Infant and Child Foods

Category 1 · Ages 0–5 · Manual v3

Method v2.0 — government-limit default (gov_floor | disclosed read_across)

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EDITION

Manual v3 · 2026-09-19 · live standard pages 9 · cert-ready 9 of 9

About this manual

Manual v3 is the Method v2 governing instrument for Category 1. Thin table of contents: the five Governing Principles; program lifecycle and statuses; mark, measurement uncertainty, CAPA, remediation, and the standards ratchet; the Lot Testing Schedule (lab-informed assignment and the 90% stay-in-program gate); and the live Cat-1 Standards Register. It does not reprint per-analyte master-table walls. The earlier Zenodo deposit is an earlier deposited edition only. V1 never certified a brand and is retired.

Pendergrass, K. (2026). Infant and Child Foods: HMTc Program Manual. Institute of Contaminant Standards.

Contents

PART 1

Governing Principles

The Heavy Metal Tested & Certified program for Infant and Child Foods is governed by five co-equal objectives. None may be sacrificed to advance another. The ruling is `docs/governance/hmtc-governing-principles.md`, the file named by the readiness manifest.

Limits do not derive from the Heavy Metal Index. Every published number traces to a named sovereign government maximum or a disclosed read-across.

1.1 Drive down contamination

The program exists to lower heavy-metal burden in products that reach infants and young children. A mark that does not change what is in the product is not the work.

1.2 Protect consumers

Limits, lot testing, and the mark are instruments of consumer protection. A certificate that cannot be trusted does not protect anyone. Incomplete claim-surface cells are not cert-ready.

1.3 Protect brands who enter

A brand that enters in good faith, tests honestly, and stays inside the published rules is not set up to fail. Certification is offered only when the program has at least 90% confidence the brand can remain in the program.

1.4 Remain legally defensible

Claim-surface cells are government floor or disclosed read-across only. Species never replace the parent total (species ≤ parent). Nothing is invented. A blank cell is HOLD.

1.5 Become the de facto standard

The program is written to be the instrument the market, retailers, and regulators can actually use. Opacity and one-off exceptions defeat that.

PART 2

Program lifecycle and instruments

This Part is the current source of truth for how a Category 1 SKU enters, is assigned a status, and is held to the mark. Except where a defined term states otherwise, every requirement is normative.

2.1 The governing rule

Certification is limit-relative and binary at the limit. For every claim-surface analyte the applicable limit is the published government floor or disclosed read-across (Method v2.0); limits do not derive from a distribution of measured values. A product is Certified only when every analyte is at or below 100% of its published limit, confirmed under the measurement-uncertainty decision rule (§2.5). There is no band above the limit that still earns the mark: at or below the limit is Certified; above the limit is not.

The eight limit analytes are lead (Pb), total arsenic (tAs), cadmium (Cd), mercury (tHg, total), nickel (Ni), tin (Sn), aluminium (Al), and chromium (Cr, total). Inorganic arsenic, methylmercury, and hexavalent chromium are pathway species. They never replace the parent total.

2.2 Program flow

1. Baseline (three lots). Every SKU is tested across a minimum of three production lots, on the full eight-total panel and required pathway speciation, before any status is assigned. A single passing lot certifies nothing. The three lots are evaluated collectively, and the entry decision is taken from the worst-performing lot.
2. Expedited baseline (prior-data credit), optional. Qualifying ISO/IEC 17025 results from the preceding twelve months may credit up to two lots, per analyte actually measured. Not available on the Confidential Remediation Track.
3. Entry. A lot that violates an applicable government legal limit is a hard stop and cannot be certified. A lot at or below every published limit (under §2.5) is eligible to be Certified; a lot above any published limit is not certified and enters Remediation.
4. Status assignment. The product is assigned Certified or Remediation from the baseline, then maintained through surveillance; Suspension and Revocation follow the rules in §2.4.
5. Schedule assignment. Risk tier and lot-testing frequency are assigned after application, from the brand laboratory's stated panel, LOQ, MU, and capability (Part 4).

2.3 Analyte tiering

Tiering sets how hard and how fast the program reacts to an exceedance. It is never permission to exceed a limit and keep the mark: no metal has a transitional band or an allowed overage.

Tier	Metals	Reaction to an exceedance

Tier 1 — Zero tolerance	Lead (Pb), Cadmium (Cd), Inorganic arsenic (iAs), Mercury (tHg, total)	Most severe reaction. Any confirmed result above 100% of the applicable limit removes the mark and moves the SKU to Remediation at once, with every-lot testing and mandatory hold-and-release; a legal-limit violation or data-integrity failure is a hard stop to Suspension.
Tier 2 — Elevated	Nickel (Ni), Aluminium (Al), Tin (Sn), Chromium (Cr, total)	Elevated reaction. An exceedance still bars the mark and moves the SKU to Remediation, but surveillance is elevated rather than an immediate hard stop, and the brand's own accredited lab may sample subject to audit.

Any quantifiable hexavalent chromium [Cr(VI)] on a credible pathway is a hard fail, evaluated as a Tier 1 exceedance.

2.4 Certification status framework

Four statuses. Status attaches to the product, not the brand. The mark is permitted only while the product is Certified.

Status	Meaning	Mark	Condition
Certified	Full compliance	Permitted	Every analyte at or below 100% of its published limit, all eight totals, native basis, confirmed under §2.5.
Remediation	Not certified — applicant or corrective	Withheld / removed	The product does not meet every published limit, or is a new applicant not yet at 100%. This is not a softer certification and not an allowed overage. Corrective action applies, with elevated (Tier 2) or every-lot hold-and-release (Tier 1) surveillance; the SKU is not listed as certified and the mark is not displayed. The Confidential Remediation Track (§2.7) is the confidential form of this status and is likewise non-certified and unmarked.
Suspension	Certification halted — hard stop	Removed	A government legal-limit violation, a data-integrity failure, or failure to execute testing, CAPA, or directives. The mark is removed from all units and marketing immediately.

Revocation	Permanent termination	Removed	Willful misconduct, data fraud, concealment of a known exceedance, or persistent unremediated suspension. Re-entry by full re-application only.

The Certification Mark shall not be used on any product, packaging, or marketing unless the product is Certified. A product above any published limit — at any margin, on any metal — is not Certified and does not display the mark.

Suspension reinstatement does not require a fresh baseline. It requires a completed CAPA with verification of effectiveness, a run of consecutive compliant lots set by the Program Operator, restored data integrity, and formal Operator approval.

2.5 Measurement uncertainty

Every result is evaluated with expanded measurement uncertainty at coverage factor k = 2 (95%). Pass: (Result + MU) ≤ Limit. Fail: (Result − MU) > Limit. Borderline: neither, confirmatory action required before any status. A borderline result alone shall not certify. Testing into compliance is prohibited.

2.6 CAPA

CAPA windows scale with the severity of the reaction, not with any percent-of-limit band.

Reaction	CAPA initiation	Full plan due	Containment
Tier 2 exceedance (Remediation)	10 business days	30 calendar days	As needed
Tier 1 exceedance (Remediation)	5 business days	15 business days	Within 48 hours
Suspension (hard stop)	2 business days	10 business days	Immediate (within 48 hours)

A product in Remediation for a Tier 2 exceedance has a 12-month default period to return to Certified; failure to show an improving trend escalates the reaction. 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.

2.7 Remediation and ratchet

Before certification, readiness awards no mark. After certification, corrective action follows the published status rules. The Confidential Remediation Track is a confidential entry-and-support pathway for products not yet at 100% of every published limit; it is expressly not a certified status, and no mark is displayed while a product is on it. Confidentiality never delays a recall, never overrides a reporting duty, and never withholds evidence from a regulator who asks. Concealment of a known exceedance is grounds for revocation.

A published limit tightens only through the Standards Ratchet: a stated trigger and a capped step. Limits do not loosen because a brand found them inconvenient.

The Heavy Metal Index is contextual evidence only. It never sets a limit and never determines a status. The reference is one-way and outbound.

PART 3

Cat-1 Standards Register

Every Cat-1 compiled record and every live subcategory page. Cert-ready means the live page carries a house DOI under prefix 10.83138 and every joined compiled variant has a complete claim-surface. Incomplete cells stay listed as not cert-ready. Live pages 9; cert-ready 9 of 9; HOLD 1.

Infant formula (powder)
`/standards/infant-formula-powder · infant-formula-powder`
cert-ready · 10.83138/hmtc.std.1.infant-formula-powder

Infant formula (ready-to-feed, liquid)
`/standards/infant-formula-ready-to-feed · infant-formula-ready-to-feed`
cert-ready · 10.83138/hmtc.std.1.infant-formula-ready-to-feed

Baby cereals & dry grain products
`/standards/baby-cereals-dry · baby-cereals-dry`
cert-ready · 10.83138/hmtc.std.1.baby-cereals-dry

Fruit purées
`/standards/fruit-purees · fruit-purees`
cert-ready · 10.83138/hmtc.std.1.fruit-purees

Non-root vegetable purées
`/standards/non-root-vegetable-purees · non-root-vegetable-purees`
cert-ready · 10.83138/hmtc.std.1.non-root-vegetable-purees

Root-vegetable purées
`/standards/root-vegetable-purees · root-vegetable-purees`
cert-ready · 10.83138/hmtc.std.1.root-vegetable-purees

Mixed meals (meat & grain combinations)
`/standards/mixed-meals · mixed-meals`
cert-ready · 10.83138/hmtc.std.1.mixed-meals

Fruit juice (not canned)
`/standards/fruit-juice-not-canned · fruit-juice-not-canned`
cert-ready · 10.83138/hmtc.std.1.fruit-juice-not-canned

Teething biscuits & finger snacks
`/standards/teething-and-snacks · teething-and-snacks`
cert-ready · 10.83138/hmtc.std.1.teething-and-snacks

Mixed meals (meat & grain combos), rice-containing
`mixed-meals-rice-containing`
`HOLD · compiled record not joined to a live /standards/ page`

PART 4

The Lot Testing Schedule

Companion to the HMTc governance rules for Infant and Child Foods. Certification is a standing obligation, verified lot by lot, for as long as the mark appears on a product.

Totals are run on every completing lot. Speciation is a pathway reflex. Risk tier and the surveillance schedule are assigned after application, from what the brand's laboratory states, not from the frequency grid alone.

4.1 Product risk tiers

The live taxonomy comprises nine subcategory standard pages.

Risk Tier	Subcategories in Tier
High-Risk	Infant formula — powder; Infant formula — ready-to-feed; Baby cereals and dry grain products
Moderate-Risk	Fruit purées; Non-root vegetable purées; Root-vegetable purées; Mixed meals
Lower-Risk	Fruit juice (non-canned); Teething and snack products

The Program Operator may raise a specific product's risk tier on documented rationale (for example, a rice-based teething product).

4.2 The Testing-Frequency Matrix

This is the starting grid. The assigned schedule is written after the lab-informed review in §4.9. Certified is the only status that carries the mark; Remediation carries no mark and is not listed as certified while any analyte is above its published limit.

Certification status	High-Risk	Moderate-Risk	Lower-Risk	Hold & Release	Independent Sampling
Certified	Monthly	Quarterly	Quarterly	Not required	Yes (per schedule)
Remediation — Tier 2 exceedance	Every lot or monthly (more frequent)	Monthly	Monthly	Mandatory	Brand's own accredited lab permitted, subject to audit
Remediation — Tier 1 exceedance	Every lot	Every lot	Every lot	Mandatory	Operator-directed third-party sampling

Reaction severity follows the toxicological tier of the exceedance and the brand's conduct, never an allowed overage. Any Tier 1 exceedance, any quantifiable Cr(VI), or a data-integrity or concealment concern takes the every-lot, Operator-directed row regardless of risk tier.

4.3 Baseline

Every SKU shall undergo baseline testing across three production lots before any certification status is assigned. Status is assigned from the worst-performing lot. Each lot runs the eight-total panel, with pathway speciation where required.

Qualifying prior ISO/IEC 17025 data from the preceding twelve months may credit up to two lots, per analyte actually measured. This pathway is not available on the Confidential Remediation Track.

4.4 Surveillance by status

Certified: High-Risk monthly with independent sampling; Moderate- and Lower-Risk quarterly. A Tier 1 result at or above 80% of its applicable limit triggers confirmatory testing, Operator notice, and speciation where applicable.

Remediation: the product carries no mark and is not listed as certified. Corrective action is mandatory and surveillance is intensified. A Tier 2 exceedance takes elevated surveillance — every lot or monthly, whichever is more frequent, with mandatory hold-and-release; the brand's own accredited sampling is permitted, subject to audit. A Tier 1 exceedance, any quantifiable Cr(VI), or a concealment or data-integrity concern takes every-lot testing, mandatory hold-and-release, and Operator-directed third-party sampling. Return to Certified requires the product to meet 100% of every published limit across a run of consecutive lots set by the Program Operator, plus completed CAPA with verification of effectiveness.

Suspension: stop-ship, mark removal, CAPA within two business days, containment Immediate (within 48 hours). Reinstatement does not require a fresh baseline.

4.5 Reflex testing

A new ingredient, supplier, origin, water source, product-contact equipment, packaging, formulation, or process change triggers a full-panel reflex on the next one or two lots. A Program Operator supplier-intelligence alert does the same.

4.6 Speciation

Metal	Form of concern	Mandatory speciation	Reflex trigger
Arsenic	Inorganic arsenic (iAs)	Products containing rice or rice-derived ingredients	Total As at or above 50% of the applicable limit
Mercury	Methylmercury (MeHg)	Products containing fish or marine ingredients	Total Hg at or above 50% of the applicable limit
Chromium	Hexavalent chromium [Cr(VI)]	Where a credible pathway exists	Anomalous total Cr, or Operator directs

Species ≤ parent. The speciated result does not replace the parent total; both ceilings must be met. Failure to perform required speciation renders the lot ineligible. The Operator may lower the 50% trigger and shall not raise it.

Any quantifiable Cr(VI) is a hard fail.

4.7 Sampling and chain of custody

Composite sampling on a lot basis, with a complete custody record. A custody breach invalidates the result. Testing shall be ISO/IEC 17025 for the methods and matrices in scope. The LOQ for each claim-surface analyte must be at or below the published limit. Results are structured data with MU. PDF submission is not acceptable.

4.8 Decision rules

Pass: (Result + MU) ≤ Limit. Fail: (Result – MU) > Limit. Borderline requires confirmatory action before any status. A result at or below 100% of every published limit is eligible to be Certified; a result above any published limit is not certified and enters Remediation; a result above an applicable government legal limit, or a data-integrity failure, is a hard stop to Suspension. No percent-of-limit band above the limit keeps the mark. Testing into compliance is prohibited.

4.9 Lab-informed schedule

The frequency matrix is not assigned by itself. After application, the Program Operator reads what the brand's laboratory states.

Inputs: panel (every Big-8 total on this matrix); LOQ (each claim-surface LOQ at or below the published limit); MU (expanded uncertainty at k = 2); capability (required pathway speciation, including rice → iAs); ISO/IEC 17025 scope; turnaround sufficient for hold-and-release.

Decision owner: Program Operator. Technical Committee recommends on request.

Fail conditions: LOQ above the published limit; missing Big-8 total; no required speciation method; no 17025 scope for the matrix; turnaround that cannot meet hold-and-release. In any of those cases the schedule is not assigned and the SKU is not certified.

4.10 90% stay-in-program certification gate

The program certifies only if there is at least 90% confidence the brand can remain in the program.

Inputs: the three-lot baseline (worst lot, not the best); headroom to the published limit (not a knife-edge pass); the lab-informed schedule inputs; documented pathway risk; whether the brand can actually run the assigned frequency; whether the brand can open and close CAPA on the published windows.

Decision owner: Program Operator.

Fail conditions: a knife-edge baseline; a laboratory that cannot support the assigned schedule; a product that would enter only to be suspended; concealment or data-integrity doubt (Suspension / Revocation path). A one-lot pass that will fail the next surveillance cycle is not a certification.

PART 5

Method and glossary

5.1 How every limit is set

The method is the government-limit default (Method v2.0). For each analyte in each subcategory, the limit is the strictest maximum level set by a credible government, converted to the product's native basis, or a disclosed read-across where no government regulates the exact cell. Nothing is invented. Occurrence data carry no compliance weight.

The 8:1 powder-to-liquid conversion applies only within infant formula. Every other subcategory takes the government limit at face value.

Claim-surface cells that are blank, monitored, subsumed, or null are HOLD. They are not cert-ready. They are not counted as certified.

Species (iAs, MeHg, Cr(VI)) are pathway reflexes. Species ≤ parent. The species result never replaces the parent total.

5.2 Glossary

percent of limit — A single analyte's measured value divided by its applicable limit, as a percentage. Used only as an operational testing trigger (for example the 50% reflex-speciation trigger and the 80% early-warning trigger); it is not a certification ladder.

Certification status — The product-level lifecycle: Certified, Remediation, Suspension, Revocation. Certified means every analyte is at or below 100% of its published limit under the measurement-uncertainty rule; the mark is permitted only then. Remediation is non-certified (applicant or corrective) and carries no mark. Suspension halts certification for a hard stop. Revocation is permanent. No percent-of-limit band above the limit keeps the mark.

Tier 1 / Tier 2 — Tier 1 is Pb, Cd, iAs, and mercury (tHg); Tier 2 is Ni, Al, Sn, Cr. Tiering sets how hard and fast the program reacts to an exceedance, never permission to exceed a limit and keep the mark. Any quantifiable Cr(VI) is a hard fail treated as Tier 1.

CAPA — Corrective and preventive action. Windows scale with status.

reflex — Testing triggered by a condition rather than the calendar.

speciation — Measuring the toxic form on a documented pathway. Both the species and the parent total must be met.

read-across — A disclosed mapping from the nearest applicable government value.

native basis — The form in which the product is sold or consumed.

Edition record

The dated editions of this manual, each kept at a stable permalink. Manual v3 is current. Zenodo deposits are earlier deposited editions only.

Edition	Date	Status	DOI	What changed
Manual v3	2026-09-19	current	USER-RUN live deposit under 10.83138/hmtc.manual.infant-and-child-foods	Method v2 governing instrument. Thin TOC: five Governing Principles; program lifecycle; mark/MU/CAPA/remediation/ratchet; Lot Testing Schedule with lab-informed assignment and the 90% stay-in-program gate; live Cat-1 Standards Register. V1 Zenodo edition retired as an earlier deposited edition only.
2026 web edition	2026-08-06	superseded	—	Nine-subcategory web reorganization under Method v2.0. Superseded by Manual v3. Did not mint a house DOI.
2026 deposit (rev.)	2026-06-20	superseded	10.5281/zenodo.20771543	Earlier deposited 384-page volume. Never certified a brand. Retired; citable only as an earlier deposited edition.
2026 deposit (v0)	2026-05-18	superseded	10.5281/zenodo.20270512	First public Zenodo deposit of the standalone 384-page volume. Retired.

The Zenodo concept DOI 10.5281/zenodo.20270511 resolves to the latest Zenodo deposited edition, which is retired. It is not the current Manual v3 identifier. House mint uses suffix hmtc.manual.infant-and-child-foods under prefix 10.83138 after CEO PASS.

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Earlier deposited edition (retired): 10.5281/zenodo.20771543.