

Single-metal regulatory limits systematically underprotect against dietary heavy-metal exposure

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CORRESPONDENCE

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Abstract

The regulatory architecture for heavy metals in food is built almost entirely on single-metal reference values. EFSA's tolerable weekly intake for cadmium, JECFA's provisional tolerable monthly intake for cadmium, the FDA's action levels for inorganic arsenic in infant rice cereal, the EU's maximum levels under Regulation 2023/915, and the parallel national-level frameworks all set thresholds one metal at a time. Three lines of recent evidence converge on the finding that this architecture systematically underprotects: even when consumers are at or near the most permissive single-metal reference value for each individual metal, their cumulative dietary exposure to the regulated metal mixture exceeds the cumulative hazard threshold for health-protective endpoints. The single-metal floor is the wrong floor.

1 | Overview

The synthesis here is that the regulatory positions, taken at face value and combined, do not add up to a health-protective outcome. A framework calibrated to cumulative exposure rather than to single-metal floors is what the convergent evidence below supports.

2 | A national-population baseline with HI greater than one (Suomi 2023)

Suomi and Tuominen 2023 is the load-bearing anchor for this synthesis. Published in Environmental Science and Pollution Research, the paper is the first cumulative dietary risk assessment for a six-metal mixture (Cd, Pb, iAs, MeHg, Ni, Al) among Finnish adults, using individual-level consumption data from the FinDiet 2012 national survey (n equals 1,295 adults aged 25 to 74) combined with Finnish national occurrence monitoring data. The authors use relative potency factors referenced to lead neurotoxicity as the index compound and calculate cumulative hazard indices for three endpoints: neurotoxicity, kidney tubular effects, and fertility effects.

The headline finding is that the cumulative hazard index exceeds 1 (the conventional non-negligible risk threshold) for the average Finnish consumer in all age groups for both neurotoxicity and kidney toxicity. This is not a worst-case framing or a high-end-consumer framing. It is the average adult in a country with strong food-safety enforcement, good drinking-water regulation, low-exposure historical baseline, and one of the cleanest reported food supplies in the European Union. The cumulative HI for that consumer exceeds the health-protective threshold using single-metal regulatory reference values as the inputs.

The age and gender breakdown sharpens the finding. Women aged 25 to 45 years have statistically significantly higher cumulative exposure than men of the same age (P less than 0.05) and than older women (P less than 0.001). More than 95 percent of Finnish women below age 45 have cumulative HI greater than 1 for neurotoxicity. The wiki's vulnerable-population framing typically treats women of reproductive age and pregnant women as a distinct exposure category for reasons that include developmental risk to the fetus; the Suomi finding documents that this population in the cleanest-diet jurisdiction studied is already above the cumulative-risk floor.

The dietary attribution in Suomi 2023 is also worth noting because it does not match the popular framing of heavy-metal exposure. The main dietary sources of cumulative exposure for adults aged 25 to 64 are bread and other cereal products, non-alcoholic beverages (coffee, tea, soft drinks, plant-based milk alternatives), and vegetables. Fish, chocolate, and rice contribute less to the cumulative Finnish total than the everyday staples; in a population that consumes those everyday staples without obvious risk markers, cumulative exposure to the regulated metal mixture is the issue, not any single high-profile food.

3 | A regulatory-internal acknowledgment of saturation (JECFA 91st 2022)

JECFA's 91st meeting (November 2020, monograph published 2022) carried the provisional tolerable monthly intake for cadmium of 25 µg/kg body weight per month, established at JECFA's 73rd meeting in 2010 (WHO Technical Report Series No. 960), forward without revision while updating the dietary exposure assessment with 2019 occurrence data. The updated exposure assessment is the load-bearing finding for this synthesis. Updated cocoa-product occurrence data pushed total dietary cadmium exposure in children aged 0.5 to 12 years to as high as 96 percent of the JECFA PTMI in subpopulations. The lighter regulatory reference value, the one with the looser end of the EFSA-JECFA divergence documented in the cadmium regulatory synthesis section of synthesis.md, is approached or saturated in the population most at developmental risk, from cadmium alone.

The JECFA finding is a single-metal saturation result, not a cumulative-exposure result. But its implication for the cumulative framing is direct. If cadmium alone reaches 96 percent of the most-permissive single-metal reference value in a vulnerable subpopulation, the cumulative HI for that subpopulation across the full regulated mixture is necessarily above 1 even before lead, arsenic, mercury, nickel, and aluminum contributions are added. The single-metal saturation finding from JECFA's own assessment is the regulatory-internal acknowledgment that the cumulative framing is needed.

The point matters because the population JECFA documents at saturation — infants and children, in the cocoa, rice cereal, and baby food matrices — is the population for which the developmental-risk case is strongest. The

JECFA finding is not from an outside-the-system researcher pointing to a gap; it is from the same body whose reference value is the operative regulatory floor in much of the world.

4 | The third independent confirmation (EFSA 2024 iAs)

EFSA CONTAM Panel 2024 is the EFSA Scientific Opinion (adopted November 2023, 191 pages) updating the 2009 inorganic arsenic risk assessment with new epidemiological evidence and integrating the revised 2021 exposure assessment. The Panel reviewed the new evidence, concluded that inorganic arsenic is a genotoxic carcinogen requiring a Margin of Exposure approach rather than a health-based guidance value, and selected a Benchmark Dose Lower Confidence Limit at 5 percent relative increase of 0.06 µg iAs/kg bw per day from a US skin cancer case-control study.

The load-bearing finding for this synthesis is what the new MOE analysis shows for actual European exposure. Adult Margins of Exposure for mean consumers range from 2 down to 0.4, and for 95th-percentile consumers from 0.9 down to 0.2. Every one of these MOEs is below the threshold MOE of 1 (which represents the exposure level associated with a 5 percent increase in background skin cancer incidence). EFSA's framing: this raises a health concern.

In the EFSA framing, MOE below 1 for inorganic arsenic at the mean adult European consumer level means the regulatory framework already recognizes that the population-average exposure to a single regulated metal exceeds the health-protective floor when the floor is set against the genotoxic-carcinogen endpoint with rigorous Benchmark Dose modeling. Combine this with the Finnish cumulative HI greater than 1 across all age groups (Suomi 2023) and the JECFA cocoa-driven cadmium saturation in the under-12 population (JECFA 91st 2022), and the synthesis is that the regulatory floor is below the protective threshold for both single-metal carcinogenic and cumulative-mixture neurotoxic and renal endpoints in well-regulated developed-economy populations.

5 | The convergent point

Three independent assessments, three different methods, three different jurisdictions, three different endpoint classes, one finding: the regulatory architecture for heavy metals in food is calibrated to a level of risk that population-level data show is regularly exceeded. Suomi 2023 measures cumulative dietary exposure against neurotoxic and renal endpoints in Finland and finds HI greater than 1 across all adult age groups. JECFA's 91st meeting measures single-metal cadmium exposure against the JECFA PTMI in the under-12 child population and finds saturation at 96 percent. EFSA 2024 measures single-metal inorganic arsenic exposure against a rigorous genotoxic-carcinogen Benchmark Dose and finds Margins of Exposure below 1 across the full adult European population.

The three studies are not measuring the same thing. They are measuring different aspects of the same architectural problem. The regulatory floors that the food-safety system relies on are not, in aggregate, health-protective for the consumers the system is built to protect. They are presented here as the regulators' own framings state them, with the gap between those framings and the population-level outcomes documented in the three anchor sources.

6 | What this synthesis does not yet rest on

A fourth anchor from the US framework would strengthen the geographic generalization. The FDA Total Diet Study elements report covering 2018-2020 (FDA TDS 2022) is in the corpus and addresses multi-metal US

dietary intake. Integrating its findings into this synthesis would close the loop between European and US regulatory frameworks. The current draft references it as corroborating context but does not anchor the synthesis on it; that change can wait for the next synthesis pass when the FDA TDS exposure-versus-reference--value analysis is fully reviewed.

The cumulative methodology in Suomi 2023 uses relative potency factors referenced to lead neurotoxicity as the index compound. This is one of several valid approaches in the cumulative-risk-assessment literature. A parallel analysis using a different index compound, or a different relative-potency framework, would test whether the HI greater than 1 finding is robust to the methodology choice. The current literature does not yet contain that parallel analysis; if it appears, the synthesis should be updated to address it.

The Margin of Exposure framing in EFSA 2024 is specific to genotoxic carcinogens. The synthesis page combines it with the threshold-toxicant cumulative HI from Suomi 2023, which is methodologically different. A unified framework that treats threshold and non-threshold endpoints in the same cumulative analysis is not yet available in the corpus. The synthesis position is that the three independent findings converge on the same conclusion even using methodologies that are not directly comparable; this is a strength of the convergence, but it should be made explicit.

7 | Implications for downstream wiki pages

vulnerable-populations, when written or expanded, should anchor on Suomi 2023 for the women-of--reproductive-age cumulative-exposure framing and on JECFA 91st for the under-12-child cadmium-saturation framing.

cadmium should carry the JECFA 91st 2022 cocoa-driven exposure update with its 96 percent of PTMI finding in children. The page should also reference the cadmium regulatory divergence content in synthesis.md which documents the EFSA-JECFA-ATSDR-EPA divergence in reference values.

arsenic-inorganic should carry the EFSA 2024 MOE update with its below-1 findings for adult European consumers across the full intake range. The MOE framing is methodologically distinct from the cadmium PTMI framing and should be presented as such; speciation discipline applies (inorganic arsenic specifically, not total arsenic).

8 | Anchor sources

- Suomi and Tuominen 2023. *Cumulative risk assessment of the dietary heavy metal and aluminum exposure of Finnish adults*, Environmental Science and Pollution Research. FinDiet 2012 national dietary survey, n=1,295 Finnish adults aged 25-74; six-metal mixture (Cd, Pb, iAs, MeHg, Ni, Al); relative potency factors referenced to lead neurotoxicity; HI greater than 1 across all adult age groups for neurotoxicity and kidney endpoints; >95 percent of women under 45 have HI greater than 1 for neurotoxicity.
- JECFA 91st meeting 2022. *Cadmium (Addendum) — 91st meeting of the Joint FAO/WHO Expert Committee on Food Additives*. Carried the 2010 PTMI (JECFA 73rd, WHO TRS 960) of 25 µg/kg b.w./month forward without revision; updated 2019 cocoa occurrence data pushed total dietary Cd exposure in children 0.5-12 years to up to 96 percent of PTMI in subpopulations.
- EFSA CONTAM Panel 2024. *Update of the risk assessment of inorganic arsenic in food*, EFSA Journal. 191-page Scientific Opinion adopted November 2023; iAs classified as genotoxic carcinogen requiring Margin of Exposure approach; BMDL05 of 0.06 µg iAs/kg bw/day from US skin cancer case-control study; adult MOEs from 2 to 0.4 (mean consumers) and 0.9 to 0.2 (95th percentile), all below threshold MOE of 1.

9 | How this page was promoted

Promoted 2026-05-13. Three independent A-tier anchors meeting all four promotion criteria: independent (different research groups, different jurisdictions, different methodologies), spans multiple metals and ingredients, not obvious from any single source, with relevance to regulator (the cumulative-exposure framework gap) and educator (the architectural argument that single-metal floors under-protect) audiences. Re-synthesis is expected when the FDA TDS 2018-2020 multi-metal exposure-versus-reference analysis is fully integrated as a fourth anchor, when a non-Suomi cumulative analysis appears in the corpus, or when EFSA or JECFA reissues a single-metal reference value in response to the cumulative framing.

References

- [1] Cumulative risk assessment of the dietary heavy metal and aluminum exposure of Finnish adults
Suomi J and Tuominen P · Environmental Science and Pollution Research · 2023 · doi.org/10.1007/s10661-023-11427-y
REVIEW
- [2] Cadmium: dietary exposure assessment
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- [3] Update of the risk assessment of inorganic arsenic in food
EFSA CONTAM Panel, Schrenk D, Bignami M, Bodin L, Chipman JK, del Mazo J, et al. · EFSA Journal · 2024 · doi.org/10.2903/j.efsa.2024.-8488
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- [4] Total Diet Study Report: Fiscal Years 2018-2020 Elements Data
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STATUS AND LICENCE

Editorially reviewed in-house; no external peer review has been completed on this finding. Published as a preprint with its review state tracked on the article page. Released under CC BY 4.0.

COMPETING INTERESTS

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DATA AVAILABILITY

Every source behind this finding is listed with its own extraction record at <https://heavymetalindex.com/synthesis/combined-exposure-underprotection#sources>, each linking to the ingest receipt, the extracted values, and the file hash of the document it was built from.

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