

Arsenic (As) — HMTc analyte

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THE ANALYTE

33 · As · Inorganic (iAs), speciated

Inorganic arsenic is limited because it is an IARC Group 1 human carcinogen for which the major assessment bodies have declined to set any safe intake threshold, and current dietary exposures already sit at or above the cancer reference point EFSA derived in its 2024 reassessment.

Why it is limited

The government and expert-body assessments that underpin limiting arsenic in food, and what each concluded. The maximum levels in force apply these findings; this page is the rationale, not the certification threshold.

BODY	YEAR	ASSESSMENT	WHAT IT CONCLUDED
IARC	2012	IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 100C — Arsenic and Arsenic Compounds (Group 1)	Classifies inorganic arsenic as Group 1, carcinogenic to humans, with the strongest dose-response evidence for lung, skin, and bladder cancer at chronic exposures including via drinking water and food.
EFSA	2024	Update of the risk assessment of inorganic arsenic in food (EFSA CONTAM Panel, EFSA Journal, doi:10.2903/j.efsa.2024.8488)	Concluded iAs is a genotoxic carcinogen and, rather than deriving a health-based guidance value, selected a Reference Point of BMDL05 = 0.06 µg iAs/kg bw per day (skin cancer, squamous cell carcinoma; US case-control study; 5% relative increase in background incidence) and applied a Margin of Exposure approach. MOEs for adults range 2 to 0.4 (mean consumers) and 0.9 to 0.2 (95th percentile), all below an MOE of 1, raising a health concern; the RP falls within the range of mean adult dietary exposure (0.03–0.15 µg/kg bw/day) and below all 95th-percentile estimates (0.07–0.33 µg/kg bw/day). Low BMDLs (≤0.17 µg/kg bw/day) were also calculated for bladder and lung cancer, respiratory disease, skin lesions, chronic kidney disease, and ischemic heart disease.
EFSA	2009	Scientific Opinion on Arsenic in Food (EFSA CONTAM Panel, EFSA Journal 2009;7(10):1351, doi:10.2903/j.efsa.2009.1351)	Reported cancer BMDL01 values of 0.3 to 8 µg iAs/kg bw/day depending on endpoint and study selection (skin, bladder, lung cancer and skin lesions), and concluded that the prior JECFA PTWI of 15 µg iAs/kg bw/week was no longer appropriate because cancer occurs at exposures below the PTWI. This 2009 BMDL01 framework was superseded by the 2024 MOE/BMDL05 approach.
JECFA	2017	Safety Evaluation of Certain Food Additives (Arsenic), 82nd Meeting of JECFA — WHO Food Additives Series 73	At its 72nd meeting (February 2010) JECFA withdrew the provisional tolerable weekly intake of 15 µg iAs/kg bw/week on the basis that inorganic arsenic causes cancer at exposures below the PTWI, working from a BMDL0.5 of 3.0 µg/kg bw/day calculated for lung cancer (WHO Technical Report Series 959). The later 82nd-meeting monograph (WHO Food Additives Series 73, 2017) retained that benchmark-dose (BMDL) framework rather than a threshold PTWI.

BODY	YEAR	ASSESSMENT	WHAT IT CONCLUDED
US EPA	2025	IRIS Toxicological Review of Inorganic Arsenic (EPA/635/R-25/005Fa, CASRN 7440-38-2)	Finalized January 2025 reassessment replacing prior IRIS values operative for decades; derives quantitative reference values for non-cancer endpoints and updated oral cancer slope factors covering lung, bladder, and skin cancer, and is the US federal scientific anchor that downstream EPA, FDA, and state actions reference.
ATSDR	2007	Toxicological Profile for Arsenic (doi:10.15620/cdc:11481)	Derived a chronic oral Minimal Risk Level (MRL) of 0.3 µg As/kg/day anchored on dermal effects (hyperpigmentation, palmar/plantar keratosis) observed in chronically exposed populations, with cancer dose-response deferred to EPA IRIS. Documents the broader non-cancer endpoint set: cardiovascular (blackfoot disease, atherosclerosis), neurodevelopmental, peripheral neuropathy, reproductive, immunological, and diabetes associations.

Toxicological basis

Inorganic arsenic is regulated because its anchoring endpoint is cancer, and the bodies that have assessed it agree there is no dietary exposure at which that risk resolves to zero.

The endpoint that governs inorganic arsenic is cancer, and the assessment that now anchors regulation treats it as a substance without a safe intake. In its 2024 reassessment EFSA declined to set a health-based guidance value and instead selected a reference point, a BMDL05 of 0.06 µg iAs/kg body weight per day derived from skin cancer (squamous cell carcinoma), and applied a margin-of-exposure approach. That framing follows from mechanism. Inorganic arsenic does not form direct DNA adducts; it acts through oxidative stress, inhibition of DNA repair, and binding to vicinal sulfhydryl groups in proteins, and its metabolic methylation to the trivalent species MMA(III) and DMA(III) is now understood as an activation step that yields more reactive intermediates rather than a simple detoxification. Because the mechanism has no threshold below which the genotoxic insult disappears, the operative question is not whether an intake is safe but how narrow the margin between everyday exposure and the reference point has become, and for inorganic arsenic that margin has effectively closed.

The population that carries this risk most acutely is the youngest. Rice and rice-based foods are the dominant dietary source of inorganic arsenic for people not exposed through groundwater, and rice cereal is frequently an infant's first solid food, so the exposure concentrates in the developmental window where per-kilogram intake is highest. EFSA reports that children under three are exposed at roughly two to three times the adult per-kilogram rate. Beyond infancy the exposed groups include frequent rice consumers, people on gluten-free or otherwise rice-heavy diets, and private-well users in arsenic-affected geographies who fall outside the EPA drinking-water rule. The documented non-cancer effects across these populations are substantial in their own right: the dermal lesions (hyperpigmentation and palmar and plantar keratosis) that anchor the ATSDR chronic oral minimal risk level of 0.3 µg/kg/day, cardiovascular disease including the blackfoot disease observed in highly exposed Taiwanese cohorts, and neurodevelopmental effects in children.

The carcinogenicity is stated by IARC with unusual confidence and, critically, by the oral route. IARC classifies inorganic arsenic in Group 1, carcinogenic to humans (Monographs Volume 100C), with the strongest dose-response evidence for lung, skin, and bladder cancer at chronic exposures that include drinking water and food. This is the feature that distinguishes arsenic from metals whose established tumour sites are confined to occupational inhalation: ingested inorganic arsenic is itself the basis of

the human cancer epidemiology, built on populations exposed to elevated arsenic through contaminated water and diet. The precision that matters for testing is the species. It is the inorganic fraction that carries the Group 1 designation; the organic arsenic that dominates most seafood, principally arsenobetaine, is not the endpoint of concern. A total-arsenic result therefore overstates the toxic fraction in fish while remaining the correct measurement to speciate in rice, where the inorganic form predominates, which is why credible testing for this analyte is defined as speciated inorganic arsenic rather than total arsenic.

What makes the regulatory posture defensible is the convergence. EFSA, JECFA, IARC, the US EPA, ATSDR, and the FDA have reached compatible conclusions from independent evidence bases. JECFA withdrew its provisional tolerable weekly intake of 15 µg/kg body weight in 2010 on the ground that cancer occurs at exposures below it; EFSA moved to a margin-of-exposure framing and, in 2024, lowered the reference point; the EPA finalized a major IRIS reassessment of inorganic arsenic in January 2025. Where a body has set a binding number it has done so downstream of that shared science: the EU maximum levels for inorganic arsenic across infant foods, juices, and rice categories, the FDA action levels of 100 µg/kg for infant rice cereal and 10 µg/kg for apple juice, and the EPA drinking-water maximum contaminant level of 10 µg/L. California's [Proposition 65](#) lists inorganic arsenic compounds as known to the state to cause cancer, consistent with those classifications. The science came first and the binding limits followed; where a harmonized tolerable intake is deliberately absent, it is because these bodies concluded that no such safe threshold exists.

Occurrence & exposure

How much inorganic arsenic food actually carries, and how close everyday dietary exposure runs to the reference point that anchors the cancer assessment.

Inorganic-arsenic-speciated composites from the FDA Total Diet Study, FY2018-2020 (prepared, as-consumed basis, µg/kg wet weight). These are the only two composites the study speciated for inorganic arsenic; its other arsenic results are reported as total arsenic and overstate the inorganic fraction. Values describe occurrence, not regulatory thresholds.

FOOD (IAS-SPECIATED COMPOSITE)	MEDIAN MG/KG	RANGE MG/KG	HIGHEST COMPOSITE MG/KG
Rice, white, enriched, cooked	41.6	41.6 (n=1)	41.6
Rice cereal, crisped	90.4	85.8–103	103

Estimated chronic dietary exposure to inorganic arsenic (µg/kg body weight per day) against EFSA's controlling reference point, a BMDL05 of 0.06 µg/kg bw/day for skin cancer (2024). Ranges span EU dietary surveys; values are exposure estimates, not thresholds.

POPULATION (EFSA ASSESSMENT)	MEAN CONSUMER MG/KG BW/DAY	95TH PERCENTILE MG/KG BW/DAY	RELATION TO THE 0.06 REFERENCE POINT
Adults, EU (EFSA 2024)	0.03–0.15	0.07–0.33	Margin of exposure 2 to 0.4 (mean) and 0.9 to 0.2 (P95); an MOE below 1 is a health concern

POPULATION (EFSA ASSESSMENT)	MEAN CONSUMER MG/KG BW/DAY	95TH PERCENTILE MG/KG BW/DAY	RELATION TO THE 0.06 REFERENCE POINT
Adults, EU (EFSA 2009)	0.13–0.56	0.37–1.22	Children under 3 exposed at 2 to 3 times the adult per-kg rate

Rice and rice-based foods drive dietary inorganic arsenic because flooded-paddy cultivation mobilizes arsenite into the grain, and the bran layer concentrates it, so brown rice runs higher than white rice from the same source. Rice cereal is often an infant's first solid food, which places the exposure in the most vulnerable window, and rice-derived ingredients such as rice flour, rice syrup, and rice protein carry the inorganic fraction into processed and free-from products where a shopper would not expect it. The FDA speciated inorganic arsenic specifically in rice and rice cereal in its Total Diet Study because that is where the inorganic form dominates; for most other foods, and for seafood especially, a total-arsenic result overstates the toxic fraction because organic species prevail.

The reason to monitor is structural rather than alarmist. There is no exposure at which the cancer risk resolves, and the current assessment places typical adult intake near the reference point and much of the population above it, so modest shifts in rice content or ingredient sourcing move a product across a line that matters. Total-arsenic testing cannot substitute for speciation, and the exposed population is disproportionately infants. Certification that verifies the inorganic fraction by speciation, against both the regulatory action levels and the tightest demonstrated occurrence, is the control that a total-arsenic number cannot provide.

Anchor dataset: FDA Total Diet Study FY2018-2020 Elements Data, an A-tier US government dataset, inorganic-arsenic-speciated composites; corroborated by EFSA's 2024 (controlling) and 2009 dietary exposure assessments for inorganic arsenic. The full occurrence corpus is on the [Heavy Metal Index](#).

How it is regulated

Binding maximum levels in force come from the EU. Commission [Regulation \(EU\) 2023/915](#) sets iAs maximum levels of 20 µg/kg for baby food for infants and young children, 10 µg/kg for infant/follow-on/young-child formula placed on the market as liquid and 20 µg/kg as powder, and 100 µg/kg for rice destined for production of infant and young-child food (with general-rice ceilings of 150 µg/kg white/non-parboiled milled rice, 250 µg/kg parboiled/husked rice and rice flour, and 300 µg/kg rice waffles/cakes/crackers) — see [/regulations/eu-2023-915](#). In the US the FDA's action level for inorganic arsenic in infant rice cereals is 100 µg/kg; this is a non-binding guidance action level finalized in 2020, which predates and is now folded into the [Closer to Zero](#) initiative rather than being an enforceable ML or a C2Z-derived value — see [/regulations/us-fda-c2z](#). Where no government regulates a given product*iAs* cell, the HMTc program reads across from the nearest government value for an analogous product rather than leaving the cell blank. The internationally harmonized picture has no tolerable-intake anchor: JECFA withdrew its PTWI and both EFSA and JECFA now characterize risk through benchmark-dose reference points, not a safe daily intake. Full per-jurisdiction derivations sit on the [cert /regulations/](#) pages; this page points outward to [/metals/arsenic](#) for the literature baseline rather than restating the numbers.

How the HMTc program treats it

Inorganic arsenic is a priority toxic: one of the four metals (with Pb, Cd, and Hg) treated as having no established safe threshold. That label is not a status ladder. Any exceedance enters Remediation unmarked; no metal has a transitional overage. Under Method v2.0 (government-limit default), the standard for each product is the strictest maximum level any credible government sets, converted to the product's native basis; where clean producers demonstrably beat the government floor the tighter pooled-occurrence value governs (min of occurrence percentile and strictest government ML). Speciation is intrinsic to the analyte definition rather than a reflex trigger: the certified analyte is inorganic arsenic specifically, quantified as speciated iAs by ICP-MS (HPLC-ICP-MS), and total-arsenic results are not interchangeable — this differs from the [chromium](#) reflex-speciation model, where total Cr is screened first and Cr(VI) speciation fires only above a trigger. Worked example: the Teething biscuits & finger snacks standard sets iAs at 100 µg/kg for rice-based products (binding FDA) and 20 µg/kg for non-rice products (binding EU 2023/915 baby food). Grounded in </standards/teething-and-snacks> and </manuals/infant-and-child-foods>.

Literature baseline

The complete peer-reviewed and regulatory literature for arsenic is maintained independently at the [Heavy Metal Index](#)[🔗]. That reference reports what the literature says; this certification site applies it. The two are kept editorially separate by design.