CR ConsumerReports™

May 8, 2023

Docket Clerk
United States Food and Drug Administration
Division of Dockets Management, HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2022-D-0278; Guidance for Industry on Action Levels for Lead in Baby Food

To Whom it May Concern:

Thank you for the opportunity to submit comments on the Food and Drug Administration's Guidance for Industry on Action Levels for Lead in Baby Food.

Founded in 1936, Consumer Reports (CR) is an independent, nonprofit and nonpartisan organization that works with consumers to create a fair and just marketplace. Known for its rigorous testing and ratings of products, CR advocates for laws and company practices that put consumers first. CR is dedicated to amplifying the voices of consumers to promote safety, digital rights, financial fairness, and sustainability. The organization surveys millions of Americans every year, reports extensively on the challenges and opportunities for today's consumers, and provides ad-free content and tools to 6 million members across the U.S.

We note that in recent years, additional studies are showing that heavy metals, especially lead, are more hazardous than previously thought with new data finding adverse effects, particularly neurobehavioral effects, at lower and lower levels. Consequently, there is enough data on the toxicity of lead heavy metals for the FDA to set mandatory standards or limits on baby foods.

FDA has proposed new guidelines to lower the levels of lead found in processed foods meant to be eaten by children under the age of two. The FDA proposal would set action levels for three categories of food. The action limit would be 10 parts per billion (ppb) for fruits; vegetables (excluding single-ingredient root vegetables); mixtures (any combination of fruits, vegetables, grains, and meat); yogurts; custard/puddings; and single-ingredient meats. The action level for single ingredient root vegetables would be 20 ppb. The action level for dry infant cereals would be 20 ppb. FDA also had data on grain-based snacks (e.g., arrowroot cookies, puffs, rusks, teething biscuits) but did not set a proposed action limit for this category of baby food.

The proposed guidelines are a good step forward. However, the action levels should be lower, mandatory, and applied to all foods fed to children under the age of 2, not just processed food. In addition, FDA should also set action limits for the grain-based snacks.

One concern we have with the FDA proposal is that it only applies to processed food. FDA defines such processed food as "food packaged in jars, pouches, tubs, and boxes represented or purported to be specifically for babies and young children less than two years old" and "does not include raw agricultural commodities, homemade foods … or any beverages."[1] Based on their exposure assessment analysis, FDA stated that their proposed limit of 10 ppb for fruits, vegetables (excluding single ingredient root vegetables), etc. would result in a 26% reduction in lead from consumption of these foods at the 90th percentile consumption levels for babies and young children; a 27% reduction for root vegetables, and a 24% reduction for dry infant cereals.

While these reductions for the covered foods sound significant, the figures are based on the implicit assumption that babies and young children less than 2 years old only eat the processed food versions of these foods and not homemade foods or raw agricultural commodities. This assumption is not true, as many parents do feed their infants and young children homemade baby food often using books, videos, and websites to guide their food preparation.

A study published last year that looked at heavy metals in 288 foods—both processed baby food and homemade baby food—and "found no evidence to suggest that homemade baby food has lower heavy metal levels than store-bought brands."[2] Since the FDA proposal only applies to processed baby food, a potential problem could be that the companies meet the action limits for the processed baby foods by rejecting ingredients that have higher lead levels, but then diverting those ingredients to the regular market, meaning that the lead levels in those products might actually increase. Consequently, we think that the FDA's proposed action limits for the various processed baby foods should apply to all versions of those foods and not just the processed versions, otherwise the projected reductions in dietary exposure to lead for babies and young children will not be achieved.

A second concern with the FDA's proposed guidelines is that the action levels appear to prioritize achievability over public health. FDA has defined "achievability" as "percentage of samples in each food category that fell at or below the proposed action level."[3] In other words, "achievability" is roughly the percentage of the market for that food category that could not meet the proposed limit, and so represents an economic cost for that food category. Rather than have the achievability be the same for the three food categories (so that each food category would roughly suffer the same relative economic cost), FDA appears to have set the action levels that prioritize "achievability" over public health. The achievability for fruits, vegetables (excluding single-ingredient root vegetables), etc. was 96% for 10 ppb; for root vegetables, achievability was 88% at 20 ppb; for dry infant cereal it was 90%. Thus, with the proposed action limits, the fruits, vegetables (excluding single-ingredient root vegetables), etc. food category would only take a 4% economic hit (that is 4% of their products would exceed the limit and so couldn't be sold), while the single-root vegetables category would be expected to take a 12% economic hit, which is three-fold higher. If the fruits, vegetables (excluding single-ingredient root vegetables), etc. food category

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[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-food-intended-babies-and-young-children

[2] Houlihan, J. 2022. Is Homemade Baby Food Better? Healthy Babies Bright Futures, August 2022. At: https://hbbf.org/sites/default/files/2023-03/BabyFoodReport2022_R11_Web.pdf

[3] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-food-intended-babies-and-young-children

had the same achievability as the root vegetables, e.g., 88%, then the action limit would be reduced significantly below 10 ppb.

In order to prioritize public health, we feel FDA should set the same achievability for all three food categories. Our 2018 testing of baby foods found that 80% of the baby foods had lead levels below 10 ppb, showing that many manufacturers can achieve lower levels. We urge FDA to prioritize public health by setting the same achievability levels for all the food categories. At minimum, FDA could set the achievability level for all the food categories at the same level as the root vegetables category, which has the lowest achievability level. FDA could decide to set the achievability at 85% or even 80% and then calculate how much lower the action limits would be for the various food categories.

A third concern is that the FDA did not set action levels for grain-based snacks (e.g., cookies, crackers, crisps, puffs, rusks, teething biscuits) since they were not sure how frequently they were consumed. In our 2018 study on heavy metals in baby foods, we found that grain-based snacks were the most problematic of the four categories we tested—baby cereals, packaged fruits and vegetables, packaged meals, and packaged snacks.[4] In addition, a CR survey found that snacks are the most common type of packaged products that babies and toddlers eat, with 72% of parents saying they feed their child one of the types of snack foods we tested.[5] Thus, we urge FDA to set action levels for grain-based snacks.

In addition to the proposed guidelines for lead in some baby foods, the FDA could take action immediately on various heavy metals in baby foods, based on CR testing results.[6] Given that there is no safe level for heavy metals, such as lead, we urge the FDA to move more quickly in setting action levels or limits for a range of baby foods. While the proposed action limits in this proposal are a good first step, we urge FDA to set an ultimate goal of having no measurable amounts of cadmium, lead, or inorganic arsenic in baby and children's food—and to use the most sensitive testing methods to determine the presence of those elements. FDA should view the proposed action limits in this guideline as an incremental target for industry to meet along the way, while continually recognizing that the end goal must always be to have no measurable amounts. The agency also should insist that manufacturers meet strong, recognized best practices—such as the Codex Alimentarius Code of Practice for the Prevention and Reduction of Lead Contamination in Foods.[7]

We applaud FDA for finalizing the inorganic arsenic (iAs) apple juice action level of 10 parts per billion (ppb) and other fruit juices at 20 ppb. Next, the FDA should set a new limit of iAs in fruit juice of 3 ppb. Our testing of heavy metals in fruit juices, published in the January 2019 issue of *Consumer Reports*, found that the majority (58%) of samples were below 3 ppb of iAs, indicating such a limit is achievable to

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[4] Hirsch, J. 2018. Heavy metals in baby food: what you need to know. *Consumer Reports*. At: https://www.consumerreports.org/health/food-safety/heavy-metals-in-baby-food-a6772370847/

[5] *Id.*

[6] https://advocacy.consumerreports.org/wp-content/uploads/2019/01/Consumer-Reports-Letter-to-FDA-on-Heavy-Elements-in-Juices-1-30-19.pdf

[7] FAO and WHO. 2022. Code of Practice for the Prevention and Reduction of Lead Contamination in Foods. Codex Alimentarius Code of Practice, No. 56-2004. Codex Alimentarius Commission. Rome. https://doi.org/10.4060/cc0579en

meet.[8] We therefore urge the FDA to set a new 3 ppb limit for inorganic arsenic that is applicable to all affected types of juice, in the form of a mandatory standard or, at a minimum, an action level.

For lead, FDA should set a mandatory standard of lead in fruit juice of 1 ppb. Although there is a 5 ppb limit for lead in bottled water, the American Academy of Pediatrics advocates for a 1 ppb lead limit for school drinking water fountains. Our testing of fruit juices found that a majority of juice samples could meet this 1 ppb limit, which demonstrates that this is an achievable standard.

For cadmium, whose risks are similar to lead, FDA should set a mandatory standard of cadmium in fruit juice of 1 ppb. Our testing of fruit juices found that over 90% of juice samples could meet this 1 ppb limit, so establishing a mandatory limit of 1 ppb cadmium for fruit juices would not be disruptive.

Finally, for the proposed Guidance on lead levels in baby foods, we urge the FDA to set action levels for all the foods covered by the guidance, both raw agricultural commodities and homemade food, and not just the processed foods. In addition to the three food categories, FDA should also set action levels for the grain-based snacks. These action levels should be lower than the levels being proposed and all the food categories should meet the same level of achievability, which at a minimum should be 88%, but should decide to set the achievability at 85% or even 80% and then calculate how much lower the action limits would be for the various food categories. Also, rather than being voluntary, these action levels should be transformed into mandatory limits.

Best,

Michael Hansen, Ph.D.
Senior Scientist
Consumer Reports
101 Truman Ave.
Yonkers, NY 10703

Brian Ronholm
Director, Food Policy
Consumer Report
101 Truman Ave.
Yonkers, NY 10703

[8] Hirsch, J. 2019. Arsenic and lead are in your fruit juice: what you need to know. *Consumer Reports*. At: https://www.consumerreports.org/food-safety/arsenic-and-lead-are-in-your-fruit-juice-what-you-need-to-know/