

Action Levels for Lead in Processed Food Intended for Babies and Young Children: Guidance for Industry

You can comment on any guidance at any time (see 21 CFR 10.115(g)(5)). Submit electronic comments to <http://www.regulations.gov>. Submit written comment to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2022-D-0278 and with the title of the guidance document.

For questions regarding this document, contact the Human Foods Program at HFP-Policy@fda.hhs.gov.

Additional copies are available at <https://www.fda.gov/FoodGuidances>.

**U.S. Department of Health and Human Services
Food and Drug Administration
Human Foods Program**

January 2025

Table of Contents

I. Introduction	3
II. Background	4
III. Lead Levels Found in Processed Food Intended for Babies and Young Children	6
A. Products and Data Included in the Evaluation of Lead in Processed Food Intended for Babies and Young Children	6
B. Toxic Elements Program and FDA Survey Data	7
C. Total Diet Study Data.....	8
D. Summary of FDA Data	8
IV. FDA’s Action Levels for Lead in Processed Food Intended for Babies and Young Children	8
A. Exposure Assessment.....	10
B. Achievability Assessment	10
C. Action Levels	11
V. Conclusion.....	12
VI. References	12
VII. Tables	15

Action Levels for Lead in Processed Food Intended for Babies and Young Children: Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

FDA is committed to reducing lead in food. FDA's *Closer to Zero* initiative is a science-based, iterative approach to decreasing toxic elements, including lead, in foods over time, including by setting action levels. The purpose of this guidance is to provide information to industry on the action levels for lead in processed food intended for babies and young children (i.e., those less than two years old). FDA considers the action levels described in this guidance to be achievable by industry when control measures are taken to minimize the presence of lead. Although action levels are levels at which FDA may regard a food as adulterated, our *Closer to Zero* initiative outlines other actions we will take to further reduce lead (as well as other toxic elements) in food and our expectation is that industry will strive for continual reductions over time.

Additionally, this document presents the background and rationale for FDA's action levels for lead in processed food intended for babies and young children. Processed food in this guidance refers to packaged food (e.g., in jars, pouches, tubs, or boxes) represented or purported to be for babies and young children less than two years old. It may include ready-to-eat foods (e.g., purees) as well as semi-prepared foods (i.e., dry infant cereals).²

The action levels for processed foods intended for babies and young children are as follows:

¹ This guidance has been prepared by the Office of Food Chemical Safety, Dietary Supplements, and Innovation; Office of Post-Market Assessment; Division of Chemical Contaminants and the Office of Policy, Regulations, and Information in the Human Foods Program at the U.S. Food and Drug Administration.

² As used in this guidance document, processed food intended for babies and young children does not include raw agricultural commodities, homemade foods (e.g., fruit purees prepared at home), or snack foods, including grain-based or freeze-dried snacks (e.g., arrowroot cookies, puffs, rusks, teething biscuits). FDA is continuing to collect additional data on grain-based snacks to inform whether an action level would be appropriate. This guidance does not apply to infant formula or any beverages, including toddler drinks. Action levels for lead in juices are addressed in a separate draft guidance, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-juice>.

Contains Nonbinding Recommendations

- 10 parts per billion (ppb³) for fruits, vegetables (excluding single-ingredient root vegetables), mixtures (including grain- and meat-based mixtures), yogurts, custards/puddings, and single-ingredient meats;
- 20 ppb for single-ingredient root vegetables;⁴ and
- 20 ppb for dry infant cereals.⁵

Consistent with 21 CFR 109.6(d), these action levels reflect levels of lead at which FDA may regard the food as adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). We intend to consider these action levels, in addition to other factors, such as our confidence in a measured analytical value, when considering whether to bring enforcement action in a particular case.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

The action levels in this guidance are not intended to direct consumers in making food choices. To support child growth and development, we recommend parents and caregivers feed children a varied and nutrient-dense diet across and within the main food groups of vegetables, fruits, grains, dairy, and protein foods.

II. Background

Lead is toxic to humans and can affect people of any age or health status. Lead is especially harmful to vulnerable populations, including infants, young children, women who are pregnant and their developing fetuses, and others with chronic health conditions. Even low lead exposure can harm children's health and development, specifically the brain and nervous system. Neurological effects of lead exposure during early childhood include learning disabilities, behavioral difficulties, and lowered IQ. Lead exposures also may be associated with immunological, cardiovascular, renal, and reproductive and/or developmental effects (Ref. 1). Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time (Ref. 2).

Lead is widely present in the environment due to both its natural occurrence and to human activities that have introduced it into the environment. Because lead may be present in environments where food crops used to make processed food intended for babies and young

³ Parts per billion (ppb) equals micrograms/kilogram (µg/kg).

⁴ The term "single-ingredient root vegetables" means a food that consists of either carrots or sweet potatoes, with or without additional ingredients such as water or preservatives. For example, a puree that consists of sweet potatoes, water, and ascorbic acid would be a "single-ingredient root vegetable." A puree that consists of carrots, white potatoes, and water would be a "mixture" and not a "single-ingredient root vegetable." Similarly, a puree that consists of sweet potatoes and apples would be a "mixture" and not a "single-ingredient root vegetable."

⁵ "Dry infant cereals" includes dried cereals without additions as well as dried cereals containing dried fruits or vegetables (e.g., apple, banana, carrot).

Contains Nonbinding Recommendations

children are grown, various foods may contain small amounts of lead. Potential sources of lead in food include contaminated soil, contaminated water, atmospheric deposition from industrial activities and old lead-containing equipment used to process food. As a result of the first three sources, agricultural crops (e.g., root vegetables) can take up lead from contaminated soil, water, and air, and contaminated soil may be deposited on plant surfaces (e.g., on leafy vegetables and cereal grains). Studies suggest that manufacturers may be able to reduce lead levels in food by using practices such as thoroughly peeling root vegetables and thoroughly washing fruits and vegetables, particularly leafy vegetables (Refs. 3, 4, 5, 6). It is possible in some cases for manufacturers who have found elevated lead levels in sources of food intended for babies and young children to choose sources of food or food ingredients with lower lead levels or no detectable lead. Manufacturers should conduct increased testing of foods that are historically known to contain elevated lead levels; this is particularly important for ingredients or processed foods intended for babies and young children. Additionally, manufacturers should examine and modify their facilities, processes, and equipment to ensure that they are not contributing to lead in their products (Refs. 7, 8).

In 1999, the Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) released a toxicological assessment for lead, which maintained the provisional tolerable weekly intake (PTWI) for lead of 25 micrograms per kilogram body weight ($\mu\text{g}/\text{kg bw}$) but noted that foods with high levels of lead remain in commerce (Ref. 9).

In 2011, JECFA reassessed the safety of lead and withdrew the PTWI for lead. JECFA further concluded that “it was not possible to establish a new PTWI [for lead] that would be considered to be health protective” (Ref. 9). JECFA concluded that in populations with prolonged dietary exposures to higher levels of lead, measures should be taken to identify major contributing sources and, if appropriate, to identify methods for reducing dietary exposure that are commensurate with the level of risk reduction (Ref. 9).

No safe level of lead exposure has been identified for protecting children’s health. In 2018, to determine if the amount of exposure to lead in food is a potential health concern, FDA developed interim reference levels (IRLs) of 3 $\mu\text{g}/\text{day}$ for children and 12.5 $\mu\text{g}/\text{day}$ for women of childbearing age (WOCBA). The IRLs replaced higher FDA provisional tolerable total daily intakes (PTTDIs), which had been developed in the early 1990s. FDA updated the IRLs in 2022 to derive IRLs of 2.2 $\mu\text{g}/\text{day}$ for children and 8.8 $\mu\text{g}/\text{day}$ for WOCBA, respectively (Ref. 2). The IRL for WOCBA is protective against possible fetal lead exposure in women who are pregnant and women not yet aware that they are pregnant (Ref. 2).

The IRL is based on the Centers for Disease Control and Prevention’s (CDC) blood lead reference value (BLRV) of 3.5 $\mu\text{g}/\text{deciliter (dL)}$ and dietary conversion factors (Refs. 2, 10). The CDC BLRV is a screening tool used to identify children who have higher levels of lead exposure and it represents the level at which CDC recommends public health interventions should be initiated.⁶ The IRL includes an additional 10x safety factor to account for variability

⁶ The BLRV is based on current blood lead levels found in children, not what is considered safe. The value is based on the 97.5th percentile of the blood lead distribution in U.S. children ages 1–5 years. This is a population-based

Contains Nonbinding Recommendations

in the conversion of dietary lead to blood lead level. Although no safe level of lead exposure has been identified for children's health, the IRL serves as a useful benchmark in evaluating the potential for adverse effects of dietary lead exposure, such as the potential for neurodevelopmental effects.

In 2021, FDA initiated *Closer to Zero* to identify actions we will take to reduce exposure to toxic elements, including lead, from foods eaten by babies and young children to as low as possible while maintaining access to nutritious foods (Ref. 11). The plan outlines an iterative approach for achieving continual improvements over time, reducing children's exposure to lead and other toxic elements from food through activities such as setting action levels. The plan commits to consulting with stakeholders, including on the achievability of reducing toxic element levels in foods intended for babies and young children, and notes the importance of minimizing the potential for unintended consequences on the availability of nutritious foods for children. FDA intends to update the IRL and this guidance if, for example, CDC updates its BLRV or if other scientific information becomes available which could help us refine our IRL. Updates to the IRL will result in an evaluation of the lead action levels to determine whether the levels continue to be appropriate.

Under the *Closer to Zero* initiative, this guidance addresses processed foods intended for babies and young children (i.e., those less than two years old). In developing the action levels for these foods, we want to ensure that dietary exposure from the identified foods does not cause consumers to exceed the IRL. To do this, we consider intake of the food and the maximum level of lead that could be in the food without causing the IRL to be exceeded. We consider intake at the 90th percentile consumption level for the food/food category. By doing this, we account for consumers with higher intakes. Our action levels also reflect the considerations discussed below.

III. Lead Levels Found in Processed Food Intended for Babies and Young Children

A. Products and Data Included in the Evaluation of Lead in Processed Food Intended for Babies and Young Children

FDA routinely monitors lead in food consumed by babies and young children through our Toxic Elements in Food and Foodware and Radionuclides in Food – Import and Domestic Compliance Program (the Toxic Elements Program or TEP),⁷ special FDA surveys,⁸ and the Total Diet Study (TDS).⁹ The TEP is a targeted monitoring program that monitors levels of certain toxic

value representing that 2.5% of the U.S. population of children has blood lead levels at or above 3.5ug/L. It is not a threshold for toxicity/adversity.

⁷ <https://www.fda.gov/food/chemical-contaminants-pesticides/toxic-elements-foods-and-foodware>

⁸ FY 2021: <https://www.fda.gov/media/164565/download>, FY 2023: <https://www.fda.gov/media/184799/download?attachment>.

⁹ <http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/default.htm>.

Contains Nonbinding Recommendations

elements, including lead, in foods and foodware.¹⁰ Foods selected for analysis include those that are suspected of having elevated levels of toxic elements based on historical data or other information available to us. For lead analysis under the TEP, we place particular emphasis on foods consumed by babies and young children, who are especially sensitive to lead's adverse health effects because of their smaller body sizes and rapid development. We augment TEP collections by periodically conducting surveys to collect and analyze toxic elements in foods of interest, in this case, processed foods for babies and young children. The TDS is an ongoing market basket study representative of the U.S. diet that includes analysis of toxic elements such as lead.

As part of our evaluation, we examined the TEP data collected between fiscal years (FY) 2009 through 2024, FDA survey data collected in FY 2013-14, FY 2021, and FY 2023 (Tables 1 and 2), and TDS data collected between FY 2014-2020 (Table 3) to determine current lead levels in processed foods intended for babies and young children. We then evaluated the ability of industry to achieve lower lead levels, using the TEP data and FDA survey data in an achievability assessment (Section IV). We also reviewed the TDS data as a complementary analysis.

B. Toxic Elements Program and FDA Survey Data

The 1,452 TEP (Ref. 12) and survey samples (Refs. 13, 14, 15) include U.S. domestic and imported products and consist of processed foods intended for babies and young children. To analyze these data for purposes of this guidance, we have separated these processed foods into the following food categories for babies and young children: dry infant cereals (e.g., rice, wheat, and multi-grain cereals); fruits (single-ingredient or combination); vegetables (single-ingredient or combination); mixtures (any combination of fruits, vegetables, grain, and meat); yogurts, custards/puddings, and single-ingredient meats (Table 1).¹¹

Table 2 shows the mean, standard deviation, and 90th and 95th percentiles of lead concentrations for each of the processed food categories for babies and young children. Lead concentrations varied among the food categories. Fruits and mixtures had low lead levels, with means of 1.2 ppb and 2.7 ppb and 90th-95th percentiles of 2.4-4.1 ppb and 6.0-9.1 ppb, respectively. Yogurts, custards/puddings, and single-ingredient meats similarly had low lead levels, with a mean of 1.1 ppb and 90th-95th percentiles of 2.6-2.9 ppb. Vegetables had a mean lead level of 4.5 ppb and 90th-95th percentiles of 11.4-18.6 ppb. When single-ingredient root vegetables were placed in a separate category, the vegetables category had a lower mean and lower 90th-95th percentiles of 2.1 ppb and 4.2-7.0 ppb, respectively. Single-ingredient root vegetables had a mean of 8.2 ppb and 90th-95th percentiles of 20.9-23.9 ppb.

Dry infant cereals had lead concentrations with a mean of 7.8 ppb and 90th-95th percentiles of 20.0-23.0 ppb.

¹⁰ FDA uses an inductively coupled plasma mass spectrometry (ICPMS) method to determine lead in food (<https://www.fda.gov/media/87509/download>). Samples were analyzed as sold. The Toxic Elements Program stipulates that samples should consist of twelve randomly selected subsamples from a single lot.

¹¹ Between the issuance of the draft and final guidances, sample size increased by 594 samples.

C. Total Diet Study Data

From FY 2014 to FY 2020, we collected and analyzed 689 samples of processed foods intended for babies and young children under the TDS program.¹² Most TDS samples are not samples of individual foods; they are composites (“averages”) of three retail samples of the same product, all from different cities. Because the compositing provides an “average” result, and our achievability analysis is based on percentiles of lead concentrations in individual samples, we did not use the TDS data in the achievability assessment. The types of baby foods analyzed included dry infant cereals, fruits (single-ingredient or combination), vegetables (single-ingredient or combination), mixtures (any combination of fruits, vegetables, grains, and meat), yogurts, custard/puddings, and single-ingredient meats.¹³ All food categories had mean lead concentrations well below 10 ppb, with the exception of root vegetables, which had a mean concentration of 11.6 ppb (Table 3). As with the TEP and FDA survey data, lower mean lead levels were observed for fruits, mixtures, yogurts, custards/puddings, and single-ingredient meats. Dry infant cereal samples from the TDS had lower mean lead levels than samples from the TEP and FDA survey data.

D. Summary of FDA Data

FDA’s review of data indicates that different types of processed food intended for babies and young children exhibit different lead concentrations (Tables 2 and 3). In addition, for the TEP and survey data, 90 percent of all processed food samples had lead levels lower than 10 ppb, while for the TDS data, 94 percent of all processed food samples had lead levels lower than 10 ppb (Tables 2 and 3). The mean lead levels for the categories of food intended for babies and young children were below 10 ppb (Tables 2 and 3) except for single-ingredient root vegetables (Table 3).

IV. FDA’s Action Levels for Lead in Processed Food Intended for Babies and Young Children

When evaluating possible action levels under 21 CFR 109.6 for lead in processed foods intended for babies and young children less than two years old, we took into account several considerations, including:

- the action level should minimize the likelihood that a consumer will be exposed to lead levels exceeding the IRL;
- as appropriate, there should be a limited number of unique action levels for simplicity;
- the action levels should result in a reduction in exposure to lead; and

¹² TDS results can be found online at: <https://www.fda.gov/food/total-diet-study/analytical-results-total-diet-study>.

¹³ Infant formula and bottled water labeled for infants are also collected through the TDS program but were not included in this analysis. TDS infant formula data collected through the TDS program indicate that the majority of samples collected contain no measurable concentration of lead (<limit of detection, which is 4.0 ppb).

Contains Nonbinding Recommendations

- for those baby foods where lead levels are already relatively low, the action levels should be established where achievability is near the 90th-95th percentile range.¹⁴

Based on these considerations, the applicable criteria in 21 CFR 109.6, and analysis of the data, we identified the following action levels for lead in processed food intended for babies and young children:

- 10 ppb for fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats;
- 20 ppb for single-ingredient root vegetables; and
- 20 ppb for dry infant cereals.

For fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats, all of which have low lead levels, action levels can be established at 10 ppb. Fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats tend to have lower levels of lead compared to single-ingredient root vegetables and dry infant cereals. We expect the action level of 10 ppb will reduce dietary exposure to lead and have an achievability rate of 97%.

Based on data used in this analysis, single-ingredient root vegetable products have higher lead levels than other processed vegetable foods (Table 2). These root vegetables can absorb lead more readily from the soil than other crops (Ref. 16). Moreover, at an action level of 10 ppb (the action level provided in this guidance for other vegetable products), the processed single-ingredient root vegetable achievability was 79%. For single-ingredient root vegetables, we expect that an action level of 20 ppb will help minimize the likelihood of significant exposure to lead, while also considering achievability. At the action level of 20 ppb, single-ingredient root vegetables have an achievability rate of 88%. Root vegetables are a source of several nutrients important in growth and development for babies and young children, and a lower action level could reduce the availability of single-ingredient root vegetable foods on the market intended for infants and young children. Therefore, we consider it appropriate to place single-ingredient root vegetables in their own category.

In evaluating data about the likelihood that a consumer will be exposed to lead levels exceeding the IRL, we also weighed certain product-specific considerations. For example, dry infant cereal is often the first food introduced to an infant population and may be the only solid food consumed for an extended period of time during a critical period of development. With these considerations in mind, we set an action level for dry infant cereal that aims to reduce dietary lead exposure while also considering achievability. At the action level of 20 ppb, dry infant cereals have an achievability rate of 91%.

¹⁴ This approach is consistent with the approach followed for setting international standards and the approach FDA has taken with respect to action levels for lead in other foods, as appropriate. The Codex Committee on Contaminants in Foods has used an achievability estimate of about 95% to recommend reductions in maximum levels (MLs) for lead in juices when more than 95% of the samples traded internationally had lead concentrations at or below proposed new MLs. FDA has used a similar approach in developing action levels for lead in juice, see <https://www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/draft-supporting-document-establishing-fdas-action-levels-lead-juice>.

Contains Nonbinding Recommendations

We discuss the exposure assessment and achievability assessments used to support these action levels in more detail below.

A. Exposure Assessment

To examine the effect of the action levels for processed food intended for babies and young children on lead exposure, we compared the estimated concentration of lead in these foods and dietary exposure to lead from these foods with and without the action levels. As shown in Table 4, the mean concentrations of lead and the 90th percentile dietary exposures from the processed foods for babies and young children (0-23 months) in the absence of the action levels are as follows:

- fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats (2.2 ppb, 0.78 µg/day);
- single-ingredient root vegetables (8.2 ppb, 0.87 µg/day); and
- dry infant cereals (7.8 ppb, 0.30 µg/day).

The upper bound percentile (90th percentile) was chosen as a health protective measure to account for babies and young children (0-23 months) who consume larger amounts of food per unit body weight and would therefore have potentially higher exposures. As shown in Table 4, for Scenario A (status quo), the 90th percentile dietary exposures for babies and young children for each food category are below the IRL for lead of 2.2 µg/day for children. For scenario B, removing all samples with lead concentrations greater than the action levels in this document from the datasets results in a decrease in the estimated mean lead concentrations and the estimated dietary exposures from these foods. The estimated mean lead concentrations and 90th percentile dietary exposures from the processed foods are as follows:

- fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats (1.7 ppb, 0.61 µg/day);
- single-ingredient root vegetables (5.8 ppb, 0.62 µg/day); and
- dry infant cereals (6.0 ppb, 0.23 µg/day).

The action levels for lead are estimated to result in the following reductions in lead exposure from consumption of these processed foods at the 90th percentile consumption level for babies and young children:

- fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats (19%);
- single-ingredient root vegetables (29%); and
- dry infant cereals (24%).

B. Achievability Assessment

To assess achievability, or manufacturers' ability to achieve the action levels for lead, we determined the percentage of samples in each food category that fell at or below the action levels. The achievability for each processed food category at the action levels is near the 90% - 95% range:

Contains Nonbinding Recommendations

- 97% for fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats, at 10 ppb;
- 88% for single-ingredient root vegetables, at 20 ppb; and
- 91% for dry infant cereals, at 20 ppb (Table 4).

In summary, for the combined category of processed fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats, an action level of 10 ppb reduces dietary exposure to lead for babies and young children by 19% at the 90th percentile consumption level and has an achievability of 97%.

An action level of 20 ppb for single-ingredient root vegetables reduces dietary exposure to lead for babies and young children by 29% at the 90th percentile consumption level and has an achievability of 88%.

An action level of 20 ppb for dry infant cereals reduces dietary exposure to lead for babies and young children by 24% at the 90th percentile consumption level and has an achievability of 91%.

C. Action Levels

Based on our review of lead levels in processed foods intended for babies and young children that we collected from FY 2009 to FY 2024, in consideration of the IRL for lead of 2.2 µg/day for children (as shown in Table 4), and in accordance with 21 CFR 109.6, we are establishing the following action levels for lead in processed foods for babies and young children:

- 10 ppb for fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats;
- 20 ppb for single-ingredient root vegetables; and
- 20 ppb for dry infant cereals.

Though not binding, these action levels are intended to encourage manufacturers to maintain lead levels in processed food intended for babies and young children below the action levels, thus reducing risks associated with dietary lead exposures. The establishment of these action levels for lead in processed food intended for babies and young children in this guidance is consistent with FDA's longstanding policy of reducing consumers' lead exposure. The action is focused on certain processed foods intended for babies and young children, who are more sensitive than adults to the neurodevelopmental effects of lead exposure.

Consistent with 21 CFR 109.6(d), these action levels reflect levels of lead at which FDA may regard the food as adulterated within the meaning of section 402(a)(1) of the FD&C Act. We intend to consider these action levels, in addition to other factors, such as our confidence in a measured analytical value, when considering whether to bring enforcement action in a particular case.

We have consulted with the United States Department of Agriculture Food Safety Inspection Service (FSIS) on the inclusion of single-ingredient meats and mixtures that include meats as an

Contains Nonbinding Recommendations

ingredient in this guidance. FSIS supports the action levels developed by FDA and intends to consider these action levels, in addition to other factors, when considering appropriate FSIS actions in a particular case.

FDA recommends that the industry producing the foods in this guidance continue to work to lower the lead concentrations in these products to the greatest extent possible under current good manufacturing practices. As part of our *Closer to Zero* initiative, we intend to further engage with stakeholders on proposed action levels for other toxic elements in foods intended for babies and young children, including the achievability of such levels, and the feasibility of further reducing the presence of lead in food. We plan to monitor the levels of lead in food and children's exposure to lead from food to assess whether to adjust the action levels for the processed foods intended for babies and young children described in this guidance, or whether to add additional foods or food categories for babies and young children to this guidance as new information becomes available.

V. Conclusion

The action levels are part of our efforts under the *Closer to Zero* initiative to reduce exposure to toxic elements from foods eaten by babies and young children to the lowest possible levels, while maintaining access to nutritious foods. In our experience, action levels have been effective tools for encouraging manufacturers to lower the levels of contaminants in their products. We established these action levels in consideration of our IRLs for dietary lead, and the action levels are achievable by industry when control measures are taken to minimize the presence of lead.

We intend to consider the action levels as an important source of information for determining whether a food for babies and young children is adulterated within the meaning of section 402(a)(1) of the FD&C Act. FDA considers on a case-by-case basis whether a food that contains a contaminant is adulterated. When considering whether to bring an enforcement action in a particular case, we will consider whether the lead causes a particular food to be adulterated under section 402(a)(1) of the FD&C Act.

VI. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them in person at this location between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. *HHS, National Toxicology Program, 2012. NTP Monograph on Health Effects of Low-Level Lead. Available at:

Contains Nonbinding Recommendations

https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffects/lowlevellead_new/issn_508.pdf.

2. Flannery, B.M., Middleton, K.B. 2022. Updated Interim Reference Levels for Dietary Lead to Support FDA's Closer to Zero Action Plan. *Reg. Toxicol. Pharmacol.*, 133.
3. Kolasinac, S.M., Lekić, S. S., Golijan, J. *et al.* 2018. Bioaccumulation Process and Health Risk Assessment of Toxic Elements in Tomato Fruit Grown under Zn Nutrition Treatment. *Environmental Monitoring and Assessment*, 190; 508.
4. *Office of Solid Waste and Emergency Response, U.S. Environmental Protection Agency, 2014. Technical Review Workgroup Recommendations Regarding Gardening and Reducing Exposure to Lead-Contaminated Soils. Available at: <https://semspub.epa.gov/work/HQ/174577.pdf>.
5. Huang, F., Zhou H., Gu, J., *et al.* 2020. Differences in Absorption of Cadmium and Lead Among Fourteen Sweet Potato Cultivars and Health Risk Assessment. *Ecotoxicology and Environmental Safety*, 203; 111012.
6. Entwistle, J. A., Amaibi, P. M., Dean, J. R., *et al.*, 2019. An Apple a Day? Assessing Gardeners' Lead Exposure in Urban Agriculture Sites to Improve the Derivation of Soil Assessment Criteria. *Environmental International*, 122; 130-141.
7. Codex Alimentarius, 2021. Revision of the Code of Practice for the Prevention and Reduction of Lead Contamination in Foods. Available at: <https://www.fao.org/3/cc0579en/cc0579en.pdf>.
8. *FDA, 2024. Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Available at: <https://www.fda.gov/media/100002/download>.
9. *FAO/WHO Joint Expert Committee on Food Additives, 2011. Evaluation of Certain Contaminants in Food, 73rd Report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series 960. Available at: https://apps.who.int/iris/bitstream/handle/10665/44515/WHO_TRS_960_eng.pdf?sequence=1.
10. Flannery, B. M., Dolan, L.C., Hoffman-Pennesi, D., *et al.* 2020. U.S. Food and Drug Administration's interim reference levels for dietary lead exposure in children and women of childbearing age. *Regulatory Toxicology Pharmacology*, 110; 104516.
11. *FDA, 2024. Closer to Zero: Reducing Childhood Exposure to Contaminants from Foods. Available at: <https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods>.
12. *FDA, 2024. Analytical Results for Arsenic, Lead, Cadmium, and Mercury in Food Intended for Babies and Young Children Sampled under the FDA's Toxic Elements in Food and Foodware and Radionuclides in Food – Import and Domestic Compliance Program, FY 2009 to FY 2024. Available at: <https://www.fda.gov/media/164564/download>.
13. *FDA Survey FY 2013-14. Available at: <https://www.fda.gov/food/metals-and-your-food/combo-combination-metals-testing>.
14. *FDA Survey FY 2021. Analytical Results for Lead in Food Intended for Babies and Young Children, FY2021. Available at: <https://www.fda.gov/media/164565/download>.
15. *FDA Survey FY 2023. Analytical Results for Lead in Processed Food Intended for Babies and Young Children, FY 2023. Available at: <https://www.fda.gov/media/184799/download?attachment>.

Contains Nonbinding Recommendations

16. *Pourrut, B., Shahid M., Dumat C., Winterton P., Pinelli E., 2011. Lead uptake, toxicity, and detoxification in plants. *Reviews of Environmental Contamination and Toxicology*, 213:113-136.

VII. Tables

- Table 1. Summary of Data Used in Analysis of Lead in Processed Foods Intended for Babies and Young Children
- Table 2. Analysis of Lead Data from the Toxic Elements Program and FDA Surveys by Category of Processed Foods Intended for Babies and Young Children
- Table 3. Analysis of Lead Data from the Total Diet Study (FY2014-2020) by Category of Processed Foods Intended for Babies and Young Children
- Table 4. Action Levels, Achievability, Mean Lead Concentrations, and 90th Percentile Lead Exposures from Processed Food Consumption for Babies and Young Children, With and Without Action Levels

Table 1. Summary of Data Used in Analysis of Lead in Processed Foods Intended for Babies and Young Children

Data Set	Fiscal Year	Number of Samples	Food Categories for Babies and Young Children
Toxic Elements Program (TEP)	2009-2024 ¹⁵	505	dry infant cereals, fruits, mixtures, vegetables, yogurts, custards/puddings
FDA Survey 1	2013-14 ¹⁶	147	dry infant cereals, mixtures
FDA Survey 2	2021 ¹⁷	414	fruits, mixtures, vegetables, yogurts, custards/puddings, single-ingredient meats
FDA Survey 3	2023 ¹⁸	386	dry infant cereals, fruits, mixtures, vegetables, yogurts, custards/puddings, single-ingredient meats

¹⁵ Available at <https://www.fda.gov/media/164564/download>.

¹⁶ These FDA survey data are available at: <https://www.fda.gov/food/metals-and-your-food/combination-metals-testing>.

¹⁷ Available at <https://www.fda.gov/media/164565/download>.

¹⁸ Available at <https://www.fda.gov/media/184799/download?attachment>.

Contains Nonbinding Recommendations

Table 2. Analysis of Lead Data from the Toxic Elements Program and FDA Surveys by Category of Processed Foods Intended for Babies and Young Children

Processed Food Category for Babies and Young Children	Number of Samples	Mean \pm std. dev (ppb)	90th Percentile (ppb)	95th Percentile (ppb)
Fruits (single-ingredient or combination)	215	1.2 \pm 1.4	2.4	4.1
Mixtures	551	2.7 \pm 4.0	6.0	9.1
Yogurts, custards/puddings, single-ingredient meats	55	1.1 \pm 1.0	2.6	2.9
Vegetables (single ingredient or combination)	220	4.5 \pm 6.1	11.4	18.6
Vegetables (single-ingredient or combination excluding single-ingredient root vegetables)	130	2.1 \pm 2.6	4.2	7.0
Single-ingredient root vegetables	90	8.2 \pm 7.8	20.9	23.9
Dry infant cereals	411	7.8 \pm 8.4	20.0	23.0

Table 3. Analysis of Lead Data from the Total Diet Study (FY2014-2020)¹⁹ by Category of Processed Foods Intended for Babies and Young Children

Processed Food Category for Babies and Young Children	Number of Samples	Mean \pm std. dev (ppb)
Fruits (single type or combination)	228	0.17 ± 0.91
Mixtures	213	2.4 ± 3.9
Yogurts, custards/puddings, single-ingredient meats	83	0.49 ± 3.4
Vegetables (single type or combination)	139	4.9 ± 7.0
Vegetables (single type or combination excluding single-ingredient root vegetables products)	89	1.1 ± 2.3
Single-ingredient root vegetables	50	11.6 ± 7.6
Dry infant cereals	23	2.6 ± 2.9

¹⁹ In 2018, the TDS sampling protocol was changed. See <http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/default.htm>. In 2019, 241 samples of baby food were collected as part of a special TDS sampling assignment.

Table 4. Action Levels, Achievability, Mean Lead Concentrations, and 90th Percentile Lead Exposures from Processed Food Consumption for Babies and Young Children, With and Without Action Levels

Processed Food Category for Babies and Young Children	Action Level	Achievability	90 th Percentile 2-day Average Intake, Eaters Only, 0-23 mo ²⁰	Scenario A: No Action Level Estimated Mean Pb Concentration	Scenario A: No Action Level Estimated Pb Exposure from Baby Food at the 90 th Percentile ²¹	Scenario B: With Action Level Estimated Mean Pb Concentration ²²	Scenario B: With Action Level Estimated Pb Exposure from Baby Food at the 90 th Percentile ²⁰	Reduction in Exposure at the 90 th Percentile ²³
	ppb	%	g/day	ppb	µg/day	ppb	µg/day	%
Fruits, vegetables (excluding single-ingredient root vegetable products), mixtures, yogurts, custards/puddings, single-ingredient meat	10	97	354	2.2	0.78	1.7	0.61	19
Single-ingredient root vegetables	20	88	106	8.2	0.87	5.8	0.62	29
Dry infant cereals	20	91	39	7.8	0.30	6.0	0.23	24

²⁰ Estimates are for eaters only, 90th percentile of the 2-day average consumption of each food category for babies and young children, 0-23 months, using baby food consumption data from What We Eat in America (WWEIA), the food consumption portion of the National Health and Nutrition Examination Survey (NHANES), 2003-2018. The term “eaters only” for the purposes of this data set means individuals from the survey that consumed this product to calculate intake.

²¹ Exposure estimates were calculated based on lead concentration data from the TEP and FDA survey data, and on baby food consumption data from What We Eat in America (WWEIA), the food consumption portion of the National Health and Nutrition Examination Survey (NHANES), 2003-2018. Estimates are for eaters only, 0-23 months. (Concentration in sample (µg/kg) * 1 kg/1000 g conversion factor * upper-level consumption (g/day) = estimated exposure (µg/day).) The 90th percentile dietary exposures for babies and young children are below the IRL for lead of 2.2 µg/day for children.

²² Mean lead concentrations in Scenario B were calculated after removal of the TEP and FDA survey data for samples with concentrations above the action level.

²³ Calculated as ((lead exposure under Scenario A- lead exposure under Scenario B) / lead exposure under Scenario A) * 100. Calculations are based on unrounded data.