to exclude infant formula, finding “merit to the concern” that posting quantitative test results where “the FDA has [not yet] adopted guidance” could “cause confusion among consumers on how to process the information that is presented.”⁴ This, in turn, could conceivably lead parents and caregivers to resort to alternative feeding options (such as homemade formulas) that do not meet FDA safety and quality standards for complete nutrition in infants and lack the nutrients necessary for infant growth and development, which can be dangerous to infants’ health and wellbeing.

We are also concerned that HB 196 would require infant formula to bear a statement about “toxic element testing.” The word “toxic” is not only inaccurate as it relates to trace levels of heavy metals in infant formula but potentially alarming for parents. Again, the FDA has stated that heavy metals in infant formula do not indicate “a public health concern.” Absent such a demonstrated concern requiring formulas to bear the word “toxic” might mislead parents and caregivers into thinking that these products are unsafe, and/or jeopardizing infant with alternatives that truly are unsafe.

² <https://www.usatoday.com/story/money/2025/03/19/infant-formulas-lead-arsenic-consumer-reports/82372887007/>.

³ See, e.g., FDA, Action Levels for Lead in Processed Food Intended for Babies and Young Children: Guidance for Industry at 3 note 2, <https://www.fda.gov/media/164684/download>.

⁴ California Assembly – Committee on Health, AB 899 Bill Analysis at 11, March 28, 2023, available at https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=202320240AB899

We do not recommend any actions that might unjustifiably erode confidence in U.S. infant formula products; inadvertently threaten infants' health; and further strain the availability of safe infant formula products that meet all FDA regulatory requirements. Further, it is worth noting any product labeling changes required to comply with Maryland law would be functionally required nationwide as retail partners determine product distribution, not infant formula manufacturers. This, too, counsels in favor of keeping Maryland's current approach, which mirrors the approach taken by California, Virginia, and Illinois (which represents almost 20% of the U.S. population).

INCA members look forward to working with the FDA to establish action levels for heavy metals in infant formula, and to enhance public awareness about the protective measures already in place across the infant formula industry. INCA believes that this measure is premature and would inadvertently harm not only Maryland's parents and infants but also have this same effect at the national level. The use of the word "toxic" should be avoided to as it would alarm parents as stated previously. We recommend the Committee take time to consider the unintended consequences of the legislation as drafted. INCA members welcome an opportunity to work with you and your staff on HB 196 to ensure that parents and caregivers that rely on infant formula have access to science-based information and continue to trust formula products to meet their child's needs.