

Action Levels for Cadmium in Processed Food Intended for Babies and Young Children: Draft Guidance for Industry

Draft Guidance

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For questions regarding this draft document contact the Human Foods Program, Office of Food Chemical Safety, Dietary Supplements, and Innovation, at 240-402-1200.

**U.S. Department of Health and Human Services
Food and Drug Administration
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Action Levels for Cadmium in Processed Food Intended for Babies and Young Children: Draft Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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

I. Introduction

FDA is committed to reducing cadmium in food. FDA's *Closer to Zero* initiative is a science-based, iterative approach to decreasing contaminants, including cadmium, in foods over time, including by setting action levels. The purpose of this guidance is to provide information to industry on the action levels² for cadmium 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 FDA considers the action levels described in this draft guidance to be achievable by industry when control measures are taken to minimize the presence of cadmium. Although action levels are levels at which FDA may regard food as adulterated, our *Closer to Zero* initiative outlines other actions we will take to further reduce cadmium (as well as other contaminants) 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 cadmium 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).³

The action levels for processed foods 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; Office of Surveillance, Strategy and Risk Prioritization; Division of Risk Assessment and Prioritization; and the Office of Regulations and International Programs, in the Human Foods Program at the U.S. Food and Drug Administration.

² An action level defines a level of contamination at which a food may be regarded as adulterated (21 CFR 109.4(c)). In setting action levels, FDA follows the requirements set forth in our regulations at 21 CFR 109.4 and 109.6.

³ As used in this guidance, "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. 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.

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- 10 parts per billion (ppb) for fruits, vegetables (excluding single-ingredient carrots), and mixtures (including grain- and meat-based mixtures);
- 25 ppb for single-ingredient carrots;
- 45 ppb for dry infant cereals;
- 20 ppb for yogurts, puddings, and custards; and
- 25 ppb for single-ingredient meats.

Consistent with 21 CFR 109.6(d), these action levels reflect levels of cadmium 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) (21 U.S.C. 342(a)(1)). 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 into 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

In general, cadmium is toxic to humans and can affect people of any age or health status. Because cadmium has a long half-life in humans, approximately 10 to 33 years,⁴ even low-level chronic cadmium dietary exposure can lead to adverse effects on the bones and kidneys (Ref. 3). In addition, dietary cadmium exposure over time may be associated with other outcomes, including adverse cardiovascular, hematological, and neurological effects (Ref. 3).

Cadmium is widely present in the environment due to both its natural occurrence and to human activities that have introduced it into the environment. Nearly everyone in the general population is exposed to cadmium through the food supply (Ref. 4). Because cadmium may be present in environments where food crops used to make processed food intended for babies and young children are grown, these foods may contain small amounts of cadmium. Potential sources of cadmium in food include contaminated soil, contaminated water, atmospheric deposition from industrial activities, and cadmium in ceramic glazes or silver-plated holloware. As a result of the first three sources, agricultural crops (e.g., root vegetables) can take up cadmium from contaminated soil, water, and air, and contaminated soil may be deposited on

⁴ Cadmium is slowly excreted, and its half-life is variable, depending on factors such as age, sex, nutritional status, and cumulative exposure. Half-life estimates are derived from models based on different datasets, which result in variability in the half-life estimates (Refs. 1, 2).

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crop surfaces (e.g., on leafy vegetables and cereal grains). Studies suggest that growers and manufacturers may be able to reduce cadmium levels in food by using various practices such as adding soil amendments to reduce the availability of cadmium for uptake by crops and thoroughly peeling root vegetables and washing fruits and vegetables, particularly leafy vegetables (Refs. 4, 5, 6). Manufacturers who have found elevated cadmium levels in sources of food intended for babies and young children may choose sources of food or food ingredients with lower cadmium levels or no detectable cadmium. Manufacturers should also consider increased testing of ingredients or finished products that are historically known to contain elevated cadmium levels; this is particularly important for ingredients or processed foods intended for babies and young children. Additionally, manufacturers should consider examining their facilities, processes, and equipment to ensure that they are not contributing to cadmium in their products (Refs. 7, 8).

In 2021, FDA initiated *Closer to Zero* to identify actions we will take to reduce exposure to contaminants, including cadmium, from foods eaten by babies and young children to as low as possible (Ref. 9). The plan outlines an iterative approach for achieving continual improvements over time, reducing children's exposure to cadmium and other contaminants from food through activities such as setting action levels. The plan commits to consulting with stakeholders, including on the achievability of reducing contaminant 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 determined that the most scientifically appropriate way to establish the level of cadmium at which we may consider a food adulterated is to compare dietary exposure to the Toxicological Reference Value (TRV). The TRV for cadmium is a range rather than a fixed value. The TRV for cadmium is for the general population and has a lower bound estimate of 0.21 micrograms per kilogram of body weight per day ($\mu\text{g/kg bw/day}$) and an upper bound estimate of 0.36 $\mu\text{g/kg bw/day}$ (Ref. 10). The cadmium TRV represents cadmium exposure levels that are associated with the most sensitive adverse health effects from cadmium exposure, which are based on well-established kidney and bone effects.⁵ To derive the TRV, we:

1. conducted a systematic review of the scientific literature to identify key human health effects (kidney and bone damage) from cadmium exposure (Ref. 3);
2. adapted a human physiologically based pharmacokinetic (PBPK) model to relate internal measures of cadmium exposure to external measures of exposure (Ref. 2); and
3. used the output from the model to determine a TRV⁶ (Ref. 10).⁷

⁵ In addition to kidney and bone effects, data are available associating early-life cadmium exposure with impaired neurodevelopment and altered growth in children at exposures similar to the TRV range (Refs. 11-13). Application of the FDA cadmium TRV to children (male and female combined 0-6 years) protects this subpopulation and aims to minimize childhood cadmium exposure and potential developmental risks.

⁶ The TRV takes into account differences in creatinine excretion based on age, sex, and body weight, which ultimately affect PBPK estimates of external doses. The upper bound estimate protects for accumulation of a critical concentration of cadmium in the kidney cortex, which is associated with kidney dysfunction (Ref. 10).

⁷ FDA's determination of the TRV underwent external peer review. The external peer review materials can be found on the FDA website at <https://www.fda.gov/science-research/peer-review-scientific-information-and-assessments/completed-peer-reviews>.

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FDA intends to update the cadmium TRV and this guidance as appropriate, including, for example, if other scientific information becomes available that could help us refine our thinking.

Under the *Closer to Zero* initiative, this draft 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, FDA considered that the action levels should minimize the likelihood that a consumer will be exposed to cadmium levels exceeding the lower bound of the TRV. To do this, we consider the intake of the food (g/kg bw) and the maximum level of cadmium (µg/kg) that could be in the food without causing the lower bound of the TRV 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. Cadmium Levels Found in Processed Food Intended for Babies and Young Children

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

FDA routinely monitors cadmium 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),⁸ special FDA surveys,⁹ and the Total Diet Study (TDS).¹⁰ The TEP is a targeted monitoring program that monitors levels of certain chemical contaminants, including cadmium, in foods and foodware.¹¹ Foods selected for analysis include those that are suspected of having elevated levels of chemical contaminants based on historical monitoring data or other elemental analysis information available to us. For cadmium analysis under the TEP, we place emphasis on foods consumed by babies and young children, who may be especially sensitive to cadmium'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 cadmium.

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 2020-22, and FY 2023-24 (Tables 1 and 2), and TDS data collected between FY 2014-2020 (Table 3) to determine current

⁸ <https://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm2006907.htm>.

⁹ FY2020-22: <https://www.fda.gov/media/195778/download>; FY2023-24: <https://www.fda.gov/media/195776/download>.

¹⁰ <http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/default.htm>.

¹¹ FDA uses an inductively coupled plasma mass spectrometry (ICPMS) method to determine cadmium in food (<https://www.fda.gov/media/87509/download>). Samples were analyzed as sold. The TEP stipulates that samples should consist of twelve randomly selected subsamples from a single lot.

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cadmium levels in processed foods intended for babies and young children and assess achievability (Section IV). We also reviewed the TDS data as a complementary analysis.

B. Toxic Elements Program and FDA Survey Data

The 1,430 TEP (Ref. 14) and survey samples (Refs. 15-17) 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 separated foods for babies and young children into the following categories: 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, puddings, and custards; 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. Cadmium concentrations varied among food categories.

- Fruits and mixtures had low cadmium levels, with means of 1.0 ppb and 4.2 ppb, and 90th-95th percentiles of 2.4-3.0 ppb and 9.2-14.0 ppb, respectively.
- Vegetables had a mean cadmium level of 6.6 ppb and 90th-95th percentiles of 17.6-24.9 ppb. When single-ingredient carrots were placed in a separate category, the vegetables category had a lower mean and lower 90th-95th percentiles of 4.4 ppb and 11.4-15.1 ppb, respectively.
- Single-ingredient carrots had a mean of 12.7 ppb and 90th-95th percentiles of 30.5-37.7 ppb.
- Dry infant cereals had higher cadmium concentrations than the other categories, with a mean of 15.0 ppb and 90th-95th percentiles of 29.8-39.9 ppb.
- Yogurts, puddings, custards, and single-ingredient meats had lower cadmium levels, with means of 0.9 ppb and 0.5 ppb, and 90th-95th percentiles of 1.7-2.1 ppb and 1.4-1.6 ppb, respectively.

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, i.e., various brands of applesauce, all from different cities. Because the compositing provides an “average” result, and our achievability assessment is based on percentiles of cadmium 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

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

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combination of fruits, vegetables, yogurt, grains, and meats); yogurts, puddings, and custards; and single-ingredient meats.¹³

All food categories had mean cadmium concentrations well below 10 ppb, except for carrots and dry infant cereals, which had mean concentrations of 19.4 and 16.8 ppb, respectively. As with the TEP and FDA survey data, lower mean cadmium levels were observed for fruits; vegetables (excluding single-ingredient carrots); mixtures; yogurts, puddings, and custards; and single-ingredient meats.

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 cadmium concentrations (Tables 2 and 3). In addition, for the TEP and survey data, 73 percent of samples had cadmium levels lower than 10 ppb, while for the TDS data, 82 percent of samples had cadmium levels lower than 10 ppb. The mean cadmium levels for the categories of food intended for babies and young children were below 10 ppb (Tables 2 and 3) except for carrots and dry infant cereals (TEP and survey data, Table 2; TDS data, Table 3). Yogurts, puddings, custards, and single-ingredient meats had the lowest mean and 90th-95th percentile cadmium values.

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

When evaluating possible action levels under 21 CFR 109.6 for cadmium 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 cadmium levels exceeding the lower bound of the TRV;
- 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 cadmium with implementation of the action levels; and
- for those baby foods where cadmium levels are already relatively low, the action levels should be established where achievability is near the 90th-95th percentile range.¹⁴

¹³ Infant formula and bottled water labeled for infants are also collected through the TDS program but were not included in this analysis. Infant formula data collected through the TDS program indicate that the majority of samples contain low levels of cadmium (mean of 2.5 ppb). Data on bottled water labeled for infants collected through the TDS program indicated that cadmium was not detectable in all samples. FDA has also tested infant formula as part of its Operation Stork Speed, with data available at: <https://www.fda.gov/food/infant-formula-homepage/fdas-infant-formula-product-testing-results>.

¹⁴ This approach is consistent with an approach followed for setting international standards and the approach FDA has taken with respect to action levels for toxic elements 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 where more than 95% of the samples traded internationally had lead concentrations at

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We took the following steps to identify possible action levels under 21 CFR 109.6 for cadmium in foods intended for babies and young children less than two years old:

- determined the dietary exposure from a food category that would not cause consumers to exceed the cadmium TRV¹⁵;
- calculated and considered the impact on exposure reduction of the action levels; and
- calculated and considered the impact on manufacturers' ability to achieve the action levels.

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

- 10 ppb for fruits, vegetables (excluding single-ingredient carrots), and mixtures (including grain- and meat-based mixtures);
- 25 ppb for single-ingredient carrots;
- 45 ppb for dry infant cereals;
- 20 ppb for yogurts, puddings, and custards; and
- 25 ppb for single-ingredient meats.

For fruits, vegetables (excluding single-ingredient carrots), and mixtures (any combination of fruits, vegetables, grains, and meats), all of which have low cadmium levels, action levels can be established at 10 ppb.

As stated above, there should be a limited number of unique action levels for simplicity. For example, we established one action level for fruits, almost all vegetables, and mixtures. However, separate action levels may be appropriate for products with higher cadmium levels or foods with different consumption patterns. For example, based on data used in this analysis, single-ingredient carrot products have higher cadmium levels than other processed vegetable foods (Table 2). Carrots can absorb cadmium more readily from the soil than other crops (Ref. 18). Moreover, at an action level of 10 ppb (the action level provided in this guidance for other vegetable products), achievability for carrots was only 55%. For single-ingredient carrots, we expect that an action level of 25 ppb will help minimize the likelihood of exposure to cadmium, while also considering achievability. At an action level of 25 ppb, single-ingredient carrots have an achievability rate of 84%. Carrots 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 carrot products on the market intended for babies and young

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>).

¹⁵ This exposure is calculated by dividing the lower bound of FDA's cadmium TRV range (in µg/kg bw/day) by dietary intake (g/kg bw/day) and multiplying by 1000 g/kg (conversion factor). Intake is calculated based on baby food consumption data from What We Eat In America, the food consumption portion of the National Health and Nutrition Examination Survey (NHANES), 2003-2018.

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children. Therefore, we consider it appropriate to place single-ingredient carrots in their own category.

For dry infant cereals, we expect that an action level of 45 ppb will help minimize exposure to cadmium. In this case, the action level will help ensure that cadmium levels do not result in exposure that exceeds the TRV. At the action level of 45 ppb, FDA may regard the dry infant cereals as adulterated. The achievability rate is 98% at this level.

For yogurts, puddings, and custards, and single-ingredient meats, where cadmium levels are already very low, and action levels of 20 ppb and 25 ppb result in 100% achievability, action levels were determined to be beneficial to help ensure that cadmium levels do not exceed levels that are considered health protective.

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 cadmium exposure, we compared the estimated concentration of cadmium in these foods and dietary exposure to cadmium from these foods with and without action levels. We calculated exposure estimates based on cadmium concentration data from the TEP and FDA survey data and on baby food consumption data from What We Eat In America, the food consumption portion of the National Health and Nutrition Examination Survey NHANES, 2003-2018.¹⁶

As shown in Table 4, the mean concentrations of cadmium 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 (Scenario A) are as follows:

- fruits, vegetables (excluding single-ingredient carrots), and mixtures (including grain- and meat-based mixtures) (3.5 ppb, 0.14 µg/kg bw/day);
- single-ingredient carrots (12.7 ppb, 0.12 µg/kg bw/day);
- dry infant cereals (15.0 ppb, 0.07 µg/kg bw/day);
- yogurts, puddings, and custards (0.9 ppb, 0.01 µg/kg bw/day); and
- single-ingredient meats (0.5 ppb, <0.01 µg/kg bw/day).

We chose the upper bound percentile intake (90th percentile) as a health protective measure to account for babies and young children (0-23 months) who consume larger amounts of food and would have potentially higher exposures.

Table 4 also shows the 90th percentile dietary exposures with the action levels in place (Scenario B). For scenario B, removing all samples with cadmium concentrations greater than the action level from the datasets results in a decrease in the estimated mean cadmium concentrations and

¹⁶ See <https://wwwn.cdc.gov/nchs/nhanes/default.aspx>.

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the estimated dietary exposures. The estimated mean cadmium concentrations and 90th percentile dietary exposures from the processed foods with the action levels are as follows:

- fruits, vegetables (excluding single-ingredient carrots), and mixtures (including grain- and meat-based mixtures) (2.5 ppb, 0.10 µg/kg bw/day);
- single-ingredient carrots (8.6 ppb, 0.08 µg/kg bw/day);
- dry infant cereals (14.1 ppb, 0.07 µg/kg bw/day);
- yogurts, puddings, and custards (0.9 ppb, 0.01 µg/kg bw/day); and
- single-ingredient meats (0.5 ppb, <0.01 µg/kg bw/day).

The 90th percentile dietary exposures for babies and young children with the action levels in place are below the lower range of the TRV for cadmium of 0.21 µg/kg bw/day.

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

- fruits, vegetables (excluding single-ingredient carrots), and mixtures (including grain- and meat-based mixtures) (28%);
- single-ingredient carrots (32%);
- dry infant cereals (5%);
- yogurts, puddings, and custards (0%); and
- single-ingredient meats (0%).

B. Achievability Assessment

To assess achievability, or manufacturers' ability to achieve the action levels for cadmium, 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, with the exception of yogurts, puddings, and custards, and single-ingredient meats, where action levels were established to help ensure that exposure levels remain health protective, although cadmium levels are already very low:

- 93% for fruits, vegetables (excluding single-ingredient carrots), and mixtures (including grain- and meat-based mixtures), at 10 ppb;
- 84% for single-ingredient carrots, at 25 ppb;
- 98% for dry infant cereals, at 45 ppb;
- 100% for yogurts, puddings, and custards, at 20 ppb; and
- 100% for single-ingredient meats, at 25 ppb (Table 4).

In summary, for the category of processed fruits, vegetables (excluding single-ingredient carrots), and mixtures (including grain- and meat-based mixtures), an action level of 10 ppb reduces dietary exposure to cadmium for babies and young children by 28% at the 90th percentile consumption level and has an achievability of 93%.

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An action level of 25 ppb for single-ingredient carrots reduces dietary exposure to cadmium for babies and young children by 32% at the 90th percentile consumption level and has an achievability of 84%.

An action level of 45 ppb for dry infant cereals reduces dietary exposure to cadmium for babies and young children by 5% at the 90th percentile consumption level and has an achievability of 98%.

Because of the low levels of cadmium in yogurts, puddings, and custards, as well as single-ingredient meats, the action levels of 20 ppb and 25 ppb have an achievability of 100% and do not result in any exposure reduction to cadmium. However, we believe it is important to set levels for these foods to help ensure that cadmium levels do not exceed levels that are considered health protective. These are commonly consumed baby foods, and FDA wants to ensure that firms continue to maintain low levels of cadmium in these foods. We will continue to monitor the available science and data and revise these levels as appropriate.

C. Action Levels

Based on our review of cadmium levels in processed foods intended for babies and young children that we collected from FY 2009 to FY 2024, in consideration of the TRV for cadmium of 0.21-0.36 µg/kg bw/day (as shown in Table 4), and in accordance with 21 CFR 109.6, this guidance, if finalized, will establish the following action levels for cadmium in processed foods intended for babies and young children:

- 10 parts per billion (ppb) for fruits, vegetables (excluding single-ingredient carrots), and mixtures (including grain- and meat-based mixtures);
- 25 ppb for single-ingredient carrots;
- 45 ppb for dry infant cereals;
- 20 ppb for yogurts, puddings, and custards; and
- 25 ppb for single-ingredient meats.

Though not binding, these action levels are intended to encourage manufacturers to maintain cadmium levels in processed food intended for babies and young children below the action levels, thus reducing risks associated with dietary cadmium exposures. The establishment of these action levels for cadmium in processed food intended for babies and young children in this guidance is consistent with FDA's work on the *Closer to Zero* initiative, reducing exposures of babies and young children to contaminants.

Consistent with 21 CFR 109.6(d), these action levels reflect levels of cadmium 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 and Inspection Service (FSIS) on the inclusion of single-ingredient meats and mixtures that include meats as an

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ingredient in this guidance. FSIS supports the action levels developed by FDA as part of the *Closer to Zero* initiative 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 cadmium 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 action levels for other contaminants in foods intended for babies and young children, including the achievability of such levels, and the feasibility of further reducing the presence of cadmium in food. We plan to monitor the levels of cadmium in food and children's exposure to cadmium from processed foods to assess whether to adjust the action levels for the processed foods intended for babies and young children described in this guidance, and 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 set forth in this guidance are part of our efforts under the *Closer to Zero* initiative to reduce exposure to contaminants 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 TRV for dietary cadmium, and the action levels are achievable by industry when control measures are taken to minimize the presence of cadmium.

We intend to consider the action levels as an important source of information for determining whether a processed 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 cadmium causes a particular food to be adulterated under section 402(a)(1) of the FD&C Act.

VI. References

Below are references FDA used in drafting this guidance. References may be accessed as follows:

The references marked with an asterisk (*) are available both electronically at <https://www.regulations.gov>, and are also on display with FDA's Dockets Management Staff. Dockets Management Staff is located at 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and references are available for in person viewing at this location between 9 a.m. and 4 p.m., Monday through Friday.

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Some may also be available at the website address, if listed. 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.

References without an asterisk are not on public display at <https://www.regulations.gov> or via a website because they have copyright restrictions. As a result, they are available for viewing only at the Dockets Management Staff location provided on the cover page of this guidance.

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VII. Tables

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Table 1. Summary of Data Used in Analysis of Cadmium in Food for Babies and Young Children

Data Set	Fiscal Year	Number of Samples	Processed Food Categories for Babies and Young Children
Toxic Elements Program (TEP)	2009-2024 ¹⁷	483	dry infant cereals; fruits; mixtures; vegetables; yogurt, custards, and puddings
FDA Survey 1	2013-14 ¹⁸	147	dry infant cereals, mixtures
FDA Survey 2	2020-22 ¹⁹	414	fruits; mixtures; vegetables; yogurts, puddings, and custards; single-ingredient meats
FDA Survey 3	2023-24 ²⁰	386	dry infant cereals; fruits; mixtures; vegetables; yogurts, puddings, and custards; single-ingredient meats

¹⁷ Available at <https://www.fda.gov/media/164682/download?attachment>.

¹⁸ These FDA survey data are available at <https://www.fda.gov/food/metals-and-your-food/combination-metals-testing>.

¹⁹ Available at <https://www.fda.gov/media/195775/download>.

²⁰ Available at <https://www.fda.gov/media/195777/download>.

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Table 2. Analysis of Cadmium Data from the Toxic Elements Program and FDA Surveys by Food Category in Foods for Babies and Young Children²¹

Processed Food Category for Babies and Young Children	Number of Samples	Mean $\pm$ standard deviation (ppb)	90th Percentile (ppb)	95th Percentile (ppb)
Fruits (single-ingredient or combination)	210	1.0 $\pm$ 1.6	2.4	3.0
Vegetables (single-ingredient or combination)	208	6.6 $\pm$ 8.4	17.6	24.9
Vegetables (single-ingredient or combination excluding single-ingredient carrots)	152	4.4 $\pm$ 5.2	11.4	15.1
Single-ingredient carrots	56	12.7 $\pm$ 11.7	30.5	37.7
Mixtures	550	4.2 $\pm$ 4.7	9.2	14.0
Dry infant cereals	407	15.0 $\pm$ 11.2	29.8	39.9
Yogurts, puddings, and custards	40	0.9 $\pm$ 0.8	1.7	2.1
Single-ingredient meats	15	0.5 $\pm$ 0.6	1.4	1.6

²¹ TDS data are presented separately in Table 3.

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Table 3. Analysis of Cadmium Data from the Total Diet Study (FY 2014-FY 2020)²² by Food Category 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)	229	0.9 $\pm$ 1.4
Vegetable (single type or combination)	139	6.7 $\pm$ 9.5
Vegetables (single type or combination excluding single-ingredient carrots)	111	3.4 $\pm$ 5.2
Single-ingredient carrots	28	19.4 $\pm$ 11.7
Mixtures	215	8.0 $\pm$ 7.0
Dry infant cereals	23	16.8 $\pm$ 8.7
Yogurts, puddings, and custards	25	0.8 $\pm$ 0.9
Single-ingredient meats	58	0.2 $\pm$ 0.5

²² In 2018, the TDS sampling protocol was changed. See <http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/default.htm>.

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Table 4. Action Levels, Achievability, Mean Cadmium (Cd) Concentrations, and 90th Percentile Cadmium Exposures from Processed Food Consumption for Babies and Young Children (0-23 months), With and Without Action Levels

Processed Food Category for Babies and Young Children	Action Level	Achievability	90th Percentile 2-day Average Intake, Eaters Only, 0-23 mo ²³	Scenario A: No Action Level Estimated Mean Cd Concentration	Scenario A: No Action Level Estimated Cd Exposure from Baby Food at the 90 th Percentile ²⁴	Scenario B: With Action Level Estimated Mean Cd Concentration ²⁵	Scenario B: With Action Level Estimated Cd Exposure from Baby Food at the 90 th Percentile ²⁴	Reduction in Exposure at the 90 th Percentile ²⁶
	ppb	%	g/kg bw/day	ppb	µg/kg bw/day	ppb	µg/kg bw/day	%
Fruits, vegetables (excluding single-ingredient carrots), and mixtures (including grain- and meat-based mixtures)	10	93	40	3.5	0.14	2.5	0.10	28
Single-ingredient carrots	25	84	10	12.7	0.12	8.6	0.08	32
Dry infant cereals	45	98	5	15.0	0.07	14.1	0.07	5
Yogurts, puddings, and custards	20	100	11	0.9	0.01	0.9	0.01	0
Single-ingredient meats	25	100	9	0.5	<0.01	0.5	<0.01	0

²³ 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.

²⁴ Exposure estimates were calculated based on cadmium concentration data from the TEP and FDA survey data, and on baby food consumption data from WWEIA, 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 lower range of the TRV for cadmium of 0.21 µg/kg bw/day.

²⁵ Mean cadmium concentrations in Scenario B were calculated after removal of the TEP and FDA survey data for samples with concentrations above the action level.

²⁶ Percent change calculated as ((cadmium exposure under Scenario A [µg/kg bw/day]- cadmium exposure under Scenario B [µg/kg bw/day]) / cadmium exposure under Scenario A [µg/kg bw/day]) * 100). Calculations are based on unrounded data.