RE: Action Levels for Lead in Juice; Draft Guidance for Industry; Availability (Docket No. FDA-2019-D-5609-0002)

The Center for Science in the Public Interest (CSPI) respectfully submits these comments to the docket (Docket No. FDA-2019-D-5609-0002). CSPI is supportive of the efforts undertaken by the U.S. Food and Drug Administration (FDA) to reduce dietary exposure to lead, especially among children, but the proposed guidance does not go far enough to protect children from dangerous levels of lead exposure. Even after finalization, the proposed action levels would allow juice to contribute a large proportion (20-30%) of the interim reference level (IRL) for lead for children. In these comments, we argue that the inadequate protection offered by these action levels is the result of the agency’s use of a flawed approach to setting action levels. We recommend revisions the agency should make to its approach to ensure that action levels are derived in a public health-driven manner rather than one that seems to cater to the needs of industry. Most pertinently, we request that FDA reverse its approach: establish an explicit public health goal, draft action levels required to achieve that goal, assess feasibility, and consider whether temporary exceptions or flexibility are necessary while improvements to agricultural and manufacturing processes are developed and implemented to further reduce lead contamination.

In light of the two recent Congressional reports documenting heavy metal contamination in baby foods,1 we appreciate FDA’s efforts to bring the levels of these contaminants “closer to zero” in foods consumed by children.2 Infants and young children are especially susceptible to the neurotoxic effects of heavy metals because their brains are still developing and because they absorb lead at higher rates than adults.3 There is no safe level of lead exposure for children, a

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fact recognized by FDA and other U.S. and global health authorities. Reducing heavy metal contamination in children’s foods is essential to protecting public health. We applaud the fact that the draft action levels for lead of 10 ppb for apple juice and 20 ppb for other juices, if finalized, would be more protective than existing standards in the United States (i.e., current FDA guidance recommends less than 50 ppb) and internationally (e.g., the Codex Alimentarius Commission sets maximum levels for lead in juices ranging from 30 ppb to 50 ppb, depending on the type of juice). However, while the draft action levels are an improvement, they are not sufficiently protective of children’s health.

CSPI is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public’s health through better nutrition and safer food. The organization does not accept government grants or corporate donations. A core part of CSPI’s mission is providing consumers with current information about their health and well-being. CSPI publishes Nutrition Action, which provides science-based advice on health and nutrition to hundreds of thousands of readers. CSPI regularly advocates for greater transparency, disclosure, and the safety of food ingredients.

A. FDA Should Establish Explicit Public Health Goals to Use in Deriving Action Levels for Lead in Foods and Beverages Consumed by Children

As authority for setting the proposed action levels for lead in juice, FDA cites regulations 21 CFR 109.4 & 109.6, which authorize FDA to set action levels based on criteria requiring, among other things, such level to be “sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.” Consistent with its regulations, FDA action levels for lead in foods, especially those consumed by children, should be standards based primarily on public health, not achievability. Action level development should start, first and foremost, with an explicit public

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health goal (e.g., a maximum acceptable level of lead exposure from juice, or a target percent reduction in current lead exposure from juice). With a goal established, action levels should then be set to achieve that goal. Considerations of achievability and feasibility should be considered as mitigating factors. Although the agency frames its “Achievability Assessment” as a separate and secondary portion of the process for proposing these action levels, it is in fact achievability, not public health, that was the foundation of the draft action levels for lead in juice.

Rather than establishing standards based on public health and adjusting them only for unavoidable contamination, as dictated by sound public health principles and contemplated in the agency’s own regulations, the agency first established an arbitrary minimum acceptable achievability (95%) and worked backward from there to derive action levels for lead in juice. Only after ensuring industrial achievability did the agency determine how action levels would influence lead exposure in children. It is implied, therefore, that FDA is only willing to consider an action level if it presents a minimal burden to industry. This approach was modeled off that used by the Codex Alimentarius Commission in setting maximum levels for lead in foods for international trade, and thus, is likely familiar and acceptable to many stakeholders. However, CSPI argues that this approach is backward. What is currently easiest for the juice industry should not be the foundation from which action levels are derived. Public health, not achievability, should be the foundation of action levels.

The Draft Supporting Document for Establishing FDA’s Action Levels for Lead in Juice describes three separate approaches FDA attempted for setting action levels for lead in juice, each of which was principally guided by achievability. For its first attempt, the agency sought to establish an action level for all juices based on 95% achievability for the most contaminated types of juice, specifically grape juice, pomegranate juice, and juices from berries. That is, they settled on a single action level of 30 ppb for all juices because, at this level, 95% of grape juices, pomegranate juices, and juices from berries could remain in compliance (i.e., only 5% would be considered adulterated and subject to enforcement action). The 95% achievability threshold is arbitrary and not grounded in protecting public health. Using the 95th percentile of most contaminated types of juice to set action levels makes it unlikely that lead levels in other types of juice would change substantially. Indeed, the agency appropriately decided to reject this approach because most other juice types had 95th percentile lead levels at or below 20 ppb, meaning implementing an action level of 30 ppb would result in minimal reduction in the lead content in most types of juice. This first approach was not sufficiently grounded in public health. The most effective way to reduce lead exposure from juice would logically include consideration of both lead contamination levels and relative consumption rates for different types of juice.

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11 Ibid.
12 Ibid.
13 Ibid. p. 8.
The agency’s second approach attempted to set an action level at 20 ppb, presumably because this represented the 95th percentile, or greater, of contamination for most juice types. FDA also rejected this approach because it also failed to account for consumption.

In its final attempt, FDA did take consumption into some consideration. Thus, of the three, this is clearly the best approach, though it is still not sufficiently grounded in public health. The agency established two separate action levels: one for apple juice (10 ppb) due to the fact that apple juice is the most commonly consumed juice among children, and one for other juices (20 ppb). Yet once again, rather than set a standard based on a public health-based target, the action level for apple juice was selected because it is equivalent to the to the 95th percentile lead level in apple juice (i.e., 95% achievability). For the other juices category, the proposed action level of 20 ppb is associated with 97% achievability, based on the agency’s achievability assessment. Within the “other juices” category, achievability ranges from 88% (grape juice) to 100% (mango juice and coconut water), with most juice types within this category exceeding 95% achievability, according to Table 3 of the Supporting Document. Specifically, achievability is higher than 95% for carrot (99%), coconut water (100%), mango (100%), mixed-type (99%), orange (99%), pear (98%), and pineapple (98%) juices, and as such, the draft action level of 20 ppb will have minimal impact on lead levels in these juice types.

It is particularly problematic that orange juice would be largely unaffected by the draft action levels because, after apple juice, citrus juice is the second-most widely consumed juice type by young children. According to a CDC analysis of National Health and Nutrition Examination Survey (NHANES) data from 2011-2012, citrus juice accounted for 9.99% of fruit intake among children aged 2-5 years old, whereas apple juice accounted for 16.78% and other fruit juices collectively accounted for 14.08% of fruit intake in this age range. Further stratification of the other juice category when setting action levels could prevent uneven impact on the various juice types, ensure incentives to reduce lead are more evenly distributed across industry, and potentially produce greater reductions in lead levels in juice. We urge FDA to adopt an action level specific to orange juice to prevent it from being largely excluded from the impact of the draft guidance.

The failure to ground this process in an explicit public health goal has led to inconsistencies in outcome. According to the agency’s exposure analysis, after finalizing these action levels, at 90th percentile consumption lead exposure via apple juice is estimated to be 0.43 µg lead per day,

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14 Ibid.  
15 Ibid.  
16 Ibid.  
17 Ibid. p. 8-9.  
18 Ibid. p. 9.  
19 Ibid. p. 24-25.  
20 Ibid.  
while exposure via other juices is estimated to be 0.64 µg/day.\textsuperscript{22} Thus, the failure to foreground public health would allow children who consume other juices to experience nearly 50% more lead exposure from juice per day compared to children who consume apple juice (i.e., \(\frac{0.64 - 0.43}{0.43} \times 100 = 49\%\)). FDA estimates these exposure levels amount to a 46% reduction in lead exposure from apple juice and a 19% reduction in lead exposure from other juice at 90th percentile consumption, relative to exposure without the proposed action levels.\textsuperscript{23} While CSPI recognizes that these are not insignificant reductions in exposure, the lack of consistency between the two categories of juice emphasizes the problems with an approach founded on achievability rather than public health.

These exposure levels—0.43 µg/day and 0.64 µg/day—are still too high to be considered protective when considering the IRL and the whole diet. FDA has established an IRL of 3 µg/day for dietary lead exposure for children.\textsuperscript{24} Apparently because lead exposure from juice at 90th percentile consumption, after finalization of the action levels, is estimated to be below 3 µg/day, the agency considered the draft action levels sufficient.\textsuperscript{25} However, the current IRL is too high (see Section C) and applies to the whole diet, not just juice. The fact that exposures from juice would be below the IRL does not necessarily mean that children’s overall dietary exposure to lead would be below the IRL. Action levels for juice need to be set in consideration of the whole diet and the relative contribution of juice to dietary lead exposure (see Section D). Furthermore, although the IRL may be useful in establishing a public health-based goal for guiding action level development, it must be noted that the U.S. Centers for Disease Control and Prevention (CDC) blood lead reference value (BLRV), on which the IRL is based, is not a level of exposure that is considered safe. The BLRV is a threshold used to identify children with relatively high levels of lead exposure.\textsuperscript{26} Exposure levels at and below the BLRV are still harmful because no safe level of lead exposure has been identified for young children. Ideally, lead exposures will be driven much lower than the IRL through the Closer to Zero action plan.

FDA based its exposure and achievability assessment on data collected as part of their Toxic Element Program (TEP) between 2005 and 2018.\textsuperscript{27} When more recent data become available, FDA should update its assessment and revise action levels accordingly.

B. FDA’s Approach Should Model That of the U.S. Occupational Safety and Health Administration, not the Codex Alimentarius Commission

Although the “achievability first” approach utilized by FDA and based on the Codex Alimentarius Commission approach might be considered desirable by some stakeholders, another federal agency tasked with protecting humans from toxic exposures demonstrates that

\textsuperscript{22} FDA, op. cit. Draft Supporting Document. p. 9.
\textsuperscript{23} Ibid.
\textsuperscript{25} FDA did not directly state that they concluded the draft action levels were sufficient based on the IRL, but they did make a point to state that exposure estimates were below the IRL of 3 µg/day.
\textsuperscript{27} FDA, op. cit. Draft Supporting Document. p. 6-7.
public health-centered approaches can be implemented. The U.S. Occupational Health and Safety Administration (OSHA) uses a public health-centered approach in setting standards for exposures to occupational hazards, including toxic chemicals. The Occupational Safety and Health Act of 1970 (OSH Act), which specifies the manner in which OSHA must develop and promulgate occupational safety and health standards, makes clear that “attainment of the highest degree of health and safety protection” is the primary goal of the OSHA standard-setting process, whereas technical and economic feasibility are among the “other considerations” the agency can make.28

When assessing technical feasibility, OSHA is not required to set standards based on what is achievable with standard technology and practices. Per a report published by the U.S. Congress Office of Technology and Assessment, “[OSHA] can set a standard at a level achievable only by the most advanced plants in an industry or one that forces the development and diffusion of new technology.”29 For economic feasibility, OSHA must, “show that the standard will not cause massive economic dislocations within, or imperil the existence of, affected industries,” but it, “need not guarantee the continued viability of individual firms that historically have lagged other regulated firms in providing safe places of employment.”30 OSHA is prohibited from using a direct benefit-cost analysis for setting health standards because, “Congress had placed the benefit of worker health above all other considerations save those making attainment unachievable.”31 FDA interprets achievability based on current levels of lead contamination found in juice across the whole industry, not what is attainable by the most advanced agricultural producers or juice manufacturers. If there are producers or manufacturers who have successfully implemented methods to reduce lead contamination in raw crops or juice, action levels should be based on what those producers or manufacturers have achieved. If no such producers or manufacturers can be identified, then FDA should set action levels that incentivize efforts to develop practices to reduce lead contamination in raw agricultural crops and juice. Instead of the “achievability first” approach used to develop the draft action levels for lead in juice, FDA should adopt a “health first” approach modeled on that used by OSHA.

C. The Interim Reference Level (IRL) for Children’s Dietary Lead Exposure Should be Revised to 2 µg/day

The IRL may be helpful in establishing a public health-based goal for steering the Closer to Zero action plan and assessing its success, but the IRL for lead for children needs to be revised. FDA currently sets the IRL for children’s dietary lead exposure at 3 µg/day,32 but this value is based on out-of-date information. FDA derived this IRL using the CDC BLRV, a U.S. Environmental Protection Agency marker for environmental lead levels.

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28 29 USC 655
30 Ibid.
31 Ibid.
Protection Agency (EPA) conversion factor to convert between dietary lead intake and blood lead levels, and an uncertainty factor, with the following formula:33

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IRL = \frac{CDC\ BLRV}{uncertainty\ factor} \times EPA\ conversion\ factor
\]

At the onset of the Closer to Zero action plan, the CDC BLRV was 5 µg/dL, the EPA conversion factor was 1 µg lead intake/day per 0.16 µg lead/dL blood, and the uncertainty factor was 10, leading to an IRL of 3 µg/day for children:

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IRL = \frac{5 \mu g/dL}{10} \times \frac{1 \mu g\ intake/day}{0.16 \mu g/dL} = 3 \mu g/day
\]

On May 14 2021, the CDC updated the BLRV to 3.5 µg/dL,34 meaning the IRL should be recalculated:

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IRL = \frac{3.5 \mu g/dL}{10} \times \frac{1 \mu g\ intake/day}{0.16 \mu g/dL} = 2 \mu g/day
\]

If the agency uses the IRL to assess adequacy of draft action levels, it should use this lower value of 2 µg/day.

**D. FDA Should Consider Lead Exposure from Juice in the Context of the Whole Diet and the Revised IRL**

It is important to contextualize lead exposure from juice within the whole diet, and absent another public health-based target, the IRL can provide a limited basis for assessing adequacy. According to an FDA assessment of Total Diet Study data from 2014-2016, mean and 90th percentile upper bound dietary lead exposures in children aged 1-6 years old exceed 2 µg/day.35 Thus, there is an urgent need to reduce lead contamination in foods and beverages consumed by children, targeting the components of the diet that contribute most to dietary lead exposure. Fruit—including whole fruit and fruit juices—was among the categories of foods that FDA found to be a major contributor to dietary lead exposure for children aged 1-6 years old.36 Nearly a quarter (24.7%) of dietary lead exposure in children aged 1-6 years old was estimated to arise from fruit and fruit juices. Grains were the primary contributors (27.5%) to dietary lead

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34 CDC, op. cit. Blood Lead Reference Value.


36 Ibid.
exposure, and dairy (16.8%) and mixture products (15.5%) were also important. Therefore, it is seemingly appropriate for FDA to prioritize lead reduction in juice as part of the Closer to Zero action plan, but it is difficult to assess adequacy of the draft action levels for apple juice and other juices without simultaneous consideration of action levels for fruits, grains, dairy, and mixture products. Nonetheless, the levels of exposure from juice that would occur even after finalization of these draft action levels seem disconcertingly high. FDA estimates that after finalizing the draft action levels juice alone could account for a substantial portion of the of the IRL for children. At 90th percentile consumption, after finalization of these action levels, exposure to lead from apple juice is estimated to be 0.43 µg/day, which would account for 21.5% of the revised IRL. Exposure to lead from other juices is estimated to be 0.64 µg/day, which would account for 32% of the revised IRL. Considering that juice and fruit, in totality, contribute to 24.7% of dietary lead exposure in children aged 1-6 years old, one could reasonably argue that lead exposure from juice and fruit should not exceed 24.7% of the IRL (0.494 µg/day) to ensure that children’s total dietary exposure remains below the IRL. According to a CDC assessment of NHANES data from 2011-2012, juice only comprises 40.85% of total fruit intake among children aged 2-5 years old, with apple juice accounting for 16.78% and all other juices accounting for 24.07% of fruit intake. Yet the draft guidance would allow lead exposure from apple juice alone to approach the limit for all fruits (0.43 µg/day vs. 0.494 µg/day) and exposure from other juices alone to exceed the limit for all fruits (0.64 µg/day vs. 0.494 µg/day), which clearly indicates these action levels are too high to be considered protective. Establishing explicit public health-based targets and considering the whole diet before drafting action levels for individual components of the diet would allow the agency and stakeholders to better assess the adequacy of draft action levels for juice.

E. Extend the Guidance to Juice Used as an Ingredient in Juice Drinks and Other Foods

The scope of the draft guidance currently applies to juice, defined in 21 CFR 120.1(a) as “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.” However, the guidance fails to specify how foods that contain less than 100% juice, including foods required to bear a percentage juice declaration under 21 CFR 101.30, will be addressed under the guidance. Juice that fails the FDA’s standards for lead could potentially be diverted for use in such products, which are commonly referred to as “fruit drinks.” Accordingly, diverting juice that is higher in lead away from 100% fruit juice and into juice drink beverages may have the unintended consequence of raising lead exposure in populations that disproportionately consume fruit drinks. For example, one study found that purchase of such

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37 Ibid.  
38 Herrick et al., op. cit.  
39 21 CFR 120.1(a)  
40 21 CFR 101.30
beverages among households with young children aged 1-5 years old is significantly higher in Non-Hispanic Black households compared to Non-Hispanic White and Hispanic households, and in low-income households than higher-income households, an outcome that may be attributable in part to a combination of lower price and targeted marketing of such beverages.41

To avoid harming individuals who disproportionately consume fruit drinks, we urge the FDA to specify that the action levels apply to all products that contain juice and will be considered with respect to the undiluted proportion of juice ingredient, rather than with respect to the end product. This will help ensure that juice that fails the standard cannot be utilized as an ingredient in juice drinks.

F. Conclusion

CSPI praises FDA’s commitment to lowering toxic element contaminants in foods, especially those marketed to children. With further refinement and additional efforts to ground the draft guidance and overall Closer to Zero action plan in public health protection, the agency could help guarantee that children’s dietary exposures to lead and other heavy metals are at near null levels.

We thank the agency for the opportunity to comment and their continued commitment to our children’s health. Questions related to this comment can be directed to Thomas M. Galligan, Principal Scientist for Food Additives and Supplements at Center for Science in the Public Interest, tgalligan@cspinet.org.

Sincerely,

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