

Lead (Pb) — HMTc analyte

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THE ANALYTE

82 · Pb · Total elemental lead

Lead is limited because its developmental neurotoxicity in young children has no demonstrated threshold — no agency can identify an intake or blood-lead level below which harm does not occur — so the governing frame is to minimize exposure as far as practicable, not to stay below a "safe" dose.

Why it is limited

The government and expert-body assessments that underpin limiting lead 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
EFSA (CONTAM Panel)	2010	Scientific Opinion on Lead in Food, EFSA Journal 2010;8(4):1570	Identified developmental neurotoxicity in young children as the most sensitive critical endpoint and derived a BMDL01 of 12 µg/L blood lead, corresponding to a dietary intake of 0.50 µg/kg b.w./day. Because effects were documented below that point, no threshold could be identified and no tolerable weekly intake could be set that is health-protective. Companion (secondary, adult) reference points: cardiovascular BMDL01 36 µg/L (1.50 µg/kg b.w./day) and chronic-kidney-disease BMDL10 15 µg/L (0.63 µg/kg b.w./day).
JECFA (Joint FAO/WHO Expert Committee on Food Additives)	2011	73rd JECFA meeting (June 2010); Evaluation of Certain Contaminants in Food, WHO Technical Report Series 960	Withdrew the provisional tolerable weekly intake (PTWI) of 25 µg/kg b.w./week, concluding it could no longer be considered health-protective because the dose-response relationship for developmental neurotoxicity has no identifiable threshold.
IARC	2006	IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 87 — Inorganic and Organic Lead Compounds	Classified inorganic lead compounds as Group 2A (probably carcinogenic to humans); organic lead compounds as Group 3 (not classifiable as to carcinogenicity to humans).
US EPA (IRIS)	2004	Lead and Compounds (Inorganic) — IRIS Chemical Assessment Summary	Declined to derive an oral reference dose (RfD), keeping the assessment qualitative, because the sensitive neurodevelopmental endpoint has no demonstrated threshold. Classified lead B2 (probable human carcinogen, animal evidence with inadequate human evidence); a quantitative cancer slope factor was not derived because the neurodevelopmental endpoint dominates regulatory action.

BODY	YEAR	ASSESSMENT	WHAT IT CONCLUDED
US ATSDR	2020	Toxicological Profile for Lead	Did not derive Minimal Risk Levels (MRLs) for lead because no threshold for its effects has been demonstrated. Documents the toxicokinetic basis for heightened child and fetal risk: child GI absorption 30–50% versus 5–15% in adults; blood-lead half-life ~30 days; bone-lead half-life 10–30 years with ~90% of adult body burden in bone; and mobilization of bone lead during pregnancy, lactation, and postmenopausal bone resorption, transferring to the fetus and nursing infant.
US CDC	2021	Blood Lead Reference Value	Set the blood lead reference value at 3.5 µg/dL — the 97.5th percentile of the NHANES 2015–2018 child distribution — explicitly a population-percentile screening threshold identifying the most-exposed 2.5% of US children, not a health-based safe level. Adverse effects are established below 5 µg/dL, within the range where most US children fall.
US FDA	2025	Closer to Zero; Action Levels for Lead in Processed Food Intended for Babies and Young Children	Set an Interim Reference Level of 2.2 µg/day for children and 8.8 µg/day for women of childbearing age, derived from the CDC blood lead reference value with a 10x safety factor for dietary-to-blood-lead variability. Issued nonbinding, enforcement-relevant baby-food action levels of 10 ppb (fruits, most vegetables, mixtures), 20 ppb (single-ingredient root vegetables), and 20 ppb (dry infant cereals).
California OEHHA (Prop 65)	n.d.	Lead and Lead Compounds — Proposition 65 Chemical Listing	Listed lead as known to cause cancer and as a reproductive/developmental toxicant. Oral No Significant Risk Level (NSRL) 15 µg/day for cancer; reproductive-toxicity Maximum Allowable Dose Level (MADL) 0.5 µg/day.

Toxicological basis

What the assessment bodies found when they examined lead, and why the governing frame is to minimize exposure rather than certify a product below a "safe" dose: the developmental endpoint that anchors regulation, the children and pregnancies it reaches, the carcinogenicity stated with route precision, and the unusual weight of agreement that no threshold exists.

The hazard that anchors dietary regulation of lead is developmental neurotoxicity in young children, and it behaves unlike almost any other food contaminant because no assessment body has been able to identify a threshold below which it does no harm. EFSA's 2010 CONTAM opinion selected developmental neurotoxicity as the most sensitive critical endpoint and derived a BMDL01 of 12 µg/L blood lead, corresponding to a dietary intake of roughly 0.50 µg/kg body weight per day; because cognitive deficits, behavioural change, and measurable IQ loss were documented in cohort studies at exposures below that benchmark, EFSA concluded it could not set a tolerable weekly intake that is health-protective. This is the empirical basis for the position, shared across the major bodies, that there is no safe level of lead for a developing child. The consequence for a certification programme is structural: the objective is not to keep a product under a reference dose that does not exist, but to drive the concentration in food as low as the supply chain can practicably reach.

The population lead reaches, and the reason a brand should treat it as a priority analyte, is defined by child and prenatal physiology. Children absorb 30 to 50 percent of the lead they ingest, against 5 to 15 percent in adults, and they take it in during the developmental window for brain maturation, so an identical concentration in food delivers a far larger internal dose to the population that can least tolerate it. Lead then accumulates in bone, with a half-life of 10 to 30 years and roughly 90 percent of the adult body burden held there, and that skeletal reservoir mobilizes during pregnancy and

lactation, delivering endogenous lead across the placenta and into breast milk decades after the original exposure. The CDC's blood lead reference value of 3.5 µg/dL underscores the point: it is the 97.5th percentile of the US child distribution, a screening value that flags the most-exposed children, explicitly not a safe level, and adverse effects are established below 5 µg/dL, within the range where most US children already fall.

Lead is also a carcinogen, and stating how is a matter of credibility rather than emphasis. IARC classifies inorganic lead compounds as Group 2A, probably carcinogenic to humans, and organic lead compounds as Group 3; the US EPA classifies lead B2, a probable human carcinogen on animal evidence with inadequate human evidence. Crucially, neither body's food limits are cancer-driven. EPA declined to derive a quantitative cancer slope factor precisely because the neurodevelopmental endpoint dominates regulatory action, and EFSA's controlling reference point is the neurodevelopmental BMDL, not a cancer estimate. The honest framing is that lead's carcinogenicity is real and independently classified, but it is a supporting concern; the developmental neurotoxicity of low-dose oral exposure in children is what actually sets the ceilings, and a page that inflated the cancer basis to sell certification would misrepresent the record.

The most striking feature of the lead literature is the convergence on an absence. EFSA reports BMDLs without a tolerable weekly intake, JECFA withdrew its provisional tolerable weekly intake of 25 µg/kg body weight per week in 2011 on the finding that it was no longer health-protective, EPA's IRIS assessment derives no oral reference dose, and ATSDR sets no minimal risk levels, each for the same reason: the dose-response for developmental neurotoxicity has no identifiable threshold. Because no body will name a safe intake, the maximum levels in force are ALARA and technology-based ceilings rather than safety thresholds back-calculated from a reference dose. California's [Proposition 65](#) sharpens the picture rather than softening it: lead is listed both as a carcinogen and as a reproductive and developmental toxicant, and unlike a right-to-know listing that sets no dietary number, Prop 65 carries an operative oral Maximum Allowable Dose Level of 0.5 µg/day for reproductive toxicity (and a 15 µg/day cancer No Significant Risk Level), a de-facto dietary labeling threshold that consumer products sold in California must respect. The science came first; the limits followed as minimize-exposure ceilings, and where a health-based safe dose might have appeared, every body left the space deliberately empty.

Occurrence & exposure

How much lead food actually carries, and the ladder of action and reference values that a minimize-exposure regime is built on. The occurrence figures are drawn from a national total diet study; the complete occurrence corpus is maintained on the Heavy Metal Index.

Lead occurrence by food, US FDA Total Diet Study FY2018–2020, prepared-food (as-consumed) composite basis. Values are µg/kg (equivalent to ppb): the median (P50), the 95th percentile, and the single highest composite measured; nd marks a median below the reporting limit. These are population occurrence values, not safety thresholds or action levels. All-zero foods (most fruits, dairy, and plain meats) are omitted; whole milk is retained as a near-zero reference.

FOOD (FDA TDS)	MEDIAN P50 MG/KG	P95 MG/KG	HIGHEST SAMPLE MG/KG
Raisins	7.8	15.2	16

FOOD (FDA TDS)	MEDIAN P50 MG/KG	P95 MG/KG	HIGHEST SAMPLE MG/KG
Bran cereal with raisins	5.2	14.9	16
Chocolate cake with chocolate icing	7.8	13.7	16
Cornbread, homemade	5.3	13.1	14
Potato, baked with peel	nd	10.5	12
Pickles, dill, cucumber	4.0	9.2	9.8
Ham, cured, baked	nd	7.7	9.3
Bread, whole wheat	4.3	6.7	7.3
Peanut butter, creamy	5.6	6.1	6.1
Bread, white, enriched	nd	5.6	23
Collards, boiled	nd	5.3	5.9
Apple juice, bottled	1.5	2.6	2.7
Milk, whole, fluid	nd	nd	nd

The lead action and reference values that define the minimize-exposure regime. These are regulatory action levels, dietary interim reference levels, binding maximum levels, and warning thresholds, not occurrence data and not health-based safe intakes (no body has set a tolerable intake for lead). FDA action levels are nonbinding but enforcement-relevant.

REFERENCE / ACTION LEVEL	VALUE	WHAT IT REPRESENTS
FDA Closer to Zero — fruits, most vegetables, mixtures	10 µg/kg	nonbinding baby-food action level
FDA Closer to Zero — single-ingredient root vegetables	20 µg/kg	nonbinding baby-food action level
FDA Closer to Zero — dry infant cereals	20 µg/kg	nonbinding baby-food action level
FDA Interim Reference Level — children	2.2 µg/day	dietary intake benchmark, from CDC blood-lead reference value with a 10x factor
FDA Interim Reference Level — women of childbearing age	8.8 µg/day	dietary intake benchmark
EU Reg 2023/915 — baby food, cereal-based food, formula powder	20 µg/kg	binding maximum level (as placed on market)
EU Reg 2023/915 — liquid infant formula	10 µg/kg	binding maximum level
California Prop 65 MADL — reproductive toxicity, oral	0.5 µg/day	consumer-product warning threshold
California Prop 65 NSRL — cancer, oral	15 µg/day	consumer-product warning threshold
CDC blood lead reference value	3.5 µg/dL	97.5th-percentile child screening value, not a safe level

Lead occurrence in the US food supply is dominated by plant matrices and the soil interface, not by the protein foods a consumer might intuitively worry about. The foods that carry the highest and most consistent lead in the national total diet data are dried fruit and raisin-containing cereals, root and tuber vegetables eaten with their peel, leafy greens, and grain and baked products, while fluid milk, plain meats, and most whole fruits sit at or below the reporting limit. The pattern reflects lead's route into food: it enters through roots, adheres to surfaces in contact with soil, and concentrates when a fruit is dried or a grain is milled and baked. That is why a category's lead profile tracks its ingredients and its soil and processing history far more than its label claims, and why sourcing and supplier control are the levers that actually move the number.

The reason to monitor lead even when a typical median reads low is that the distribution matters more than the average and the governing frame has no safe floor to fall back on. The same foods that read near the reporting limit at the median produce occasional composites several times higher, so a lot that passes on average can still carry a child-relevant dose in the tail, and there is no reference dose that makes such a lot acceptable by definition. Because every major body has declined to set a tolerable intake, the operative benchmarks are action levels, dietary reference levels, and binding maximum levels aimed at pushing exposure down rather than certifying it as safe. For a programme certifying foods eaten by infants and young children, the population that absorbs the most and can tolerate the least, that combination of a skewed distribution and an absent threshold is the entire case for testing lead lot by lot rather than trusting a category mean.

Anchor occurrence dataset: US FDA Total Diet Study FY2018–2020 (A-tier government monitoring dataset), prepared-food composite basis, lead analyte. Regulatory benchmarks corroborated by FDA [Closer to Zero](#) (action levels and interim reference levels), Commission [Regulation \(EU\) 2023/915](#) (binding maximum levels), the CDC blood lead reference value, and California OEHHA Proposition 65 (NSRL and MADL). The full occurrence corpus is on the [Heavy Metal Index](#)⁷.

How it is regulated

No regulator has set a health-based tolerable intake for lead — JECFA withdrew its PTWI, EFSA reports BMDLs without a TWI, EPA IRIS derives no oral RfD, and ATSDR sets no MRLs — so the maximum levels in force are ALARA/technology-based ceilings rather than safety thresholds derived from a reference dose. For infant and child foods the strictest in-force government maximum level governs each product: Commission Regulation (EU) 2023/915 sets 20 µg/kg for baby food and processed cereal-based food and for formula powder, and 10 µg/kg for liquid formula, on an as-placed-on-market basis ([/regulations/eu-2023-915](#)); [Codex CXS 193](#) and FDA Closer to Zero sit near these values, with FDA's nonbinding baby-food action levels at 10 ppb (fruits, most vegetables, mixtures), 20 ppb (single-ingredient root vegetables), and 20 ppb (dry infant cereals) ([/regulations/us-fda-c2z](#)). Where no government regulates the exact product, the applicable value is read across from the nearest analogous government limit. The literature-native derivation and the full cross-jurisdiction table are maintained independently at the Index ([heavymetalindex.com/metals/lead](#)⁷).

How the HMTc program treats it

Lead is a priority toxic on the claim-surface panel — one of the four metals (Pb, Cd, iAs, MeHg/tHg) with no established safe threshold — and it is equal at the gate with every other claim analyte. Any exceedance enters Remediation unmarked; no metal carries an allowed overage. Lead triggers no speciation reflex (those apply to [arsenic](#), [mercury](#), and [chromium](#), not lead). Under Method v2.0 the published lead limit is set as min(occurrence percentile, strictest government maximum level); in the published Infant and Child Foods standards it resolves to the EU 20 µg/kg maximum converted to the product's native as-sold basis (for example, teething biscuits and finger snacks). The program's regulatory hard-stop blocks certification of any product that violates an actual legal lead limit regardless of HMTc status, so the certified ceiling can only ever sit at or below every applicable sovereign limit.

Literature baseline

The complete peer-reviewed and regulatory literature for lead is maintained independently at the [Heavy Metal Index](#)^[2]. That reference reports what the literature says; this certification site applies it. The two are kept editorially separate by design.