Infant and Child Foods

Category 1 · Ages 0–5 · 2026 Edition

Government-limit default — Method v2.0

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EDITION

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About this manual

The complete Heavy Metal Tested & Certified standard for Category 1, Infant and Child Foods, as one citable volume: why the program exists (Part 1), its governance and certification-status framework (Part 2), the standards themselves — all nine subcategories with their full derivations (Part 3), the lot-testing and surveillance schedule (Part 4), and the methodology, adversarial read, and glossary (Part 5). Every limit traces to a named sovereign government maximum; nothing is selected from measured data. Part 3's numbers are identical to the web edition at heavymetalcertified.com/-manuals/infant-and-child-foods.

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PART 1

Why HMTc Exists

Heavy Metal Tested & Certified (HMTc), published by the Institute of Contaminant Standards (ICS), exists because the instruments that currently govern toxic metals in infant and child food do not, in combination, bound a child's actual exposure. Each instrument is individually defensible and collectively insufficient. This Part states the structural problem the program answers, explains why the obvious remedy — a single category-wide limit — is the wrong instrument, and sets out the design principles that follow from that diagnosis. The provisions that give these principles operative effect are specified in the Parts that follow; this Part explains what they are for.

1.1 The structural problem

Three features of the existing landscape combine into a single gap.

Narrow panels. Regulatory attention and most commercial testing concentrate on four metals — arsenic, lead, cadmium, and mercury. A finished infant or child food, however, can carry a wider set. HMTc evaluates eight limit analytes — lead (Pb), inorganic arsenic (iAs), mercury (tHg, total), cadmium (Cd), chromium (Cr, total), nickel (Ni), tin (Sn), and aluminium (Al) — with mandatory speciation reflexes layered on top: inorganic-arsenic determination for rice-based matrices, methylmercury for relevant matrices, and hexavalent chromium [Cr(VI)] on any credible pathway. A four-metal panel cannot detect what it does not measure, and a certification built on one inherits the same blind spot.

The enforcement gap. Where limits exist, they are typically single-product action levels verified — if at all — occasionally rather than continuously. The 2021 U.S. House Oversight staff report that helped open this litigation wave documented a major manufacturer that had not tested its finished products for heavy metals until 2019; the resulting product-liability actions are now consolidated as MDL No. 3101 (In re: Baby Food Products Liability Litigation). A limit that is not measured on a defined schedule, by an independent sampler, under documented chain of custody, is a number with no record behind it.

Aggregate exposure. This is the decisive point. Regulatory action levels are set one product at a time, but a child does not eat one product. Full compliance with every applicable single-product federal action level, across four common categories in a single day — ready-to-feed formula, dry infant cereal, a fruit purée, and a root-vegetable purée — yields on the order of 10.4 µg of lead per day, about 4.7 times the FDA's own Interim Reference Level of 2.2 µg/day for young children. Per-product compliance therefore does not bound aggregate intake; it permits an aggregate several times over the health-based benchmark while every individual product remains within limits.

1.2 Why a category-wide limit is the wrong instrument

The intuitive fix — one blanket concentration limit for all infant and child food — fails on contact with the data. The foods in this category do not carry the same metals at the same baselines. Rice-based products carry inorganic arsenic; root vegetables concentrate lead and cadmium from soil; juices, cereals, purées, and formulas each present a different profile. A single number set loose enough to be achievable for the highest-baseline food is meaningless for the lowest; set tight enough to discipline the cleanest food, it is

unattainable for the rest and certifies nothing. A category-wide limit also invites compliance by serving-size manipulation wherever it is expressed per serving rather than per concentration.

HMTc resolves this with subcategory-specific, per-analyte limits. The standard divides infant and child food into nine subcategories — infant formula (powder), infant formula (ready-to-feed), baby cereal, fruit purée, non-root vegetable purée, root-vegetable purée, mixed meals, fruit juice, and teething and snack products — and sets a limit for each analyte in each. Limits are expressed as concentrations (parts per billion, as sold), never per serving, so that compliance cannot be engineered by resizing a portion.

1.3 Design principles

The following principles govern the standard and are given operative effect in later Parts.

Government-limit default. For each subcategory and analyte, the applicable limit shall default to the strictest maximum level set by a credible government regulator, converted to the product's native basis; where the law itself splits a limit by formulation, the standard adopts the law's own split and cites it. Certification status is not a matter of judgment but of measurement: a product's status is driven by its MaxPoL — its measured concentration divided by the applicable limit — so that every determination is government-limit-relative and traceable to a published number.

Toxicological tiering. The eight metals are classified into two tiers by toxicology, and the classification carries governance consequences. Tier 1 — lead, cadmium, inorganic arsenic, and mercury — are carcinogenic, neurotoxic, or bioaccumulative with no established safe threshold in children; any confirmed exceedance escalates, with no transitional variance at any margin. Tier 2 — nickel, aluminium, tin, and chromium — have established tolerable intakes or shorter biological half-lives and are eligible for a defined transitional allowance up to 150 percent of the applicable limit. Any quantifiable hexavalent chromium on a credible pathway is a hard fail and is evaluated as Tier 1. A brand asked why a nickel result received transitional treatment while a smaller lead result did not must be able to answer from the comparative toxicology, not from administrative convenience.

Aggregate calibration. Because the failure of single-product regulation is aggregation, the standard is calibrated across subcategories so that a child's intake across the category sits below the health-based benchmark, not merely below each single-product floor. No published limit exceeds the lowest applicable government maximum in the brand's markets of sale.

Action levels, not safety thresholds. HMTc limits are risk-management action levels, not safety thresholds. Exceeding one obliges corrective and preventive action; it does not by itself establish that a product is unsafe or that any child was harmed. Certification does not certify safety, and the mark shall not state or imply "heavy metal free," "no toxic metals," "100% safe," or the absence of risk. The program operates under an ALARA obligation — As Low As Reasonably Achievable — treated as enforceable rather than aspirational.

Measurement-uncertainty disclosure. A limit is only as honest as the decision rule that applies it. Every pass/fail determination shall incorporate the laboratory's expanded measurement uncertainty (coverage factor k = 2, approximately 95 percent confidence) on a two-sided rule: a lot passes only if the result plus its uncertainty is at or below the limit; it fails only if the result minus its uncertainty exceeds the limit; a result in between is borderline and shall be resolved by confirmatory testing before any status is assigned. The rule is biased toward neither the brand nor the regulator but toward analytical accuracy, and it is disclosed rather than buried. The program correspondingly prohibits testing into compliance: undocumented resampling, lab-shopping, and selective reporting are data-integrity violations that cost a brand its status.

Confidential remediation as a structural feature. A staged standard must have an honest entry point for brands that do not yet meet it, or it selects only for those who already comply and improves nothing. The Confidential Remediation Track is therefore built into the program rather than bolted on: a brand whose baseline does not reach Status A or B may enrol for confidential remediation support, provided every tested lot meets the applicable legal heavy-metal limits in its markets of sale at the time of testing. Enrolment status, test data, corrective-action documents, and remediation progress are treated as confidential business information under the license. The Certification Mark shall not be used on any product, packaging, or marketing until at least one SKU reaches Status A or B. Confidentiality has express limits: it never delays a recall, never overrides a reporting duty, and the data shall be produced to a regulator on request.

The evidence base, cited one way. Limits do not derive from the Heavy Metal Index. Every limit value in this standard traces to a named sovereign government maximum (see Government-limit default, above, and Part 5); the Index sets no limit and supplies no selection statistic. The Heavy Metal Index (heavymetalindex.com) is a curated synthesis of the heavy-metals-in-food literature that the Institute of Contaminant Standards maintains as a separate property, and this program cites it only as contextual evidence — for category context and prioritization — never for a compliance value. The reference is one-way and outbound: the certification program cites the Index, the Index does not endorse the program, and this manual does not re-host, mirror, or reproduce Index content or assert any cross-domain canonical relationship with it.

Method disclosure. Literature processing in support of limit-setting is AI-assisted and cross-vendor-verified; threshold-setting itself is a human determination made under a named principal investigator. This is disclosed here, at the front of the manual, so that no reader has to discover it: the instrument that assembles the literature does not set the number, and every value still resolves to a named sovereign government maximum independent of the tool that gathered it.

A standard that tightens. HMTc limits are designed to tighten over defined review cycles as a certified subcategory's market improves, and never to loosen. Tightening fires only on defined triggers, is capped per cycle, and transitions on a published schedule with existing certifications carried through the transition. Certification is therefore a commitment to a moving floor — bounded, forecast, and announced in advance — not to a fixed number a market can grow complacent against.

PART 2

The HMTc Program

This Part sets out the governance architecture of the Heavy Metal Tested & Certified (HMTc) Program for Infant and Child Foods: how a product enters the Program, how its certification status is determined and maintained, and the corrective, evidentiary, and data-integrity obligations that attach to each status. The Program is published and administered by the Institute of Contaminant Standards (ICS). Except where a defined term states otherwise, every requirement in this Part is normative, and the Program Operator issues binding determinations under it.

Certification status is governed by a single metric, MaxPoL, defined in Section 2.1. Status is limit-relative: it is computed from measured lot results against the applicable government limit under the government-limit default (Method v2.0), and by nothing else. No distribution of measured values, market aggregate, or external dataset sets a limit or determines a status.

2.1 Program Flow and Analyte Tiering

The governing metric: MaxPoL

For each compliance analyte, Percent-of-Limit (PoL) = (measured result ÷ applicable limit) × 100. The applicable limit is the governing regulatory limit for that analyte in the product's market of sale, applied under the government-limit default. MaxPoL (Maximum Percent-of-Limit) is the highest PoL among all compliance analytes in a lot. Certification status is a function of MaxPoL only. A limit is never derived from the distribution of measured values; it is the government limit, and MaxPoL measures a lot against it.

Program flow

1. Baseline (three lots). Every SKU entering the Program shall be tested across a minimum of three production lots, on the full heavy-metals panel and under Program methodology, before any status is assigned. A single passing lot certifies nothing. The three lots are evaluated collectively, and initial status is assigned from the worst-performing lot.
2. Expedited baseline (prior-data credit), optional. A brand with qualifying accredited testing history may credit up to two of the three baseline lots and complete the baseline with one new full-panel HMTc lot. Credited lots must be ISO/IEC 17025-accredited, from distinct production runs tested within the twelve months preceding application, submitted as structured (machine-readable) data with intact chain of custody, and credited on a per-analyte basis only. Prior-data credit is not available on the Confidential Remediation Track (Section 2.4).
3. Entry gate. A lot testing above 200% MaxPoL, or violating an applicable regulatory limit, is Not Eligible and cannot enter the staged status framework. Such a SKU must resolve the exceedance before baseline.
4. Status assignment. Status A–E is assigned per Section 2.2 from the baseline result, then maintained through ongoing surveillance.
5. Surveillance. Lot-testing frequency is set by the product risk tier and the current certification status (frequency matrix below).

The certification panel

The certification panel is eight limit analytes: lead (Pb), inorganic arsenic (iAs), mercury (tHg, total), cadmium (Cd), chromium (Cr, total), nickel (Ni), tin (Sn), and aluminium (Al). Three mandatory speciation reflexes attach to the panel — inorganic-arsenic determination for rice-based matrices, methylmercury for relevant matrices, and hexavalent chromium [Cr(VI)] on any credible pathway. A speciation reflex is not a separate limit analyte; where it applies, the speciated result supersedes the corresponding total (see Speciation, below).

Analyte tiering

Tiering governs whether any exceedance can be tolerated. It is a distinct axis from the product risk tier.

Tier	Metals	Rule
Tier 1 — Zero Tolerance	Lead (Pb), Cadmium (Cd), Inorganic arsenic (iAs), Mercury (tHg, total)	No transitional variance at any margin. Any confirmed result above 100% of the applicable limit escalates the SKU to Status C or higher.
Tier 2 — Transitional	Nickel (Ni), Aluminium (Al), Tin (Sn), Chromium (Cr, total)	A transitional exceedance above 100% and up to 150% may qualify for Status B under Section 2.3.

Methylmercury is the speciated form governing the mercury determination in relevant matrices; where required, the methylmercury result supersedes total mercury for compliance. Chromium is evaluated as total chromium, with Cr(III) assumed an essential nutrient; Cr(VI) speciation is required only where a credible hexavalent pathway exists. Any quantifiable hexavalent chromium [Cr(VI)] on a credible pathway is a hard fail, evaluated as a Tier 1 exceedance regardless of the total-chromium result. On new evidence, the Program Operator may, on Technical Committee recommendation and with a defined transition period, reclassify a metal between tiers or add analytes to the panel.

Speciation

Speciation is mandatory for inorganic arsenic in rice-based products, for methylmercury in fish-containing products, and for Cr(VI) where a credible hexavalent pathway exists. Where a speciated form applies, a total-metal result at or above 50% of the applicable total-metal limit triggers reflex speciation; the Program Operator may lower, but not raise, this trigger. The speciated result supersedes the total-metal result for compliance. Failure to perform a required speciation renders the lot ineligible.

Product risk tiers and surveillance frequency

The live taxonomy comprises nine subcategories: infant formula (powder), infant formula (ready-to-feed), baby cereal, fruit purée, non-root vegetable purée, root-vegetable purée, mixed meals, fruit juice, and teething/snack. Each SKU is assigned a product risk tier:

- High: infant formula (powder and ready-to-feed), baby cereal.
- Moderate: fruit purées, non-root vegetable purées, root-vegetable purées, mixed meals.
- Lower: fruit juice, teething and snack products.

The Program Operator may adjust an individual product's risk tier on documented rationale (for example, a rice-based teething product elevated to Moderate). Surveillance frequency follows both the risk tier and the current status:

Product risk tier	Status A	Status B	Status C
High	Monthly, independent sampling	Every lot or monthly (more frequent)	Every lot + mandatory hold-and-release
Moderate	Quarterly	Monthly, independent	Every lot + mandatory hold-and-release
Lower	Quarterly	Monthly, independent	Every lot + mandatory hold-and-release

Within Status C, third-party sampling is tied to the probation band, not to the product risk tier: the High Probation band (MaxPoL 176–200%) additionally requires Operator-directed third-party sampling, and the Low Probation band (151–175%) does not (Section 2.2). A lot in the 101–150% band that also carries any Tier 1 exceedance is treated as Status C — every lot, mandatory hold-and-release, and independent sampling — regardless of product risk tier.

2.2 Certification Status Framework (A–E)

Status is assigned from MaxPoL and the Tier 1/Tier 2 classification of any exceedance. Bands are integer and non-overlapping.

Status	Designation	MaxPoL / trigger	Mark use
A	Certified — Full Compliance	MaxPoL ≤ 100% for all analytes	Permitted, unrestricted
B	Certified — Transitional	101–150%, exceedance limited to Tier 2 only, no Tier 1 above 100%, no hard-stop	Permitted, flagged transitional in the registry
C	Probation	151–200% for any analyte; or any Tier 1 above 100% at any margin; or repeated Status B without improvement; or systemic control failure; or unmet transitional conditions	Not on new production; lot-by-lot release only where that lot tests at A/B level
D	Suspension	Above 200% MaxPoL for any analyte; or any hard-stop (regulatory-limit violation or data-integrity failure); or failure to execute testing, CAPA, or directives on probation	Prohibited; Mark removed from all units and marketing immediately
E	Revocation	Persistent suspension without correction; severe or repeated nonconformance; willful misconduct or data fraud	Permanently prohibited; license terminated

A lot above 200% MaxPoL or in violation of a regulatory limit at entry is Not Eligible and cannot enter the framework (Section 2.1).

Status C — graduated severity

- Low Probation: MaxPoL 151–175%. Every-lot hold-and-release; the brand's own accredited sampling is permitted, subject to audit.

- High Probation: MaxPoL 176–200%. Every-lot hold-and-release plus mandatory Operator-directed independent third-party sampling.

Exit from Probation requires both a minimum of five consecutive passing lots at A/B level and completion of all CAPA milestones with verified effectiveness. Neither condition alone is sufficient.

Status D — actions and reinstatement

Status D triggers stop-ship, seal removal, and market correction, with CAPA initiated within two business days and containment immediately (within 48 hours). Reinstatement requires a completed CAPA with verification of effectiveness (VOE), a run of consecutive compliant lots set by the Program Operator, restored data integrity, and formal Operator approval. Reinstatement does not require a fresh baseline.

Status E — revocation

Revocation is permanent and terminates the license. Re-entry is by full re-application only, at the Program Operator's discretion. Concealment of a known exceedance is grounds for revocation.

2.3 Transitional Variance (Status B)

Status B is a time-limited, conditional certification for a Tier 2 exceedance. All of the following conditions must hold:

- MaxPoL is above 100% but no greater than 150%.
- The exceedance is limited to Tier 2 metals; no Tier 1 metal exceeds 100%.
- No other hard-stop condition is triggered.
- The Certification Mark is permitted, flagged transitional in the registry.
- Surveillance is elevated: monthly independent sampling minimum, with every-lot testing where a risk assessment requires it.
- A CAPA is mandatory: opened within 10 business days, with a detailed plan within 30 calendar days, and VOE demonstrating a measurable reduction across subsequent lots.
- A default 12-month period applies to reach Status A; the Program Operator may extend for documented complexity.

A Status B SKU shall escalate immediately to Status C if any lot exceeds the 150% cap, if any Tier 1 exceedance occurs, or if the SKU fails to show an improving trend.

2.4 The Confidential Remediation Track

The Confidential Remediation Track is an entry and support pathway for brands whose initial baseline does not reach Status A or B, provided every tested lot meets the applicable legal heavy-metal limits in its markets of sale at the time of testing. It is a route into the Program for products not yet certifiable, not a post-certification mechanism.

- Confidentiality. Enrolment status, test data, CAPA documents, and remediation progress are treated as confidential business information under the license agreement.
- Support. Enrolled brands receive confidential remediation support — reformulation and technical assistance — together with supplier intelligence and access to the Program's testing infrastructure.

- Mark-use rule (hard). The Certification Mark shall not be used on any product, packaging, or marketing until at least one SKU achieves Status A or B.
- Interaction with prior-data credit. The Track is not available together with the Expedited Baseline (prior-data credit) pathway.
- Timelines. The Track uses the standard governance CAPA windows (Section 2.8); it carries no separate remediation windows.

Confidentiality has defined limits: enrolment and its documentation never delay a product recall, never override any regulatory reporting duty, and shall be produced to a regulator on request. Participation is positioned as a good-faith, third-party-verified quality-improvement initiative, generating documented, timestamped evidence of due diligence.

2.5 The Evidence Base: heavymetalindex.com

The Heavy Metal Index (heavymetalindex.com) is contextual evidence only. It never sets a limit, supplies no selection statistic, and never determines a status. Every limit value in this Program traces to a named sovereign government maximum (Section 2.1 and Part 5); certification status is computed solely from measured lot results against that applicable limit (MaxPoL). The Index may inform category context and prioritization; it carries no compliance weight of its own.

The reference is one-way and outbound. The Program cites the Index; the Index does not endorse the Program. This manual does not re-host, mirror, or reproduce Index content, and asserts no cross-domain canonical relationship with it. The Institute of Contaminant Standards maintains the Index as a separate property.

2.6 Decision Rules Under Measurement Uncertainty

Every result is evaluated against its limit using the laboratory's expanded measurement uncertainty (MU), reported at the 95% confidence level (coverage factor k = 2). The rule is two-sided:

Outcome	Rule
Pass	(Result + MU) ≤ Limit
Fail	(Result − MU) > Limit
Borderline	Neither condition met — confirmatory action required before any status

A borderline result alone shall not certify. Resolution requires at least one of: confirmatory re-analysis of the same extract; a confirmatory test on a new sample from the same lot under strict chain of custody; or lot hold-and-release. The action and its basis shall be documented, and the more conservative interpretation governs on divergence.

Testing into compliance is prohibited. Ad-hoc retesting to obtain a pass is not permitted; any retest must follow a pre-approved, scientifically justified pathway. Undocumented resampling, lab-shopping, and selective reporting are data-integrity violations and lead to suspension or revocation.

Where a laboratory does not report MU, the result is evaluated directly against the limit — a result above the limit fails, and a result at or below the limit passes. Laboratories unable to report MU are disfavored, and the Program Operator may require transition to a conforming laboratory.

2.7 Data Governance and Integrity

- Structured data. Laboratories shall provide the Program Operator written access to underlying data in machine-readable form. PDF-only submissions are not permitted. Machine-readability enables trend analysis and aggregate Program surveillance.
- Laboratory and LOQ. All testing shall be performed by ISO/IEC 17025-accredited laboratories using methods fit for the matrix, with a limit of quantitation (LOQ) at or below the applicable HMTc action level per analyte. Where the LOQ exceeds the limit, a non-detect is not acceptable proof of compliance and the result is indeterminate pending retest.
- Chain of custody. Chain of custody is required for every sample. An enumerated custody breach invalidates the result, and the default disposition is invalidation, treated as a data-integrity matter; minor, well-documented lapses may be excused at the Program Operator's discretion.
- Composite sampling. Composite samples shall be drawn from units across the lot such that the result supports 95% confidence that the lot meets requirements. Alternative sampling designs require prior written approval.
- Integrity as hard-stop. Falsification, manipulation, selective omission, or unauthorized alteration of data results in immediate Status D and, in the ordinary case, Status E. Enumerated violations include falsified results, failure to report required results, use of unauthorized non-accredited laboratories, undocumented custody breaks, and undisclosed retesting or lab-shopping. The Program Operator audits integrity and may require random verification testing at designated laboratories.

2.8 Corrective and Preventive Action (CAPA)

CAPA timelines scale with severity:

Status	CAPA initiation	Full plan due	Containment
B	10 business days	30 calendar days	As needed
C	5 business days	15 business days	Within 48 hours
D	2 business days	10 business days	Immediate (within 48 hours)

For Status B, a 12-month default period to return to Status A applies; failure to demonstrate an improving trend escalates the SKU to Status C.

Required elements

Every CAPA shall contain: Issue Identification (SKU, affected lots, analytes, numeric results, applicable limits, and PoL/MaxPoL); Impact Quantification; Immediate Containment; Root-Cause Analysis using a structured method (5-Why, fishbone, or fault-tree); Corrective Actions; Preventive Actions; and a VOE plan specifying validation lots and success criteria.

Closure

A CAPA closes only after VOE demonstrates return to controlled status against the defined success criteria and the Program Operator formally approves closure. Where criteria are unmet, the Operator extends the CAPA or requires additional actions.

Escalation and early warning

A Status B lot that exceeds the 150% cap, any Tier 1 exceedance, or the absence of an improving trend escalates the SKU immediately to Status C. As an early-warning control distinct from the 50% reflex-speciation trigger, any Tier 1 result reaching or exceeding 80% of its applicable limit shall trigger a confirmatory test on the next lot, notification of the Program Operator, enhanced monitoring, and speciation where a speciated form applies.

Regulatory hard-stop

Any lot violating an applicable regulatory limit (as distinct from an HMTc action level) in any market of sale — regardless of HMTc status — triggers immediate licensee notification, a mandatory hold or market correction, CAPA within two business days, and Program Operator cooperation with regulators. Regulatory compliance takes absolute precedence over Program status.

2.9 Appeals

A licensee may appeal a determination made under this Part. Appeals proceed in two tiers. A Tier 1 appeal is reviewed internally by the Program Operator. A Tier 2 appeal is referred to an independent three-reviewer body; a Tier 2 reversal binds the Program Operator and applies retroactively to the affected determination. The Program Operator publishes the filing and review windows for each tier and applies them uniformly.

PART 3

The Standards

The certification limits for all nine subcategories, as one master matrix, with each subcategory's full government-by-government derivation. Every limit is the strictest maximum level set by any credible government worldwide, in the product's native basis, with a disclosed read-across where no government regulates the exact product. Nothing is selected from measured data; every value traces to a named sovereign limit.

3.1 Master limit matrix — all nine subcategories

All values in µg/kg (ppb) in each row's native basis. Split cells show the formulation or matrix variants (cow/soy, rice/non-rice); n/m marks a not-material analyte controlled by reflex speciation. Each subcategory's full derivation follows.

Subcategory	Lead	iAs	tAs	Hg	Cd	Cr	Ni	Sn	Al	Basis
Infant formula (powder)	20	20	50	15	10 cow / 20 soy	2000	250 cow / 400 soy	5000	4000 cow / 8000 soy	as sold
Infant formula (ready-to-feed, liquid)	10	10	50	4	5 cow / 10 soy	300	100	5000	500 cow / 1000 soy	as consumed
Baby cereals & dry grain products	20	20	50	8	40	1000	3000	5000	500	as sold
Fruit purées	10	20	50	8	40	n/m	500	5000	500	as consumed
Non-root vegetable purées	10	20	50	8	40	500	500	5000	500	as consumed
Root-vegetable purées	20	20	50	8	40	500	500	5000	500	as consumed
Mixed meals (meat & grain combinations)	10	20	50	8	40	500	500	5000	500	as consumed
Fruit juice (not canned)	20	20	50	10	10	n/m	250	5000	500	as consumed
Teething biscuits & finger snacks	20	20	50	8	40	n/m	3000	5000	500	as sold

3.2 Infant formula (powder) (as-sold)

Every government maximum in force worldwide, in the as-sold basis; the HMTc limit is the strictest and the Binds column names the law that sets it. A blank cell means that government sets no limit for this analyte in this product.

Analyte	EU	UK	Codex	Canada	China	India	Brazil	GSO	AU/NZ	HMTc	Binds
Lead (Pb)	20	50	80[1]	80[1]	80	200	80[1]	80[1]	80[1]	**20**	EU
Inorganic arsenic (iAs)	20	–	–	–	–	–	160[1]	–	–	**20**	EU
Total arsenic (tAs)	–	–	–	–	500	50	–	–	–	**50**	India
Mercury (tHg)	–	–	–	–	–	–	–	–	–	**15**	IL
Cadmium (Cd)	10	10	–	–	–	100	80[1]	10	–	**10**	EU
Total chromium (Cr)	–	–	–	–	2000	–	–	–	–	**2000**	China
Nickel (Ni)	250	–	–	–	–	–	–	–	–	**250**	EU
Tin (Sn)	–	–	–	–	–	5000	–	–	–	**5000**	India
Aluminium (Al)	–	–	–	–	–	–	–	–	4000[1]	**4000**	AU/NZ

Variants on this page: cow and soy. Where a cell differs between them the master matrix shows both; the derivation below is for cow.

3.3 Infant formula (ready-to-feed, liquid) (as-consumed)

Every government maximum in force worldwide, in the as-consumed basis; the HMTc limit is the strictest and the Binds column names the law that sets it. A blank cell means that government sets no limit for this analyte in this product.

Analyte	EU	UK	Codex	Canada	China	India	Brazil	GSO	AU/NZ	HMTc	Binds
Lead (Pb)	10	10	10	10	10	20	10	10	10	**10**	EU
Inorganic arsenic (iAs)	10	–	–	–	–	–	20	–	–	**10**	EU
Total arsenic (tAs)	–	–	–	–	–	–	–	–	–	**50²**	read-across
Mercury (tHg)	–	–	–	–	–	–	–	–	–	**4**	IL
Cadmium (Cd)	5	5	–	–	–	100	10	5	–	**5**	EU
Total chromium (Cr)	–	–	–	–	–	–	–	–	–	**300²**	read-across
Nickel (Ni)	100	–	–	–	–	–	–	–	–	**100**	EU
Tin (Sn)	–	–	–	–	–	5000	–	–	–	**5000**	India
Aluminium (Al)	–	–	–	–	–	–	–	–	500	**500**	AU/NZ

Variants on this page: cow and soy. Where a cell differs between them the master matrix shows both; the derivation below is for cow.

3.4 Baby cereals & dry grain products (as-sold)

Every government maximum in force worldwide, in the as-sold basis; the HMTc limit is the strictest and the Binds column names the law that sets it. A blank cell means that government sets no limit for this analyte in this product.

Analyte	EU	UK	Codex	Canada	China	India	Brazil	GSO	FDA	HMTc	Binds
Lead (Pb)	20[1]	50[1]	20[1]	–	–	200[1]	20[1]	–	20[1]	**20**	EU
Inorganic arsenic (iAs)	20	–	–	100[1]	200[1]	–	150[1]	–	100[1]	**20[2]**	read-across
Total arsenic (tAs)	–	–	–	–	–	50[1]	–	–	–	**50**	India
Mercury (tHg)	–	–	–	–	–	–	–	–	–	**8[2]**	read-across
Cadmium (Cd)	40[1]	40[1]	–	–	60[1]	100[1]	50[1]	40[1]	–	**40**	EU
Total chromium (Cr)	–	–	–	–	–	–	–	–	–	**1000**	HK
Nickel (Ni)	3000[1]	–	–	–	–	–	–	–	–	**3000**	EU
Tin (Sn)	–	–	–	–	–	5000[1]	–	–	–	**5000**	India
Aluminium (Al)	–	–	–	–	–	–	–	–	–	**500[2]**	read-across

Variants on this page: rice-based and non-rice. Where a cell differs between them the master matrix shows both; the derivation below is for rice-based.

3.5 Fruit purées (as-consumed)

Every government maximum in force worldwide, in the as-consumed basis; the HMTc limit is the strictest and the Binds column names the law that sets it. A blank cell means that government sets no limit for this analyte in this product.

Analyte	EU	UK	China	India	Brazil	GSO	HMTc	Binds
Lead (Pb)	—	50[1]	—	100[1]	20[1]	100[1]	**10**	PA
Inorganic arsenic (iAs)	20[1]	—	200[1]	—	150[1]	—	**20**	EU
Total arsenic (tAs)	—	—	—	—	—	—	**50[2]**	read-across
Mercury (tHg)	—	—	—	—	—	—	**8[2]**	read-across
Cadmium (Cd)	40[1]	40[1]	60[1]	—	100[1]	40[1]	**40**	EU
Total chromium (Cr)	—	—	—	—	—	—	**n/m[3]**	controlled
Nickel (Ni)	500[1]	—	—	—	—	—	**500**	EU
Tin (Sn)	—	—	—	—	—	—	**5000[2]**	read-across
Aluminium (Al)	—	—	—	—	—	—	**500[2]**	read-across

3.6 Non-root vegetable purées (as-consumed)

Every government maximum in force worldwide, in the as-consumed basis; the HMTc limit is the strictest and the Binds column names the law that sets it. A blank cell means that government sets no limit for this analyte in this product.

Analyte	EU	UK	India	Brazil	GSO	HMTc	Binds
Lead (Pb)	20[1]	50[1]	200[1]	10	—	**10**	Brazil
Inorganic arsenic (iAs)	20[1]	—	—	—	—	**20**	EU
Total arsenic (tAs)	—	—	50[1]	—	—	**50**	India
Mercury (tHg)	—	—	—	—	—	**8**[2]	read-across
Cadmium (Cd)	40[1]	40[1]	100[1]	—	40[1]	**40**	EU
Total chromium (Cr)	—	—	—	—	—	**500**	HK
Nickel (Ni)	500[1]	—	—	—	—	**500**	EU
Tin (Sn)	—	—	5000[1]	—	—	**5000**	India
Aluminium (Al)	—	—	—	—	—	**500**[2]	read-across

3.7 Root-vegetable purées (as-consumed)

Every government maximum in force worldwide, in the as-consumed basis; the HMTc limit is the strictest and the Binds column names the law that sets it. A blank cell means that government sets no limit for this analyte in this product.

Analyte	EU	UK	India	GSO	AU/NZ	FDA	HMTc	Binds
Lead (Pb)	20[1]	—	100[1]	100[1]	—	20[1]	**20**	EU
Inorganic arsenic (iAs)	20[1]	—	—	—	—	—	**20**	EU
Total arsenic (tAs)	—	—	—	—	—	—	**50**[2]	read-across
Mercury (tHg)	—	—	—	—	—	—	**8**[2]	read-across
Cadmium (Cd)	40[1]	40[1]	—	40[1]	100[1]	—	**40**	EU
Total chromium (Cr)	—	—	—	—	—	—	**500**	HK
Nickel (Ni)	500[1]	—	—	—	—	—	**500**	EU
Tin (Sn)	—	—	—	—	—	—	**5000**[2]	read-across
Aluminium (Al)	—	—	—	—	—	—	**500**[2]	read-across

3.8 Mixed meals (meat & grain combinations) (as-consumed)

Every government maximum in force worldwide, in the as-consumed basis; the HMTc limit is the strictest and the Binds column names the law that sets it. A blank cell means that government sets no limit for this analyte in this product.

Analyte	EU	UK	Codex	China	India	Brazil	GSO	HMTc	Binds
Lead (Pb)	–	–	20[1]	–	200[1]	10	–	**10**	Brazil
Inorganic arsenic (iAs)	20[1]	–	–	200[1]	–	150[1]	–	**20**	EU
Total arsenic (tAs)	–	–	–	–	50[1]	–	–	**50**	India
Mercury (tHg)	–	–	–	–	–	–	–	**8**	IL
Cadmium (Cd)	40[1]	40[1]	–	60[1]	100[1]	50[1]	40[1]	**40**	EU
Total chromium (Cr)	–	–	–	–	–	–	–	**500**	HK
Nickel (Ni)	500[1]	–	–	–	–	–	–	**500**	EU
Tin (Sn)	–	–	–	–	5000[1]	–	–	**5000**	India
Aluminium (Al)	–	–	–	–	–	–	–	**500[2]**	read-across

3.9 Fruit juice (not canned) (as-consumed)

Every government maximum in force worldwide, in the as-consumed basis; the HMTc limit is the strictest and the Binds column names the law that sets it. A blank cell means that government sets no limit for this analyte in this product.

Analyte	EU	UK	Codex	Canada	India	GSO	FDA	HMTc	Binds
Lead (Pb)	20[1]	30[1]	30[1]	—	50[1]	30[1]	50[1]	**20**	EU
Inorganic arsenic (iAs)	20[1]	—	—	30[1]	—	—	—	**20**	EU
Total arsenic (tAs)	—	—	—	—	—	—	—	**50[2]**	read-across
Mercury (tHg)	—	—	—	—	—	—	—	**10**	IL
Cadmium (Cd)	20[1]	—	—	—	—	—	—	**10**	IL
Total chromium (Cr)	—	—	—	—	—	—	—	**n/m³**	controlled
Nickel (Ni)	250[1]	—	—	—	—	—	—	**250**	EU
Tin (Sn)	—	—	—	—	—	—	—	**5000[2]**	read-across
Aluminium (Al)	—	—	—	—	—	—	—	**500[2]**	read-across

3.10 Teething biscuits & finger snacks (as-sold)

Every government maximum in force worldwide, in the as-sold basis; the HMTc limit is the strictest and the Binds column names the law that sets it. A blank cell means that government sets no limit for this analyte in this product.

Analyte	EU	UK	Codex	Canada	China	India	Brazil	GSO	AU/NZ	FDA	HMTc	Binds
Lead (Pb)	20[1]	50[1]	20[1]	—	—	200[1]	20[1]	—	—	20[1]	**20**	EU
Inorganic arsenic (iAs)	20	—	—	100[1]	200[1]	—	150[1]	100[1]	—	—	**20[2]**	read-across
Total arsenic (tAs)	—	—	—	—	—	50[1]	—	—	—	—	**50**	India
Mercury (tHg)	—	—	—	—	—	—	—	—	—	—	**8[2]**	read-across
Cadmium (Cd)	40[1]	40[1]	—	—	60[1]	100[1]	50[1]	40[1]	100[1]	—	**40**	EU
Total chromium (Cr)	—	—	—	—	—	—	—	—	—	—	**n/m[3]**	controlled
Nickel (Ni)	3000[1]	—	—	—	—	—	—	—	—	—	**3000**	EU
Tin (Sn)	—	—	—	—	—	5000[1]	—	—	—	—	**5000**	India
Aluminium (Al)	—	—	—	—	200000[1]	—	—	—	—	—	**500[2]**	read-across

Variants on this page: rice-based and non-rice. Where a cell differs between them the master matrix shows both; the derivation below is for rice-based.

[1] basis-converted at the 8:1 powder-to-liquid ratio (China GB 2762). [2] read-across from the nearest government value for an analogous product. [3] not material in this matrix; controlled by reflex speciation, not a number.

PART 4

The Lot-Testing Schedule

Companion document to the HMTc Governance Policy, published by the Institute of Contaminant Standards (ICS) · Heavy Metal Tested & Certified, Infant and Child Foods Standards Program · Controlled document — uncontrolled when printed.

Certification is not a one-time event. It is a standing obligation, verified lot by lot, for as long as the Certification Mark appears on a product. This Part sets the minimum surveillance a Licensee shall maintain to hold each certified SKU in good standing, and the escalation that follows when a lot does not meet its applicable limits.

Two independent axes govern every testing decision:

1. Certification status — the SKU's current standing (A, B, C, D, E), assigned from measured performance.
2. Product risk tier — the exposure weight of the food category itself (High, Moderate, Lower), independent of any measured result.

Status is determined exclusively by MaxPoL — the highest Percent-of-Limit among all analytes, where PoL = (Result ÷ Applicable Limit) × 100%. MaxPoL is government-limit-relative in every instance; applicable limits are set under the HMTc Standards methodology on the government-limit default (Method v2.0). The contextual literature evidence base that informs Standards development is published and maintained independently by the Institute of Contaminant Standards at heavymetalindex.com; this manual references it outbound only, does not re-host, mirror, or reproduce it, and asserts no cross-domain canonical relationship. It sets no limit and determines no status.

4.1 Product Risk Tiers

A product's risk tier is a function of typical consumption frequency, volume relative to body weight, and the degree to which the food may serve as a sole or dominant source for the target population. A testing gap in a high-consumption, high-share category carries the greatest exposure consequence, so the schedule tests it most often.

Risk Tier	Definition	Subcategories in Tier
High-Risk	May serve as a sole-source or dominant food for infants; consumed in high volume relative to body weight, often multiple times daily.	Infant formula — powder; Infant formula — ready-to-feed; Baby cereals and dry grain products
Moderate-Risk	Consumed regularly, typically as part of a diversified diet, at moderate volume relative to body weight.	Fruit purées; Non-root vegetable purées; Root-vegetable purées; Mixed meals

Lower-Risk	Consumed occasionally or intermittently, at lower volumes relative to body weight, and not typically a dominant dietary component.	Fruit juice (non-canned); Teething and snack products

These are the nine subcategories of the live Infant and Child Foods taxonomy.

Operator adjustment. The Program Operator may adjust a specific product's risk tier on the basis of production volume, historical testing results, known ingredient risk profiles, and consumption data. For example, a teething product made primarily from rice — a high-risk ingredient for arsenic — may be elevated from Lower-Risk to Moderate-Risk. Any adjustment shall be documented and communicated to the Licensee.

4.2 The Testing-Frequency Matrix

The table below states the minimum testing frequency for routine surveillance. The Program Operator may increase frequency at any time. All testing follows the full heavy-metals panel (eight priority metals, plus required speciation) unless otherwise specified.

Certification Status	High-Risk	Moderate-Risk	Lower-Risk	Hold & Release	Independent Sampling
Status A	Monthly	Quarterly	Quarterly	Not required	Yes (per schedule)
Status B	Every lot or monthly (more frequent)	Monthly	Monthly	Recommended	Yes, monthly
Status C — Low (151–175%)	Every lot	Every lot	Every lot	Mandatory	Brand's own accredited lab permitted, subject to audit
Status C — High (176–200%)	Every lot	Every lot	Every lot	Mandatory	Operator-directed third-party sampling

Band boundaries use the clean, non-overlapping integer ranges (101–150% / 151–175% / 176–200%) that govern the MaxPoL status map (§4.8). A lot at MaxPoL 101–150% that carries any Tier 1 metal above 100% is Status C notwithstanding its band: it shall be tested every lot, held-and-released mandatorily, and sampled independently, per the Status C provisions below.

Key definitions.

- Independent Sampling — Samples are collected and submitted to the laboratory by a party independent of the brand's production team (the Program Operator, a designated third-party auditor, or a Program-Operator-approved party). Independent sampling provides evidence that testing was not subject to selection bias.
- Hold-and-Release — The finished-product lot is physically quarantined and may not ship until laboratory results are received and the lot is confirmed to meet, at minimum, its applicable status criteria. The Licensee shall document quarantine location, responsible personnel, and release authorization.

- Third-Party Sampling — Mandatory only at High Probation (MaxPoL 176–200%). At that band the Program Operator directs independent third-party sampling at the brand's expense, and the third party submits directly to a Program-designated laboratory. At Low Probation (151–175%), independent third-party sampling is not mandatory; the brand's own accredited-lab sampling is permitted, subject to audit.

4.3 Baseline Testing and Program Entry

Three-lot baseline

Every SKU entering the HMTc Program shall undergo baseline testing across three (3) production lots before any certification status is assigned. A single passing lot certifies nothing.

- Each of the three lots shall represent a distinct production run — different dates, shifts, or ingredient lots where possible.
- Each lot shall be tested against the full heavy-metals panel (all eight priority metals), with speciation where required by the Standards methodology (inorganic arsenic for rice-containing products; methylmercury for fish-containing products; hexavalent chromium where a credible pathway exists).
- Samples shall be prepared by the composite method, and chain-of-custody documentation is required for all baseline samples.

Status assignment. The three lots are evaluated collectively, and status is assigned from the worst-performing lot among the three. If one lot tests at Status A and another at Status B, the initial assignment is Status B.

Expedited Baseline via Prior-Data Credit

A mature, accredited lot-testing program may complete the three-lot baseline with a single new full-panel lot, under the following conditions:

- Up to two of the three baseline lots may be satisfied by qualifying prior results — ISO/IEC 17025-accredited, generated within the prior twelve months, structured and chain-of-custody documented, and basis-comparable — credited per analyte only, for the analytes those lots actually measured.
- The completing lot shall use independent sampling and chain-of-custody per §4.7 and shall run the full panel, including any analyte not present in the credited data.
- For an analyte established by the completing lot alone, the next two routine surveillance lots serve as confirmatory baseline points. In high-risk categories under monthly surveillance, that confirmation completes within the first surveillance cycle.
- This pathway is not available on the Confidential Remediation Track.

4.4 Surveillance Protocols by Status

Status A — Routine Surveillance

- Definition: demonstrated full compliance — MaxPoL at or below 100% for all analytes.
- Frequency: High-Risk, monthly with independent sampling; Moderate- and Lower-Risk, quarterly.
- Trend monitoring: the Licensee shall perform a formal trend analysis at least quarterly, using control charts or an equivalent method.
- Internal Warning Trigger (80% PoL reflex): if any analyte result on routine surveillance reaches or exceeds 80% of its HMTc limit, the Licensee shall perform confirmatory testing on the next available lot and institute enhanced monitoring. For a Tier 1 metal at or above 80% PoL, the Licensee shall additionally notify the Program Operator and perform speciation where applicable — regardless of whether the standard speciation trigger has been met.
- Lot release: hold-and-release is not mandatory at Status A but is strongly recommended. On an unexpected fail, the lot shall be isolated and the noncompliance procedures activated immediately.

Status B — Elevated Surveillance

- Definition: a transitional exceedance on one or more Tier 2 metals — MaxPoL above 100% but at or below 150% — with no Tier 1 metal above 100%.
- Frequency: High-Risk, every lot or monthly, whichever is more frequent; Moderate- and Lower-Risk, monthly with independent sampling.
- Hold-and-release: not mandated, but strongly recommended — particularly for the first several lots following CAPA implementation. A lot that exceeds the 150% transitional cap, or that involves any Tier 1 metal exceedance, may not be released as certified.
- Escalation to Status C (any one trigger): MaxPoL above 150% for any analyte; any Tier 1 metal above 100%; two or more consecutive lots showing no improvement or worsening results relative to baseline; or failure to initiate or execute CAPA within the required timelines.

Status C — Probation Surveillance

- Definition: probation for significant exceedances, repeated non-improvement, or any Tier 1 metal violation.
- Frequency: all Status C products, regardless of risk tier, are tested every lot. There are no exceptions. The Program Operator may require split-sample testing across two independent laboratories.
- Hold-and-release, mandatory: no product may leave quarantine until laboratory results are received and the lot is confirmed to meet at least Status A or Status B criteria. The Probation Lot Release Plan shall specify quarantine location and procedures, authorized personnel, laboratory and turnaround, pass criteria (Status A or B), and fail handling (rework, downgrade to non-certified, sticker-over, or withdrawal).
- Graduated controls:
- Low Probation (MaxPoL 151–175%): every lot plus mandatory hold-and-release; the brand's own accredited-lab sampling is permitted, subject to audit and possible unannounced verification sampling.
- High Probation (MaxPoL 176–200%): every lot plus mandatory hold-and-release plus mandatory independent third-party sampling directed by the Program Operator, submitted directly to a Program-designated laboratory.

- Exit criteria (both required): a minimum of five (5) consecutive lots individually testing at Status A or B levels (the Operator may require more), and completion of all CAPA milestones plus a documented Verification of Effectiveness.

Status D — Suspension and Reinstatement

- Definition: MaxPoL above 200% for any analyte, or any hard-stop (regulatory-limit violation or data-integrity failure), or failure to execute testing, CAPA, or directives on probation.
- Immediate actions: stop-ship, Mark removal from all units and marketing, and market correction. CAPA is initiated within two business days, with containment immediately (within 48 hours).
- Reinstatement: a suspended SKU is reinstated only on a completed CAPA with verification of effectiveness (VOE), a run of consecutive compliant lots set by the Program Operator, restored data integrity, and formal Operator approval. Reinstatement does not require a fresh baseline.

4.5 Reflex Testing Triggers

Reflex tests carry the same weight as routine surveillance results and are subject to the same decision rules and status implications. A reflex nonconformance triggers a status transition and CAPA immediately, regardless of where the product sits in the routine cycle.

Trigger Category	Specific Triggers	Testing Requirement
Ingredient Changes	New ingredient, new supplier, change in ingredient origin or grade	Full panel on next 2 lots after change
Water Source Changes	New municipal source, well change, treatment-system modification	Full panel on next 2 lots after change
Equipment Changes	New product-contacting equipment, repairs involving metal surfaces	Full panel on next lot after change
Packaging Changes	New packaging material or supplier, change in liner or closure	Full panel on next 2 lots (migration over time)
Formulation Changes	Any change in ingredient ratios; addition or removal of ingredients	Full panel on next 2 lots after change
Process Changes	Changes in contact time, temperature, pH, mechanical stress, or sequence	Full panel on next lot after change
Upstream Supplier Notification	Supplier notifies of a change in their own sourcing or processing	Full panel on next lot using the affected ingredient
Surveillance Warning	Any Tier 1 metal result at or above 80% PoL on routine testing	Confirmatory test on next lot; speciation if applicable
Supplier Intelligence Alert	Program Operator issues an anonymized alert on a supplier or ingredient category	Full panel on next lot using the flagged ingredient or supplier

4.6 Speciation Requirements

Metal	Form of Concern	Mandatory Speciation	Reflex Trigger
Arsenic	Inorganic arsenic (iAs)	All products containing rice or rice-derived ingredients	Total As at or above 50% of the applicable limit
Mercury	Methylmercury (MeHg)	All products containing fish or marine ingredients	Total Hg at or above 50% of the applicable limit
Chromium	Hexavalent chromium [Cr(VI)]	Only where a credible pathway exists (certain water sources, processing)	Total Cr anomalously high, or Operator directs
Lead, Cadmium, Nickel, Aluminium, Tin	Total element only	Not required	Not applicable

Normative riders.

- When speciation is performed, the speciated result becomes the compliance result for that metal, superseding the total-element concentration.
- Failure to perform required speciation renders the lot ineligible for certification.
- The reflex speciation trigger is operationally defined as reaching 50% of the applicable HMTc limit for the total metal. The Program Operator may lower this threshold but shall not raise it above 50%. This 50% reflex trigger is distinct from, and coexists with, the 80% PoL internal warning of §4.4.

Hexavalent chromium — hard fail. Where a credible hexavalent pathway exists, Cr(VI) speciation is mandatory, and reflex Cr(VI) speciation is triggered when total chromium is anomalously high or the Program Operator directs. When Cr(VI) speciation is performed, the speciated Cr(VI) result supersedes total chromium and chromium is evaluated as a Tier 1 analyte with zero transitional tolerance. Because hexavalent chromium has no tolerable exceedance, any quantifiable Cr(VI) result — any speciated hexavalent-chromium value at or above the laboratory's limit of quantification — is a hard fail: the lot is ineligible for certified release and shall be handled as a Tier 1 exceedance, forcing escalation to Status C at minimum and to the regulatory hard-stop procedure wherever any applicable legal limit is exceeded.

4.7 Sampling Methodology and Chain-of-Custody

Composite sampling. All certification testing is conducted on a lot basis. The analytical sample is a composite prepared from multiple consumer-unit samples drawn from across the lot, designed to represent the lot's average quality with 95% confidence that the lot meets requirements. The sampling plan is subject to Program Operator approval; alternative plans (stratified, continuous batch) require prior written approval.

Chain-of-custody. A complete custody record is required from the point of collection through laboratory receipt and analysis, documenting the collector and affiliation; when and where samples were taken; sealing, labeling, and transport; the laboratory receiver; and integrity confirmation on receipt.

- Breach = invalidation. Any documented breach in chain-of-custody invalidates the result and is treated as a data-integrity issue under Governance Policy §8.2. Enumerated breaches include a custody gap, a broken seal, non-conforming labeling, transport non-conformance, and a receipt discrepancy. A breached lot shall be retested under an Operator-approved confirmatory protocol; repeated breaches escalate as a data-integrity matter and may result in Status D suspension.
- Discretion. The Operator may excuse minor procedural lapses where substantive sample integrity is preserved (for example, a timestamp recorded one hour late). The default disposition for any chain-of-custody ambiguity is invalidation.

Laboratory and LOQ. Testing shall be performed by an ISO/IEC 17025-accredited laboratory for the methods and matrices in scope. The LOQ for each analyte must be at or below the HMTc action level. A non-detect (below LOQ) is treated as zero only where the LOQ meets this requirement; where the LOQ exceeds the Program limit, the result is indeterminate and the lot shall be retested by a more sensitive method.

Reporting. Results shall be reported on a finished-product basis (as sold), stating each analyte and its form (total versus speciated), together with the LOQ and Measurement Uncertainty (MU), in a structured, machine-readable format. PDF submission is not acceptable.

4.8 Decision Rules and the MaxPoL Status Map

Measurement-uncertainty rule. For every result, applying a coverage factor k = 2 (95% confidence interval):

- Pass if (Result + MU) is at or below the limit.
- Fail if (Result − MU) is above the limit.
- Borderline if neither condition is met — a borderline result requires confirmatory action before any status is assigned.

MaxPoL status map.

MaxPoL Range	Metal Tier	Status	Action Required
0–100%	Any	Status A	Routine surveillance
101–150%	Tier 2 only	Status B	CAPA within 10 business days; elevated testing
101–150%	Any Tier 1 metal	Status C	CAPA within 5 business days; every-lot, mandatory hold-and-release
151–175%	Any	Status C (Low)	CAPA within 5 business days; every-lot, mandatory hold-and-release

176–200%	Any	Status C (High)	CAPA within 5 business days; every-lot + third-party sampling
> 200%	Any	Status D	Stop-ship; CAPA within 2 business days; Mark removal

No testing into compliance. Repeated ad hoc retesting to obtain a passing result is strictly prohibited. Any retest must proceed under a pre-approved confirmatory plan that is scientifically justified and documented. Undocumented resampling or lab-shopping is a data-integrity violation subject to suspension or revocation.

4.9 CAPA Timelines Summary

The periods below are maximum allowable; faster action is always expected. Every CAPA shall include problem identification, impact assessment, containment, root-cause analysis (5-Why, fishbone, or fault-tree), corrective and preventive actions, and a Verification of Effectiveness (VOE) plan.

Element	Status B	Status C	Status D	Status E
CAPA initiation	10 business days	5 business days	2 business days	As directed
Full plan submission	30 calendar days	15 business days	10 business days	N/A
Containment	As needed	Within 48 hours	Immediate (within 48 hours)	As directed
Return path	12 months to A	Per CAPA	Reinstatement (see rider)	Re-application
VOE required	Yes	Yes	Yes	If re-applying
Exit requirement	Improving trend + Status A criteria	5+ consecutive passing lots + CAPA closure	Reinstatement set (see rider)	Full re-application

Status D reinstatement rider. A suspended SKU is reinstated only on a completed CAPA with verification of effectiveness (VOE), a run of consecutive compliant lots set by the Program Operator, restored data integrity, and formal Operator approval. Reinstatement does not require a fresh baseline.

End of Part 4.

PART 5

Reference and Back-Matter

5.1 How Every Limit Is Set

Every limit in this manual is set the same way, and the method is deliberately mechanical so that any reviewer can reproduce it and no value depends on the Program Operator's discretion.

The default is the government floor. For each analyte in each subcategory, the limit is the strictest maximum level set by any credible government worldwide, converted to the product's native basis (the form in which it is sold, consumed, or prepared). No published value is ever above the lowest applicable government maximum, and no limit is derived by selecting a value out of program or brand test data — each traces to a named sovereign limit in the regulation references. Where the strictest sovereign value sits below a familiar domestic action level, that is a function of which government is strictest for that cell, not of any adjustment by the program.

Basis conversion is narrow. The 8:1 powder-to-liquid conversion applies only within infant formula, where a limit expressed on a reconstituted basis must be restated on the as-sold powder. Every other subcategory takes its government limit at face value; no other basis manipulation is performed.

Where no government regulates the exact cell, the value is read across, not invented. A read-across maps the limit from the nearest applicable government value and discloses that derivation. Where an analyte is neither regulated for the product nor material in that matrix, it is marked n/m and controlled by reflex speciation rather than assigned a number. Chromium is the standing example: total chromium is screened, hexavalent chromium [Cr(VI)] speciation is reflexed on a credible pathway, and any quantifiable Cr(VI) is a hard fail — Cr(III) being an assumed nutrient, and hexavalent chromium an IARC Group 1 carcinogen (established on occupational-inhalation evidence and assessed by US EPA as likely carcinogenic by the oral route).

Toxicology, not the number, decides how an exceedance is treated. The eight metals are tiered. Tier 1 — lead (Pb), cadmium (Cd), inorganic arsenic (iAs), and mercury (tHg, total; screened as total mercury with reflex methylmercury speciation on a credible fish pathway, the speciated result superseding total) — are zero-tolerance: any result above 100% of limit escalates, at any margin. Tier 2 — nickel (Ni), aluminium (Al), tin (Sn), and total chromium (Cr) — carry a bounded 150% transitional allowance on defined conditions. This is why a small Tier 1 exceedance can outrank a larger Tier 2 one; the ordering is comparative toxicology, engineered in on purpose, not administrative convenience.

Status is a comparison, never a selection. A measured value divided by its applicable limit is that analyte's PoL (percent-of-limit); the highest PoL across all analytes in a lot is the lot's MaxPoL, and MaxPoL — a mechanical, government-limit-relative computation — drives the product's Status (Part 2.2). Because the input is the measured value and the divisor is a named government maximum, the derivation is firewall-clean: nothing in status assignment reaches back into any distribution of results.

5.2 The Program Under Adversarial Read

This manual is written to be read by hostile reviewers. The challenges below are the ones most likely to be put to a plaintiff's or a defense expert; each is stated at its strongest, with the program's answer. The full program-level adversarial read is maintained in the governance record; this is the load-bearing subset.

Challenge — the limits are arbitrary, stricter than the government's for marketing. Response. Every limit is the strictest applicable government maximum for that subcategory and analyte, converted to native basis (5.1); it is not chosen to sell a mark. Where a limit sits below a domestic action level, it does so because a stricter sovereign governs the cell, or because single-product federal levels do not account for a child eating across categories in a day — the aggregate-exposure basis is set out in Part 1. The deviation is labeled by rationale, not papered over. A standard that shows its work survives being read aloud.

Challenge — it is pay-to-play; the certifier is paid by the brands it certifies and sets its own limits. Response. The limits are set from published government maximums and an independent literature evidence base — not from certified brands' data. That evidence base is the Heavy Metal Index (heavymetalindex.com), operated as an architecturally separate property, referenced outbound only; the standard is not the certifier's self-published justification. Status is driven by MaxPoL, a mechanical ratio to a government limit, leaving no discretionary lever to sell.

Challenge — the limits were set with AI. Response. Limit values were produced using AI instruments under a named human principal investigator, with cross-vendor verification, and the manual discloses this openly at its front (Part 1). The disclosure does not weaken the result because every value still resolves to a named sovereign government maximum (5.1); the derivation is reproducible independent of the instrument that assembled it.

Challenge — enrolling generates a record the plaintiff can subpoena. Response. Conceded, and stated plainly (Part 2.4). The testing data carries no attorney-client or work-product privilege and is potentially compellable; the operator commits to notifying the licensee and cooperating with its defense. But for products sold under California AB 899 or Maryland's baby-food heavy-metal testing law the lot-testing record must exist regardless — the live choice is whether it is generated inside one disciplined program or ad hoc. The program explicitly disclaims being a substitute for a counsel-directed program that may carry stronger privilege in a specific matter.

Challenge — a passing certificate is one lot, chosen and timed by the brand. Response. Certification is not a snapshot. It rests on a three-lot baseline with status assigned from the worst-performing lot, then a fixed risk-based surveillance schedule, independent sampling, documented chain of custody (a break invalidates the result), reflex testing on defined change events, and a machine-readable dataset. The schedule is fixed by protocol, not chosen by the brand, and testing into compliance — undocumented resampling or lab-shopping — is a data-integrity violation that costs status. A record that could not have been curated cannot be impeached as curated, and one kept as a regular practice carries the trustworthiness the business-records rule was written to admit.

Challenge — the pass/fail rule is tuned to favor the brand. Response. The decision rule (Part 2.6) applies the laboratory's expanded measurement uncertainty two-sidedly: a lot passes only if result + uncertainty ≤ limit, and fails only if result − uncertainty > limit (k = 2, 95%); anything between is borderline and requires confirmatory testing before any status issues. The rule is biased toward analytical accuracy, not toward the brand or the regulator — which is precisely why a cross-examiner cannot recharacterize it as a thumb on the scale.

Challenge — the mark tells parents the product is safe. Response. The mark is disciplined against exactly that. Claims of "heavy-metal free," "no toxic metals," or "100% safe" are prohibited; the manual states the mark does

not certify safety. It certifies testing against defined limits under ongoing surveillance, and only Status A or B products may bear it. Forbidding the absolute claim removes the misrepresentation hook rather than supplying one.

Challenge — as the mark becomes a condition of shelf space, it is an antitrust problem, and in any event it is a liability shield. Response. The standard is voluntary, openly published, reproducible, and available on equal terms; at current scale the standard-setting risk is low, and the program applies ordinary voluntary-standard hygiene as adoption grows. It is not immunity — a government-limit exceedance is a hard stop regardless of status, and the program characterizes itself as risk mitigation and an evidentiary posture, never a safe harbor. Setting client expectations there is part of using it correctly.

5.3 Glossary

Terms and abbreviations as used across this manual. Where a fuller treatment exists, the governing Part is named.

PoL (percent-of-limit) — A single analyte's measured value divided by its applicable limit, expressed as a percentage; below the limit is under 100%. A Tier 1 result reaching 80% of limit triggers a confirmatory test and enhanced monitoring.

MaxPoL (maximum percent-of-limit) — The highest PoL among all analytes in a lot — the worst-performing analyte — and the value that drives the product's Status. A mechanical, government-limit-relative ratio; never a selection from a distribution of results.

Status A–E — The product-level status ladder (Part 2.2); a status attaches to a product, not a brand. A: full compliance, routine protocol, MaxPoL ≤ 100% on every analyte. B: transitional, elevated protocol, MaxPoL > 100% to ≤ 150%, Tier 2 analytes only, with no Tier 1 analyte above 100%. C: probation, MaxPoL > 150% to ≤ 200% on any analyte, or any Tier 1 analyte above 100% at any margin, or unmet transitional conditions (graduated Low band 151–175%, High band 176–200%; the High Probation band adds mandatory Operator-directed third-party sampling). D: suspension, MaxPoL > 200%, or any hard stop. E: revocation, permanent, re-application only.

Tier 1 / Tier 2 — The toxicological tiering of the eight metals. Tier 1 — Pb, Cd, iAs, and mercury (tHg, total; methylmercury governs by reflex speciation) — zero-tolerance, no transitional variance at any margin. Tier 2 — Ni, Al, Sn, Cr — variance-eligible up to the 150% transitional allowance on defined conditions. Any quantifiable Cr(VI) on a credible pathway is a hard fail evaluated as Tier 1.

CAPA (corrective and preventive action) — The response required on a confirmed exceedance. Windows scale with status — B: initiate within 10 business days, full plan within 30 calendar days, default return to A within 12 months; C: 5 business days / 15 business days / containment within 48 hours; D: 2 business days / 10 business days / containment immediate (within 48 hours). Required elements include identification, impact, containment, root-cause analysis, corrective action, preventive action, and a verification-of-effectiveness (VOE) plan.

reflex — Testing triggered by a condition rather than the calendar — a result crossing a threshold (speciation is reflexed at 50% of the applicable limit), or a defined change event (new supplier, new water source, packaging or formulation change). A reflex result carries the same weight as a routine one.

speciation — Measuring the specific toxic form rather than the total: inorganic arsenic (iAs) for rice, methylmercury (MeHg) for fish, hexavalent chromium [Cr(VI)] on a credible pathway. The speciated result supersedes the total; failure to speciate where required renders the lot ineligible.

read-across — A disclosed mapping of a limit from the nearest applicable government value where no government regulates the exact product or analyte, so the value is derived transparently rather than invented.

n/m (not material) — An analyte neither regulated for the product nor toxicologically material in that matrix; controlled by reflex speciation rather than assigned a numeric limit.

native basis — The physical form in which a product is sold, consumed, or prepared (as sold / as consumed / as prepared), to which a government limit is converted before comparison.

government-limit default (Method v2.0) — The current limit-setting method: default each limit to the strictest applicable government maximum, convert to native basis, read across where unregulated, mark n/m where not material — nothing invented, every value traceable to a named sovereign limit.

8:1 basis — The powder-to-liquid reconstitution conversion, applied only within infant formula; all other subcategories take government limits at face value.

measurement-uncertainty decision rule — The two-sided pass/fail test (Part 2.6): pass only if result + uncertainty ≤ limit; fail only if result − uncertainty > limit; otherwise borderline, requiring confirmatory testing ($k = 2$, 95%).

chain of custody — The documented handling record for a sample; a break invalidates the result and is treated as a data-integrity matter.

three-lot baseline — The minimum of three production lots, full panel, tested before any status is assigned; status is taken from the worst-performing lot.

testing into compliance — The prohibited practice of undocumented resampling, lab-shopping, or selective reporting to manufacture a passing number; a data-integrity violation that costs status.

hard stop — A condition that overrides the staged framework — a government-limit exceedance or a data-integrity breach — moving a product to suspension regardless of MaxPoL.

Cr(VI) / hexavalent chromium — An IARC Group 1 carcinogen (established on occupational-inhalation evidence and assessed by US EPA as likely carcinogenic by the oral route); screened by reflex speciation from total chromium on a credible pathway and evaluated as Tier 1, with any quantifiable Cr(VI) a hard fail (Cr(III) being an assumed dietary nutrient).

Confidential Remediation Track — The confidential entry and support pathway (Part 2.4) for brands whose baseline does not reach Status A or B, provided every tested lot meets applicable legal limits in its markets of sale; the Certification Mark may not be used until at least one SKU reaches Status A or B.

Program Operator — The Institute of Contaminant Standards (ICS) in its operative role: the body that owns this manual, assigns status, and administers appeals, CAPA, and the surveillance schedule.

Edition record

The dated editions of this manual, each kept at a stable permalink. This 2026 web edition is the current standard set; the 384-page deposited editions are prior, superseded volumes and are not served against it.

Edition	Date	Status	DOI	What changed
2026 web edition	2026-08-06	current	pending (Crossref)	Reorganized to the nine rendered subcategories under the government-limit default (Method v2.0). Consolidated, version-pinned PDF now published (v2); a DOI is minted on deposit.
2026 deposit (rev.)	2026-06-20	superseded	10.5281/zenodo.20771543	384-page deposited volume; revision incorporating the Expedited Baseline (Governance §4.5) and Lot Testing Schedule v2.1.
2026 deposit (v0)	2026-05-18	superseded	10.5281/zenodo.20270512	First public deposit of the standalone 384-page volume.

The concept DOI 10.5281/zenodo.20270511 always resolves to the latest deposited edition. The current 2026 web edition has no DOI yet (Crossref deposit pending); this manual is citable by its permalink in the meantime.

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