March 26, 2023

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Submitted to on-line docket

Re: Comments on "Action Levels for Lead in Food Intended for Babies and Young Children; Draft Guidance for Industry" at Docket No. FDA-2022-D-0278

To Whom it May Concern:

The Environmental Defense Fund (EDF) appreciates the opportunity to comment on Food and Drug Administration's (FDA) recently released draft guidance for action levels for lead in food intended for babies and young children. The proposed action levels are:

- 10 parts per billion (ppb) for fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats;
- 20 ppb for root vegetables (single ingredient); and
- 20 ppb for dry infant cereals.[1]

The Environmental Defense Fund (EDF) is an international, non-profit environmental organization dedicated to using science, economics, and law to build a vital Earth – for everyone. EDF's Healthy Communities program strives to make air, water, food, and household products safer through cutting-edge research, wide-ranging partnerships, and a focus on strengthening laws and policies that protect health.

If finalized without change, these levels would be the most stringent in the world, including current European standards of 20 ppb adopted in 2021.[2] For that FDA deserves credit.

We also compliment FDA for its clear statement in the proposal regarding the risks posed by lead:

> "Even low lead exposure can harm children's health and development, specifically the brain and nervous system. Neurological effects of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Lead exposures also may be associated with immunological, cardiovascular, renal, and reproductive and/or developmental effects. Because

[1] January 25, 2023 *Federal Register* notice at https://www.federalregister.gov/documents/2023/01/25/2023-01384/action-levels-for-lead-in-food-intended-for-babies-and-young-children-draft-guidance-for-industry, FDA Draft Guidance at https://www.regulations.gov/document/FDA-2022-D-0278-0002.
[2] Commission Regulation (EU) 2021/1317, August 9, 2021 at https://eur-lex.europa.eu/eli/reg/2021/1317/oj.

lead can accumulate in the body, even low-level chronic exposure can be hazardous over time."[3] *[References omitted]*

Nonetheless, FDA needs to do more to translate that clear statement into real progress. It must do better in three areas in order to strengthen its Closer to Zero Initiative:

- Improve the draft action levels by more closely applying the criteria FDA described in the draft guidance;
- Improve the process that FDA uses to develop and communicate this and future action levels in its Closer to Zero Initiative; and
- Along with USDA and industry, encourage and invest in research to reduce lead in baby food.

These improvements are important for two reasons. First, these proposed action levels will reduce babies' and young toddlers' dietary exposure to lead by a mere 3.6%, according to an analysis commissioned by Healthy Babies Bright Futures (HBBF) that the organization will share in its separate comments on the proposal. While we recognize that 3.6% technically fulfills the goal of getting closer to zero, it is far too little to address the challenge posed by lead to children.

Second, millions of babies and young toddlers currently exceed the agency's Interim Reference Level – essentially as daily maximum intake level – of 2.2 micrograms of lead per day (µg/day). For young children living in a home without lead pipes or lead paint, diet is the dominant source of their lead exposure.[4] Potential sources of lead in food include contaminated soil where crops are grown, contaminated water, atmospheric deposition from industrial activities and small-engine aircraft, food containers and handling equipment (including brass and bronze in water fixtures and tin alloys used to make food cans), and old lead-containing equipment used to process food.

I. Recommendations to improve the draft action levels by more closely applying the criteria FDA described in the draft guidance.

In its proposed guidance, FDA said:

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

- the action level should minimize the likelihood that a consumer will be exposed to lead levels exceeding the IRL (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."

[3] FDA Draft Guidance at https://www.regulations.gov/document/FDA-2022-D-0278-0002, p. 4.
[4] Valerie Zartarian, Jianping Xue, Rogelio Tornero-Velez, and James Brown 2017, Children's Lead Exposure: A Multimedia Modeling Analysis to Guide Public Health Decision-Making, Environmental Health Perspectives 125:9 CID: 097009 https://doi.org/10.1289/EHP1605. See also EDF Health Blog, New EPA model enables comparison of various sources of childhood exposure to lead, Sept. 14, 2017, https://blogs.edf.org/health/2017/09/14/new-epa-model-lead/.

To conduct our analysis, we combined into one file the three datasets[5] FDA published to support its proposed guidance on the day the action was announced.[6] Then we applied FDA's achievability target of 90th percentile to develop four recommendations to improve the action-level proposal and further reduce dietary exposure to lead for babies and young toddlers.

As we explain later in this comment, we provide specific recommendations to improve the criteria the agency has developed. Specifically, we think FDA should use a stricter target for infants and babies—as it did for inorganic arsenic in infant rice cereal.[7] Nonetheless, for this category of recommendations, we apply the criteria FDA developed.

a) **The 20-ppb action level for dry infant cereals should be limited to rice cereals; other grains should have a 10-ppb action level.**

   For the 299 rice cereal samples, the 90th percentile was 21 ppb of lead, and 28% had levels of 10 ppb or more. By contrast, only 1 of 85 samples (1.2%) for non-rice or multigrain cereals had 10 ppb or more of lead, and the 90th percentile was 8 ppb—so a 10-ppb level can be met and is justified consistent with FDA's criteria including the one limiting the number of unique action levels for simplicity. Note that rice cereal is also high in inorganic arsenic.

b) **Beyond dry infant cereals, foods that contain no root vegetables as ingredients should have an action level of 5 ppb instead of 10 ppb.**

   For 478 samples without root vegetables,[8] the 90th percentile was 3.3 ppb of lead, while 6% had 5 ppb or more. Note that half of those over 5 ppb had quinoa as an ingredient. Based on these results, foods other than dry cereals that do not have root vegetables should have an action level of 5 ppb. For 110 samples of food with root vegetables as one of multiple ingredients, the 90th percentile was 11 ppb of lead and 22% had 5 ppb or more. For those foods, an action level of 10 ppb is consistent with FDA's criteria. For foods whose only ingredient is a root vegetable, a 20-ppb action level is consistent with FDA's criteria.

c) **Grain snacks, such as teething biscuits, puffs, snack bars, and cookies should have an action level of 20 ppb; they are some of the most contaminated baby foods.**

   For 123 samples of these foods collected in 2013-14, the 90th percentile was 18 ppb of lead and 26% had 5 ppb or more. While the samples are old, there are sufficient samples of these popular products with high enough levels that the agency should set a level of 20 ppb consistent with FDA's criteria.

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[5] 1) Toxic Element Program consisting of 420 samples of dry infant cereals, fruits, mixtures and vegetables collected from 2008-2021; 2) FDA Survey 1 consisting of 407 samples of dry infant cereals and mixtures collected from 2013 to 2014; and FDA Survey 2 consisting of 416 samples of fruits, mixtures, vegetables, yogurts, custards/puddings, and single-ingredient meats collected in 2021. FDA reports in the Table 1 of the draft guidance that it used only 356, 147, 360 respectively of the sample results from those three sources. It appears that FDA used 147 samples from Survey 1 by only considering the categories labeled infant/toddler cereals and stage 2 toddler foods. We are unable to reconcile the other numbers and would appreciate FDA including a transparent explanation of which foods were excluded from the underlying datasets used in their analysis.

[6] We appreciate that on March 1, FDA published the data for some of the samples in one file and included results for cadmium, arsenic, and mercury as we requested. However, we received the information too late to use. We encourage the agency to release all the information when guidance is released.

[7] In its 2018 sample results, 764% of the 149 samples were at or below the 100 ppb limit for inorganic arsenic in infant rice cereal. When FDA proposed the limit in 2016, only 47% of samples could meet the limit, based on 76 infant rice cereals sampled in 2014.

[8] Excluding dry infant cereals.

d) **Quinoa, an increasingly popular ingredient for baby food, requires greater scrutiny, starting with increased sampling, since almost half of the samples with quinoa as the sole or main ingredient have lead levels of 20 ppb or more.**

The levels of lead in quinoa were worse than rice cereal, grain snacks, or root vegetables. While the data set is older (from 2014) and much smaller (30 samples), the 90th percentile was an astounding 90 ppb of lead. In addition, 41% had 20 ppb or more of lead and 58% were over 10 ppb.[9] Without more data, FDA should maintain a limit of 20 ppb for dry cereal and 10 ppb if that cereal is combined with other ingredients.

II. Recommendations to the process that FDA uses to develop and communicate this and future action levels in its Closer to Zero Initiative.

a) Rename draft guidance to "food intended for babies and young toddlers" to reduce confusion.

The title of the draft guidance promises more than it delivers. The term "young children" is misleading because the scope of the proposal is focused only on foods intended for individuals younger than 24 months of age, whereas the term "young children" generally includes children older than 24 months. For example, the National Association for Education of Young Children (NAEYC) considers "young children" to refer to children in the period of early childhood development, from birth through approximately age 8.[10] Less than two years is a very narrow definition of young children, especially since children up to or at age six are particularly vulnerable to the harm that lead causes to their brains.

Other federal agencies set standards for this broader range and use it in virtually all of their communications about lead. For example Environmental Protection Agency (EPA) says children six years old and younger are most susceptible to the effects of lead,[11] Centers for Disease Control and Prevention says lead is most harmful to children between the ages of 9 months and six years,[12] and the Department of Housing and Urban Development, Consumer Product Safety Commission and EPA say lead is especially dangerous for children under six.[13]

Therefore, we recommend that FDA rename the guidance from "food intended for babies and young *children*" to "food intended for babies and young *toddlers*." We retain the word "young" because toddlers are generally considered to be between 1 and 3 years of age.[14]

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[9] We included all 29 samples that FDA identified as quinoa, even if the agency did not also identify them as dry cereal.

[10] NAEYC at https://www.naeyc.org/resources/position-statements/dap/glossary#.

[11] See for example: EPA. Learn about Lead. Updated 2022. https://www.epa.gov/lead/learn-about-lead#effects and EPA. Children's Health Month: Preventing Lead Exposure for Children Before it Occurs. 2021. https://www.epa.gov/sciencematters/childrens-health-month-preventing-lead-exposure-children-it-occurs.

[12] See for example CDC. Morbidity and Mortality Weekly Report 34(5);66-8,73, 1985. https://www.cdc.gov/mmwr/preview/mmwrhtml/00000659.htm#:~:text=Lead%20is%20most%20harmful%20to,these%20same%20groups%20becomes%20feasible.

[13] HUD, EPA, and CPSC, Protect Your Family from Lead in Your Home, .https://www.hud.gov/sites/documents/PROTECT_FAMILY_LEAD_2012.PDF

[14] Centers for Disease Control and Prevention at https://www.cdc.gov/ncbddd/childdevelopment/positiveparenting/toddlers2.html and American Academy of Pediatrics at https://www.healthychildren.org/English/ages-stages/Pages/default.aspx.

b) Clearly articulate a plan to set action levels for other foods commonly eaten by babies and young toddlers, as well as other young children.

We fully support FDA's decision to prioritize food intended for babies and young toddlers. They are the most vulnerable population, and these foods make up a major part of the market for foods intended for young children. In addition, parents and caregivers are often paying a premium for these products.

We understand that FDA intends to use its process of continuous improvement to address lead in other foods. However, the plan for addressing three major types of food consumed by babies and young toddlers as well as other young children (see below) is not mentioned in "Planned Action Items" of the Closer to Zero Initiative webpage. This suggests that they are not in the plan.

Therefore, we recommend that FDA establish and effectively communicate through the final guidance and revisions to the Initiative's webpage a timeline to set action levels for the follow types of foods:

1. *Fruits, cereals, and vegetables that parents use to make homemade foods for their babies and young toddlers*.

   Healthy Babies Bright Futures' (HBBF) "Report: Is Homemade Baby Food Better?" made clear that homemade foods are often likely to be as or more contaminated than baby food. This is true whether or not the ingredients are labelled as organic.

   We expect that the difference will become greater in the future as companies marketing food for babies and young toddlers more tightly manage their ingredient suppliers to avoid lead contamination in their products. If FDA fails to address this type of food, it will be doing a disservice to parents who assume that homemade food will be better, or who cannot afford or access commercially prepared baby food.

2. *Food marketed for a general audience (e.g., raisins, applesauce, canned food) that parents commonly feed to children*.

   Families on tight budgets often cannot justify the premium that baby food companies charge for their products. Fortunately, the U.S. Department of Agriculture's Special Supplemental Nutrition Program for Women, Infants, and Children (also known as WIC) includes baby foods in their program, providing critical access to these foods for millions of babies and young children. But gaps remain.

   For health equity reasons alone, FDA should address foods marketed to a general audience that parents commonly feed to children. The agency can use existing surveys from What We Eat in America (WWEIA) and Gerber's Feed Infants and Toddlers Study (FITS) to identify the types and amounts of these general-audience foods that children commonly eat.

   FDA already set this precedent when it prioritized lead in juice in its April 2022 draft guidance. Those action levels applied to all juice, and based on the justification in the document, FDA selected juice because children commonly consumed it and because it is often contaminated with lead.

3. *Food marketed to young children over age 2, including kids' meals and some snack bars.*

   As noted earlier, CDC, EPA, and HUD use six years of age as the cutoff for defining young children because lead can pass through the blood-brain barrier and harm the developing brain. FDA needs to define young children similarly. Then, FDA needs to clearly and effectively articulate a schedule to issue action levels for foods marketed to these young children.

c) **Improve Transparency in Decision-Making to Enhance Credibility and Effectiveness by More Clearly Explaining Options Considered and Rationale for Action Level Selection**

FDA's current approach only compares the selected option to the status quo. We know many of the excellent FDA staff working on the issue and how seriously they approach this effort. They surely considered many variations before settling on the proposed option. However, that information is largely omitted from the proposed guidance and supporting materials. This omission makes it more difficult to provide constructive comments to the agency and undermines the credibility of the decision.

We also think that including more information on the options considered and why the Agency chose the proposed option might accelerate review by the White House's Office of Management and Budget (OMB). In general, FDA develops action levels through guidance rather than rulemaking because it claims that the process enables the agency to move more quickly and to make updates more easily. Guidance has typically been subject to less stringent interagency review by OMB.[15]

Nonetheless, FDA's action levels for lead and inorganic arsenic in food have undergone OMB review, and that review has been quite lengthy.[16] The delays have been significant enough that FDA revised its *Closer to Zero* Action Plan in January by:

- Changing its commitment to publish draft action levels for lead and arsenic to only submitting the document for interagency review. These documents are not public until finalized.
- Eliminating its commitments to finalize all of its draft action levels.
- Dropping the word "Action" from the title of the program.

A clearer explanation of the options considered and why the selected option was chosen is an element that OMB typically considers in regulatory reviews. We believe that inclusion of this element might help streamline OMB review of action levels moving forward.

d) **Take into account dietary exposures that protect more than just the 90th percentile of children.**

FDA typically uses the 90th percentile to evaluate exposure to contaminants and additives. We have not seen a rationale for selecting this value over more protective ones—like the 95th – 99th percentiles commonly used in Europe for food[17] or, in the U.S., using the 97.5th percentile to set an elevated blood lead level (CDC).

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[15] Specifically, OMB's Office of Information and Regulatory Affairs (OIRA).

[16] For example: 1) Lead in food intended for babies and young toddlers where proposed guidance was under OMB review for 9 months; 2) Lead in juice where proposed guidance was under OMB review for 13 months; 3) Inorganic arsenic in infant rice cereal where final guidance was under OMB review for 4 months; and 4) Inorganic arsenic in apple juice where final guidance has been under OMB review for 21 months and counting.

[17] European Food Safety Authority. Overview of the procedures currently used at EFSA for the assessment of dietary exposure to different chemical substances. EFSA Journal 2011;9(12):2490. https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2490

As part of its commitment to continuous improvement, and to enhance transparency, FDA should estimate dietary exposures at the 95th, 97.5th, and 99th percentile and consider how action levels will reduce exposure for these highly exposed consumers.

As we explained in a blog on the lead-in-juice proposal, while percentiles may seem abstract, we think it is important to recognize that, in this case, they represent lead-exposed children. Using the 90th percentile means that the 2.4 million children ages 1 to 6 years who are exposed to higher levels of lead are not taken into account.[18] When including children younger than age 1, the number is even greater.

e) **Calculate the socioeconomic benefits of the options considered and the one selected.**

As we explained in a blog on the lead-in-juice proposal, we encourage FDA to use methods developed by EPA (and accepted by OMB) to quantify the societal benefits of reducing young children's exposure to lead. We applied that method to estimate that a 6% reduction in exposure for children younger than six years of age would yield $1 billion per year in benefits. We think this approach is a valuable tool to help the agency and stakeholders consider options. It would also prompt industry to provide realistic estimates of the cost to achieve the limits, rather than the vague claims it often relies on.

f) **Transparently compare the options considered to their impact on FDA's Interim Reference Level (IRL) of 2.2 µg/day for children.**

In 2018, FDA established an IRL of 3.5 µg/day. The agency describes this value as the "maximum daily intake for lead from food" of lead for children. This is not a health-based level—rather it is a target the agency uses to drive lead contamination lower through its 2021 Closer to Zero Action Plan. Using FDA's own analysis, we estimated that more than 1 million young children (aged 2-6 years) exceeded the IRL.

In July 2022, FDA lowered the IRL to 2.2 µg/day to conform to changes in CDC's Blood Lead Reference Level. We estimated that 7 million young children (one-third of all children in this age group) exceeded this level and called on FDA to more rigorously compare its proposal—including options considered—to the IRL. We also asked the agency to estimate the number of children who would no longer exceed the IRL as a result of each option. In the draft guidance document, FDA states that under the status quo "the 90th percentile dietary exposures for babies and young children are below the IRL for lead of 2.2 µg/day for children." While the agency shows that 90th percentile intake of specific groupings of foods are below the IRL, the agency provides no details for how it reached that conclusion, which should apply to dietary intake from all sources and not just those covered by the action levels.[19]

In other words, when making comparisons to the IRL, FDA should include the contribution from all foods, i.e., also including those not covered by the proposed action levels, such as: 1) juices; 2) grain snacks (e.g., teething biscuits, cookies, and puffs); 3) fruits, cereals, and vegetables that parents use to make homemade foods for their babies and young toddlers, even though these products are often likely to be as or more contaminated, regardless of whether they are organic; and 4) foods marketed for a general audience such as applesauce and canned food, that parents (especially those on tight budgets) commonly feed to children.

[18] Approximately 4 million children are born each year in the United States. Over a six-year period, that would mean ~24 million children in the age range.

[19] The three values in the sixth column of Table 4 add up to 2.02 µg/day but that is not a valid method for 90th percentiles.

In addition, the Agency's assertion contradicts that of an FDA scientist who estimated in 2019 that children 12 to 36 months had a 90th percentile lead intake of 2.6 µg/day from their diet.[20] It is unclear if this is due to differences in methodology, or a true decrease in exposure between then and now.

Assuming the claim is true and that the 90th percentile is at 2.2 µg/day, it still means that 10% of the approximately four million children born each year— or about 400,000 children – exceed the IRL. This illustrates the flaw in choosing the 90th percentile to represent an "upper bound" and "a health protective measure to account for babies and young children (0-23 months) who consume larger amounts of food and would therefore have higher exposures."

As we have previously commented, FDA's choice of the 90th percentile is out of step with other agencies, including CDC and EPA. The agency should not only be transparent about its calculations, but it should be clear how many children will be brought below the IRL with each option considered in order to provide critical context for the strengths and weaknesses of the agency's analysis.

g) **Post a red-lined version of the document that compares the original version submitted to OMB for review and the final version.**

Agencies, including EPA and FDA, post a comparison that shows the changes made to its rule and accompanying justification as a result of the OMB review. FDA does not do that for OMB review of guidance. The comparison helps stakeholders understand the key issues, and it poses little burden to either agency. FDA should post the red-lined version.

h) Use FITS to estimate exposures.

We are concerned that FDA's analysis largely relies on What We Eat in America (WWEIA) to identify the types and amounts of foods that babies and young toddlers commonly eat. While WWEIA is an excellent source of information, the number of babies and young toddlers in the two-year cycle is relatively small. Combining multiple cycles increases the numbers but then misses trends in foods.

We encourage FDA to supplement WWEIA with the results from Gerber's Feed Infants and Toddlers Study (FITS). Because FITS surveys many more babies and young toddlers in greater detail, it will allow the agency to have more accurate dietary exposure estimates that better reflect market trends. This is especially true for foods like grain-based snacks where the amount consumed is smaller than grain-based cereals.

We understand that use of a proprietary database like FITS raises concerns with transparency and the Information Quality Act. There ways to work through these issues, especially through the use of peer-reviewed studies.

i) Use data provided by food companies, NGOs, labs, and growers

FDA relied entirely on the results of analytical testing of food conducted by its lab. We are concerned that this approach ignores excellent analytical testing conducted by labs of samples provided by food companies, growers, and advocates. HBBF in particular has conducted significant testing of baby food and has offered to provide the data to the agency to no avail.

[20] Based on the hybrid estimate from the report. Note that the lower bound is 1.8 and upper bound 4.4 µg/day.

The agency should be gathering as much trustworthy data as possible from all sources. This approach gives 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.

We understand concerns about how to ensure the data is indeed trustworthy. Rather than ignoring the data, the agency should communicate what information it would need to ensure trustworthiness. This could include using labs that have demonstrated proficiency using a third-party evaluator and are operated consistent with ISO 17025 (or equivalent). The agency could insist on additional detail in the lab report – referred to as Level II or Tier 2 reporting – so it can verify the lab's performance. It can also require the submitter to provide documentation on the product identification and chain of custody.

The practical effect of this approach would likely be to encourage more trustworthy testing and transparency.

Put simply, ignoring trustworthy data is not consistent with "FDA's steadfast commitment to ensuring our decisions will continue to be guided by the best science."[21]

III. FDA, USDA, and industry need to invest in research to reduce lead in baby food.

Beyond these specific proposed action levels, FDA, USDA, and industry need to support research if we are to make progress in reducing toxic element contamination. We identify seven research needs.

a) **Rice is highly contaminated with lead, as well as with high levels of inorganic arsenic.**

Rice has long-been recognized as the primary source of young children's dietary exposure to inorganic arsenic. FDA's data now make clear that lead contamination is also a significant issue. For the 299 rice cereal samples, the 90th percentile was 21 ppb of lead, and 28% had levels of 10 ppb or more. In contrast, only 1 of 85 samples (1.2%) for non-rice or multigrain cereals had 10 ppb or more of lead, and the 90th percentile was 8 ppb, so a 10-ppb level can be met and is justified.

In 2020, FDA highlighted that inorganic arsenic concentrations for infant rice cereal had dropped from 64% greater than 100 ppb in 2011-13 to 53% in 2014 to 26% in 2018. Some of this progress can be attributed to baby food companies screening out rice with higher levels, a change that shifts the more highly contaminated products to general market. However, there is also compelling research showing that improved growing and processing methods such as intermittent flooding of fields, removing bran, and decanting cooking water significantly reduce inorganic arsenic contamination.

More research is needed to reduce lead contamination in rice and how it correlates to inorganic arsenic levels). And, more work is needed to finalize an approach to account for the cumulative effects of multiple toxic elements in food.

[21] Cavazzoni P, Marks P, Mayne S et al. "FDA career officials: We're committed to science-based health decisions." *USA Today*, Sept. 10, 2020.

b) **Sweet potatoes commonly have significant lead contamination, but research shows promise.**

Baby food sweet potatoes had one of the highest mean lead concentrations of any food tested, according to the TDS FY 2018-FY2020 report, and lead contamination of baby food sweet potatoes was significant enough that FDA set an action level for foods where they were the only ingredient. FDA's three data sources evaluated 14 samples of baby food sweet potato puree and half of the samples were above 15 ppb with the highest at 34 ppb.

Several years ago, EDF funded Dr. Arthur Villordon at Louisiana State University's Sweet Potato Research Center to investigate lead contamination and identify potential research opportunities. He and his team determined that much of the contamination was in the peel, suggesting that optimized peeling would be beneficial. They also identified the possible role of type of sweet potato—as well as opportunities to manage essential nutrient availability—to reduce uptake of lead.

Along with researchers from Mississippi State University, University of California—Davis, Colorado State University, and two units of USDA's Agricultural Research Service, Dr. Villordon and his team applied to USDA last month for significant research support to evaluate those and other opportunities. This and similar research should be supported and the findings disseminated to baby food growers and manufacturers.

c) **Quinoa is highly contaminated with lead and cadmium. Arsenic levels were not provided.**

The levels of lead in quinoa were significantly higher than rice cereal, grain snacks, or root vegetables. While the data set is older (from 2014) and much smaller (29 samples), the 90th percentile was an astounding 90 ppb of lead. In addition, 41% had 20 ppb or more of lead and 58% were over 10 ppb.[3] In addition, cadmium was also present in all but two of the samples ≥ 10 ppb and 75% were ≥ 50 ppb.

EDF talked with one of the leading researchers on quinoa, Dr. Lori Hoagland of Purdue University, about opportunities to reduce contamination. She thought that changing strains of quinoa might be the best strategy, although research funds are limited. Clearly, more research is needed to better understand lead contamination in quinoa and how it can be reduced.

d) **Carrots also have significant lead contamination.**

As with sweet potatoes, FDA data showed that carrots were also contaminated with lead, although at lower levels than sweet potatoes—the other root vegetable common in baby food. For the 39 samples of carrot puree, the 90th percentile was 15 ppb of lead, and 20% had levels of 10 ppb or more.

Several years ago, EDF funded Dr. Hoagland to investigate lead contamination in carrots and identify potential research opportunities. She and her team determined that much of the contamination was in the outer areas of the carrots, suggesting that optimized peeling would be beneficial. They also found that a particular strain of carrot showed promise in reducing uptake of lead and cadmium.

Along with researchers from Michigan State University, Cornell University, University of Buffalo, University of California—Davis, and a unit of USDA's Agricultural Research Service, Dr. Hoagland and her team applied to USDA last month for significant research support to determine more effective ways of reducing lead in carrots. Again, this and similar research should be supported, and the results disseminated to baby food growers and manufacturers.

e) **Cocoa powder and baking powder had the highest lead concentrations in the FY2018-FY2020 TDS Elements Report but few samples were tested.**

As noted in the TDS FY2018-FY2020 report, the "highest lead concentrations were in baking powder and cocoa powder; but as these foods were added to the National Food List in FY2020, there is only one sample representing each food, and results may not be representative and indicate a need for further testing." The report also notes that "cocoa powder can contain higher levels of lead than other foods and ingredients (Abt et al., 2018)." It should thus be a priority for further testing and for efforts to reduce contamination levels.

f) **Baby food teething biscuits and sandwich cookies, along with baby food sweet potatoes, had the highest mean lead concentrations according to the TDS FY 2018-FY 2020 report.**

As noted in the TDS FY2018-FY2020 report, "foods with the highest mean lead concentrations were baby food sweet potatoes, baby food teething biscuits, and sandwich cookies." It also states that "sandwich cookies have cocoa powder as an ingredient and that might explain the source of the lead." Rice flour in the teething biscuits is a likely contributor to high levels in teething biscuits. Clearly, research is needed to drive down these levels. These findings also underscore the importance of FDA establishing action levels for baby food teething biscuits and sandwich cookies as a priority.

g) **Additive or Synergistic Impacts of Lead, Cadmium, Arsenic, and Mercury**

FDA's *Closer to Zero* Action Plan focuses on four toxic elements—lead, cadmium, inorganic arsenic, and mercury. One of the early goals was to consider the cumulative effects of these toxic elements on children's developing brains.

Dr. Piper Reid Hunt and a team at FDA's Office of Applied Research and Safety Assessment have been studying the harm to the developing nervous systems of nematodes (*C elegans*) because they are similar enough to human neural development to allow helpful insights. Her important research is not yet made public.

In summary, we encourage FDA, USDA, and industry to invest in research to reduce contamination of foods with toxic elements and evaluate and act on that research to reduce the presence of these substances in the diet and their effect on children.

Thank you for considering our comments. You can contact us at tneltner@edf.org for more information.

Sincerely,

Tom Neltner

Tom Neltner, JD
Senior Director, Safer Chemicals Initiative
Environmental Defense Fund

Lisa Y. Lefferts, MSPH
Environmental Health Consultant