



## **Toxic Elements in Baby and Toddler Foods Backgrounder Updated July 2023**

### **Situation**

With the publication of several high-profile reports in recent years, there is growing concern among consumers about the presence of heavy metals in food intended for babies and young children and the potential public health impact that consumption of these products could have.

In response to some of these reports, FDA published an action plan, [Closer to Zero](#), which identifies the approach the Agency plans to take to reduce exposure to toxic elements in foods commonly eaten by babies and young children—to the lowest possible levels. Some of the activities outlined in *Closer to Zero* include research and evaluation of changes in dietary exposures to toxic elements, setting action levels, encouraging adoption of best practices by industry, and monitoring progress.

### **What are toxic elements and why are toxic elements in food a concern?**

Metals – both beneficial and harmful – can be present in foods. This is because they are in the air, water or soil where foods are grown, raised or processed. The amount found in food depends on many factors, including: growing conditions; industrial, manufacturing, and agricultural processes; the DNA of the food crops; and past or current environmental contamination. Some metals the human body needs, such as iron, are intentionally added to certain foods, including breakfast cereals and infant formulas, to enhance their dietary benefits. Other metals known as “toxic elements,” such as arsenic, lead and mercury, have no established health benefit, and have been shown to lead to illness, impairment, and in high doses, death.

### **What is FDA doing to monitor metals and other elements?**

The FDA monitors levels of metals and other elements in food and food contact surfaces to inform and enforce FDA rules and guidance. The FDA tests for metals and other elements through the [Total Diet Study](#); the [FDA’s Toxic Elements in Food and Foodware, and Radionuclides in Food compliance program](#); and through targeted sampling assignments. Sampling assignments may be conducted in response to reports of elevated levels of toxic metals or other elements in certain foods or to focus on a specific food, food additive, or specific food group (such as foods commonly eaten by infants and toddlers). [FDA’s testing](#) shows that children are not at an immediate health risk from exposure to toxic elements at the levels found in foods.

### **What are the current regulatory requirements?**

Manufacturers of food intended for babies and young children have a legal responsibility under the Federal Food, Drug, and Cosmetic Act to ensure the safety of their products. FDA uses its

authority to take action on a case-by-case basis when the level of metals in FDA regulated products is determined to be unsafe. FDA has set action levels for specific hazardous chemicals in specific commodities. Information on the levels of chemicals that are prohibited in certain foods are included in [Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed](#).

### **Action Levels and Tolerances**

"Action levels for **poisonous or deleterious substances** are established by the FDA to control levels of contaminants in human food and animal feed. Action levels and tolerances are established based on the **unavoidability** of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable. The blending of a food or feed **containing a substance in excess of an action level** or tolerance with another food or feed is not permitted, and the final product resulting from blending is unlawful, regardless of the level of the contaminant.

Action levels and tolerances represent limits at, or above which FDA will take legal action to remove products from the market. Where no established action level or tolerance exists, FDA may take legal action against the product at the minimal detectable level of the contaminant. The action levels are established and revised according to criteria specified in Title 21, Code of Federal Regulations, Parts 109 and 509 and are revoked when a regulation establishing a tolerance for the same substance and use becomes effective" ([FDA Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed](#), August 2000).

### **FDA has set Action Levels or Recommended Maximum Levels for the following:**

- *Food Intended for Babies and Young Children* ([Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry Draft Guidance - Jan 2023](#))
  - Fruits, vegetables (excluding single-ingredient root vegetables), mixtures (including grain and meat-based mixtures), yogurts, custards/puddings, and single-ingredient meats – 20 ppb
  - Root vegetables (single ingredient) – 20 ppb
  - Dry infant cereals – 20 ppb
- *Mercury in Fish, shellfish, crustaceans, other aquatic animals (fresh, frozen or processed)* - 1 ppm methyl mercury in edible portion (CPG 540.600)
- *Mercury in Wheat (pink kernels only)* - 1 ppm on pink kernels and an average of 10 or more pink kernels/500 g (CPG 578.400)
- *Drinking water* - The EPA has set an action level for lead in drinking water at 15 ppb and an action level for Copper at 1.3 ppm ([EPA Lead and Copper Rule](#))
- *Bottled water* – allowable levels for Inorganic substances in bottled water
  - Arsenic 10 ppb ([FDA Small Entity Compliance Guide: Bottled Water and Arsenic](#))

- Cadmium 5 ppb
  - Lead 5 ppb
  - Mercury 2 ppb
  - For allowable levels for inorganic substances in bottle water see: [FD&C Act - Quality Standard for Bottled Water](#)
- *Lead in Candy likely to be consumed by small children* – 0.1 ppm (100 ppb) is the recommended maximum level for lead in candy likely to be consumed frequently by small children ([Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children](#))
  - *Lead in Juice* – 50 ppb ([Guidance for Industry: Juice HACCP Hazards and Controls Guidance First Edition](#))
  - *Inorganic Arsenic in Apple Juice* – 10 ppb ([Action Level for Inorganic Arsenic in Apple Juice: Guidance for Industry – June 2023](#))
  - *Inorganic Arsenic in Rice Cereals for Infants* – 100 ppb ([Inorganic Arsenic in Rice Cereals for Infants: Action Level Guidance for Industry](#))

### **Import Alerts**

FDA currently has [Import Alerts](#) for toxic elements in food, including for arsenic in fruit juice, bottled water and dietary supplement products and for lead in candy, dried fruits, spices, dietary supplements, and other foods.

### **Requirements under the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule**

Under the [Preventive Controls for Human Food](#) rule, FDA requires food facilities conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control. (This includes chemical hazards such as heavy metals.). If the heavy metal is a known or foreseeable hazard, it should be controlled and should include some type of verification activity.

FDA provides guidance on chemical hazards, such as heavy metals, in their [Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food](#). The *Guidance* specially addresses chemical hazards in chapter 3 section 3.4.1.3 which states that.

- “Heavy metals, including lead, cadmium, arsenic, and mercury, may be of concern in certain foods as a result of agricultural practices (e.g., use of pesticides containing heavy metals or because crops are grown in soil containing elevated levels of heavy metals due to industrial waste), or the leaching of heavy metals from equipment, containers or utensils that come in contact with foods.”

- “When your hazard analysis identifies a heavy metal that requires a preventive control, the type of control would depend on how the heavy metal could get into your food product. In some cases, high levels of heavy metals may result from the environment (e.g., high lead levels in carrots that were grown in lead-contaminated soil). If your food product contains a food crop that is known to have been contaminated with a heavy metal through contaminated soil, a preventive control such as a supply-chain control with a verification program to ensure that the grower conducts an assessment of the growing region prior to its use for agriculture may be appropriate.”

The [Guidance](#) addresses Supply Chain Controls for Heavy Metals in Section 4.6.3.

- “Heavy metals are principally a concern in raw agricultural commodities grown in soils that are contaminated either naturally or through industrial activity. If you determine through your hazard analysis that a heavy metal hazard requires a preventive control, and that control is applied by your supplier, you would have a supply-chain program in which you would verify that suppliers source raw agricultural commodities from regions that do not have high levels of heavy metal contamination in soil, and specifications that heavy metals in raw materials and other ingredients will be within permitted levels.”

For example, your preventive control where the control is applied by your supplier, you could “establish and implement a risk-based supply-chain program with supplier approval and verification activities (as a means of ensuring that raw materials and other ingredients are procured from those suppliers that can meet company specifications and have appropriate programs in place).”

### **What analytical practices and methodology are used?**

The analytical practices and methodology FDA uses when performing sample analyses is outlined in their [Elemental Analysis Manual for Food and Related Products \(EAM\)](#). In addition to the analytical information and procedures and laboratory methods, the EAM provides insight from analysts about using these methods.

Additionally, FDA’s [ORA Laboratory Manual](#) provides information on FDA’s internal policies and procedures to be used when testing consumer products, training laboratory staff, writing reports, safety, research, review of private laboratory reports, court testimony, and other laboratory activities.

### **Additional Background Information**

#### ***Congressional Reports***

U.S. House of Representatives Subcommittee on Economic and Consumer Policy Committee on Oversight and Reform Congressional Report (February 2021)

[Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury](#)

U.S. House of Representatives Subcommittee on Economic and Consumer Policy Committee on Oversight and Reform Congressional Report (September 2021)

[New Disclosures Show Dangerous Levels of Toxic Heavy Metals in Even More Baby Foods](#)

***FDA Information***

FDA Letter to Industry on Chemical Hazards, including Toxic Elements, in Food (March 2021)

<https://www.fda.gov/media/146423/download>

FDA Closer to Zero

<https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods>

FDA Total Diet Study

<https://www.fda.gov/food/science-research-food/fda-total-diet-study-tds>

FDA Testing Results for Arsenic, Lead, Cadmium and Mercury

<https://www.fda.gov/food/environmental-contaminants-food/testing-results-arsenic-lead-cadmium-and-mercury>

FDA Environmental Contaminants in Food

<https://www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food>