

Issue Brief: Heavy Metals (Lead, Arsenic, and Cadmium)

August 2026

Lead, arsenic, and cadmium are naturally occurring and human influenced environmental contaminants that may be present across the food supply due to trace levels in soil, water, and air. Because these elements cannot be eliminated entirely from the environment, regulators generally focus on evaluating the potential health risk, monitoring the food supply, and implementing practical measures to limit exposure to the greatest extent feasible, rather than achieving complete removal.

This brief summarizes key U.S. federal, state, and international frameworks relevant to lead, arsenic, and cadmium in foods.

Overview

The presence of heavy metals in the U.S. food supply is primarily driven by the presence of heavy metals in the environment where foods are grown, raised, or processed. The levels of heavy metals present in the environment vary based on natural geographical differences and proximity to current or past pollution, and the level present in foods can be driven by the characteristics of the food itself and its ability to absorb heavy metals from the environment. Consumer advocacy groups have played a key role in the development of regulatory frameworks for managing heavy metals in the food supply in the U.S. Testing by consumer advocacy groups brought congressional scrutiny to this issue, particularly with respect to foods frequently consumed by infants and young children, and as public and congressional attention has been directed to these matters, the Food and Drug Administration (“FDA” or “the agency”) and states have established regulatory frameworks to address the presence of heavy metals in foods.

Currently, heavy metals in foods are regulated in the U.S. through a combination of federal and state requirements. Unlike some international jurisdictions, the U.S. does not establish uniform maximum limits for lead, arsenic, or cadmium across all food categories. Instead, the current regulatory approach is primarily risk-based and relies on a combination of action levels, guidance documents, preventive controls requirements, and enforcement actions.

Federal Framework

FDA’s jurisdiction over heavy metals is grounded in the adulteration standard in the Federal Food, Drug, and Cosmetic Act (“FFDCA”), which allows the agency to take enforcement or other regulatory action where the agency determines the food is adulterated or otherwise presents a safety concern. Under this authority, FDA’s primary regime for heavy metals is

the Closer to Zero (“C2Z”) initiative. This program is aimed at reducing dietary exposure to lead, arsenic, cadmium, and mercury in foods intended for infants and young children. Rather than establishing binding limits across all foods, FDA uses evolving benchmarks and guidance to encourage continual reduction of heavy metals while maintaining access to nutritious foods. Although these efforts are specifically tied to products intended for infants and young children, the resulting action levels can influence commercial requirements across all products.

In addition to this proactive initiative, FDA has specific regulations limiting heavy metals in certain commodities and requires companies to consider heavy metals as potential chemical hazards under the Food Safety Modernization Act (“FSMA”) preventive controls framework. The agency has the ability to take enforcement action against companies when heavy metals at levels of concern are detected in products, including requesting recalls, detaining import entries, and placing products on import alert. As a result, food companies should consider whether they have established procedures and controls to monitor and mitigate the potential presence of heavy metals in ingredients and finished products where necessary and appropriate, paying particular attention when the product is intended for infants or young children.

State-Level Requirements

The states have adopted varying approaches to heavy metal regulation, with three notable schemes emerging:

1. California’s Proposition 65: Establishes exposure-based thresholds that may trigger warning requirements for lead, cadmium, and inorganic arsenic.
2. Testing Requirements for Infant Foods: Several states have enacted testing, disclosure, or reporting requirements for foods intended for infants and young children.
3. New York Category-Specific Approach: New York has adopted certain category-specific requirements and continues to evaluate heavy metals in selected categories (e.g., spices).

California’s Proposition 65 often represents the most stringent practical compliance consideration for companies because it is based on consumer exposure rather than product concentration.

International Framework

At the international level, heavy metals are primarily regulated through specific, commodity-driven maximum limits. Codex Alimentarius, the European Union, and United Kingdom all follow this framework, which has different compliance considerations than the approach employed in the U.S. As a result, companies selling products in both markets need to establish programs to address both regulatory schemes.

Considerations for Industry

Companies working to comply with these varying regulatory frameworks should work to develop internal controls to address the regulatory, commercial, and consumer expectation considerations associated with the potential presence of heavy metals. Generally, this risk is most acute for manufacturers producing foods or ingredients intended for products for infants and young children, however companies are required to comply with applicable FSMA preventive control requirements, California's Proposition 65 framework, and the adulteration standard in the FFDCA. As a result, companies should consider whether their hazard analyses and supply chain programs adequately address these risks where applicable.

U.S. Federal Regulatory Framework

FDA's authority to regulate heavy metals in the food supply is grounded in the Federal Food, Drug, and Cosmetic Act's ("FFDCA") adulteration standard and its prohibition against introducing adulterated foods into interstate commerce. Section 402(a)(1) of the FFDCA considers a food adulterated when it contains a "poisonous or deleterious substance which may render it injurious to health."¹ Under this standard, FDA can take enforcement or other regulatory action when the presence of heavy metals in a food causes concern.² Unlike pathogens, the mere presence of heavy metals in a food does not render it adulterated, rather the heavy metal must be present in a concentration that could cause the food to be adulterated based on the relevant exposure and risk assessment.

FDA regulates heavy metals in the food supply in a variety of different forms, including regulations, guidance, action levels, and surveillance and enforcement activities. Most notably, FDA's Closer to Zero initiative has been focused on establishing action levels related to the presence of

¹ 21 U.S.C. § 342(a)(1).

² This principle was recognized in *U.S. v. Lexington Mill & Elevator Co.*, which held that the mere

certain heavy metals in products intended for infants and young children. Each of these regulatory activities is summarized below.

Regulations

FDA has established limits for heavy metals in certain products by regulation. For example, in FDA's standard of quality for bottled water, the agency establishes limits for the amount of arsenic, cadmium, lead, and mercury that can be present in a liter of bottled water along with a number of other inorganic substances.³ The standard also specifies the approved methodologies for measuring heavy metal levels in bottled waters.

Guidance: Closer to Zero

Established in 2021, the Closer to Zero (C2Z) initiative is FDA's primary policy framework for reducing dietary exposure to lead, arsenic, cadmium, and mercury in foods intended for infants and young children.⁴ The initiative is aimed at balancing the goal to reduce dietary exposure to these metals as much as possible with the need for access to nutritious foods. To do this, FDA takes a science-based, iterative approach that involves (1) evaluating the scientific basis for action levels for certain metals and foods, (2) proposing action levels, (3) consulting with stakeholders on the feasibility and achievability of the proposed action levels, and (4) finalizing action levels. The agency repeats this approach to establish a cycle of continuous improvement. Although action levels set under the C2Z framework are useful tools to reduce exposure to heavy metals from certain foods, the agency does not need a set action level to take enforcement action against a product that would be considered adulterated.

For frozen foods, C2Z is most relevant where the product is intended to be used as an infant or toddler food or as an ingredient in an infant or toddler food. However, actions levels set under the C2Z framework have historically been used by all sectors of industry to establish controls and product specifications. More information on the current action levels set for products intended for infants and young children is available in the below section on federal action levels.

³ 21 CFR § 165.110(b)(4)(iii)(A).

⁴ Closer to Zero: Reducing Childhood Exposure to Contaminants from Foods, <https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods>

Guidance: FSMA and Preventive Controls

Under the hazard analysis and preventive controls framework, companies are required to consider heavy metals in their hazard analyses and implement preventive controls to address these hazards when determined necessary. The updated guidance in Appendix 1 to the Hazard Analysis and Risk-Based Preventive Controls for Human Foods draft guidance provides additional granularity regarding heavy metals by including arsenic, cadmium, and lead in its tables of “Known or Reasonably Foreseeable Hazards.”⁵ This guidance does not identify specific action levels for any heavy metals and does not list foods for infants and toddlers, which are covered under the C2Z initiative. In its guidance chapter on potential hazards associated with manufacturing, processing, packing, and holding food, FDA explains that when a hazard analysis identifies a heavy metal that requires a preventive control, the type of control depends on how the heavy metal enters the food.⁶ FDA is anticipated to provide more guidance on heavy metal controls in its forthcoming chapter under this guidance covering preventive controls for chemical hazards.

As part of the preventive controls framework, FDA requires companies to ensure suppliers, including foreign suppliers, are controlling heavy metal hazards as needed as part of the company’s supply chain control program. For example, in late 2023, FDA and the Center for Disease Control investigated elevated blood lead levels in children linked to consumption of certain cinnamon-flavored applesauce pouches. Testing revealed lead levels more than 200 times the action levels FDA had proposed in its January 2023 draft guidance. The incident underscored the potential risks associated with imported ingredients (the source was found to be cinnamon) and prompted renewed calls from state Attorneys General for FDA to accelerate its Closer to Zero timelines. The incident demonstrated FDA’s existing enforcement authority even absent finalized action levels. The importing companies involved in this matter received warning letters citing violations of FDA’s Foreign Supplier Verification Program (FSVP),

⁵ FDA, *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food, Appendix 1: Known or Reasonably Foreseeable Hazards (“Potential Hazards”)* (2024). <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food>.

Appendix 1 does not address mercury, which is principally a hazard in seafood products that are not covered by this guidance.

⁶ FDA, *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food, Chapter 3: Potential Hazards Associated with the Manufacturing, Processing, Packing and Holding of Human Food* (2024). <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food>

which is designed to ensure companies are verifying foreign suppliers are complying with all FDA requirements. As part of its response to this incident, FDA has suggested that additional testing requirements for ingredients and finished products can help verify that the programs in place are effective in addressing the potential presence of heavy metals in the foreign supply chain.

Imports

Import procedures allow the agency to detain potentially violative products entering the U.S., and foods across all categories may be subject to refusal and/or enforcement action where FDA identifies information suggesting heavy metals may be present at levels of concern. FDA can place a product on an Import Alert after discovering a violation and then detain future shipments of the product without having to test or otherwise physically examine it, referred to as “detention without physical examination” (DWPE). Specifically for heavy metal concerns, FDA utilizes Import Alert 99-42: Detention without Physical Examination of Foods Due to Heavy Metal (Toxic Element) Contamination to prevent foods from entering the country due to the presence of heavy metals. The import alert notes that FDA has established action levels for certain foods and that when an action level has not been established, FDA will evaluate the presence of a contaminant on a case-by-case basis. This case-by-case assessment will consider: (1) the properties of the heavy metal in the product, (2) the amount of the heavy metal present in the product, (3) U.S. consumption data for the product, and (4) the impact on vulnerable populations.⁷

Federal Action Levels

As discussed above, although FDA has not established action levels for lead, arsenic, or cadmium across all foods, it has begun establishing action levels for foods intended for babies and young children to advance its Closer to Zero initiative and has set limits for certain commodities by regulation. The table below summarizes the current FDA regulatory action levels established through guidance or regulation.

⁷ FDA. Import Alert 99-42 (Aug. 7, 2026), https://www.accessdata.fda.gov/cms_ia/importalert_1167.html#:~:text=Reason%20for%20Alert:case%20Dby%20case%20basis..

Current federal limits for lead, arsenic, and cadmium and their occurrence in foods.

Heavy Metal	Intended Consumer	Product	Established Limit
Lead	All consumers	Bottled Water	5 ppb ⁸
		Candy	100 ppb ⁹
		Ready-to-Drink Apple Juice	10 ppb ¹⁰
		Single-Strength Fruit and Vegetable Juice	20 ppb ¹¹
	Infants and Young Children ¹²	- Fruits - Vegetables (excluding single-ingredient root vegetables) - Mixtures (including grain- and meat-based mixtures) - Yogurts, custards or puddings - Single-ingredient meats	10 ppb
		- Single-ingredient root vegetables - Dry infant cereals	20 ppb
Arsenic	All Consumers	Bottled Water	10 ppb ¹³
		Apple Juice	10 ppb ¹⁴
	Infants and Young Children	Rice Cereal	100 ppb ¹⁵
Cadmium	All Consumers	Bottled Water	5 ppb ¹⁶
	Infants and Young Children	<i>Anticipated draft guidance on Cadmium in foods for infants and young children. (Summer 2026)</i>	

⁸ 21 CFR § 165.110(b)(4)(iii)(A).

⁹ FDA Guidance for Industry: Lead in Candy Likely to be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy (Nov. 2006), available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-lead-candy-likely-be-consumed-frequently-small-children>.

¹⁰ FDA Draft Guidance for Industry: Action Levels for Lead in Juice (April 27, 2022). Docket No. FDA-2019-D-5609, available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-juice>.

¹¹ *Id.*

¹² FDA Guidance for Industry: Action Levels for Lead in Processed Food Intended for Babies and Young Children (January 6, 2025). Docket No. FDA-2022-D-0278, available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-lead-processed-food-intended-babies-and-young-children>.

¹³ 21 CFR § 165.110(b)(4)(iii)(A).

¹⁴ FDA Guidance for Industry: Action Level for Inorganic Arsenic in Apple Juice (June 1, 2023), available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-apple-juice>.

¹⁵ FDA Guidance for Industry: Action Level for Inorganic Arsenic in Rice Cereals for Infants (August 2020), available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-rice-cereals-infants>.

¹⁶ 21 CFR § 165.110(b)(4)(iii)(A).

Additional Considerations:

- **Lead:** For all foods, FDA aims to limit consumer exposure of lead to the greatest extent feasible and manages its prevalence in food using an Interim Reference Level (IRL), which serves as a benchmark to evaluate whether dietary exposure may be a concern.¹⁷ FDA's revised 2022 IRL is 2.2 µg/day for children and 8.8 µg/day for women of childbearing age. These values underpin exposure assessments and help FDA assess risk and inform guidance to prioritize public health action, but they do not themselves function as regulatory levels for foods.
- **Arsenic:** Current research indicates that the level of toxicity and the associated health effects are more severe from exposure to inorganic arsenic than from organic arsenic. As a result, evaluating "total arsenic" can be misleading. As FDA continues to evaluate current science as part of its C2Z initiative, the agency also plans to issue draft guidance on action levels for inorganic arsenic in foods intended for babies and young children in addition to infant rice cereals and apple juice.
- **Cadmium:** Cadmium is still in the evaluation and development phase under C2Z, and FDA has not finalized action levels for cadmium in food, including in baby foods. However, FDA's draft action levels for cadmium in processed foods intended for infants and young children are expected to be issued imminently. FDA has adopted a toxicological reference value (TRV) range for cadmium, 0.21-0.36 micrograms (µg) per kilogram body weight per day, based on health effects on bone and kidneys.¹⁸ For cadmium, FDA uses the terms "IRL" and "TRV" interchangeably.

Practical Implications for Food Manufacturers

- **Lead:** Fruit juices and concentrates have been subject to recent Import Alerts due to lead. Spices like cinnamon, have been subject to recent recalls and Import Alerts. Food manufacturers may consider

¹⁷ FDA. Lead in Food, Foodwares, and Dietary Supplements (January 2025), available at: <https://www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements>. Flannery, B. M., & Middleton, K. B. (2022). Updated interim reference levels for dietary lead to support FDA's Closer to Zero action plan. Regulatory toxicology and pharmacology: RTP, 133, 105202. <https://doi.org/10.1016/j.yrtph.2022.105202>.

¹⁸ FDA. Cadmium in Food and Foodwares. <https://www.fda.gov/food/environmental-contaminants-food/cadmium-food-and-foodwares>.

whether certain ingredients, suppliers, or product categories warrant additional review based on known risk factors.

- **Arsenic:** Fruit juices, mashed fruit inputs, fruit concentrates, and rice-based products have been placed on recent Import Alerts due to arsenic.
- **Cadmium:** Cadmium is currently monitored and actionable under the adulteration standard for all foods. Fruit juices and concentrates have been implicated in recent Import Alerts due to cadmium. Commercial expectations may continue to evolve even before FDA establishes any formal cadmium action levels. Cereals and cereal products, vegetables, nuts and pulses, starchy roots or potatoes, and meat products contribute most to dietary cadmium exposure.

Potential U.S. Legislative and Regulatory Developments

Federal-level actions on heavy metals in food reflect a convergence of legislative pressure and FDA's ongoing implementation of the Closer to Zero initiative, particularly for foods consumed by infants, toddlers, and children. Although Congress has not yet enacted mandatory limits, proposed legislation and ongoing advocacy indicate strong support for more enforceable standards. FDA's actions to date, particularly the finalization of lead action levels and integration of heavy metals into preventive controls, suggest that FDA's C2Z work may influence future regulatory expectations. Although the current focus is on infants and young children, the mechanisms being built (IRLs, exposure modeling, supply chain controls) are transferable to broader food categories. For the frozen food sector, these developments suggest that companies may see greater regulatory and customer attention to these issues, even in advance of formal limits for arsenic, cadmium, and lead.

U.S. State Regulatory Framework

California Proposition 65 Regulation

California Proposition 65 ("Prop 65"),¹⁹ the Safe Drinking Water and Toxic Enforcement Act of 1986, is a right-to-know law requiring businesses to provide a "clear and reasonable" warning when consumers may be exposed to listed Prop 65 chemicals above defined safe harbor levels.²⁰ Listed

¹⁹ Proposition 65. Office of Environmental Health and Hazard Assessment (OEHHA), State of California. <https://oehha.ca.gov/proposition-65>.

²⁰The law also provides a very narrow exemption from the warning requirement for naturally occurring substances. The warning can be provided by various means, but for packaged

substances are those “known” to the State of California to cause cancer, birth defects, or reproductive harm.

Under California’s Proposition 65, “safe harbor” exposure levels are established as either No Significant Risk Levels (NSRLs) or Maximum Allowable Dose Levels (MADLs), depending on the type of toxicity involved. NSRLs apply to chemicals listed as causing cancer and represent the daily exposure level associated with no more than a one-in-100,000 lifetime excess cancer risk; exposures below this level do not require a warning. In contrast, MADLs apply to chemicals listed as causing reproductive toxicity and are set at levels that pose no observable reproductive effect, incorporating a 1,000-fold safety margin. Both NSRLs and MADLs are expressed as micrograms per day and are based on total daily exposure rather than concentration in a single food.²¹

This distinction is important because a single chemical may have both an NSRL and a MADL (e.g., lead and cadmium), or only one established endpoint (e.g., inorganic arsenic has an NSRL for cancer but no widely applied oral MADL). In practice, businesses must assess anticipated consumer exposure relative to the applicable threshold; if exposure exceeds the relevant NSRL or MADL, a Proposition 65 warning is required unless another exemption applies.

NSRL and MADL are exposure-based thresholds, not concentration limits, and compliance depends on total daily intake, which varies with serving size and consumption frequency.

Inorganic arsenic, cadmium, and lead are all listed under Proposition 65. The representative food sources reinforce that heavy metals are not confined to a single commodity group but are broadly distributed across food categories due to heavy metal presence in the environment.

Although exemptions for naturally occurring contaminants may apply, they are narrow and fact-oriented, requiring demonstration that exposure results solely from natural sources and has not been materially increased by human activity. Importantly, Proposition 65 includes a private right of action (bounty hunter provision) that enables third parties to enforce warning requirements independent of federal regulatory enforcement.

food items or other consumer products, labeling the product with the appropriate statement — e.g., “WARNING: This product contains a chemical known to the State of California to cause cancer.” — is the typically utilized format.

²¹ Proposition 65 No Significant Risk Levels (NSRLs) and Maximum Allowable Dose Levels (MADLs). <https://oehha.ca.gov/proposition-65/general-info/proposition-65-no-significant-risk-levels-nsrls-and-maximum-allowable-dose-levels-madls>.

California Proposition 65 thresholds for lead, arsenic, and cadmium.

Heavy Metal	Nature of Toxicity	Safe Harbor Exposure Levels	Representative Food Sources
Lead²²	Cancer and reproductive toxicity	0.5 µg/day (MADL); 15 µg/day (NSRL)	• Certain spices (turmeric) • Some vinegars • Dietary supplements • Imported candies (chili & tamarind)
Inorganic Arsenic²³	Cancer	10 µg/day (NSRL); 0.5 µg/day (NSRL) – inhalation	• Rice and rice-based ingredients • Certain seaweeds • Some herbal products
Cadmium²⁴	Reproductive toxicity	4.1 µg/day (MADL) – oral; 0.5 µg/day (NSRL) – inhalation	• Leafy vegetables (spinach, depending on soil conditions) • Shellfish and seafood • Cocoa products

Note: Thresholds are daily exposure limits, not concentration limits, and depend on:

- Contaminant levels in the product
- Serving size and consumption patterns

Proposition 65 operates independently of FDA action levels and the C2Z initiative. Proposition 65 often presents one of the most significant practical compliance considerations for companies selling foods in California due to its exposure-based framework and active private enforcement. Because safe harbor levels are tied to daily intake, not product concentration, foods with high consumption frequency or multi-ingredient formulations may warrant exposure assessments.

²² Proposition 65, Chemicals Considered or Listed Under Proposition 65, Lead.
<https://oehha.ca.gov/proposition-65/chemicals/lead>.

²³ Proposition 65, Chemicals Considered or Listed Under Proposition 65, Arsenic.
<https://oehha.ca.gov/proposition-65/chemicals/arsenic-inorganic-arsenic-compounds>.

²⁴ Proposition 65, Chemicals Considered or Listed Under Proposition 65, Cadmium.
<https://oehha.ca.gov/proposition-65/chemicals/cadmium>.

Other State Initiatives

In addition to Proposition 65, additional states have begun passing legislation to regulate the presence of heavy metals in foods.

- **California AB 899.**²⁵ Established a requirement for manufacturers of baby food to test and disclose the levels of arsenic, cadmium, lead, and mercury that may be present in the products and to meet certain labeling requirements. Testing is required monthly and must be made publicly available on the manufacturer's website. Product labels must include QR codes or other machine-readable code that links to a webpage with the monthly test results and FDA's guidance for consumers on the health effects of heavy metals in children. Three states have passed nearly identical laws including Maryland (Rudy's Law SB 723),²⁶ Illinois (SB 0073),²⁷ and Virginia (HB 1844).²⁸
- **California SB 1033 (introduced Feb. 11, 2026).**²⁹ This bill would require a manufacturer of a bulk or packaged protein product that is sold, manufactured, delivered, held, or offered for sale in this state to test a representative sample of each lot of the product for arsenic, cadmium, lead, and mercury. Additionally, the bill would require public disclosure of test results on company website and would require the product label and online ordering information page to direct consumers to the company webpage with that information. If enacted, the bill would come into effect January 1, 2028.
- **New York Approach to Heavy Metals.**³⁰ The New York Department of Agriculture and Markets has established proposed action levels for heavy metals in spices and a related recall classification system. Under this system, a class two recall would be warranted for levels above 0.21 ppm for lead, 0.26 ppm for cadmium, and 0.21 ppm for inorganic arsenic.

²⁵ Cal. HSC §§ 110962-110963, https://leginfo.ca.gov/faces/billCompareClient.xhtml?bill_id=202320240AB899.

²⁶ Md. Code Regs. § 21-330.4, <https://govt.westlaw.com/mdc/Document/NCD73717089BB11F0AD14E751E5FED49D>.

²⁷ 410 ILCS 620/11.7, <https://my.ilga.gov/legislation/ilcs/fulltext?DocName=041006200K11.7>.

²⁸ 3.2 Va. Admin. Code § 3.2-5125.1, <https://law.lis.virginia.gov/vacode/3.2-5125.1/>.

²⁹ California SB 1033 (Feb. 11, 2026), <https://sd18.senate.ca.gov/news/senator-padilla-introduces-legislation-protect-consumers-heavy-metals-protein-products>

³⁰ 1. Heavy Metals in Spices, Department of Agriculture and Markets, New York State, <https://agriculture.ny.gov/heavy-metals-spices>.

International Frameworks

In contrast to the United States' exposure-based, guidance-driven approach, internationally, heavy metals are primarily regulated through commodity-specific maximum limits (e.g., in the European Union (EU)) or surveillance-based risk assessment frameworks (e.g., Canada and the United Kingdom). This creates distinct compliance considerations for U.S. products exported to these markets because the products must meet concentration-based limits in the export markets and manage exposure-based requirements in the U.S. The continued tightening of cadmium limits in the EU and the broader policy shift toward reducing exposure in the absence of safe thresholds reinforce the importance of continued attention to supply chain controls.

- Codex and World Health Organization (WHO): The Codex Alimentarius establishes maximum levels for heavy metals (lead, arsenic, cadmium, mercury, etc.), and the Joint FAO/WHO Expert Committee on Food Additives and Contaminants (JECFA) sets health-based guidance values (e.g., PTWI, exposure metrics).³¹ In general, Codex provides international trade reference points and informs EU limits and various national frameworks.
- European Union: Heavy metals are regulated in the EU as food contaminants under European Commission Regulation (EC) No 2023/915, which establishes binding maximum levels (MLs) for specific heavy metals in defined food categories. The specific maximum limits vary significantly by food category, with stricter thresholds applied to vulnerable groups like infants. The maximum levels are set based on the 'As Low as Reasonably Achievable' (ALARA) principle to protect public health.

³¹ Codex General Standard for Contaminants and Toxins in Food and Feed (Codex Stan 193-1995), http://www.codexalimentarius.org/download/standards/17/CXS_193e.pdf.

European Commission Regulation No 2023/915 maximum levels for heavy metals.³²

Heavy Metal	Product	Representative Maximum Levels (ML)
Lead	- Milk - Infant formula powder - Baby foods and cereals	0.02 mg/kg
	- Fruit (excluding berries and small fruit) - Vegetables (excluding brassica, leafy vegetables, fresh herbs, and fungi) - Fats and oils	0.10 mg/kg
	Berries and small fruit	0.20 mg/kg
Arsenic	- Parboiled rice and husked rice - Rice flour	0.25 mg/kg
	- Infant formula powder - Baby foods and cereals - Fruit juices, concentrated fruit juices as reconstituted and fruit nectars	0.20 mg/kg
	Non-parboiled milled rice (polished or white rice)	0.15 mg/kg
	Rice waffles, rice wafers, rice crackers, rice cakes, rice flakes and popped breakfast rice	0.30 mg/kg
Cadmium	- Meat - Fish - Fruits and vegetables (excluding leafy vegetables, fresh herbs, fungi, root vegetables, and potatoes) - Barley and Rye	0.05 mg/kg
	- Celeries - Leaf vegetables (excluding spinaches, mustard seedlings, and fresh herbs) - Root vegetables - Potatoes - Oilseeds (excluding rape, mustard, sunflower, and poppy seeds, linseeds, and peanuts and soybeans)	0.10 mg/kg
	- Citrus fruits, pome fruits, stone fruits, table olives, kiwi fruits, bananas, mangoes, papayas and pineapples - Radishes (excluding tiger nuts) - Fruiting vegetables (excluding aubergines)	0.02 mg/kg

- Canada: Health Canada and the Canadian Food Inspection Agency (CFIA) follow a risk-based, surveillance-driven approach to monitoring the concentrations of lead, cadmium and arsenic across various foods by

³² 23. Commission Regulation (EC) No 2023/915 of 25 April 2023 setting maximum levels for certain contaminants in food. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02023R0915-20250101>. Note this is not a comprehensive list.

conducting Total Diet Studies. A recent survey (2022-23) did not identify levels posing human health concerns.³³ Regulatory focus in Canada remains a combination of monitoring and risk assessment rather than broad, universal limits across all foods.

Health Canada – Maximum levels for heavy metals (List of Contaminants and Other Adulterating Substances in Foods).³⁴

Heavy Metal	Product	Representative Maximum Levels (ML)
Lead	Beverages except fruit juice and fruit nectar	0.2 ppm
	Condensed and evaporated milk	0.15 ppm
	Edible bone meal	10 ppm
	Fish protein	
	Whole tomatoes	0.5 ppm
	Fruit juice and fruit nectar	0.05 ppm
	Infant formula	
	Water in sealed containers	0.01 ppm
Inorganic Arsenic	Tomato paste and sauce	1.5 ppm
	Fruit juice	0.01 ppm
	Grape juice and grape nectar	0.03 ppm
	Husked (brown) rice	0.35 ppm
	Polished (white) rice	0.2 ppm
	Rice-based foods intended for infants and young children	0.1 ppm

- United Kingdom (UK): The UK framework is largely aligned with the European Union contaminant regulations. Their current regulatory approach is risk-based, and consistent with EU-derived contaminant controls with no independent, comprehensive arsenic MLs.

³³ Health Canada. Lead. <https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/chemical-contaminants/environmental-contaminants/lead.html>, and Health Canada. Arsenic. <https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/chemical-contaminants/environmental-contaminants/arsenic.html>.

³⁴ Health Canada. List of Contaminants and Other Adulterating Substances in Foods. <https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/chemical-contaminants/contaminants-adulterating-substances-foods.html>.

Key Takeaways for Food Manufacturers

Although FDA maintains relatively few binding contaminant limits for lead, cadmium, and arsenic in food, regulatory expectations are rapidly evolving. FDA's focus on heavy metals in infant and toddler foods may result in new end user specifications, which in turn could affect supply chains for affected commodities and ingredients. Companies should continue to evaluate heavy metals as part of their broader food safety, regulatory compliance, and supply chain programs, with risk-based controls tailored to the nature of the product, ingredients, and intended consumers.

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