

Nickel (Ni) — HMTc analyte

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THE ANALYTE

28 · Ni · Total elemental nickel

Nickel is limited because EFSA's 2020 reassessment set a chronic tolerable daily intake of 13 µg Ni/kg body weight/day on a reproductive-developmental endpoint that mean European dietary intake already exceeds, and because sensitized individuals react to oral doses far below that; contamination is largely controllable through sourcing and process control.

Why it is limited

The government and expert-body assessments that underpin limiting nickel 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)	2020	Update of the Risk Assessment of Nickel in Food and Drinking Water, EFSA Journal 2020;18(11):6268	Established a chronic tolerable daily intake (TDI) of 13 µg Ni/kg b.w./day, anchored on a BMDL10 of 1.3 mg Ni/kg b.w./day for increased post-implantation loss in rats; reproductive and developmental endpoints (post-implantation loss, decreased fetal weight, reduced viability) are the most sensitive chronic endpoints and dominate the dietary risk assessment. The TDI was lowered substantially from prior values. EFSA further found that mean dietary nickel exposure across European Member States routinely exceeds this TDI, particularly among toddlers and other children.
EFSA (CONTAM Panel)	2020	Update of the Risk Assessment of Nickel in Food and Drinking Water, EFSA Journal 2020;18(11):6268	For acute oral exposure, identified eczematous flare-up reactions in nickel-sensitized humans (systemic contact dermatitis) as the critical effect. A BMDL could not be derived; the LOAEL of 4.3 µg Ni/kg b.w. was selected as the reference point, using a margin-of-exposure approach with MOE >= 30 as the threshold for low health concern.
US NTP (National Toxicology Program)	2021	Nickel Compounds and Metallic Nickel — 15th Report on Carcinogens	Classifies nickel compounds (as a class) as known to be human carcinogens (since the 10th RoC, 2002) and metallic nickel as reasonably anticipated to be a human carcinogen (since the 1st RoC, 1980). Lung and nasal cancer are the primary tumor sites, documented in occupational inhalation cohorts (refinery, stainless-steel/nickel-alloy production, electroplating). Dietary nickel at typical levels has not been associated with cancer; the cancer risk is operationally an inhalation/occupational concern.

BODY	YEAR	ASSESSMENT	WHAT IT CONCLUDED
IARC	1990, 2012	IARC Monographs Vol. 100C (2012), Nickel and Nickel Compounds; and IARC Monographs Vol. 49 (1990), Chromium, Nickel and Welding	Classifies nickel compounds as Group 1 (carcinogenic to humans), the classification originally established in the 1990 Volume 49 monograph and affirmed in the 2012 Volume 100C 'Review of Human Carcinogens' re-evaluation. Metallic (elemental) nickel is classified Group 2B (possibly carcinogenic to humans) per the 1990 Volume 49 evaluation; the 2012 100C chapter prints only the Group 1 classification for nickel compounds and does not itself restate a Group 2B designation for metallic nickel. Consistent with the NTP finding, this is an inhalation/occupational endpoint (lung and nasal/nasal-sinus cancer); typical dietary nickel intake is not associated with cancer.
EU Commission (risk management)	2024	Commission Regulation (EU) 2024/1987 amending (EU) 2023/915, Annex entry 3.6 — binding food maximum levels for nickel	Set the EU's first binding nickel maximum levels in food, a risk-management response to the EFSA exceedance finding. Category limits range from 0.10 mg/kg for liquid infant formula to higher values for cereals and seaweed (e.g. infant formula powder 0.25 mg/kg non-soy and 0.40 mg/kg soy-isolate, baby food excluding juices 0.50 mg/kg, processed cereal-based baby food 3.0 mg/kg, cereals 0.80 mg/kg); most entries apply from 1 July 2025 and cereal limits from 1 July 2026.
US ATSDR	2024	Toxicological Profile for Nickel	Derives Minimal Risk Levels (MRLs) for nickel by exposure route and duration as health-guidance values, supporting the multi-route toxicity basis.

Toxicological basis

What the assessment bodies found when they examined nickel, and why it warrants a limit: the dietary endpoint that anchors regulation, the sensitized population it reaches at far lower doses, and the carcinogenicity that does — and does not — apply to food.

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, accompanied by reduced fetal weight and reduced offspring viability. EFSA's 2020 reassessment set the chronic tolerable daily intake at 13 µg Ni/kg body weight per day from a BMDL10 of 1.3 mg/kg, a value it lowered substantially from its earlier reference under revised benchmark-dose methodology. This is the endpoint governments regulate against, and it is not academic: EFSA found that mean dietary nickel exposure across European member states already exceeds the tolerable intake, with toddlers and young children the most exposed on a body-weight basis.

A second, lower-dose endpoint reaches a far larger population. Nickel is among the most common contact allergens, sensitizing an estimated 8 to 19 percent of adults and 13 to 18 percent of women, and once a person is sensitized, oral doses well below the chronic tolerable intake can provoke systemic contact dermatitis; EFSA set the acute reference at a LOAEL of 4.3 µg Ni/kg body weight for eczematous flare-ups in sensitized volunteers. Systemic Nickel Allergy Syndrome, which affects roughly one in five nickel-allergic patients, extends the picture beyond the skin: controlled and open-label low-nickel-diet trials report symptom improvement in nickel-sensitized patients with chronic dermatitis, irritable bowel syndrome, refractory reflux, recurrent aphthous stomatitis, and endometriosis-associated gastrointestinal symptoms, and a nickel-free diet has been shown to nearly double *Helicobacter pylori* eradication when added to standard therapy. The evidence ranges from

double-blind oral-challenge studies to small pilots; its breadth is the point, because it means dietary nickel is a clinically active exposure for a population much wider than the reproductive endpoint alone describes.

Nickel is also a carcinogen, and being precise about how is a matter of credibility. The US National Toxicology Program lists nickel compounds as known human carcinogens and metallic nickel as reasonably anticipated to be one, and IARC classifies nickel compounds in Group 1. The tumour sites — lung and nasal-sinus — were established in occupational cohorts inhaling nickel dust and fume, not in people eating nickel; typical dietary nickel intake has not been associated with cancer. The program states that plainly rather than blur an inhalation hazard into a food-safety claim the record does not support.

These are not the finding of a single body. EFSA, the US Agency for Toxic Substances and Disease Registry (which derives route- and duration-specific minimal risk levels), the National Toxicology Program, and IARC independently characterise nickel's reproductive, sensitization, and carcinogenic hazards, and they converge. California adds a further mark of concern: its [Proposition 65](#) programme lists soluble nickel compounds as reproductive and developmental toxicants and nickel compounds as carcinogens, yet — as a right-to-know statute that sets no food standard — it adopts no oral safe-harbour and no dietary limit, so the operative dietary reference defaults to EFSA's tolerable intake while the United States sets no maximum level in food at all. That convergence of hazard findings, together with EFSA's exposure exceedance, is what moved the European Union to adopt its first binding nickel maximum levels in food in 2024. The science came first; the limits followed, and where they have not yet followed, the gap is visible.

Occurrence & exposure

How much nickel food actually carries, and how close everyday dietary exposure runs to the health-based guidance value. This is the empirical basis for carrying nickel in the panel, drawn from a national total diet study; the complete occurrence corpus is on the Heavy Metal Index.

Nickel by food group — BfR MEAL Study (Germany, 2022), 840 food pools. Values are µg/kg (ppb), upper-bound, ready-to-eat basis: the group mean and the single highest item measured. These are population occurrence values, not safety thresholds.

FOOD GROUP	MEAN MG/KG	RANGE MG/KG	HIGHEST SINGLE ITEM
Legumes, nuts, oil seeds & spices	1,583	60–5,350	cashew nuts 5,350
Coffee, cocoa & tea	1,488	13–11,050	cocoa powder 11,050
Sugar & confectionery	601	30–2,800	dark chocolate 2,800
Meat-alternative / vegan products	386	48–1,000	soy protein extrudate 1,000
Grains & grain products	359	20–1,975	chia seeds 1,975
Infant & toddler foods	185	20–1,040	porridge / millet powder 1,040
Fruit & fruit products	112	16–1,080	dried fruit 1,080
Sauces & condiments	111	10–565	soy sauce 565

FOOD GROUP	MEAN MG/KG	RANGE MG/KG	HIGHEST SINGLE ITEM
Vegetables	84	17–340	vegetable crisps 340
Milk & dairy	48	6–295	ice cream 295
Fish & seafood	30	16–165	shellfish 165
Meat	27	16–60	liver sausage 60

Dietary nickel intake against the EFSA tolerable daily intake of 13 µg/kg body weight per day. BfR MEAL Study, upper-bound; the share of the tolerable intake reached by the median (P50) and high (P95) consumer.

POPULATION	MEDIAN (P50)	HIGH (P95)	
Adults & adolescents	11%	24%	
Children, 0.5–<5 y	42%	82%	~2% already exceed the TDI
Children, 1–<2 y (highest)	45%	84%	the most-exposed subgroup

Grains and grain products are the single largest contributor to children's nickel intake, followed by sugar and confectionery, dairy, and dedicated infant and toddler foods — every one a category the program certifies. Cocoa, nuts, seeds and soy carry the highest concentrations per kilogram, so a product built on those ingredients inherits nickel as a leading concern.

The exposure sits exactly where the program works. Child dietary nickel already reaches the majority of the tolerable intake, a measurable fraction of young children exceed it, and the foods driving that intake are child-food staples rather than exotic exposures. That is the empirical case for quantifying nickel in every certified lot rather than treating it as a trace afterthought.

German Federal Institute for Risk Assessment (BfR), Communication 033/2022 — a government total diet study of 840 nationwide food pools (evidence tier A). EFSA's 2020 pan-European reassessment reaches the same conclusion: mean dietary nickel exposure across Member States exceeds the tolerable intake, children most of all. The full occurrence corpus is on the [Heavy Metal Index](#).

How it is regulated

The binding maximum level in force for infant and child foods is the EU's, adopted under Method v2.0 (government-limit default) as the strictest sovereign limit by lookup. The EU is effectively the only jurisdiction that regulates nickel in food (limits introduced by Reg (EU) 2024/1987 amending 2023/915, Annex 3.6): liquid infant formula 100, non-soy formula powder 250, soy-isolate formula powder 400, baby food except juices 500, cereals 800, and processed cereal-based baby food / pseudocereals and millet 3000 µg/kg (see cert [/regulations/eu-2023-915](#)). No US/FDA, Codex, UK, Canada, China, India, Brazil or AU/NZ nickel food ML exists, so the EU value governs across the program and, where no government regulates the exact product, a disclosed read-across from the nearest EU value is applied rather than an invented number. For teething and finger snacks the EU processed-cereal-based value

(3000 µg/kg) binds; the law's own formulation split (250 cow-milk vs 400 soy powder) is adopted verbatim per Method v2.0 rather than derived. Do not restate the full derivation table — see the cert standards pages and /regulations/ for the side-by-side.

How the HMTc program treats it

Nickel is a claim analyte on the eight-total panel, equal at the gate with every other published limit. Under Method v2.0 the government limit is adopted directly (occurrence pooling is reserved for priority toxics and no-ML cells). A product is certified only at or below its published limit, and a product above it enters Remediation — non-certified, with the mark withheld — until it returns to compliance. The certification species is Total elemental nickel; nickel carries NO speciation trigger — unlike [arsenic](#) (iAs), [mercury](#) (MeHg/tHg) and [chromium](#) (reflex Cr-VI speciation above 100 ppb). The regulatory hard-stop still applies: any actual legal-limit violation blocks certification regardless of HMTc status. The program frames nickel as largely controllable through ingredient sourcing and process control.

Literature baseline

The complete peer-reviewed and regulatory literature for nickel 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.