

Heavy Metal Tested & Certified (HMTc) Infant and Child Foods Standards

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CATEGORIES:

- ✓ Infant Formula
- ✓ Baby Cereals
- ✓ Purées
- ✓ Mixed Meals
- ✓ Fruit Juice
- ✓ Teething & Snacks

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Statement of Purpose

The HMTc Standards define category-specific action levels for finished products across key infant food categories -infant formula (powder and ready-to-feed), baby cereals (dry grains), fruit purées, non-root and root-vegetable purées, mixed meals (e.g. meat-grain entrées), fruit juice (not canned), and teething/snack products (rice- and non-rice-based).

These limits are anchored to the best available occurrence data and major regulatory benchmarks, and are set at levels that roughly 80% of current products can achieve, thereby being feasible for industry while still driving reformulation, safer sourcing, and improved process controls.

Importantly, these values are feasibility-based action levels - not safety thresholds. Exceeding a limit should trigger corrective action and reformulation under an “as low as reasonably achievable” (ALARA) paradigm, even if acute risk is low. Implementation of HMTc requires validated analytical testing and a documented heavy-metal control program encompassing raw ingredient specifications, agricultural and water quality controls, packaging/contact material standards, and ongoing surveillance.

Ultimately, the purpose of the HMTc Standards is to facilitate independent third-party certification for infant and early-childhood foods, supporting risk-based product development and supply-chain management. By progressively reducing heavy metal contents, the Standards aim to minimize cumulative exposure in early life and preserve wide safety margins as consumption patterns and sourcing evolve. The standard will be periodically updated as new toxicological data and food-occurrence data emerge, ensuring it remains protective and science-aligned.

Anti-Circumvention & Integrity

The Heavy Metal Tested & Certified (HTMc) Standard uses ppb ($\mu\text{g}/\text{kg}$) limits on an as-sold basis rather than per-serving limits to ensure that compliance cannot be achieved through serving-size or portion-definition adjustments.

Concentration-based limits provide a consistent, testable, and comparable basis for certification and are intended to drive meaningful reductions in heavy metal content through product formulation and supply-chain controls, rather than through labeling strategies.

Serving-based limits permit nominal compliance through arbitrary or manipulable portion definitions without requiring changes to underlying contaminant concentrations. As a result, such approaches fail to reliably reduce exposure, particularly in populations with variable or elevated intake relative to labeled serving sizes, including infants and young children.

For these reasons, serving-based thresholds are considered structurally inadequate for certification programs intended to achieve contamination reduction and lack regulatory integrity when used as a substitute for concentration-based controls.

Product Categories

Infant Formula

Powder and ready-to-feed
liquid formulations

Baby Cereals

Grain products (dry)

Purées

Fruit, non-root vegetable,
and root-vegetable varieties

Mixed Meals

Meat & grain combinations

Fruit Juice

Not canned

Teething & Snacks

Non-rice and rice-based
products

Terms and Abbreviations

EFSA	European Food Safety Authority. An EU agency that produces scientific opinions on food and feed risks, including contaminant risk assessments used by regulators.
Infants and Young Children	In this document, refers to children from birth up to ~5 years of age (typical age range for infant and toddler food and child foods).
JECFA	Joint FAO/WHO Expert Committee on Food Additives. An international expert body convened by the Food and Agriculture Organization of the United Nations and the World Health Organization to evaluate risks from food additives, contaminants, and residues and to derive health-based guidance values where possible.
TWI	Tolerable Weekly Intake. A health-based guidance value expressed as an amount per kilogram body weight per week that is considered tolerable over a lifetime for substances where a threshold is assumed or can be used for risk management.
PTWI	Provisional Tolerable Weekly Intake. An older term used when the guidance value was considered provisional due to data limitations or expected updates; in practice it functioned like a TWI.
BMD	Benchmark Dose. A dose associated with a predefined change in response (the benchmark response) compared with background. It is used in dose–response modeling.
BMDL	Benchmark Dose Lower Confidence Limit. The lower bound of the statistical confidence interval around the BMD, commonly used as a conservative point of departure in risk assessment.
BMDL01	A BMDL corresponding to a benchmark response of 1 percent (for quantal endpoints such as incidence) or an equivalent small change for continuous endpoints, as defined by the assessor; it is used as a conservative reference point for deriving guidance values or characterizing risk.
IRL	Interim Reference Level. In the FDA context, a risk-management intake level used to prioritize and evaluate actions to reduce exposure, not a safety threshold.
bw	Body weight, usually expressed in kilograms, used to normalize intake or dose (for example, $\mu\text{g}/\text{kg bw}/\text{day}$).
ppb	Parts per billion by mass in foods, typically equivalent to micrograms per kilogram ($\mu\text{g}/\text{kg}$). For liquids, it is often treated as micrograms per liter ($\mu\text{g}/\text{L}$) when density is close to 1 kg/L , which is a reasonable approximation for ready-to-feed formula.
$\mu\text{g}/\text{L}$	Micrograms per liter. A concentration unit commonly used for blood lead (and for dilute liquids).
$\mu\text{g}/\text{day}$	Micrograms per day. An intake unit used to express daily dietary exposure.
ALARA	As Low As Reasonably Achievable. A risk-management principle used for contaminants, especially when there is no clearly established safe threshold, emphasizing feasible, continual reduction over time.
Action level	A practical concentration limit used to trigger sourcing, process, and quality actions to reduce contamination. It is set partly on feasibility and risk reduction and should not be interpreted as a definitive safety threshold.

Lead (Pb) Standards

Scope/measurement. Total lead (Pb) shall be measured in the finished product as placed on the market. Powders shall be analyzed as sold, and liquids or concentrates shall be analyzed after preparation in accordance with label instructions. Lead shall be determined as total elemental Pb, with results expressed in $\mu\text{g}/\text{kg}$ (ppb) and used directly for compliance determination.

Category	HMTc Standards (ppb)	EU/FDA
Infant formula (powder)	10 ppb	20 ppb
Infant formula (ready-to-feed, liquid)	5 ppb	10 ppb
Baby cereals / grain products (dry)	10 ppb	20 ppb
Fruit purées (general)	10 ppb	20 ppb
Non-root vegetable purées	10 ppb	20 ppb
Root-vegetable purées	10 ppb	20 ppb
Mixed meals	10 ppb	20 ppb
Fruit juice (not canned)	10 ppb	20 ppb
Teething & Snacks	10 ppb	20 ppb



Toxicology and Margin of Safety

Lead has no safe exposure threshold in children.

EFSA's 2010 risk assessment applied a benchmark-dose approach to pooled cohort data, deriving a BMDL01 of $\sim 12 \mu\text{g/L}$ blood lead for a one-point decrement in children's IQ; this benchmark is used because evidence indicates neurodevelopmental effects continue to occur at the lowest observed blood lead levels, and small shifts in population IQ are considered adverse from a public-health perspective.

JECFA (2011) withdrew its former PTWI for lead on the basis that conventional tolerable intake values were no longer health-protective at contemporary effect levels given the absence of a threshold. Consistent with this, FDA's current Interim Reference Level (IRL) for dietary lead intake in young children – $2.2 \mu\text{g/day}$, derived with an added safety factor – is intended for risk management prioritization rather than as a "safe dose." Because there is no known threshold below which neurodevelopmental effects can be ruled out, cumulative daily intake across multiple food categories is the relevant exposure metric.

Even when individual foods meet "achievable" action levels, aggregate intake can exceed the IRL; for example, a day's consumption comprising 800 mL ready-to-feed formula at 5 ppb, one 20 g serving of dry cereal at 20 ppb, one 113 g fruit purée at 10 ppb, and one 113 g root-vegetable purée at 20 ppb would yield approximately $7.8 \mu\text{g}$ lead/day, illustrating how typical dietary patterns can result in total intakes substantially above the IRL and underscore the need for broad mitigation across the food supply.



This demonstrates why HMTc cutoffs should be interpreted as transitional action levels designed to drive measurable reductions and continuous improvement, not as health-based safety thresholds.

Arsenic (iAs) Standards

Scope/measurement. Arsenic shall be measured in the finished product as placed on the market, with powders analyzed as sold and liquids or concentrates analyzed after preparation in accordance with label instructions. Products containing rice or rice-derived ingredients shall be evaluated based on **inorganic arsenic (iAs)**, while all other products may be screened using total arsenic, with reflex iAs speciation required when total arsenic approaches or exceeds the applicable limit. Results shall be expressed in µg/kg (ppb) and used directly for compliance determination.

Category	HMTc Standards (ppb)	EU/FDA
Infant formula (powder)	10 ppb	No EU ML
Infant formula (ready-to-feed, liquid)	1 ppb	No EU ML
Baby cereals / grain products (dry)	10 ppb	20 ppb
Fruit purées (general)	2 ppb	20 ppb
Non-root vegetable purées	3 ppb	20 ppb
Root-vegetable purées	5 ppb	20 ppb
Mixed meals	6 ppb	20 ppb
Fruit juice (not canned)	3 ppb	20 ppb
Teething & Snacks	10 ppb	20 ppb



Toxicology and Margin of Safety

Inorganic arsenic is carcinogenic and lacks a known safe threshold in children.

Inorganic arsenic (iAs) is a genotoxic human carcinogen for which no safe threshold is assumed, particularly in early life. As a result, cancer risk is characterized using benchmark-dose reference points and a margin of exposure framework rather than tolerable intake values. EFSA's earlier assessments identified BMDL01 values for lung, skin, and bladder cancers spanning approximately 0.3 to 8 $\mu\text{g}/\text{kg}$ body weight per day, noting that estimated dietary exposures in parts of the population overlapped this range and therefore offered little margin of safety. EFSA's most recent reassessment further reinforces this concern, deriving a conservative cancer reference point of approximately 0.06 $\mu\text{g}/\text{kg}$ bw/day from human data and concluding that margins of exposure at current intake levels remain low, indicating a persistent public health concern.

This is especially relevant for infants and toddlers, whose higher food consumption per kilogram body weight causes even low single-digit ppb concentrations to translate into disproportionately higher doses. Consequently, foods that individually appear compliant can meaningfully contribute to cumulative exposure approaching or exceeding cancer-relevant reference points. HMTc category limits in the low single-digit ppb range should therefore be interpreted as risk-management action levels designed to drive population-level exposure reduction and improve margins of exposure, not as evidence of safety. This further underscores why program governance should emphasize aggregate exposure control and continuous downward pressure on concentrations over time under an ALARA framework.



This demonstrates why HMTc category limits in the low single-digit ppb range should therefore be interpreted as risk-management action levels designed to drive population-level exposure reduction and improve margins of exposure, not as evidence of safety.

Tin (Sn) Standards

Scope/measurement. Tin shall be measured in the finished product as placed on the market, with powders analyzed as sold and liquids or concentrates analyzed after preparation in accordance with label instructions. Tin shall be determined as total elemental tin (Sn); speciation is not required. Results shall be expressed in $\mu\text{g}/\text{kg}$ (ppb) and used directly for compliance determination.

Category	HMTc Standards (ppb)	EU Regulation
Infant formula (powder)	100 ppb	50,000 ppb
Infant formula (ready-to-feed, liquid)	20 ppb	50,000 ppb
Baby cereals / grain products (dry)	200 ppb	50,000 ppb
Fruit purées (general)	150 ppb	50,000 ppb
Non-root vegetable purées	150 ppb	50,000 ppb
Root-vegetable purées	200 ppb	50,000 ppb
Mixed meals	300 ppb	50,000 ppb
Fruit juice (not canned)	20 ppb	100,000 ppb
Teething & snacks	100 ppb	No EU ML



Toxicology and Margin of Safety

While inorganic tin is generally considered to have low toxicity, infants and toddlers are more vulnerable due to their small body mass and high food intake relative to their weight.

Dietary tin exposure in infants and young children is predominantly inorganic and arises primarily from migration from tinplate packaging or metal contact surfaces, particularly in acidic foods and beverages. Tin is not a cumulative systemic toxicant. Its primary toxicological endpoint is acute gastrointestinal irritation following short-term high exposure, rather than chronic toxicity or carcinogenicity. Consequently, tin risk management is directed toward preventing episodic concentration excursions associated with packaging or process failures, not toward long-term intake control.

However, acute gastrointestinal effects have been reported at concentrations of approximately 150 mg/kg in beverages and 250 mg/kg in other canned foods. These effect levels are derived from adult data and were established to identify packaging corrosion, lacquer degradation, or adverse storage conditions. No infant-specific toxicological thresholds for tin have been established. Accordingly, infant risk characterization necessarily relies on conservative extrapolation from adult acute-effect data, with additional consideration of higher intake per kilogram body weight and developmental gastrointestinal sensitivity.

Further, emerging evidence in neonatal populations suggests that tin may not be biologically inert during early life, with associations reported between tin exposure and altered gut microbiome composition during critical windows of immune and microbial development. While causality and dose thresholds remain uncharacterized, these findings support precautionary exposure control in infant and young-child foods.

Within the HMTc program, tin limits set in the tens to low hundreds of ppb establish margins exceeding 1,000-fold relative to concentrations associated with acute gastrointestinal effects, even when conservatively bridged to infant exposure scenarios. At these concentrations, tin functions as a sentinel marker of packaging integrity and process control, while maintaining a substantial margin of safety for infants and young children.



HMTc tin limits are exposure-management action levels, not safety thresholds, reflecting tin's acute, packaging-driven risk profile and the need to prevent episodic migration events rather than manage cumulative dietary toxicity.

Nickel (Ni) Standards

Scope/measurement: Nickel shall be measured in the finished product as placed on the market, with powders analyzed as sold and liquids or concentrates analyzed after preparation in accordance with label instructions. Nickel shall be determined as total elemental nickel (Ni); speciation is not required. Results shall be expressed in µg/kg (ppb) and used directly for compliance determination.

Category	HMTc Standards (ppb)	EU Regulation
Infant formula (powder)	100 ppb	250 ppb; 400 ppb (soy)
Infant formula (ready-to-feed, liquid)	20 ppb	~100 ppb
Baby cereals / grain products (dry)	500 ppb	3,000 ppb
Fruit purées (general)	150 ppb	500 ppb
Non-root vegetable purées	120 ppb	500 ppb
Root-vegetable purées	200 ppb	500 ppb
Mixed meals	150 ppb	500 ppb
Fruit juice	100 ppb	250 ppb; 1,000 ppb (passion fruit, cocoa fruit, berries, coconut)
Teething & snacks	500 ppb	3,000 ppb



Toxicology and Margin of Safety

Nickel poses a disproportionate risk in infants and young children because high intake per kilogram body weight and developing biological systems sharply narrow margins of safety.

Nickel has historically been treated as a contact allergen rather than a dietary toxicant, but EFSA's 2020 reassessment moved nickel from a trace concern to a strictly regulated contaminant. EFSA established a chronic TDI of 13 $\mu\text{g}/\text{kg}$ bw/day and characterized acute dietary risk using a margin-of-exposure approach based on human data, declining to set a numeric ARFD. The acute reference points identified were notably low, with a BMDL10 of ~ 1.1 $\mu\text{g}/\text{kg}$ bw and a LOAEL of ~ 4.3 $\mu\text{g}/\text{kg}$ bw for eczematous flare-ups in nickel-sensitized individuals, placing routine dietary exposures closer to effect levels than previously assumed.

Under current Heavy Metal Tested & Certified ceilings, a conservative "day-at-the-limit" intake scenario delivers approximately 70–80 μg nickel per day, corresponding to ~ 7 –11 $\mu\text{g}/\text{kg}$ bw/day for a 7–10 kg child. This falls at or below the TDI for most infants and toddlers but with limited margin, particularly when cumulative exposure across multiple foods is considered. This narrow buffer is the regulatory concern driving recent EU regulation: nickel does not need to exceed legacy toxicity thresholds to become biologically relevant.

Beyond classical host toxicity, emerging metallomics research indicates that dietary nickel may act as a catalytic driver of microbial metabolism and virulence disproportionately in the infant and child gut, and may be implicated in often fatal cases of infant necrotizing enterocolitis, and other dysbiotic states. Excess dietary nickel may therefore foster pathogenic processes while undermining host nutritional immunity, reframing nickel as a systems-level risk factor rather than a passive contaminant. The United States currently has no explicit dietary limits for nickel, and routine testing is uncommon. For future-oriented brands, testing for nickel and aligning with global benchmarks is a clear form of regulatory and scientific future-proofing, reducing avoidable exposure now in anticipation of tighter oversight later while signaling leadership in an area where the toxicology is already pointing in one direction.

Nickel's narrow toxicological margins and ubiquitous dietary presence mean that cumulative intake, rather than exceedance of a single limit, is the primary risk driver. Low-ppb limits are therefore designed to constrain total daily exposure, protect high-consumption infants and sensitive subpopulations, and future-proof products against evolving regulatory and mechanistic evidence.



This underscores why HMTc nickel limits function as exposure-control benchmarks, not declarations of safety.

Cadmium (Cd) Standards

Scope/measurement. Cadmium shall be measured in the finished product as placed on the market, with powders analyzed as sold and liquids or concentrates analyzed after preparation in accordance with label instructions. Cadmium shall be determined as total elemental cadmium (Cd); speciation is not required. Results shall be expressed in µg/kg (ppb) and used directly for compliance determination.

Category	HMTc Standards (ppb)	EU Regulation
Infant formula (powder)	5 ppb	10 ppb (cows' milk); 20 ppb (soy)
Infant formula (liquid, RTF)	3 ppb	5 ppb (cows' milk); 10 ppb (soy)
Baby cereals / grain products (dry)	20 ppb	40 ppb
Fruit purées (general)	5 ppb	40 ppb
Non-root vegetable purées	8 ppb	40 ppb
Root-vegetable purées	15 ppb	40 ppb
Mixed meals	10 ppb	40 ppb
Fruit juice	3 ppb	20 ppb
Teething & snacks	20 ppb	40 ppb



Toxicology and Margin of Safety

Chronic dietary Cd targets the kidney (tubular dysfunction) and bone.

Cadmium (Cd) is a cumulative toxicant with an exceptionally long biological half-life (years to decades), targeting the kidney (proximal tubular dysfunction) and bone as critical organs. Chronic dietary exposure is the dominant concern. EFSA established a TWI of 2.5 µg/kg bw/week, derived from human dose-response relationships linking urinary cadmium to β₂-microglobulin excretion, a sensitive marker of early tubular injury. JECFA similarly characterizes risk using a Provisional Tolerable Monthly Intake (PTMI) of 25 µg/kg bw/month, reflecting cadmium's persistence and cumulative burden.

Applying HMTc proposed category ceilings to a conservative "day-at-the-limit" menu yields approximately 7.7 µg cadmium/day, equivalent to ~0.96 µg/kg bw/day for an 8 kg infant, or ~6.7 µg/kg bw/week. This exceeds EFSA's TWI and approaches or exceeds the JECFA PTMI when expressed on a weekly basis. The implication is not that compliant products are unsafe in isolation, but that aggregate exposure across multiple foods can rapidly erode margin, particularly in infants and toddlers with high intake per kilogram body weight.

This concern is reinforced by epidemiological and mechanistic evidence showing that low-level cadmium exposure during early life is associated with oxidative stress, DNA damage, protein modification, and increased long-term risk of renal dysfunction, bone effects, cardiovascular disease, and certain cancers, even in populations without overt toxicity. Cadmium readily crosses the placenta, accumulates in the kidney cortex, and can disrupt essential metal homeostasis and DNA repair pathways during critical windows of development.

Accordingly, cadmium control in infant and child foods must be framed around cumulative exposure management, with particular emphasis on keeping median lots well below category ceilings and prioritizing high-leverage controls for ingredients and food types known to drive intake.



HMTc cadmium limits are exposure-management action levels, not safety thresholds, reflecting cadmium's extreme persistence, narrow population-level margins, and the disproportionate impact of cumulative dietary exposure during early life.

Chromium (Cr) Standards

Scope/measurement. Chromium shall be measured in the finished product as placed on the market, with powders analyzed as sold and liquids or concentrates analyzed after preparation in accordance with label instructions. Chromium shall be determined as total elemental chromium (Cr), with hexavalent chromium [Cr(VI)] speciation required only when a credible Cr(VI) pathway exists or when total chromium is anomalously elevated. Results shall be expressed in $\mu\text{g}/\text{kg}$ (ppb) and used directly for compliance determination.

Category	HMTc Standards (ppb)	EU Regulation
Infant Formula (Powder)	30 ppb	No ML
Infant Formula (Liquid, RTF)	5 ppb	No ML
Baby Cereals / Grain Products (Dry)	200 ppb	No ML
Fruit Purées (General)	50 ppb	No ML
Non-Root Vegetable Purées	60 ppb	No ML
Root-Vegetable Purées	80 ppb	No ML
Mixed Meals (Meat & Grain Combos)	80 ppb	No ML
Fruit Juice (Infant/Young Child)	10 ppb	No ML
Teething & Snacks (Dry)	200 ppb	No ML



Toxicology and Margin of Safety

In infants and young children, high intake per kilogram body weight and reliance on liquid and acidic foods compress margins of safety, making chromium an important indicator of process and contact-material integrity beyond simple nutritional exposure.

Chromium presents a speciation-dependent hazard profile that is relevant to certification primarily as a process and equipment integrity indicator, rather than as an agricultural contaminant. EFSA's CONTAM Panel established a tolerable daily intake (TDI) of 0.3 mg/kg body weight/day (300 µg/kg bw/day) for trivalent chromium (Cr(III)). For dietary exposure assessment, we consider chromium in foods to be predominantly Cr(III), which is not genotoxic and has a wide margin of safety.

In contrast, hexavalent chromium (Cr(VI)) is genotoxic and carcinogenic, and no health-based guidance value has been established. EFSA evaluates Cr(VI) using a margin-of-exposure (MOE) approach and has identified drinking water as the dominant contributor to Cr(VI) exposure. While MOEs for the general population indicate low concern, EFSA specifically notes that infants have higher relative intake via water, making early life a sensitive window. Importantly, even a small Cr(VI) fraction within total chromium would disproportionately increase risk, given its potency relative to Cr(III).

Within the food supply, elevated chromium is more often a signal of processing or contact-material failure than of raw ingredient contamination. Chromium is a major constituent of stainless steel, and leaching can occur under acidic conditions, particularly in older, worn, or improperly passivated equipment. Liquid and acidic products such as fruit purées, juices, formulas, and canned foods therefore represent higher-risk matrices where total chromium serves as a practical sentinel marker for equipment corrosion, weld degradation, or process control failures, rather than for agricultural uptake.

Accordingly, HMTc chromium testing in liquid and acidic foods functions primarily as a process-integrity safeguard, identifying abnormal chromium contributions that may signal equipment or water-source issues rather than normal dietary exposure.



HMTc chromium limits are exposure-management action levels, not safety thresholds, reflecting chromium's speciation-dependent hazard, infant sensitivity to Cr(VI) exposure pathways, and the use of total chromium as a marker for processing and contact-material control.

Aluminum (Al) Standards

Scope/measurement. Aluminum shall be measured in the finished product as placed on the market, with powders analyzed as sold and liquids or concentrates analyzed after preparation in accordance with label instructions. Aluminum shall be determined as total elemental aluminum (Al); speciation is not required. Results shall be expressed in µg/kg (ppb) and used directly for compliance determination.

Category	HMTc Standards (ppb)	EU Regulation
Infant Formula (Powder)	1,500 ppb	No ML
Infant Formula (Liquid, RTF)	200 ppb	No ML
Baby Cereals / Grain Products (Dry)	1,000 ppb	No ML
Fruit Purées (General)	800 ppb	No ML
Non-Root Vegetable Purées	800 ppb	No ML
Root-Vegetable Purées	1,000 ppb	No ML
Mixed Meals (Meat & Grain Combos)	1,000 ppb	No ML
Fruit Juice (Infant/Young Child)	100 ppb	No ML
Teething & Snacks (Dry)	1,000 ppb	No ML



Toxicology and Margin of Safety

Aluminum poses a disproportionate risk in infants and young children because cumulative exposure can accrue during early life, when intake per kilogram body weight is high, elimination capacity is limited, and neurodevelopment is ongoing.

Aluminum is a non-essential metal with low gastrointestinal absorption but a long biological half-life, allowing cumulative tissue burden over time. EFSA therefore established a Tolerable Weekly Intake (TWI) of 1 mg Al/kg body weight/week, identifying neurodevelopmental and skeletal effects as critical endpoints. This framework reflects concern about aggregate exposure, not acute toxicity.

Infants and young children are uniquely sensitive because renal clearance is immature, intake per kilogram body weight is high, and exposure occurs during periods of rapid brain and bone development. Clinical evidence from preterm populations demonstrates that higher aluminum exposure from standard nutrition solutions is associated with measurable neurodevelopmental deficits, including lower Mental Development Index scores in infancy, with more recent data suggesting associations with impaired fine motor development. These findings establish aluminum as developmentally relevant even at exposure levels that do not produce acute toxicity.

Under HMTc category ceilings, a conservative “all items at the limit” scenario yields approximately 0.43–0.53 mg/kg bw/week for an 8–10 kg child, corresponding to 43–53% of EFSA’s TWI. Real-world median concentrations are typically well below category limits, preserving margin; however, the calculation illustrates that cumulative intake across multiple foods is the appropriate risk metric for aluminum in early life. Accordingly, HMTc aluminum controls are designed to limit avoidable accumulation, drive reductions where feasible, and prevent high-variance product types from disproportionately contributing to total exposure, rather than to define a point of safety.



HMTc aluminum limits are exposure-management action levels, not safety thresholds, reflecting aluminum’s cumulative toxicokinetics, documented neurodevelopmental sensitivity in early life, and the need to minimize avoidable exposure during periods of rapid brain and skeletal development.

Mercury (Hg) Standards

Scope/measurement. Mercury shall be measured in the finished product as placed on the market, with powders analyzed as sold and liquids or concentrates analyzed after preparation in accordance with label instructions. Total mercury (Hg) shall be measured for all products, with methylmercury (MeHg) speciation required for products containing fish or marine-derived ingredients, or when total mercury approaches or exceeds the applicable category limit. Results shall be expressed in µg/kg (ppb), with speciation results governing compliance where required.

Category	HMTc Standards (ppb)	EU Regulation
Infant Formula (Powder)	1,500 ppb	No ML
Infant Formula (Liquid, RTF)	200 ppb	No ML
Baby Cereals / Grain Products (Dry)	1,000 ppb	No ML
Fruit Purées (General)	800 ppb	No ML
Non-Root Vegetable Purées	800 ppb	No ML
Root-Vegetable Purées	1,000 ppb	No ML
Mixed Meals (Meat & Grain Combos)	1,000 ppb	No ML
Fruit Juice (Infant/Young Child)	100 ppb	No ML
Teething & Snacks (Dry)	1,000 ppb	No ML



Toxicology and Margin of Safety

Mercury warrants continuous surveillance in infant and child foods because neurodevelopmental risk is species-specific, margins are intake-dependent, and cumulative low-level exposure can become consequential during early life even in the absence of a single dominant source.

Mercury toxicity is highly species-dependent, with methylmercury (MeHg) driving neurodevelopmental risk and inorganic mercury (iHg) primarily targeting the kidney. Health-based guidance values therefore distinguish between forms. The U.S. Environmental Protection Agency reference dose for MeHg is approximately 0.1 µg/kg body weight/day, while European Food Safety Authority established a tolerable weekly intake (TWI) of 1.3 µg/kg bw/week for MeHg based on developmental neurotoxicity. For inorganic mercury, EFSA set a higher TWI of 4 µg/kg bw/week, reflecting renal toxicity as the critical endpoint.

In the general food supply, MeHg exposure is overwhelmingly associated with fish and seafood, where bioaccumulation and biomagnification dominate risk. In non-fish infant and child foods, mercury is typically present at much lower concentrations and is predominantly inorganic. Under the proposed Heavy Metal Tested & Certified category ceilings, a conservative “all items at the cap” intake scenario across multiple non-seafood categories yields approximately 3-4 µg total mercury per day for an 8-10 kg infant. On a weekly, body-weight-adjusted basis, this approaches but generally remains below the inorganic-mercury TWI, while remaining well below MeHg guidance values in the absence of fish-derived sources. In real-world conditions, median concentrations are substantially lower, resulting in large margins of exposure to both MeHg and inorganic mercury reference points.

From a risk-assessment perspective, this pattern underscores that mercury management in infant and child foods is not about reacting to frequent exceedances, but about preventing avoidable background exposure and cumulative intake. This is particularly important in early life, when intake per kilogram body weight is high, neurological development is ongoing, and small contributions from multiple foods can narrow margins of safety even when individual products appear compliant.



HMTc mercury limits should be interpreted as exposure-management action levels under feasibility and ALARA principles, not safety thresholds. Continuous monitoring and reduction of background mercury is essential to preserve margin, prevent cumulative drift, and ensure that infant and child diets remain protective as consumption patterns and ingredient sourcing evolve.