Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments 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 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

January 2023

Table of Contents

I. INTRODUCTION 3

II. BACKGROUND 4

III. LEAD LEVELS FOUND IN FOOD INTENDED FOR BABIES AND YOUNG CHILDREN 6

A. Products and Data Included in the Evaluation of Lead in Food Intended for Babies and Young Children 6

B. Toxic Elements Program and FDA Survey Data 6

C. Total Diet Study Data 7

D. Summary of FDA Data 8

IV. FDA'S ACTION LEVELS FOR LEAD IN FOOD INTENDED FOR BABIES AND YOUNG CHILDREN 8

A. Exposure Assessment 9

B. Achievability Assessment 10

V. CONCLUSION 11

VI. REFERENCES 12

VII. TABLES 14

Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA or we) on this topic.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 at the phone number listed on the title page.

I. Introduction

FDA is committed to reducing lead in food. FDA's *Closer to Zero* action plan 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 food intended for babies and young children. 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* action plan 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 will present the background and rationale for FDA's action levels for lead in processed food intended for babies and young children:[2]

- 10 parts per billion (ppb) 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 root vegetables (single ingredient); and
- 20 ppb for dry infant cereals.

[1] This guidance has been prepared by the Office of Food Safety, Division of Plant Products and Beverages in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] Processed food intended for babies and young children refers to food packaged in jars, pouches, tubs, and boxes represented or purported to be specifically 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). It does not include raw agricultural commodities or homemade foods (e.g., fruit purees prepared at home). This guidance does not apply to infant formula, or any beverages, including toddler drinks. 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.

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.

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, people who are pregnant and their 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, behavior 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 food intended for babies and young children are grown, various foods may contain small amounts of lead. Potential sources of lead in food include contaminated soil where crops are grown, 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 and contaminated soil may be deposited on plant surfaces (e.g., 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 could also consider increased testing of ingredients or finished products that are historically known to contain elevated lead levels; this is particularly important for ingredients or finished products intended for babies and young children. Additionally, manufacturers could consider examining their facilities, processes, and equipment to ensure that they are not contributing to lead in their products (Refs. 7, 8).

In 1999, the Joint World Health Organization (WHO)/Food and Agriculture Organization (FAO) 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 (µg/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. 7). 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. To help assess risk from lead, in 2018, FDA developed interim reference levels (IRLs) for dietary lead to replace FDA provisional tolerable total daily intakes (PTTDIs), which had been developed in the early 1990s. FDA updated the IRLs in 2022 (Ref. 2), using the Centers for Disease Control and Prevention's (CDC) updated blood level reference value (BLRV) of 3.5 µg/deciliter (dL) blood lead level and dietary conversion factors calculated by the Environmental Protection Agency to derive IRLs of 2.2 µg/day for children and 8.8 µg/day for women of child-bearing age (WOCBA), respectively. The IRL for WOCBA is protective against possible fetal lead exposure in women who are not yet aware that they are pregnant (Ref. 2).

The IRL is tied to a biological marker of exposure (blood lead levels) and represents the dietary lead needed to achieve a blood lead level 10 times lower than that associated with the CDC's BLRV. The CDC BLRV is a screening tool used to identify children who have higher levels of lead exposure and represents the level at which public health interventions should be initiated. The IRL represents the maximum daily dietary intake of lead from food that corresponds to the CDC's BLRV of 3.5 ug/dl, with an additional 10x safety factor applied. Even though no safe level of lead exposure has yet been identified for children's health, the IRL serves as a useful benchmark in evaluating the potential for adverse effects of dietary lead. In particular, FDA is focused on the potential for neurodevelopmental effects from lead exposure, as review of the scientific literature indicates that such adverse effects of lead consistently occur at a blood lead level associated with FDA's IRL for children.

In 2021, FDA initiated the *Closer to Zero* action plan that identifies 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 (Ref. 10). 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. We will identify IRLs for certain toxic elements as appropriate and may use the IRLs to help inform the development of 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.

As the next step toward developing action levels under the *Closer to Zero* action plan, this guidance evaluates processed foods intended for babies and young children. 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 high intake in our analysis of what the maximum lead level could be in the food without causing the consumer to be exposed to lead levels exceeding the IRL. Our proposed action levels also reflect the considerations discussed below.

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

A. Products and Data Included in the Evaluation of Lead in 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),[3] special FDA surveys, and the Total Diet Study (TDS).[4] The TEP is a targeted monitoring program that monitors levels of certain toxic elements, including lead, in foods and foodware. 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, 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) 2008 through 2021, FDA survey data collected in FY 2013-14 and FY 2021 (Tables 1 and 2), and TDS data collected between FY 2014-20 (Table 3) to determine current lead levels in foods intended for babies and young children. We then evaluated the ability of industry to achieve lower lead levels, using TEP data and FDA survey data. We also reviewed the TDS data as a complementary analysis.

B. Toxic Elements Program and FDA Survey Data

The 863 TEP (Ref. 11) and survey samples (Refs. 12, 13) include U.S. domestic and imported products, and consist of processed foods made specifically for babies and young children. To analyze these data for purposes of this guidance, we have separated these processed foods into

[3] https://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm2006907.htm.
[4] http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/default.htm.

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).

Table 2 shows the mean, standard deviation, and 90th and 95th percentiles of the data for each of the food categories for babies and young children. Lead concentrations varied among food categories for babies and young children. Fruits and mixtures had low lead levels, with means of 1.0 ppb and 3.0 ppb and 90th-95th percentiles of 2.4-3.7 ppb and 6.8-11.1 ppb, respectively. Yogurts, custards/puddings, and single-ingredient meats similarly had low lead levels, with a mean of 0.9 ppb and 90th-95th percentiles of 1.7-2.3 ppb. Vegetables had a mean lead level of 5.6 ppb and 90th-95th percentiles of 16.0-20.5 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 2.3 ppb and 6.6-10.2 ppb, respectively. Root vegetables had a mean of 8.5 ppb and 90th-95th percentiles of 20.2-25.7 ppb (Table 2, italics).

Dry infant cereals had higher lead concentrations than fruits, vegetables, mixtures, yogurts, custards/puddings, and single-ingredient meats, with a mean of 8.3 and 90th-95th percentiles of 20.1-23.0 ppb.

C. Total Diet Study Data

From FY 2014 to FY 2020, we collected and analyzed 686 samples of processed foods intended for babies and young children under the TDS program.[5] Most TDS samples are not samples of individual foods; they are composites ("averages") of three retail samples, 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 analysis. 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), and yogurts, custard/pudding, and single-ingredient meats.[6] 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. As with the TEP and FDA survey data, lower mean lead levels were observed for fruits, mixtures, yogurts, custards/puddings, and single-ingredient meats. However, dry infant cereal samples in the TDS had lower mean lead levels than samples from the TEP and FDA survey data.

[5] TDS results can be found online at: https://www.fda.gov/food/total-diet-study/analytical-results-total-diet-study.
[6] Infant formula and bottled water labeled for infants are also collected through the TDS program, but were not included in this analysis because they are composite samples (see section III.C). TDS infant formula data indicate that the majority of samples collected contain no lead (<limit of detection, which is 4.0 ppb). Grain-based snacks (e.g., arrowroot cookies, puffs, rusks, teething biscuits) also were analyzed; however, they are not addressed in this guidance. FDA is seeking additional information on this category of foods to inform whether an action level would be appropriate.

D. Summary of FDA Data

FDA's review of data indicates that different types of food intended for babies and young children exhibit different lead concentrations (Tables 2 and 3). In addition, for the TEP and survey data, 85 percent of samples had lead levels lower than 10 ppb, while for the TDS data 97 percent of samples had lead levels lower than 10 ppb. 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 root vegetables (Table 3).

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

When evaluating possible action levels under 21 CFR 109.6 for lead in 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
- for those baby foods where lead levels are already relatively low, the action levels should be established where achievability is in the 90th-95th percentile range.[7]

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 root vegetables (single ingredient); 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.

Based on data used in this analysis, single-ingredient root vegetable products have higher lead levels than other vegetables (Table 2, italics). Root vegetables can absorb lead more readily

[7] 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.

from the soil than other crops (Ref. 14). Moreover, at an action level of 10 ppb (the action level provided in this guidance for other vegetable products), root vegetable achievability was only 71%. For 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, 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 is sufficiently health protective. At the action level of 20 ppb, dry infant cereals have an achievability rate of 90%.

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 proposed action levels for 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 (representing an upper bound) dietary exposures 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 (2.3 ppb, 0.81 µg/day);
- root vegetables (8.5 ppb, 0.89 µg/day); and
- dry infant cereals (8.3 ppb, 0.32 µg/day).

This 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 and would therefore have higher exposures. As shown in Table 4, for Scenario A, the 90th percentile dietary exposures for babies and young children 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 level 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 are as follows:

- fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats (1.7 ppb, 0.60 µg/day);
- root vegetables (6.2 ppb, 0.65 µg/day); and
- dry infant cereals (6.3 ppb, 0.25 µg/day).

The action levels for lead are estimated to result in the following reductions in lead exposure from consumption of these 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 (26%);
- root vegetables (27%); 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 proposed action levels. The achievability for each food category at the proposed action levels is in the 90 - 95% range identified in Section IV, with the exception of root vegetables, as shown below:

- 96% for fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats, at 10 ppb;
- 88% for root vegetables, at 20 ppb; and
- 90% for dry infant cereals, at 20 ppb (Table 4).

In summary, for the combined category of 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 26% at the 90th percentile consumption level and has an achievability of 96%.

An action level of 20 ppb for single-ingredient root vegetables reduces dietary exposure to lead for babies and young children by 27% 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 90%.

Based on our review of lead levels in foods intended for babies and young children that we collected from FY 2008 to FY 2021, 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:

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

Though not binding, these action levels are intended to encourage manufacturers to maintain lead levels in 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 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 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 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* action plan, 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 food intended for babies and 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* action plan to reduce exposure to toxic elements from foods eaten by babies and young children to the lowest possible levels. 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 proposed 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: https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffectslowlevellead_newissn_508.pdf.*
2. Flannery, B.M., K. B. Middleton., 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, 2018. Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Available at https://www.fda.gov/media/100002/download.*
9. WHO/FAO Joint Expert Committee on Food Additives, 2011. Evaluation of Certain Contaminants in Food, 73rd Report of the World Health Organization/Food and Agriculture Organization of the United Nations Joint 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. FDA, 2021. Closer to Zero: Action Plan for Baby Foods. Available at https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods.*

11. FDA, 2023. Analytical Results for Lead 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 2008 to FY 2021. Available at https://www.fda.gov/media/164564/download.*
12. FDA Survey FY 2013-14. Available at: https://www.fda.gov/food/metals-and-your-food/combination-metals-testing.*
13. 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.*
14. Pourrut, B., M. Shahid, C. Dumat, P. Winterton, E. Pinelli, 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 Food for Babies and Young Children

Table 2. Analysis of Lead Data from the Toxic Element Program and FDA Surveys by Food Category

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

Table 4: Summary Data for Food Categories for Babies and Young Children: Action Levels, Achievability, and Mean Lead Concentations/90th Percentle Lead Exposures from Food Consumption for Babies and Young Children (0-23 months) With and Without Action Levels

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

Data Set	Fiscal Year	Number of Samples	Food Categories for Babies and Young Children
Toxic Element Program (TEP)	2008-2021[8]	356	dry infant cereals, fruits, mixtures, vegetables
FDA Survey 1	2013-14[9]	147	dry infant cereals, mixtures
FDA Survey 2	2021[10]	360	fruits, mixtures, vegetables, yogurts, custards/puddings, single-ingredient meats

Table 2. Analysis of Lead Data from the Toxic Element Program and FDA Surveys by Food Category

Food Category for Babies and Young Children	Number of Samples	Mean ± std. dev (ppb)	90th Percentile (ppb)	95th Percentile (ppb)
Fruits (single ingredient or combination)	110	1.0 ± 1.2	2.4	3.7
Mixtures	266	3.0 ± 5.0	6.8	11.1
Yogurts, custards/puddings, single-ingredient meats	33	0.9 ± 0.7	1.7	2.3
Vegetables (single ingredient or combination)	98	5.6 ± 7.3	16.0	20.5
Vegetables (single ingredient or combination excluding single-ingredient root vegetable products)	*47*	*2.3 ± 3.6*	*6.6*	*10.2*
Root vegetables	*51*	*8.5 ± 8.4*	*20.2*	*25.7*
Dry infant cereals	356	8.3 ± 8.8	20.1	23.0

[8] Available at https://www.fda.gov/media/164564/download.
[9] These FDA survey data are available at: https://www.fda.gov/food/metals-and-your-food/combination-metals-testing.
[10] Available at https://www.fda.gov/media/164565/download.

Table 3. Analysis of Lead Data from the Total Diet Study (FY2014-2020)[11] by Food Category for Babies and Young Children

Food Category for Babies and Young Children	Number of Samples	Mean ± std. dev (ppb)
Fruits (single type or combination)	231	0.17 ± 0.91
Mixtures	210	2.5 ± 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
Root vegetables	50	11.6 ± 7.6
Dry infant cereals	23	2.6 ± 2.9

[11] 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. Summary Data for Food Categories for Babies and Young Children: Action Levels, Achievability, and Mean Lead Concentrations/90th Percentile Lead Exposures from Food Consumption for Babies and Young Children (0-23 months) With and Without Action Levels

Food Category for Babies and Young Children	Action Level	Achiev - ability	90th Percentile 2-day Average Intake, Eaters Only, 0-23 mo[12]	Scenario A: No Action Level Estimated Mean Pb Concen- tration	Scenario A: No Action Level Estimated Pb Exposure from Baby Food at the 90th Percentile[13]	Scenario B: With Action Level Estimated Mean Pb Concentration[14]	Scenario B: With Action Level Estimated Pb Exposure from Baby Food at the 90th Percentile[13]	Reduction in Exposure at the 90th Percentile[15]
	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	96	353	2.3	0.81	1.7	0.60	26
Root Vegetables	20	88	105	8.5	0.89	6.2	0.65	27
Dry infant cereals	20	90	39	8.3	0.32	6.3	0.25	24

[12] Concentration in sample (ug/kg) * 1 kg/1000 g conversion factor*upper-level consumption (g/day) = estimated total exposure (µg/day).

[13] 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. The 90th percentile lead exposures (representing an upper bound) from baby foods for NHANES/WWEIA respondents were calculated as products of the 90th percentile of the 2-day average consumption of each food category for babies and young children and the mean lead concentration in that food category. The term "eaters only" for the purposes of this data set means individuals from the survey that consumed this product to calculate intake. The 90th percentile dietary exposures for babies and young children are below the IRL for lead of 2.2 µg/day for children.

[14] 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.

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