HEAVY METAL CERTIFIED · STANDARDS BRIEFING

The Big 8

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Abstract

Where the big four came from

The four metals that define nearly every heavy-metal claim on a food label, lead, arsenic, cadmium, and mercury, entered the public vocabulary through one document. On February 4, 2021, the Subcommittee on Economic and Consumer Policy of the U.S. House Committee on Oversight and Reform published a staff report titled after those four elements: baby foods, it found, were tainted with dangerous levels of arsenic, lead, cadmium, and mercury [1]. The report tested for those four, named those four, and set the agenda around those four.

The framing was consequential and, on its own terms, sound. Those four metals are genuine hazards with no safe threshold at the developmental endpoints that matter most in early childhood, and the report's central finding, that manufacturers were not reliably testing finished product, was correct and overdue. What the report did not do, because it was not its purpose, was assert that only four metals warrant attention. The number four is an artifact of which elements that investigation happened to measure, not a toxicological conclusion that the other contaminants in the food supply are benign.

The convention hardened anyway. California's Assembly Bill 899 requires baby-food manufacturers to test for and disclose the same four [5]. The FDA's Closer to Zero program and its 2025 action levels for lead in processed foods for babies and young children work the same territory [6]. The major voluntary marks, from retailer screening panels to third-party purity seals, settled on the same four-metal screen. A number chosen by one subcommittee in one report became the industry's definition of thorough. It is worth stating plainly that the definition was never revisited against what regulators did next.

What regulators did next

While the four-metal convention was setting, the regulatory floor underneath it was moving to eight.

The European Union consolidated its contaminant limits in Commission Regulation (EU) 2023/915, which carries binding maximum levels not only for lead, cadmium, arsenic, and mercury but for tin in canned foods, including a limit of 50 mg/kg for canned infant and young-child foods that is one-quarter of the general canned-food cap [2]. In 2024 the Union went further and set its first binding food maximum levels for nickel, in Commission Regulation (EU) 2024/1987 amending 2023/915, a risk-management response to EFSA's finding that high, 95th-percentile dietary nickel exposure exceeds the tolerable level in infants, toddlers, and other children [3][7]. Those nickel limits adopt the law's own formulation split, 0.25 mg/kg for cow-milk-based infant formula powder and 0.40 mg/kg for soy-isolate formula powder, rather than a single blended value [3][7].

The pattern is not confined to Europe. The Australia New Zealand Food Standards Code sets a single maximum level for aluminium in infant formula products, 0.05 mg/100 mL as prepared (about 500 µg/kg), applying to all products including soy-based, and at Schedule 19 sets limits for tin in canned foods, extending the enforceable list well beyond the four [4]. Aluminium is the more striking case because that FSANZ entry is close to the only per-food aluminium maximum level any government has adopted;

elsewhere the metal is controlled through intake-based reference values rather than a concentration cap [4][11].

No single instrument regulates all eight in one place, and that is the point rather than a weakness in it. Different jurisdictions have limited different metals as their science and their priorities allowed: the EU leads on nickel and tin, FSANZ on aluminium, the FDA on lead. Read together, the enforceable floor already spans eight metals. A four-metal mark does not sit at that floor. It sits at the 2021 convention, several regulatory cycles behind the law it is meant to reassure buyers about.

The case for each of the four additions

Nickel. The hazard that anchors dietary regulation is reproductive and developmental: across multi-generation rat studies the most sensitive and consistently reproduced effect of oral nickel is increased post-implantation loss, and EFSA's 2020 reassessment set a chronic tolerable daily intake of 13 µg Ni/kg body weight per day, a value it raised from the 2.8 µg Ni/kg body weight per day of its 2015 opinion, the increase reflecting revised benchmark-dose methodology rather than reduced concern [7]. That intake is not comfortably distant from the diet: EFSA found that high, 95th-percentile chronic exposure exceeds the tolerable level in infants, toddlers, and other children, while mean exposure remained at or below it, with young children the most exposed on a body-weight basis, and a large sensitized population reacts to oral nickel well below the chronic threshold [7]. IARC classifies nickel compounds as Group 1, though that classification rests on occupational inhalation cancer rather than diet [8]. The European Union acted on the exposure finding in 2024 with its first binding food limits [3]. HMTc treats nickel as a Tier 2 analyte, adopting the EU limit and its formulation split directly, and measures it as total elemental nickel with no speciation trigger.

Tin. Inorganic tin migrating from a tinplate can produces an acute, local, reversible gastrointestinal effect, with a wide margin between the regulated canned-food caps and the roughly 1,000 to 1,400 mg/kg that reliably irritates the gut in controlled human challenge. Codex sets 250 mg/kg for canned foods and 150 mg/kg for canned beverages, grounded in that acute endpoint and the underlying JECFA evaluation [9][10]; the EU is tighter at 200 and 100 mg/kg, and 50 mg/kg for canned infant foods [2]; the ANZ Food Standards Code carries tin limits for canned products as well [4]. Because tin occurrence is a packaging phenomenon rather than a property of the food, an elevated result is diagnostic: it flags a corroding, under-lacquered, or over-stored can. HMTc carries tin as a Tier 2 analyte and treats it as a packaging-integrity sentinel rather than a chronic toxicant, which is the honest reading of the toxicology.

Aluminium. The concern is chronic and cumulative rather than acute. EFSA set a tolerable weekly intake of 1 mg Al/kg body weight, integrating neurotoxic, reproductive, and developmental endpoints from animal studies and corroborated in humans by the dialysis encephalopathy and osteomalacia of the 1970s and 1980s, and concluded the tolerable intake is exceeded across a meaningful share of the population, with soy-formula-fed infants among the most exposed [11]. JECFA's provisional tolerable weekly intake of 2 mg/kg and the US ATSDR minimal risk level are independent derivations from the same evidence base, differing in conservatism [10][11]. Aluminium is the metal no other food or supplement certification limits: outside the lone FSANZ infant-formula entry, almost no government sets a per-food cap, and control runs through intake reference values instead [4][11]. That gap is precisely why carrying aluminium in the panel is a coverage decision rather than a lookup, and HMTc sets its limit by disclosed read-across from the FSANZ value.

Chromium. Chromium is two substances sharing a name. Trivalent chromium, which dominates in food, is low in toxicity and was long treated as an essential trace element; hexavalent chromium is the species of concern, an IARC Group 1 carcinogen on occupational-inhalation evidence and assessed by the US EPA's 2024 IRIS review as likely to be carcinogenic to humans following oral exposure, with an oral reference dose anchored on duodenal lesions in the animal bioassay [8][12]. No government sets a chromium maximum level in any food, because measured food chromium is overwhelmingly trivalent and reported food Cr(VI) is frequently a method artifact [12]. HMTc follows that evidence rather than inventing a number: chromium is carried as total chromium as a first-pass screen, with reflex hexavalent-chromium speciation triggered above a defined total-chromium threshold and any quantifiable Cr(VI) treated as a hard fail. NSF/ANSI 173 is, to date, the one other food-adjacent certification that reaches hexavalent chromium at all [14].

Why a four-metal mark is now an uncovered exposure

The gap between four metals and eight has stopped being academic, because of where these cases are now decided. As set out in Briefing 2, the Supreme Court's 2026 decision in Hain Celestial Group v. Palmquist made federal court materially harder for defendants to reach, so heavy-metal claims will increasingly be tried in state courts, before state juries, with the retailer anchored in the room (After Palmquist). That forum rewards a simple, legible narrative, and a coverage gap is a simple, legible narrative.

A plaintiff's expert does not need novel science to exploit a four-metal certificate. The argument writes itself from the public record: the European Union limits nickel, the Food Standards Code limits aluminium and tin, EFSA and IARC have assessed all of them, and the certificate the brand paid for and displayed tested for none of them. A mark that is silent on the metals regulators already limit does not merely fail to help in that room; it hands the other side a documented boundary of what the brand chose to look for. The narrower the panel, the sharper the line an expert can draw around it. Coverage that tracks the regulatory floor removes the line before it can be drawn.

What HMTc covers

HMTc certifies against eight metals: lead, arsenic, mercury, cadmium, chromium, nickel, tin, and aluminium. Because species drive both toxicity and law, three of the eight are split, and the certified panel resolves to ten analytes. Total arsenic is accompanied by speciated inorganic arsenic; total mercury by methylmercury; and chromium is screened as total chromium with hexavalent chromium determined on trigger. The table below sets out the panel and the toxicological tier of each metal.

Metal	Certified analyte(s)	Tier	Who already limits it in food
Lead (Pb)	Total lead	Tier 1	FDA action levels; EU 2023/915; Codex
Arsenic (As)	Total arsenic; inorganic arsenic (iAs)	Tier 1	EU 2023/915; FDA; Codex
Mercury (Hg)	Total mercury; methylmercury (MeHg)	Tier 1	EU 2023/915; Codex
Cadmium (Cd)	Total cadmium	Tier 1	EU 2023/915; Codex
Chromium (Cr)	Hexavalent chromium (Cr-VI), on trigger; total-Cr screen	Tier 2	No food ML; NSF/ANSI 173 (supplements)
Nickel (Ni)	Total nickel	Tier 2	EU 2024/1987 (first binding food limits)
Tin (Sn)	Total tin	Tier 2	EU 2023/915; Codex CXS 193; ANZ Schedule 19
Aluminium (Al)	Total aluminium	Tier 2	ANZ Food Standards Code (infant formula); EFSA/JECFA intake limits

Two properties of the panel are worth stating precisely. First, the four original metals are not diminished by the additions; they remain the Tier 1 zero-tolerance toxics, each anchored in an EFSA opinion or an IARC Group 1 classification, tested exactly as a four-metal program would test them [8][13]. The additions extend the panel; they do not dilute it. Second, the panel does not change by product. Every certified product is tested on the full ten-analyte panel in every subcategory, rather than a metal being dropped because a given category is assumed not to carry it. Assumption is what a coverage gap is made of.

On coverage the defensible claim is narrow and, within its scope, strong. As of this writing, and on a documented competitive scan, HMTc is the only food certification that sets a published limit for all eight metals; the nearest programs stop at the four or, in the case of NSF/ANSI 173, at five with hexavalent chromium added, and the pharmaceutical elemental-impurity standard ICH Q3D reaches seven but excludes aluminium and is a drug standard rather than a food seal [14][15]. Aluminium is the universal gap: no other food or supplement certification sets a limit for it. What HMTc does not claim is to sit below every government on every metal. The program's method is to adopt the strictest existing limit set by a credible government regulator for each product-analyte pair, converted to the product's native basis, and to state where its own threshold is tighter and why. The comprehensiveness claim is about how many metals are covered, not about being lower than the law everywhere.

Closing

The 2021 report told the industry which four metals to test. It did not tell the industry to stop at four, and the regulators who read it did not. A standard that still ends where that one document ended is not cautious; it is simply out of date with the law it invokes. Certifying against eight metals is not a claim to have gone beyond the science. It is the more modest and more defensible thing: keeping the certificate level with where regulators already stand, so that the brand displaying it is not the one left explaining the difference.

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Bibliographic record

Cite this briefing