UNLEADED KIDS | CENTER FOR ENVIRONMENTAL HEALTH | CENTER FOR FOOD SAFETY | CONSUMER FEDERATION OF AMERICA | CONSUMER FEDERATION OF CALIFORNIA | CONSUMER REPORTS | DEFEND OUR HEALTH | EARTHJUSTICE | ECOMADRES | ENVIRONMENTAL WORKING GROUP | FOOD & WATER ACTION | HEALTHY BABIES BRIGHT FUTURES | MOM'S CLEAN AIR FORCE

February 5, 2025

Dr. Sara Brenner, Acting Commissioner
U.S. Food & Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Ln., Rm. 601
Rockville, MD 20852

Sent by FedEx on February 5, 2024

Re: Petition for Reconsideration of Guidance to Industry Regarding Action Levels for Lead in Processed Food Intended for Babies and Young Children, Docket No. FDA-2022-D-0278-002

Dear Acting Commissioner Brenner:

PETITION FOR RECONSIDERATION
Docket No. FDA-2022-D-0278-002

Unleaded Kids, Center for Environmental Health, Center for Food Safety, Consumer Federation of America, Consumer Federation of California, Consumer Reports, Defend Our Health, Earthjustice, EcoMadres, Environmental Working Group, Food & Water Action, Healthy Babies Bright Futures, and Mom's Clean Air Force respectfully submit this petition for reconsideration of the decision of the Commissioner of Food and Drugs in Docket No. FDA-2022-D-0278-002 to issue final guidance to industry regarding action levels for lead in processed food intended for babies and young children that was published in the January 7, 2025 *Federal Register*.[1]

We submit this petition pursuant to 21 C.F.R. § 10.33(a) and the "inherent right of any administrative official to reopen and reconsider any matter, at any time, on his own initiative or on the petition of any interested person, for any reason whatever."[2] Because "a well-defined administrative record delineates the data and information on which a decision is reached, and where the decision is in writing," the petition for reconsideration is the most appropriate means to ask the Commissioner to address the serious flaws in the guidance (though the Commissioner has the inherent authority to rely on any information, irrespective of whether it is in the record).[3]

A. DECISION INVOLVED

On January 7, 2025, the Food and Drug Administration ordered a notice to be published in the *Federal Register* announcing that it was making available its final guidance for industry regarding action levels in processed food intended for babies and young children. The notice stated that Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs, signed the notice on December 27, 2024. See Appendix A for Administrative Record.

B. ACTION REQUESTED

We request that the Commissioner of Food and Drug Administration (FDA) revise the guidance by:

1. Removing the exemptions for packaged snack foods, beverages, and infant formula.
2. Setting an action level no higher than 4 parts per billion (ppb) for infant formula and all its ingredients.
3. Narrowing the 20 ppb action level for dry infant cereal to only those products with rice as the primary ingredient and for single-ingredient root vegetables to only carrots or sweet potatoes.
4. Reducing the action level for all processed baby foods to 7 ppb with a delayed effective date of January 1, 2027.
5. Expanding the scope of the guidance to food intended for children younger than six years of age with a delayed effective date of January 1, 2028.

Beyond this specific guidance, we ask that the Commissioner significantly accelerate and improve the agency's Closer to Zero program. The highest priorities should be publishing draft action levels as a necessary step in the process of adopting strong final action levels for:

- Cadmium in processed baby food that the agency had committed to releasing by the end of 2024.
- Lead, cadmium, and arsenic in carrots, sweet potatoes and rice, quinoa, leafy greens and other products that are significant contributors to total dietary exposure with a target of reducing that exposure by at least 25%.

As FDA sets those action levels, it should:

- Request that state health departments with the authority to demand submission of baby food testing results ask manufacturers for the information and provide it to the FDA so that FDA can make better decisions in setting action levels.
- Improve transparency in decision-making to enhance credibility and effectiveness by:
    a) More clearly explaining options considered and rationale for action level selection;
    b) Responding to comments received in response to posting of draft guidance;
    c) Calculating incremental dietary lead exposure reduction based on babies total estimated daily intake at 50th, 90th, and 97.5th percentiles.
    d) Calculating the socioeconomic benefits of the options considered and the one selected.
    e) Transparently comparing the options considered to their impact on exposures relative to FDA's Interim Reference Level (IRL).
    f) Considering the cumulative effects including additive and synergistic impacts of lead, arsenic, cadmium, and mercury in food.
    g) Explaining accommodations made for nutritional value, measurability, and feasibility.

C. ADMINISTRATIVE RECORD AND TERMINOLOGY

Administrative Record: Appendix 1 provides descriptions of the documents in the Administrative Record for the guidance at https://www.regulations.gov/docket/FDA-2022-D-0278. The requests are based on issues raised primarily in three comments:

- Comment from Environmental Defense Fund (EDF), Posted May 8, 2023, FDA-2022-D-0278-0069. See https://www.regulations.gov/comment/FDA-2022-D-0278-0069.

- Comment from Healthy Babies Bright Futures (HBBF), Posted Mar 27, 2023, ID FDA-2022-D-0278-0044. See https://www.regulations.gov/comment/FDA-2022-D-0278-0044.
- Comment from of 23 state attorneys general[4] ("23 State AGs"), Posted May 8, 2023, FDA-2022-D-0278-0067. See https://www.regulations.gov/comment/FDA-2022-D-0278-0067.

We include in the administrative record, a study published by FDA scientists on September 5, 2024 that was not referenced in the guidance or posted in the docket even though it was submitted for publication by FDA on June 24, 2024, almost 6 months before it published the final guidance.

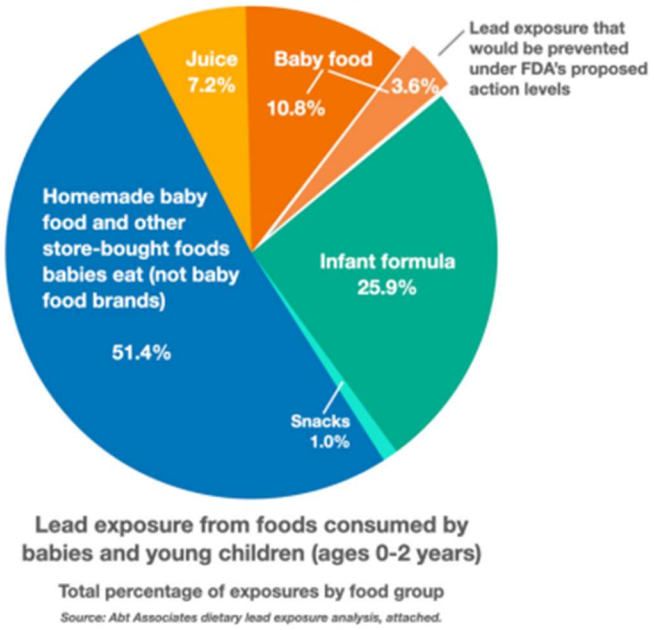
- Dana Hoffman-Pennesi, Sarah Winfield, Alexandra Gavelek, Sofia M. Santillana Farakos & Judith Spungen (05 Sep 2024): Infants' and young children's dietary exposures to lead and cadmium: FDA total diet study 2018–2020, Food Additives & Contaminants: Part A, DOI: 10.1080/19440049.2024.2396910.

Terminology: In the guidance, FDA sets action levels for "processed food intended for babies and young children." It describes "young children" as those younger than 2 years old, even though this terminology is inconsistent with a September 2024 study by agency scientists, where they defined "young children" as those aged 1 to 6 years. [5] In addition, the agency states that the food covered by the guidance "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)" as well as "infant formula or any beverages, including toddler drinks." Some of these foods are commonly marketed as baby foods.

For purposes of this petition for reconsideration, we refer to food covered by the guidance as "**baby food**" and the children who are intended to be protected by the action levels as "**babies.**" We chose this terminology for simplicity and to avoid confusion with FDA's inconsistent or vague definitions.

Figure 1

FDA's proposed action levels for lead contamination in baby food would reduce exposures by only 3.6%



Lead exposure from foods consumed by babies and young children (ages 0-2 years)

Total percentage of exposures by food group

Source: Abt Associates dietary lead exposure analysis, attached.

D. SUMMARY OF STATEMENT OF GROUNDS

Babies' dietary exposure to lead reduces their potential lifetime earnings by as much as $29,400 for an average child. Eliminating that exposure would likely result in societal benefits of up to $107 billion per year. While eliminating lead may not be realistic, reducing dietary exposure by at least 25% for babies is achievable and will yield societal benefits of more than $26 billion a year, a potentially huge return on the investment.

As shown in Figure 1, FDA's January 2025 guidance setting action levels for baby food will reduce that exposure by a paltry 3.6%, primarily because it impacts only one-seventh of their dietary intake of lead. In addition, FDA's failure to define an ill-conceived exemption for "snack foods" and to narrow the type

of grains and root vegetables that qualify for the less protective 20 parts per billion (ppb) action level, creates loopholes that may further minimize those anticipated benefits.

FDA's decision is at odds with the four criteria the agency established to evaluate possible action levels under 21 C.F.R. § 109.6. Specifically, FDA said:

1. *"The action level should minimize the likelihood that a consumer will be exposed to lead levels exceeding the IRL (interim reference level)."* A 2024 FDA analysis shows that more than 500,000 babies and more than 2.6 million children younger than six years exceed FDA's IRL, its benchmark for total dietary exposure. Unfortunately, FDA compared the IRL to exposure from only baby foods covered by the guidance, even though those foods represent only one-seventh of babies' dietary lead exposure. The agency provides no explanation for why it chose to ignore the contribution from other foods that babies eat. In addition, FDA's analysis is based on intake at the 90th percentile consumption level for the food/food category, claiming it is health protective, even though the IRL is derived from the Centers for Disease Control and Prevention's (CDC's) Blood Lead Reference Value, which is based on protecting the 97.5 percentile of children aged 1 to 6 years. FDA's use of the 90th percentile is unreasonable because it would allow 360,000 children born each year to lose more than 0.70 IQ points resulting in each of those children losing an estimated $29,400 in their potential lifetime earnings.

2. *"As appropriate, there should be a limited number of unique action levels for simplicity."* FDA's guidance is far from simple. It exempted snack foods and beverages from the action levels without appropriate justification and without defining the terms. This is important because baby foods often come in purees and pouches that are hard to classify. Eliminating the exemptions for snack food and beverages would be simpler. The agency also allowed all dry infant cereals to have a less protective action level of 20 ppb, even though its data shows that cereals without rice are consistently below 10 ppb. Narrowing the dry infant cereal exemption to only rice cereals would further simplify the action levels.

3. *"The action levels should result in a reduction in exposure to lead."* FDA's action levels will reduce babies' dietary exposure to lead by only 3.6% because they impact only baby foods that represent less than one-seventh of their lead consumption. Yes, the action levels will result in a reduction in exposure to lead but implicit in the criteria is that the reduction will be meaningful. A 3.4% reduction falls short of meaningful and is far less than what FDA makes it out to be in the justification for the guidance.

4. *"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."* FDA reports that 97% of the foods covered the baseline action level of 10 ppb already meet that limit. If the agency had lowered the action level for these foods to 7 ppb, then 91% would achieve it, a percentage that is within FDA's target range. The agency provides no explanation for why it ignored the criteria and set less protective action levels.

FDA's guidance did not use the best available data. Specifically,

- *FDA failed to ask for more current and detailed data on lead levels in baby foods.* Since the beginning of 2024, baby food companies have been required by California law to test each lot of their products for arsenic, cadmium, lead, and mercury to at least 6 ppb using a lab that is accredited under international standards and demonstrates proficiency through independent testing. The companies were required to submit the test results to the state health department upon request. Despite repeated suggestions from stakeholders, FDA did not ask the state health

department to request the data, even though it would have provided detailed information on the most relevant foods, those currently on the market. Instead, FDA relied on its own sample collection and lab analysis that includes samples collected more than a decade ago.

- *FDA failed to use more accurate data on the types and amounts of food babies eat.* FDA used the federal "What We Eat in America" survey to evaluate babies' diet. The survey covers all ages and includes only a small number of babies. Without explanation, the agency failed to use published information from Gerber's Feed Infants and Toddlers Study (FITS) that it knew was available and would allow more accurate dietary exposure estimates that better reflect market trends.

FDA also fails to consider the marketplace for baby food in three critical ways:

- FDA implicitly assumes that all foods in its datasets were made using ingredients that were grown, harvested, and processed using methods that reduce lead contamination. There is no basis for this assumption. The agency does not appear to have considered whether the industry followed established international standards.

- FDA does not take into account that baby food is a product where manufacturers charge a premium by marketing the food as designed to support a baby's health. This premium enables them to conduct more extensive testing on ingredients and reformulate products to reduce reliance on ingredients that may have higher levels of lead contamination. Manufacturers can also screen out suppliers that do not meet stringent standards for ingredient quality. This can often be accomplished without compromising nutritional value or quality or significantly increasing costs.

- FDA's approach to setting action levels focuses on what is currently on the market. As a result, rather than pressing industry to do better, it implicitly gives permission for all but the worst performers to maintain the status quo. By looking only at what was on the market, FDA is not pressing the industry to invest in developing and implementing the practices needed to make food safer and drive lead levels closer to zero. The possibility that FDA will revise the guidance in the future is not sufficient to motivate the food industry to make the necessary investment.

The guidance is the first final agency action in its Closer to Zero program. The decision's myriad flaws reveal broader problems with how the agency sets action levels. The process fails to evaluate various alternatives, does not clearly explain its rationale for exclusions, ignores extensive comments without providing any explanation, and, despite commitments to the contrary, evaluates harm from lead exposure in isolation without regard to presence of cadmium and arsenic in the foods. The lack of transparency undermines the credibility and effectiveness of the guidance.

We now explain these flaws in greater detail and highlight why our requests would fix the problem.

- Section E: FDA did not evaluate the tremendous societal benefits of reducing dietary lead exposure
- Section F: FDA failed to follow its own criteria when setting action levels
- Section G: FDA did not use the best available data
- Section H: Petitioners' grounds for specific requests to revise the guidance
- Section I: Petitioners' grounds to revise the process to set action levels as part of Closer to Zero

E. FDA DID NOT EVALUATE THE TREMENDOUS SOCIETAL BENFITS OF REDUCING DIETARY LEAD EXPOSURE

The Environmental Protection Agency (EPA) has developed sophisticated tools to quantify the societal benefits of reducing exposure to lead in terms of increased lifetime earnings and fewer low birthweights infants, people with attention deficit hyperactive disorder (ADHD), and premature cardiovascular disease (CVD) deaths. The agency uses these validated tools to rigorously evaluate rulemaking options and make more informed decisions.

In its comments on the draft guidance,[6] EDF encouraged FDA to use the methods developed by EPA (and accepted by the Office of Management and Budget (OMB)) to quantify the societal benefits of reducing young children's exposure to lead. EDF explained that quantifying the societal benefits is a valuable tool to help the agency and stakeholders consider options and that it would prompt industry to provide realistic estimates of the cost to achieve the limits, rather than the vague claims it often relies on. EDF has repeatedly made this request to FDA since the agency launched its Closer to Zero program, including its June 28, 2022 comments on FDA's draft guidance on lead in juice.[7]

Unfortunately, FDA failed to use these OMB-authorized, publicly available tools to evaluate potential action levels to reduce lead in food in its final guidance for lead in baby food, relying instead on an outdated, formulaic approach.

As described below, we calculate the societal benefits of reducing dietary lead exposure to babies and young children using the latest version of EPA's publicly available tools[8] and FDA's September 2024 study[9] that updated an earlier FDA study[10] estimating dietary exposure to lead.

Focusing only on lead's impact on IQ, we calculated that eliminating dietary lead exposure would likely increase an average child's potential lifetime earnings up to $29,400, resulting in societal benefits of up to $107 billion per year. While eliminating lead may not be realistic, reducing dietary exposure by at least 25% is achievable and should yield societal benefits of about $26 billion a year, a potentially huge return on the investment.

Basis for Estimates

In 2020, FDA acknowledged that "no safe level of lead exposure has yet been identified for children's health."[11] Recognizing that lead is an unavoidable contaminant in food and that this exposure can harm children and fetuses, FDA has established Interim Reference Levels (IRLs).[12]

The agency currently describes the IRL as "a benchmark the FDA may use to determine if the amount of exposure to the contaminant in food is a potential health concern. IRLs also may be used to inform action levels, which are the level of contaminant in a food above which the FDA may consider a food harmful to health and in violation of the FDA's safety laws."[13]

In 2022, FDA updated its IRLs for lead to 2.2 micrograms of lead per day (µg/day) for children and 8.8 µg/day for females of childbearing age (to protect the fetus).[14] The agency estimated that this dietary exposure corresponds to a blood lead level (BLL) of 0.35 micrograms of lead per deciliter of blood (µg/dL).

FDA's IRL is designed to keep the dietary contribution of lead to less than 1/10th of the Blood Lead Reference Value (BLRV) for young children set by the Centers for Disease Control and Prevention (CDC). The BLRV is effectively CDC's action level for lead and is based on the 97.5 percentile of young

children's blood lead levels obtained through National Health and Nutrition Examination Survey's (NHANES) biomonitoring program.[15]

In September 2024, FDA estimated infants' and young children's dietary exposures to lead and cadmium, based on its Total Diet Study (TDS) samples collected from 2018 to 2020.[16] The agency calculated[17] that for:

- Infants of 0 to 11 months of age, the mean exposure was 1.3 µg/day and the 90th percentile was 2.4 µg/day; and
- Young children between 1 and 6 years of age, the mean exposure was 1.5 µg/day and the 90th percentile was 2.4 µg/day.

Therefore, a sustained dietary lead exposure of 1.5 µg/day would be expected to result in a BLL of 0.24 µg/dL.[18]

For sound decision making, it is critical to understand what a BLL of 0.24 µg/dL means to society. To address this need in other contexts, decades ago the Environmental Protection Agency (EPA) undertook a sustained and rigorous process to identify concentration-response functions that quantify those societal impacts in order to better evaluate options for rulemaking designed to reduce people's exposure to lead. By quantifying these benefits, it can compare them to the estimated costs to comply with rules.

More than 15 years ago, EPA quantified the impacts of blood lead levels on IQ points and estimated the societal value of avoiding those lost IQ points. More recently, it developed the tools needed to quantify the impact of blood lead levels on premature CVD mortality, low birthweights, and incidence of ADHD. The most recent version of its analysis was published in October 2024 when EPA finalized its improvements to its Lead and Copper Rule (LCR) for drinking water.[19]

It is important to appreciate how rigorous the process was that EPA followed to develop these tools.[20] The agency:

- Reviewed all available studies which could be used to develop quantitative relationships between changes in lead exposure and/or changes in blood lead levels and changes in health endpoints.
- Evaluated the studies for quality and potential biases.
- Developed a separate report for each health endpoint. In addition to the quality review findings, each report provides quantitative estimates, based on the identified functions, of potential changes in the health endpoint.
- Had the reports for quantified health endpoints reviewed by EPA experts and external peers.
- Successfully completed inter-agency review through OMB.

We do not understand why FDA has not made use of EPA's tools to evaluate the benefits of reducing dietary exposure to lead since it is a valuable means to carefully compare options and make sound decisions.

Since FDA has failed to consider the societal benefits when it finalized the lead in baby food guidance, we conducted a limited analysis using EPA's published, peer-reviewed tools in order to justify our requests in this petition. We focused on the IQ impacts since the guidance is designed to reduce babies' exposure to lead and FDA has recognized the quantitative relationship between BLL and IQ points.

In its economic analysis for the LCR rule, EPA uses the formula below to calculate IQ point benefits for reducing a baby's exposure to lead. The formula is based on the independent analysis in Crump et al. 2013.[21]

$$IQ\ Loss = \beta \times \ln\left(\frac{PbB_1 + 1}{PbB_2 + 1}\right) \qquad \text{(Equation 10)}$$

Where:

β = Lifetime beta estimate from Crump et al. (2013) independent analysis (-3.25)

PbB_1 = Pre-rule BLL

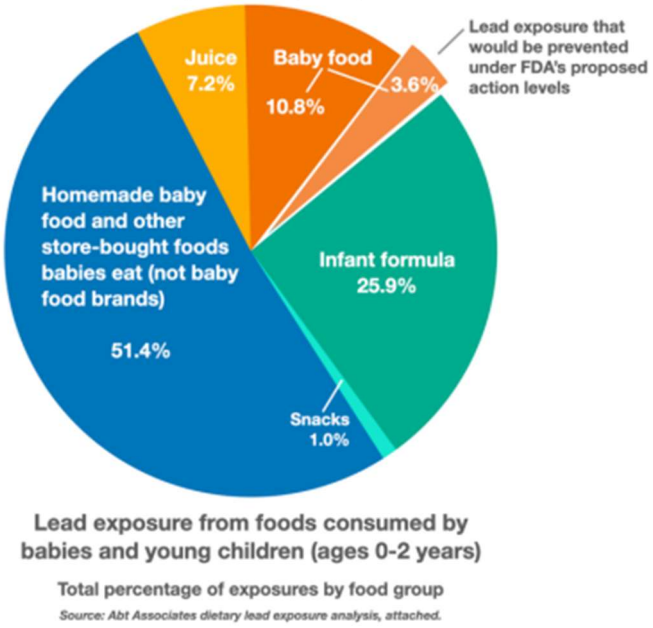
PbB_2 = Post-rule BLL

We calculated that an average child would gain 0.70 IQ points based on 0.24 µg/dL[22] as the pre-rule BLL, zero µg/dL as the post-rule BLL.

EPA also calculated that a one IQ point loss would reduce a child's lifetime earnings by $42,226 in 2022 dollars at a 2% discount rate.[23] Smaller IQ losses would result in a proportionally lower, but still significant, reduction in a child's lifetime earnings.

As explained in Table 1, we estimate that eliminating lead from food would improve an average child's lifetime earnings by about $29,400 with a societal benefit of more than $107 billion per year.

Figure 2
FDA's proposed action levels for lead contamination in baby food would reduce exposures by only 3.6%



Lead exposure from foods consumed by babies and young children (ages 0-2 years)

Total percentage of exposures by food group

Source: Abt Associates dietary lead exposure analysis, attached.

Table 1. Estimated impacts of mean dietary exposure to lead of 1.5 µg/day

Model	IQ Loss	Lifetime cost of IQ loss at 2% discount	Societal cost per year from lost IQ points
EPA 2024 of Crump et al. (2013) independent analysis for "Early" blood lead level variable	0.70	$29,400	$107 billion
Based on mean blood lead level of 0.24 µg/dL, 3,667,758 live births in 2022, and a 2% discount rate.			

An analysis by HBBF found that FDA's proposed action levels will reduce dietary exposure to lead from processed baby food by 25%, for an overall reduction of 3.6%.[24] See Figure 2. The societal benefits of this reduction would be as much as $3.7 billion per year.

If FDA had applied the same 25% reduction to all dietary lead exposure sources, the societal benefits would have been far greater, as much as $26 billion. Unfortunately, the agency failed to consider those options in response to comments and HBBF's analysis.

F. FDA FAILED TO FOLLOW ITS OWN CRITERIA WHEN SETTING ACTION LEVELS

FDA established four criteria to set action levels for lead in processed baby food. It said:

> "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 (interim reference level);
> - 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."

Unfortunately, FDA did not rigorously follow the four criteria it set when it finalized the action levels despite extensive comments highlighting the shortcomings. In some cases, the variation is clear. In others, it is subtle. And nowhere does the agency provide an explanation. We examine each of the criteria in detail below.

Criteria #1: "The action level should minimize the likelihood that a consumer will be exposed to lead levels exceeding the IRL (interim reference level)."

FDA failed to follow this criterion in two crucial ways. First, it claims without justification that setting action levels on the 90th percentile of babies' dietary exposure is health protective despite that exposure exceeding the IRL. Second, it bases the analysis on only babies' exposures from foods covered by the guidance and not babies' total dietary exposure to lead.

Regarding the 90th percentile, FDA rationalizes its use in the guidance by stating that

> 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.
>
> 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%).

The claim that the 90th percentile is health protective is contrary to scientific evidence that, because babies' brains are rapidly developing, even relatively short term exposure to lead is likely to have long-term harm. It is also difficult to reconcile the claim with the agency's acknowledgement that "no safe level of lead exposure has yet been identified for children's health."[25]

The 90th percentile means the agency considers an action level to be "health protective" when 360,000 children born each year are likely to lose more than 0.66 IQ points due to dietary lead exposure. This loss results in an estimated $27,900 reduction in their individual potential lifetime earnings.

FDA's arbitrary selection of the 90th percentile is also inconsistent with the 97.5 percentile that CDC uses to set the BLRV, on which the IRL is based. In their comments, both EDF and the 23 State AGs raised these concerns and called on FDA to base its analysis on the 97.5th percentile. FDA completely ignored these comments.

The agency should base the IRL on the 97.5th percentile to be consistent with CDC and the scientific evidence. We recognize that tightening levels on baby food alone may not be sufficient. For that reason, it should expand the scope of the guidance to include more foods.

Regarding the scope of the analysis, FDA compared the IRL to the dietary lead exposure from only those foods covered by the action levels. Yet these foods contribute less than one-seventh the dietary exposure for babies and young children younger than two years of age according to the analysis by HBBF.[26] See Figure 1. The agency provides no explanation for why it chose to ignore the contribution from other foods.

FDA's approach is contrary to its stated purpose of the IRL as "a benchmark the FDA may use to determine if the amount of exposure to the contaminant in food is a potential health concern." The benchmark has little value if each group of food is allowed to have a 90th percentile of exposure up to 2.2 µg/day without regard to the cumulative impact.

It is more than a theoretical concern. A September 2024 study by Hoffman et al.[27] estimated the dietary exposure of two key groups of children: 1) infants 0-11 months who are not fed human milk; and 2) children 1-6 years. The study showed one in ten children in each group consumed more than 2.4 micrograms of lead per day (µg/day) from food. This means that more than *more than 2.6 million children exceeded FDA's target of 2.2 µg/day.*

FDA should evaluate the impact of the action levels on the overall exposure and not narrow the set of foods it has chosen to address.

Criteria #2: "As appropriate, there should be a limited number of unique action levels for simplicity."

FDA's action levels are inconsistent with this criterion in three ways. First, the guidance exempts three types of baby foods—snack foods, beverages, and infant formula—from the action levels. This creates complications, especially since the exemptions are buried in a footnote. For simplicity alone, in addition to the fact that they are not supported by the law or science, it should remove these exemptions.

Second, FDA should reduce the complexity of the guidance by narrowing the scope of foods subject to the 20 ppb action levels. For root vegetables, FDA's data shows that only sweet potatoes and carrots exceed 10 ppb. Rather than leave an opening for industry to switch to other root vegetables, the agency should limit the 20 ppb to only sweet potatoes and carrots.

The issue is more significant for dry infant cereals. FDA's data shows that only rice exceeds 10 ppb. In addition, FDA does not define dry infant cereals. Rather than leave an opening for industry to switch to other grains or pseudo grains such as quinoa, the agency should limit the 20 ppb to only rice.

Finally, FDA fails to define which processed baby foods are not considered snack foods or beverages, not just giving examples of what fits into the exemption. This is important because baby foods often come in purees and pouches that are hard to classify. The result is that baby food manufacturers are incentivized to exploit the exemption by classifying some of their products as snack foods or beverages, rendering the

terms meaningless, leaving consumers confused, and undermining the anticipated benefits of the actions levels.

We recommend that FDA remove the exemption. If it continues to keep the exemptions, despite the complexity it brings, the agency's definition should be clear about what foods are not snack foods or beverages by referring to specific characteristics and not just more examples.

Criteria #3: "The action levels should result in a reduction in exposure to lead."

As explained above, HBBF's analysis in its comments show that FDA's proposed action levels will reduce babies' dietary exposure to lead by a paltry 3.6%.[28] Yes, the action levels will result in a reduction in exposure to lead but implicit in the criteria is that the reduction will be meaningful. A 3.4% reduction falls short of meaningful and is far less than what FDA makes it out to be in the justification for the guidance.

Criteria #4: "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."

In the guidance, FDA says that

> 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%.

The agency does not explain why it settled on 97%, despite EDF's and 23 State AGs and other commenters' raising concerns, FDA's data shows that 91% of the foods other than dry infant cereal and single ingredient root vegetables are below 7 ppb and half of those are grain-based snacks that are exempt from the guidance. FDA should lower the default action level from 10 ppb to 7 ppb, which appears to be the limit of quantification for FDA for these foods in recent years.

G. FDA DID NOT USE THE BEST AVAILABLE DATA

The agency relied on two sets of data to set action levels: 1) test results from 1,400 samples of processed baby food that it collected over the past decade; and 2) federal data on what people eat from the What We Eat In America (WWEIA) survey. While useful, the data is not the best available. If FDA had used the more detailed and current data that was available at the time of their analysis, it would have better understood the current marketplace for baby food and what levels of lead were in products, possibly resulting in more effective action levels. EDF raised this issue in its comments.

Failure to ask for more current and detailed data on lead levels in baby foods.

FDA relied on a dataset of 1,400 samples that it had collected from 2014 to 2024. More than a quarter of the samples were collected before 2021, the year that FDA launched its Closer to Zero program. The market has changed dramatically over the years, both in terms of what foods babies are eating and the lead levels in those foods as the industry responded to the threat of FDA action. Only 36% of the samples were from 2023 or 2024.

In contrast, FDA could have obtained from all baby food manufacturers the lab results listing the arsenic, cadmium, lead, and mercury levels in each and every lot of the manufacturers' products made since the beginning of 2024, when California law AB899[29] went into effect. The data is of high quality because the baby food manufacturers were required to use a lab accredited under international standards that demonstrates proficiency through independent testing to at least 6 ppb.

The California law targets foods "specifically for babies and young children less than two years of age." The only processed baby food that is exempt is infant formula. Snack foods and beverages are included.

FDA could have secured the data by arranging for the California Department of Public Health (CDPH), its state partner on food safety, to request the test results from the baby food manufacturers. The law requires the companies to provide the data to CDPH upon request. Despite repeated suggestions from stakeholders, FDA apparently did not ask CDPH to request the data even though it has an agreement with the agency regarding food safety that includes information sharing.

FDA failed to use more accurate data on the types and amounts of food babies.

FDA used the federal "What We Eat in America" survey to evaluate what babies eat. The survey covers all ages and includes only a small number of babies. Without explanation, the agency failed to use published information from the Nestle Feeding Infants and Toddlers Study (FITS) that it knew was available and that would have allowed more accurate dietary exposure estimates that better reflect babies' diets.

The long-term success of the Closer to Zero Initiative rests on fulfilling the agency's stated commitment to a cycle of continuous improvement. That cycle means that FDA needs a structure to accept third-party testing data so it maximizes the quality, objectivity, utility, and integrity of the information it uses.

The agency should be gathering as much trustworthy data as possible from all sources. This approach would give the agency better information on which to make decisions and better leverages the agency's resources, especially as it establishes a program of continuous improvement.

H. PETITIONERS' GROUNDS FOR SPECIFIC REQUESTS TO REVISE THE GUIDANCE

We ask the Commissioner to make five specific revisions to the guidance based on the following rationale.

Request #1: Remove the exemptions for packaged snack foods, beverages, and infant formula.

In the second footnote in the guidance, FDA exempts three types of processed baby foods—snack foods, beverages, and infant formula—from the scope of the guidance.[30] As a result, there are no action levels for lead in these products, leaving it for the manufacturers to determine how much lead would result in the food being considered adulterated within the meaning of section 402(a)(1) of the FD&C Act. Many commenters, including EDF, HBBF, and 23 State AGs, raised concerns with these exemptions.

We request that the Commissioner remove the three exemptions by deleting the second footnote for the following reasons:

A. Snack Food Exemption

FDA exempted "snack foods, including grain-based or freeze-dried snacks such as arrowroot cookies, puffs, rusks, and teething biscuits" from the scope of the guidance.

There are two significant problems with the snack food exemption:

1. **Exemption is unnecessary.** If FDA removed the exemption, 89% of grain-based snacks would meet the 10 ppb default action level, showing it is achievable.
2. **Definition is ambiguous.** FDA fails to adequately define the term, effectively leaving manufacturers with the option to reclassify some of their products as snack foods and avoid the action level.

Regarding whether there is any need to exempt "snack foods" from the guidance, we evaluated FDA's four published datasets totaling 1,400 test results for products that were related to baby foods. See Appendix 1 for a description and links to each of the datasets. The agency designated 93 products collected from 2014 to 2023 as "grain-based snacks."

We found that lead levels in 98% of the 93 grain-based snacks were below 20 ppb and in 89% were below 10 ppb. For the 22 grain-based snacks that FDA tested in 2023, lead levels in all but two were at or below 10 ppb. The two above that level were both carrot blueberry puffs. For comparison, a blueberry puffs product tested the same year was below the limit of detection. Of the 16 teething wafers FDA tested in 2023, the highest lead level was 10 ppb. Based on this information, manufacturers of these snack foods can achieve 10 ppb. Those with high levels of lead can reformulate their snack foods to meet the action level with minimal disruption to availability of these products.

Regarding the ambiguous definition, FDA attempts to define "snack foods" in the guidance by giving examples for foods that are included within the term. However, the guidance fails to define what is **not** a snack food effectively giving baby food manufacturers the option to classify many of their products, such as purees, as snack foods.

We searched FDA's regulations for a definition of "snack food" and found little insight.

- The food additive regulations at 21 C.F.R. § 170.3(n)(37) designates "snack foods, including chips, pretzels, and other novelty snacks" as one of 43 general food categories. The categories are designed to help FDA and industry when describing uses of a food additive or generally recognized as safe substance. It provides additional examples, but none would appear to include foods intended for babies.
- The labeling regulations at 21 C.F.R. § 101.12 address snack foods by establishing serving sizes for them. It says "Snacks: All varieties, chips, pretzels, popcorn, extruded snacks, fruit and vegetable-based snacks (e.g., fruit chips), grain-based snack mixes." It also includes "dehydrated fruits" and "crackers that are usually used as snacks." The rule assigns a serving size of 30 grams for snacks, a much larger size than is typically found for the snacks (puffs, rusks, and teething biscuits) described in FDA's guidance.
- The nutrition quality guidelines at 21 C.F.R. § 104.20(a) state that "the Food and Drug Administration does not encourage indiscriminate addition of nutrients to foods, nor does it consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies and carbonated beverages." None of these examples are like those in FDA's guidance.

FDA should be providing specific characteristics of snack foods and not giving more examples.

B. Beverages Exemption

FDA exempted "beverages, including toddler drinks" from the scope of the guidance.

As with snack foods, FDA provides no rationale for exempting beverages. It does imply that the action level is unnecessary because juices will be addressed by draft action levels that the agency published in April 2022 and plans to finalize this year.[31]

There are three significant problems with the beverage exemption:

- **No action levels for milk and other non-juice beverages.** The draft action level for juice exempts many processed foods intended for babies, in particular milk. This omission is critical since the exemption means that there would be no action level for these foods, leaving it for the manufacturers to determine what levels would be sufficient for a food to be considered adulterated within the meaning of section 402(a)(1) of the FD&C Act.
- **Tighter limits for juices intended for babies are achievable and appropriate.** FDA set the draft action level for juices based on ensuring that at least 95% of products can comply. However, for baby foods, FDA set a more protective benchmark of 90-95%, stating "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." FDA should apply this criterion to juices—and all beverages—because they are achievable.
- **Fruit or vegetable purees could be exempt beverages.** FDA's draft guidance on lead in juices states that juice means "the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree." This overlap would leave it to manufacturers to determine whether fruit or vegetable purees are beverages and, therefore, exempt from the guidance.

If FDA removed the exemption for beverages, products made of single-ingredient root vegetables would be subject to the 20 ppb action level, with the remainder covered by the 10 ppb level. Baby food manufacturers should be able to achieve these levels with minimal disruption to availability of these products.

C. Infant Formula Exemption

As with snack foods and beverages, FDA provides no rationale for exempting infant formula. Presumably, the agency sets lead limits as part of its review of those products, but we found nothing in the rules. For example, FDA's infant formula rules address lead limits in two sections:

- 21 C.F.R. § 106.20(f) requires that water used in making infant formula meets EPA's drinking water limits. EPA's Lead and Copper Rule does not have a maximum allowed level, rather its lead action level is 10 ppb.
- 21 C.F.R. § 106.40(e)(3) says "a manufacturer shall not reprocess or otherwise recondition an ingredient, container, or closure rejected because it is contaminated with microorganisms of public health significance or other contaminants, such as heavy metals.

The problem with the exemption is that FDA periodically finds lead in infant formula (both milk and soy) through its Total Diet Study. The most recent was in winter of 2019 when FDA found 10 ppb in a composite of three different milk-based powered formula products that it collected and reconstituted with distilled water. If the lead was only in one of those three products, the powder could have had more than 200 ppb.[32]

The fact that FDA may also evaluate infant formula in a separate program does not justify exempting the products from the scope of the guidance.

Request #2: Set an action level no higher than 4 ppb for infant formula and all its ingredients.

Half of all babies are totally dependent on infant formula for many months[33] at a time when their brains are most vulnerable to harm from lead. For the first six months, more than half of infants depend entirely on infant formula for sustenance. And they are likely to stick with a single brand, placing them at even greater risk if the manufacturer has higher levels of lead or any other toxic element. The problem with lead in baby formula is exacerbated by the fact that the formula can be mixed with drinking water contaminated with lead – and it will be a more than a decade before EPA's Lead and Copper Rule Improvements result in lead pipes being replaced.

Rather than exempt infant formula from the guidance, FDA should set an action level at the lowest possible limit of quantification (LOQ). Based on the agency's test results for its Total Diet Study from 2018 to 2021, the LOQ is 4 ppb.

Given the risk of harm, FDA should go further and set a 4 ppb action level for all ingredients of infant formula. If each ingredient is below 4 ppb, the final product is much more likely to have even lower levels.

Request #3: Narrow the 20 ppb action level for dry infant cereal to only those products with rice as the primary ingredient and for single-ingredient root vegetables to only carrots and sweet potatoes.

For dry infant cereals, we evaluated the test results in FDA's four published datasets totaling 1,400 test results for products that were related to baby foods. The agency designated 298 products collected from 2014 to 2023 as "dry infant cereals."

Of the 298 dry infant cereals, lead levels in 92.3% were less than 20 ppb and in 83.9% were less than 10 ppb. However, all the cereals at 10 ppb or more were made of rice. Clearly, the problem is with rice and not all grains.

Rather than establish a less protective action level of 20 ppb for all dry infant cereals, FDA should narrow the action level to just dry infant rice cereals. This will ensure that baby food manufacturers select non-rice cereal ingredients that achieve the 10 ppb action level. By adopting this approach, FDA will limit future increases in lead levels in dry infant cereals.

Since infant rice cereal is already the primary source of a baby's exposure to inorganic arsenic, FDA should carefully consider the cumulative effect of lead and inorganic arsenic on the baby's developing brain.

For single-ingredient root vegetable products, we evaluated the test results in FDA's four published datasets totaling 1,400 test results for products that were related to baby foods. We found 88 products in this category and they consisted of only carrots or sweet potatoes. Of these 88, 11 had lead levels over 20 ppb and 24 over 10 ppb. 12% and 28% respectively.

We ask that FDA narrow the 20 ppb action level for single-ingredient root vegetables to those that consist of only carrots or sweet potatoes. The narrower focus would simplify the guidance and reduce the risk of baby food manufacturers switching to other suppliers or to other nutritious root vegetables that may be

contaminated with lead over 10 ppb. By adopting this approach, FDA will limit future increases in lead levels in root vegetables.

Request #4: Reduce the action level for all processed baby foods to 7 ppb with a delayed effective date of January 1, 2027.

FDA's approach to setting action levels is based on its assessment of what appears to be currently on the market. As a result, rather than pressing industry to do better, it implicitly gives permission for all but the worst performers to maintain the status quo.

FDA should be signaling to the food industry in the guidance that the action levels will tighten several years in the future. Through this type of signaling, the agency can drive companies to invest in developing and implementing the practices needed to make food safer. That process can take several growing seasons.

This technology-forcing approach is consistent with the standards of 21 C.F.R. § 109.6 on which it relies to set actions levels. If the industry finds that a standard cannot be achieved or significantly compromises quality or nutritional value, it can make the case to FDA. If the agency is convinced there is a problem, it can relax or extend the deadline.

Therefore, we urge FDA to signal that the action levels will be simplified to 7 ppb for all processed baby foods, including dry infant rice cereal and products made of only carrots or of sweet potatoes. This level is roughly the upper LOQ for the many of the products covered by the guidance. This simplification also advances one of FDA's four criteria.

For the 1,400 test results in FDA's four published datasets for all baby food products, including grain-based snacks, 84.5% already meet the 7 ppb limit. With two years of advanced notice, industry should be able to achieve 7 ppb across all product types.

Request #5: Expand the scope of the guidance to food intended for children younger than six years of age with a delayed effective date of January 1, 2028.

In October, FDA's scientists published a study estimating the dietary intake of lead and cadmium for two groups: 1) young children (those aged 1 to 6 years of age inclusive); and 2) infants excluding those fed human milk—about half of the infants aged 0 to 11 months.[34] The grouping of young children aged 1 to 6 years of age is similar to CDC's BLRV of 3.5 µg/dL, which is based on the 97.5th percentile for children aged 1 to 5.[35] FDA's IRL is based on CDC's BLRV.

CDC, EPA and the Department of Housing and Urban Development focus their lead poisoning prevention programs on young children aged 1 to 5 because they are particularly vulnerable to risks of neurological harm from exposure to lead. Consistent with this recognition, FDA should extend it guidance for processed baby food from children younger than two years of age to all children younger than 6 years.

We request that FDA do that by changing the upper age limit for the guidance from 2 to 6 effective January 1, 2028. By giving industry three years to comply, FDA will be signaling to the food industry in the guidance that the action levels will tighten in three years and will be giving them time to invest in developing and implementing the practices needed to make food safer. That process can take several growing seasons.

This technology-forcing approach is consistent with the standards of 21 C.F.R. § 109.6 on which it relies to set actions levels. If the industry finds that it cannot be achieved or significantly compromises quality or nutritional value, they can make the case to FDA. If the agency is convinced there is a problem, it can relax or extend the deadline.

I. PETITIONERS' GROUNDS TO REVISE THE PROCESS TO SET ACTION LEVELS AS PART OF CLOSER TO ZERO

The guidance is the first final agency action in its Closer to Zero program. The decision's many flaws described above reveal broader problems with how the agency sets action levels. The process fails to evaluate various alternatives, does not clearly explain its rationale for exclusions, ignores extensive comments without providing any explanation, and, despite commitments to the contrary, evaluates harm from lead exposure in isolation without regard to presence of cadmium and arsenic in the foods. The lack of transparency and failure to consider cumulative effects undermines the credibility and effectiveness of the guidance. EDF's, HBBF's and 23 State AGs comments as well as many others raised these concerns articulated in this petition.

The agency's decision lacks transparency and accountability, running contrary to what parents demand from FDA, and the Administrative Procedures Act expects.

We ask that FDA significantly accelerate and improve the agency's Closer to Zero program. The highest priorities should be publishing draft action levels for:

- Cadmium in processed baby food that the agency had committed to releasing by the end of 2024.
- Lead, cadmium, and arsenic in carrots, sweet potatoes, rice, quinoa, leafy greens and other products that are significant contributors to total dietary exposure with a target of reducing that exposure by at least 25%.

As FDA sets those action levels, it should

- Request that companies and states provide testing results for their products and use the provided data in developing draft and final action levels.
- Improve transparency in decision-making to enhance credibility and effectiveness by:
    - More clearly explaining options considered and rationale for action level selection;
    - Responding to comments received in response to posting of draft guidance;
    - Calculating incremental dietary lead exposure reduction based on babies total estimated daily intake at 50^{th}, 90^{th}, and 97.5^{th} percentiles.
    - Calculating the socioeconomic benefits of the options considered and the one selected.
    - Transparently comparing the options considered to their impact on FDA's Interim Reference Level (IRL).
    - Consider the cumulative effects including additive and synergistic impacts of lead, cadmium, arsenic, and mercury in food.
    - Explaining accommodations made for nutritional value, measurability and feasibility.

CONCLUSION

FDA's regulations dictate that the Commissioner of Food and Drugs "shall grant" a petition for reconsideration where:

1. The petition demonstrates that relevant information or views contained in the administrative record were not previously or adequately considered.

2. The petitioner's position is not frivolous and is being pursued in good faith.
3. The petitioner has demonstrated sound public policy grounds supporting reconsideration.
4. Reconsideration is not outweighed by public health or other public interests.[36]

For the reasons in earlier sections, this reconsideration petition satisfies these four requirements. We ask that the Commissioner move quickly to revise the guidance to protect babies and young children from lead in food.

Respectfully submitted February 5, 2025.

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Appendix 1
Administrative Record

FDA's Constituent Update: "FDA Issues Final Guidance for Industry on Action Levels for Lead in Processed Food Intended for Babies and Young Children" January 6, 2025, https://www.fda.gov/food/hfp-constituent-updates/fda-issues-final-guidance-industry-action-levels-lead-processed-food-intended-babies-and-young.

FDA's Notice of Final Guidance: Food and Drug Administration, Action Levels for Lead in Processed Food Intended for Babies and Young Children; Guidance for Industry; Availability, Posted Jan 7, 2025, Docket ID: FDA-2022-D-0278-0075 at https://www.regulations.gov/document/FDA-2022-D-0278-0075.

FDA's Final Guidance Document, "Guidance for Industry: Action Levels for Lead in Processed Food Intended for Babies and Young Children" January 2025, at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-lead-processed-food-intended-babies-and-young-children and https://www.fda.gov/media/164684/download.

FDA's Final Guidance Document references 16 documents in Section IV. The guidance notes that the items marked with an asterisk (*) are on display at the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

1. *HHS, National Toxicology Program, 2012. NTP Monograph on Health Effects of LowLevel Lead. Available at: https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffectslowlevellead_newissn_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-zeroreducing-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-yourfood/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.
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.

Testing Results References in Guidance: FDA posted the following testing results on its Lead in Food and Foodwares webpage at https://www.fda.gov/food/environmental-contaminants-food/lead-food-and-foodwares

1. Analytical Results for Arsenic, Lead, Cadmium, and Mercury in Food Intended for Babies and Young Children- TEP (FY2009-FY2024) in PDF, in XLSX. The samples were collected under the FDA's Toxic Elements in Food and Foodware, and Radionuclides in Food – Import and Domestic Compliance Program between FY2009 and FY2024.

2. Analytical Results for Lead in Processed Food Intended for Babies and Young Children (FY2023) in PDF, in XLSX. The samples were collected in FY2023 as part of FDA's survey of toxic elements in foods intended for babies and young children

3. Analytical Results for Lead in Food Intended for Babies and Young Children (FY2020-2021) in PDF, in XLSX. The samples were collected in FY2020 and FY2021 as part of an FDA survey of toxic elements in foods intended for babies and young children.

4. Dataset for Lead and Cadmium in Infant and Toddler Foods (FY2013-FY2014) in XLSX. The samples were collected in FY2013 and FY2014 as part of an FDA survey of infant and toddler foods.

Comments Received in Docket in Response to Proposed Guidance Posted at https://www.regulations.gov/docket/FDA-2022-D-0278.
(*sorted newest to oldest)

1. Comment from Senator Amy Klobuchar et al, Posted Dec 1, 2023, FDA-2022-D-0278-0074
2. Comment from FMI and FPPI, Posted Nov 16, 2023, FDA-2022-D-0278-0073
3. Comment from Clean Label Project- Baby Coalition, Posted May 17, 2023, FDA-2022-D-0278-0072

4. Comment from Safe Food and Fertilizer, Posted May 10, 2023, FDA-2022-D-0278-0071
5. Comment from Consumer Reports, Posted May 8, 2023, FDA-2022-D-0278-0068
6. Comment from American Association for Laboratory Accreditation (A2LA), Posted May 8, 2023, FDA-2022-D-0278-0064
7. Comment from Apple Processors Association, Posted May 8, 2023, FDA-2022-D-0278-0070
8. Comment from Office of the New York State Attorney General, Posted May 8, 2023, FDA-2022-D-0278-0067
9. Comment from New York State Department of Agriculture and Markets, Posted May 8, 2023, FDA-2022-D-0278-0065
10. Comment from King County Hazardous Waste Mgt Program, Posted May 8, 2023, FDA-2022-D-0278-0066
11. Comment from Environmental Defense Fund, Posted May 8, 2023, FDA-2022-D-0278-0069
12. Comment from Anonymous, Posted May 4, 2023, FDA-2022-D-0278-0063
13. Comment from Anonymous, Posted Apr 17, 2023, FDA-2022-D-0278-0062
14. Comment from Office of the Attorney General of the State of New York, Posted Mar 29, 2023, FDA-2022-D-0278-0060
15. Comment from Consumer Brands Association, Posted Mar 28, 2023, FDA-2022-D-0278-0055
16. Comment from Association for Sustainable Food Safety, Posted Mar 28, 2023, FDA-2022-D-0278-0052
17. Comment from Office of the Attorney General of the State of New York, Posted Mar 28, 2023, FDA-2022-D-0278-0054
18. Comment from Gerber Products Company, Posted Mar 28, 2023, FDA-2022-D-0278-0053
19. Comment from Clean Label Project- Baby Coalition, Posted Mar 28, 2023, FDA-2022-D-0278-0059
20. Comment from Center for Science in the Public Interest (CSPI), Posted Mar 28, 2023, FDA-2022-D-0278-0050
21. Comment from Stantec ChemRisk, Posted Mar 28, 2023, FDA-2022-D-0278-0051
22. Comment from Public Interest Research Group (PIRG), Posted Mar 28, 2023, FDA-2022-D-0278-0057
23. Comment from National Center for Health Research (NCHR), Posted Mar 28, 2023, FDA-2022-D-0278-0056
24. Comment from U.S. Public Interest Research Group Education Fund, Posted Mar 28, 2023, FDA-2022-D-0278-0058
25. Comment from Environmental Defense Fund, Posted Mar 27, 2023, FDA-2022-D-0278-0042
26. Comment from FMI, Posted Mar 27, 2023, ID FDA-2022-D-0278-0049
27. Comment from Healthy Babies Bright Futures, Posted Mar 27, 2023, ID FDA-2022-D-0278-0044
28. Comment from Children's Wisconsin, Posted Mar 27, 2023, FDA-2022-D-0278-0048
29. Comment from International Fresh Produce Association & Western Growers, Posted Mar 27, 2023, FDA-2022-D-0278-0047
30. Comment from Institute of Food Technologists (IFT), Posted Mar 27, 2023, FDA-2022-D-0278-0041
31. Comment from Center for American Progress, Posted Mar 27, 2023, FDA-2022-D-0278-0043
32. Comment from American Bakers Association et al, Posted Mar 27, 2023, FDA-2022-D-0278-0045
33. Comment from Michigan Carrot Committee, Posted Mar 27, 2023, FDA-2022-D-0278-0046
34. Comment from Farah Sevareid, Posted Mar 24, 2023, FDA-2022-D-0278-0037
35. Comment from American Academy of Pediatrics, Posted Mar 24, 2023, FDA-2022-D-0278-0040

36. Comment from Caleb Merendino, Posted Mar 24, 2023, FDA-2022-D-0278-0039
37. Comment from Michigan Vegetable Council, Posted Mar 24, 2023, FDA-2022-D-0278-0038
38. Comment from Seth Frisbie, Posted Mar 20, 2023, FDA-2022-D-0278-0034
39. Comment from Better Life Laboratories, Inc., Posted Mar 20, 2023, FDA-2022-D-0278-0035
40. Comment from Palak Madan, Posted Mar 10, 2023, FDA-2022-D-0278-0033
41. Comment from Anonymous, Posted Mar 9, 2023, FDA-2022-D-0278-0032
42. Comment from Robert Thomas, Posted Mar 9, 2023, FDA-2022-D-0278-0031
43. Comment from Anonymous, Posted Feb 24, 2023, FDA-2022-D-0278-0030
44. Comment from Anonymous, Posted Feb 8, 2023, FDA-2022-D-0278-0029
45. Comment from Anonymous, Posted Feb 2, 2023, FDA-2022-D-0278-0028
46. Comment from Conny Zhu, Posted Feb 1, 2023, FDA-2022-D-0278-0027
47. Comment from DuPage County Health Department, IL, Posted Feb 1, 2023, FDA-2022-D-0278-0026
48. Comment from VIRGINIA GOMEZ, Posted Jan 30, 2023, FDA-2022-D-0278-0024
49. Comment from CHARLES SMITH, Posted Jan 30, 2023, FDA-2022-D-0278-0025
50. Comment from Ryan Hassan, Posted Jan 26, 2023, FDA-2022-D-0278-0020
51. Comment from Anonymous, Posted Jan 26, 2023, FDA-2022-D-0278-0022
52. Comment from LYNN MARKHAM, Posted Jan 26, 2023, FDA-2022-D-0278-0018
53. Comment from LYNN MARKHAM, Posted Jan 26, 2023, FDA-2022-D-0278-0019
54. Comment from David Schwinne, Posted Jan 26, 2023, FDA-2022-D-0278-0021
55. Comment from robert smistik, Posted Jan 26, 2023, FDA-2022-D-0278-0023

FDA's scientists published the following study but did not reference it in the guidance on post it in the docket.

1. Dana Hoffman-Pennesi, Sarah Winfield, Alexandra Gavelek, Sofia M. Santillana Farakos & Judith Spungen (05 Sep 2024): Infants' and young children's dietary exposures to lead and cadmium: FDA total diet study 2018–2020, Food Additives & Contaminants: Part A, DOI: 10.1080/19440049.2024.2396910.

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[1] FDA, Action Levels for Lead in Processed Food Intended for Babies and Young Children; Guidance for Industry; Availability, 90 *Federal Register* 1135, January 7, 2025. See https://www.federalregister.gov/documents/2025/01/07/2024-31534/action-levels-for-lead-in-processed-food-intended-for-babies-and-young-children-guidance-for.

[2] FDA, Administrative Practices and Procedures, Proposed Rule, Docket No. 75N-0001 40 *Federal Register* 40687, September 3, 1975, at page 40682.

[3] FDA, Action Levels for Lead in Processed Food Intended for Babies and Young Children; Guidance for Industry; Availability, 90 *Federal Register* 1135, January 7, 2025. See https://www.federalregister.gov/documents/2025/01/07/2024-31534/action-levels-for-lead-in-processed-food-intended-for-babies-and-young-children-guidance-for.

[4] The Attorneys General of New York, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Mexico, New Jersey, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Washington and Wisconsin.

[5] In a scientific study published in September 2024 as part of its Closer to Zero program, FDA scientists use the term "young children" to mean children aged one to 6 years, inclusive. See Brenna M. Flannery, Laurie C. Dolan, Dana Hoffman-Pennesi, Alexandra Gavelek, Olivia E. Jones, Richard Kanwal, Beverly Wolpert, Kathleen Gensheimer, Sherri Dennis, Suzanne Fitzpatrick, U.S. Food and Drug Administration's interim reference levels for dietary lead exposure in children and women of childbearing age, Regulatory Toxicology and Pharmacology, Volume 110, 2020, 104516, https://doi.org/10.1016/j.yrtph.2019.104516.

[6] Comment from Environmental Defense Fund (EDF), Posted May 8, 2023, FDA-2022-D-0278-0069. See https://www.regulations.gov/comment/FDA-2022-D-0278-0069.
[7] Comment from Environmental Defense Fund (EDF), Posted June 28,2022, FDA-2019-D-5609-0013. See https://www.regulations.gov/comment/FDA-2019-D-5609-0013.
[8] EPA, Economic Analysis of the Reconsideration of the Dust-Lead Hazard Standards and Dust-Lead Post-Abatement Clearance Levels Final Rule, EPA 810-R-24-005, October 2024, https://www.epa.gov/system/files/documents/2024-10/508_lcri_final_ea_10-21-2024.pdf. See Section 5.5.
[9] Dana Hoffman-Pennesi, Sarah Winfield, Alexandra Gavelek, Sofia M. Santillana Farakos & Judith Spungen (05 Sep 2024): Infants' and young children's dietary exposures to lead and cadmium: FDA total diet study 2018–2020, Food Additives & Contaminants: Part A, DOI: 10.1080/19440049.2024.2396910.
[10] Spungen JH. 2019. Children's exposures to lead and cadmium: FDA total diet study 2014-16. Food Addit Contam Part A Chem Anal Control Expo Risk Assess. 36(6):893–903. doi: 10.1080/19440049.2019.1595170.
[11] Brenna M. Flannery, Laurie C. Dolan, Dana Hoffman-Pennesi, Alexandra Gavelek, Olivia E. Jones, Richard Kanwal, Beversly Wolpert, Kathleen Gensheimer, Sherri Dennis, Suzanne Fitzpatrick, U.S. Food and Drug Administration's interim reference levels for dietary lead exposure in children and women of childbearing age, Regulatory Toxicology and Pharmacology, Volume 110, 2020, 104516, https://doi.org/10.1016/j.yrtph.2019.104516.
[12] FDA first established an IRL in 2018, referring to the IRL as "a maximum daily intake for lead." See https://web.archive.org/web/20181231200702/https://www.fda.gov/food/foodborneillnesscontaminants/metals/ucm2006791.htm. The agency reduced the IRL in 2022 in response to changes made to the Blood Lead Reference Value by CDC in 2021. It also clarified the purpose of the IRL to the current version. See https://www.cdc.gov/lead-prevention/php/news-features/updates-blood-lead-reference-value.html.
[13] FDA, Lead in Food and Foodwares, accessed on January 17, 2025, at https://www.fda.gov/food/environmental-contaminants-food/lead-food-and-foodwares.
[14] Brenna M. Flannery, Karlyn B. Middleton, Updated interim reference levels for dietary lead to support FDA's Closer to Zero action plan, Regulatory Toxicology and Pharmacology, Volume 133, 2022, 105202, https://doi.org/10.1016/j.yrtph.2022.105202.
[15] CDC, National Health and Nutrition Examination Survey, accessed on January 26, 2025 at https://www.cdc.gov/lead-prevention/php/data/nhanes.html.
[16] Dana Hoffman-Pennesi, Sarah Winfield, Alexandra Gavelek, Sofia M. Santillana Farakos & Judith Spungen (05 Sep 2024): Infants' and young children's dietary exposures to lead and cadmium: FDA total diet study 2018–2020, Food Additives & Contaminants: Part A, DOI: 10.1080/19440049.2024.2396910.
[17] See Table 2. These values are based on the hybrid model where values less than the reporting limit (RL) are set to zero if there were no detections from 2013 to 2020; otherwise, values less than the RL set to 0.5*RL.
[18] Based on a linear relationship. A 1.5 µg/day mean dietary exposure for children 1 to 6 years of age divided by 2.2 µg/day multiplied by 0.35 µg/dL.
[19] EPA, Economic Analysis of the Reconsideration of the Dust-Lead Hazard Standards and Dust-Lead Post-Abatement Clearance Levels Final Rule, EPA 810-R-24-005, October 2024, https://www.epa.gov/system/files/documents/2024-10/508_lcri_final_ea_10-21-2024.pdf. See Section 5.5.
[20] EPA, Economic Analysis of the Reconsideration of the Dust-Lead Hazard Standards and Dust-Lead Post-Abatement Clearance Levels Final Rule, EPA 810-R-24-005, October 2024, https://www.epa.gov/system/files/documents/2024-10/508_lcri_final_ea_10-21-2024.pdf. See Section 5.5.
[21] Crump, K.S., C. Van Landingham, T.S. Bowers, D. Cahoy, and J.K. Chandalia. 2013. A statistical reevaluation of the data used in the Lanphear et al. (2005) pooled-analysis that related low levels of blood lead to intellectual deficits in children. Critical Reviews in Toxicology 43(9): 785–799. Doi:10.3109/10408444.2013.832726.
[22] We are using a β of -2.41 instead -3.25 to
[23] EPA, Economic Analysis of the Final Lead and Copper Rule Improvements, Lead Hazard Standards and Dust-Lead Post-Abatement Clearance Levels Final Rule, October 2024, https://www.epa.gov/system/files/documents/2024-10/508_lcri_final_ea_10-21-2024.pdf. See Section 5.5.2, Exhibit 5-25 using value for male and female combined.

[24] HBBF, Comment on Proposed lead in Baby Food Guidance, March 27, 2023, at https://www.regulations.gov/comment/FDA-2022-D-0278-0044. Since FDA did not change the action levels when it finalized the guidance, the estimates should still be accurate.
[25] Brenna M. Flannery, Laurie C. Dolan, Dana Hoffman-Pennesi, Alexandra Gavelek, Olivia E. Jones, Richard Kanwal, Beverly Wolpert, Kathleen Gensheimer, Sherri Dennis, Suzanne Fitzpatrick, U.S. Food and Drug Administration's interim reference levels for dietary lead exposure in children and women of childbearing age, Regulatory Toxicology and Pharmacology, Volume 110, 2020, 104516, https://doi.org/10.1016/j.yrtph.2019.104516.
[26] HBBF, Comment on Proposed lead in Baby Food Guidance, March 27, 2023, at https://www.regulations.gov/comment/FDA-2022-D-0278-0044. Since FDA did not change the action levels when it finalized the guidance, the estimates should still be accurate.
[27] Dana Hoffman-Pennesi, Sarah Winfield, Alexandra Gavelek, Sofia M. Santillana Farakos & Judith Spungen (05 Sep 2024): Infants' and young children's dietary exposures to lead and cadmium: FDA total diet study 2018–2020, Food Additives & Contaminants: Part A, DOI: 10.1080/19440049.2024.2396910.
[28] HBBF, Comment on Proposed lead in Baby Food Guidance, March 27, 2023, at https://www.regulations.gov/comment/FDA-2022-D-0278-0044. Since FDA did not change the action levels when it finalized the guidancfflannery
e, the estimates should still be accurate.
[29] Section 11092 and 110963 of the California Health and Safety Codes as amended by AB-899 that was effective on October 10, 2023. See https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202320240AB899.
[30] Raw agricultural commodities and homemade foods would remain exempt.
[31] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-juice.
[32] 10 ppb X 3 X 7 since the 10 ppb was in the reconstituted composite of three products. The powder was reconstituted with seven times more water.
[33] Dana Hoffman-Pennesi, Sarah Winfield, Alexandra Gavelek, Sofia M. Santillana Farakos & Judith Spungen (05 Sep 2024): Infants' and young children's dietary exposures to lead and cadmium: FDA total diet study 2018–2020, Food Additives & Contaminants: Part A, DOI: 10.1080/19440049.2024.2396910.
[34] *Id.*
[35] CDC, Testing for Lead Poisoning in Children, accessed at https://www.cdc.gov/lead-prevention/testing/ on February 4, 2025.
[36] 21 C.F.R. § 10.33(d).