



March 5, 2021

Dear Baby and Toddler Food Manufacturers and Processors:

The U.S. Food and Drug Administration (FDA or “we”) is taking this opportunity to remind all baby and toddler food manufacturers and processors covered by the preventive control provisions of the rule *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food*, issued on September 17, 2015 (80 Fed. Reg. 55908), of your responsibility under the rulemaking to consider chemical hazards that may be present in foods when conducting your hazard analysis. See 21 CFR 117.130(b)(1)(ii). Similarly, baby and toddler food manufacturers covered under other food safety regulations requiring a hazard analysis, such as 21 CFR Parts 120 and 123, should consider chemical hazards that may be present in a food when conducting a hazard analysis. We are reminding you of this responsibility in light of a report released on February 4, 2021, by the U.S. House of Representatives Committee on Oversight and Reform Subcommittee on Economic and Consumer Policy that raises important questions on what more can be done to reduce toxic elements in baby food.

FDA takes exposure to toxic elements in the food supply extremely seriously, especially when it comes to protecting the health and safety of the youngest and most vulnerable in the population. Toxic elements, such as arsenic and lead, are present in the environment and may enter the food supply through soil, water, or air (<https://www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food>). Our goal is to reduce exposure to toxic elements in foods to the greatest extent feasible and to further advance progress in this area through more research and enhanced collaboration among stakeholders.

FDA regulations and monitoring help to ensure the safety of baby and toddler foods sold or manufactured in the United States. However, when the levels of toxic elements or other chemicals in foods do pose a health risk, FDA takes steps to remove those foods from the market. For example, on Jan. 15, 2021, FDA obtained a consent decree from a federal court ordering a U.S. company to stop distributing adulterated juice products containing potentially harmful levels of inorganic arsenic and the mycotoxin patulin until the company complies with the Federal Food, Drug, and Cosmetic Act and other requirements (<https://www.fda.gov/news-events/press-announcements/federal-judge-enters-consent-decree-against-washington-state-juice-processor>). FDA has also worked with several manufacturers whose products contained elevated levels of toxic elements to remove them from the market. In addition, between 2019-2020, approximately 65 import-related actions kept products with potentially elevated levels of toxic elements from entering the U.S. Currently we have multiple [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.

Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1)) provides in part that a food is deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. Information on some potential chemical hazards, including toxic elements,

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mycotoxins, and pesticides, is available on FDA’s website (www.fda.gov), including, for example, here (<https://www.fda.gov/food/chemicals-metals-pesticides-food>). FDA’s *Draft Guidance for Industry on Hazard Analysis and Risk-Based Preventive Controls for Human Food* (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food>) addresses chemical hazards, including hazards such as toxic elements, in Chapter 3: Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food. Although not FDA guidance, Codex Alimentarius also has a General Standard for Contaminants and Toxins in Food and Feed (http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXS%2B193-1995%252FCXS_193e.pdf) and a number of Codes of Practice for prevention and reduction of toxic elements in foods, including a Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice (http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXC%2B77-2017%252FCXC_077e.pdf) and a Code of Practice for the Prevention and Reduction of Lead Contamination in Foods (http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXC%2B56-2004%252FCXP_056e.pdf).

FDA and industry share a common goal of ensuring the safety of food. We appreciate your attention to your obligation to consider potential chemical hazards, including toxic elements, when conducting a hazard analysis.

Sincerely,

A handwritten signature in black ink that reads "Susan T. Mayne". The signature is fluid and cursive, with a long horizontal line extending to the right.

Susan T. Mayne, Ph.D., F.A.C.E.
Director
Center for Food Safety and Applied Nutrition