



## **Toxic Elements in Baby and Toddler Foods Backgrounder Updated August 2022**

### **Situation**

In February 2021 a congressional report entitled "[\*Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury\*](#)" was published by the U.S. House of Representatives Subcommittee on Economic and Consumer Policy Committee on Oversight and Reform.

In response to reports alleging high levels of toxic heavy metals in baby foods, in November 2019, the Subcommittee on Economic and Consumer Policy requested internal documents and test results from baby food manufacturers in the United States. Companies who responded to the Subcommittee's request and provided their internal testing policies, test results for ingredients and/or finished products, and documentation about what the companies did with ingredients and/or finished products that exceeded their internal testing limits.

In September 2021, a second congressional report, entitled "[\*New Disclosures Show Dangerous Levels of Toxic Heavy Metals in Even More Baby Foods\*](#)" was published by the U.S. House of Representatives Subcommittee on Economic and Consumer Policy Committee on Oversight and Reform.

### **What findings were included in the reports?**

The February 2021 report stated that "according to internal company documents and test results obtained by the Subcommittee, commercial baby foods are tainted with significant levels of toxic heavy metals, including arsenic, lead, cadmium, and mercury."

Of the companies who responded to the Subcommittee's request

- Arsenic, Lead and Cadmium was present in baby foods made by all responding companies.
- Mercury was detected in baby food of the only responding company that tested for it.

### **What recommendations were included in the Congressional Reports?**

The Report highlights the following recommendations from the Subcommittee:

- **Mandatory testing**—Baby food manufacturers should be required by FDA to test their finished products for toxic heavy metals, not just their ingredients.
- **Labeling**—Manufacturers should be required by FDA to report levels of toxic heavy metals on food labels.
- **Voluntary phase-out of toxic ingredients**—Manufacturers should voluntarily find substitutes for ingredients that are high in toxic heavy metals or phase out products that

have high amounts of ingredients that frequently test high in toxic heavy metals, such as rice.

- **FDA standards**—FDA should set maximum levels of toxic heavy metals permitted in baby foods. One level for each metal should apply across all baby foods. And the level should be set to protect babies against the neurological effects of toxic heavy metals.
- **Parental vigilance**—Parents should avoid baby foods that contain ingredients testing high in toxic heavy metals, such as rice products. Instituting recommendations one through four will give parents the information they need to make informed decisions to protect their babies.

### **What was FDA’s response to Congressional Report published by the U.S. House of Representatives Committee on Oversight and Reform Subcommittee on Economic and Consumer Policy?**

In response to the Congressional Report, FDA issued a [letter](#) to baby and toddler food manufacturers and processors covered by the *Preventive Controls for Human Food* rule as a reminder of their existing responsibility to consider risks from chemical hazards, including toxic elements, when conducting a hazard analysis (See 21 CFR 117.130(b)(1)(ii), including for products for babies and young children. The preventive control provisions require industry to implement controls to significantly minimize or prevent any identified chemical hazards requiring a control. For example, some manufacturers may conduct verification activities like testing the final product.

In the [March 5<sup>th</sup>, 2021 Constituent Update](#), and in a [Press Statement](#), FDA announced they plan to take the following actions to reduce toxic elements in food for babies, young children:

- Review current action levels, as well as developing additional action levels, to help make food safer, including finalizing the arsenic in apple juice draft guidance and publishing a draft guidance with action levels for lead in juices.
- Focused compliance and enforcement activities, including inspections.
- Provide guidance to industry on how to meet obligations under current regulations.
- Continue their ongoing surveillance sampling assignment targeting these products.
- Work with federal partners, academia, and other stakeholders to inform the development of action levels of lead, cadmium, mercury, and arsenic in foods for babies and young children.
- Look at additional sources of data and continue to build our understanding of this issue.
- Host a workshop in the coming year to bring together stakeholders to share knowledge on these issues and discuss potential mitigation strategies.

On April 8, 2021, FDA announced the release of their action plan, [Closer to Zero](#), which identifies the approach the Agency plans to take reducing exposure to toxic elements in foods commonly eaten by babies and young children—to the lowest possible levels.

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

“Metals – both beneficial and harmful – are in many foods. This is because our air, water and soil all contain metals (and elements that combine metals and nonmetals called metalloids). The levels found in food depend on many factors, including: growing conditions; industrial, manufacturing, and agricultural processes; the DNA of the food crops; and past or current environmental contamination. In addition, 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.” (FDA: Metals and Your Food: <https://www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food>)

Certain metals, 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 and test for 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).

#### **Metals Tested for in FDA’s Total Diet Study**

##### **Metals with Daily Intake Requirements**

Calcium, Chromium, Copper, Iron, Magnesium, Manganese, Molybdenum, Potassium, Sodium, Zinc

##### **Metals that are Harmful to Health**

Aluminum\*, Antimony\*, Arsenic, Barium\*, Beryllium\*, Cadmium, Lead, Mercury, Silver\*, Strontium, Nickel, Thallium\*, Uranium, Vanadium (\*Tested in bottled drinking water only)

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

For the most part, 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 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.” ([FDA Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed](#))

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

- *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 ([FDA Draft Guidance for Industry: Arsenic in Apple Juice - Action Level](#))
- *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.

**What is the difference between a tolerance and action level?**

According to FDA Guidance ([\*Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed, August 2000\*](#))

"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."

**Additional Background Information**

FDA Metals in Your Food: <https://www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food>