

## **Heavy Metals Regulation: Infant Formula Global Landscape**

In March 2025, the US Department of Health and Human Services announced [Operation Stork Speed](#), an initiative that would, among other things, increase testing for heavy metals and other contaminants in infant formula and other foods children consume. This announcement builds upon a previously announced initiative by the US Food and Drug Administration (FDA) to set heavy metal limits in foods commonly eaten by babies and young children as part of their [Closer to Zero Initiative](#). Infant Nutrition Council of America (INCA) supports these efforts. In the meantime, our members already have established heavy metal limits and regularly test for them as part of our longstanding commitment to provide safe, high quality infant formula products. In addition to adhering to these limits, in line with international standards and regulatory limits, and conducting routine testing, our members also comply with FDA's Good Manufacturing Practice (GMP) and quality-related regulations for food (21 CFR 110 and 21 CFR 117) and infant formula (21 CFR Part 106), which requires that manufacturers 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 metal levels across raw materials and finished product. 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. Our members 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 meet international standards and regulatory limits.

For specific heavy metals addressed in Maryland HB 196, maximum levels have already been established for infant formula in the European Union (EU), Canada, and Australia/New Zealand (FSANZ). But even among other countries, there is variation on which environmental contaminants to monitor. The EU sets the most extensive maximum allowable limits for infant formula contaminants, including lead, cadmium and arsenic. By comparison, Australia has proposed maximum limits for only 4 infant formula contaminants (lead, vinyl chloride, aluminum, and acrylonitrile) in its own 2023 updated review on the regulation of infant formula products. For Canada, maximum limits are set for lead (0.01 ppm) in infant formula. Codex Alimentarius (Codex), an international food standards body established by the Food and Agriculture Organization (FAO) and World Health Organization (WHO) provides another reference with recently updated lead contaminant limits for infant formula. It is important to note that in countries where standards have been set, there is no labeling requiring disclosure of testing results to consumers due to the fact that consumers cannot interpret this data and its relationship to human health.

	<b>US FDA</b> <a href="#">Closer to Zero</a>	<b>European Commission</b> <a href="#">EU 2023/915</a>	<b>Health Canada</b> <a href="#">NOM/ADM C-2020-2</a>	<b>Codex</b> <a href="#">CXS 193-1995</a>	<b>FSANZ</b> <a href="#">Schedule 19</a>
Inorganic Arsenic	No limit established	0.020 ppm, as powder 0.010 ppm, as liquid	No limit established	No limit established	No limit established
Cadmium	No limit established	0.010 ppm, cow milk-based powder 0.005 ppm, cow milk-based liquid 0.020 ppm, soy- or soy + cow milk-based powder 0.010 ppm, soy- or soy + cow milk-based liquid	No limit established	No limit established	No limit established
Lead	No limit established	0.020 ppm, as powder 0.010 ppm, as liquid	0.01 ppm, as-fed	0.01 ppm, as-fed	0.01 ppm, as-fed
Mercury	No limit established	0.01 ppm, as-fed*	No limit established	No limit established	No limit established

\* EU regulates mercury as a pesticide residue and does not have a specific regulatory limit for infant formula. However, the default pesticide limit of 0.01 ppm (as-fed) would apply to mercury in infant formula per Commission Delegated Regulation EU 2016/127