



Dockets Management Staff (HFA-305)  
Food and Drug Administration  
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March 27, 2023

**RE: Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry; Availability (Docket No. FDA-2022-D-0278)**

The Center for Science in the Public Interest (CSPI) respectfully submits these comments on FDA's draft action levels and guidance on lead in food intended for babies and young children to the docket (Docket No. FDA-2022-D-0278). CSPI supports the efforts undertaken by the U.S. Food and Drug Administration (FDA) to reduce children's dietary exposure to lead.

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.

There is no safe level of lead exposure for children, a fact recognized by FDA<sup>1</sup> and other U.S.<sup>2,3</sup> and global<sup>4</sup> health authorities. Reviews by Rice et al. and Mushak concluded that 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.<sup>5,6</sup> Reducing heavy metal contamination in children's foods is essential to protecting public health.

As there are currently no standards for lead in children's foods, we applaud the fact that the FDA has drafted action levels for lead of 10 ppb for fruits, vegetables, mixtures, yogurts, custards/puddings, and single-ingredient meats and 20 ppb for single-ingredient root vegetables

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<sup>1</sup> U.S. Food and Drug Administration. Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry. January 2023. Accessed 24 January 2023. Available: at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-food-intended-babies-and-young-children..>

<sup>2</sup> U.S. Centers for Disease Control and Prevention. Health Effects of Lead Exposure. 9 March 2022. Accessed: 21 June 2022. Available at: <https://www.cdc.gov/nceh/lead/prevention/health-effects.htm..>

<sup>3</sup> U.S. Environmental Protection Agency. Basic Information about Lead in Drinking Water. 25 May 2022. Accessed: 21 June 2021. Available at: <https://www.epa.gov/ground-water-and-drinking-water/basic-information-about-lead-drinking-water>

<sup>4</sup> World Health Organization. Lead Poisoning. 11 Oct 2021. Accessed: 21 June 2022. <https://www.who.int/news-room/fact-sheets/detail/lead-poisoning-and-health>.

<sup>5</sup> Rice D, Barone S Jr. Critical Periods of Vulnerability for the Developing Nervous System: Evidence from Humans and Animal Models. *Environ Health Perspect.* 2000 Jun;108 Suppl 3(Suppl 3):511-33. doi: 10.1289/ehp.00108s3511. PMID: 10852851; PMCID: PMC1637807

<sup>6</sup> Mushak M. Gastro-Intestinal Absorption of Lead in Children and Adults: Overview of Biological and Biophysical-Chemical Aspects. *Chem. Speciation Bioavailability.* 1991; 3(3/4):87-104. doi: 10.1080/09542299.1991.11083160.

and dry infant cereals.<sup>7</sup> Additionally, we are encouraged by the recent reduction of the interim reference level (IRL) for lead in children from 3 µg/day (used in the juice guidance)<sup>8</sup> to 2.2 µg/day in the current guidance.<sup>9</sup> The IRL is “a measure of exposure from food that the FDA may use to determine if the amount of exposure to an individual element across foods could result in a specific health impact.”<sup>10</sup> While the level of 2.2 µg/day may still be too high considering that no level of lead exposure is safe, it is an improvement from the previously established IRL. We urge the agency to utilize the 2.2 µg/day level or below when it finalizes both the current draft guidance and the draft guidance for juice.

While we are supportive of the agency’s goal and recognize that these action levels will help reduce children’s dietary lead exposures, we have concerns about the manner in which these action levels were derived and find the lack of detail in the draft guidance lowers our confidence that these proposed action levels are the most protective action levels the agency could propose.

Unlike in FDA’s draft guidance on lead in juice, which explicitly used a problematic achievability-driven approach to setting action levels (i.e., the agency specified that action levels were set using an approach intended to ensure 95% of products on the market would meet the standard)<sup>11</sup>, in the present draft guidance, the agency framed its approach as one driven by exposure. In comments submitted to the agency last June, CSPI criticized FDA for its use of an achievability-driven approach when proposing action levels for lead in juice.<sup>12</sup> Thus, we were encouraged to see this purported refocusing on exposure, rather than achievability. However, due to a lack of detail, it is unclear how the agency operationalized this shift in focus. In particular, it is unclear what the quantitative exposure benchmarks of success were and whether those benchmarks were directly used as the foundation for the proposed action levels for lead in foods intended for children. We are concerned that these action levels were arbitrarily derived and give undue deference to achievability.

Moreover, CSPI considers the term “achievability,” as used by the FDA in its’ Closer to Zero Action Plan, to be a misnomer. As with juice, the agency defined achievability in this draft guidance based on current levels of contamination (i.e., what the market has already

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<sup>7</sup> U.S. Food and Drug Administration. Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry. January 2023. Accessed 24 January 2023. Available: at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-food-intended-babies-and-young-children>.

<sup>8</sup> U.S. Food and Drug Administration. Action Levels for Lead in Juice: Draft Guidance for Industry. 27 April 2022. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-juice>. Accessed: 21 June 2022.

<sup>9</sup> Flannery BM, Middleton KB. Updated Interim Reference Levels for Dietary Lead to Support FDA’s Closer to Zero Action Plan. *Regul Toxicol Pharmacol*. 2022 Aug; 133(105202). doi: 10.1016/j.yrtph.2022.105202. Epub 2022 Jun 8. PMID: 35690180

<sup>10</sup> U.S. Food and Drug Administration. FDA Releases Action Plan for Reducing Exposure to Toxic Elements from Foods for Babies, Young Children. 8 April 2021. <https://www.fda.gov/news-events/press-announcements/fda-releases-action-plan-reducing-exposure-toxic-elements-foods-babies-young-children>. Accessed 14 March 2023.

<sup>11</sup> U.S. Food and Drug Administration. Draft Supporting Document for Establishing FDA’s Action Levels for Lead in Juice. 27 April 2022. <https://www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/draft-supporting-document-establishing-fdas-action-levels-lead-juice>. Accessed: 21 June 2022.

<sup>12</sup> Center for Science in the Public Interest. Comments on Action Levels for Lead in Juice; Draft Guidance for Industry; Availability (Docket No. FDA-2019-D-5609-0002). 28 June 2022.

achieved).<sup>13</sup> Instead, achievability should be based on what is attainable through implementation of existing best practices or development of new best practices to limit lead in these products (i.e., what industry can achieve in the future with the most advanced efforts to drive lead contamination to zero using existing or novel techniques). In other words, if there are manufacturers that have already developed and implemented effective methods for limiting lead content in finished baby food products, FDA should determine what level of lead contamination in the market might be achieved if all manufacturers implemented those same practices.

Therefore, in these comments, we ask that FDA further revise its approach to better ground the Closer to Zero action plan in public health protection. FDA should establish an explicit public health goal, draft action levels required to achieve that goal, assess achievability (as we define it above, not as defined currently by FDA) in accomplishing that goal, and consider whether exceptions or flexibility are necessary while improvements to agricultural and manufacturing processes are sought and implemented to further reduce lead contamination in children's foods.

Furthermore, we present results from a novel analysis we performed in response to the fear that enactment of strict action levels would result in reduced availability of nutritious foods for infants and young children. We show that the baby food industry requires less than 0.5% of all the carrots and sweet potatoes available on the U.S. market to meet the demands of children under 24 months of age. These findings should be considered when assessing the achievability of the baby food industry meeting strict health-protective action levels for root vegetable products. Responsible sourcing practices, either currently available or feasibly developed, should be able to reserve the least contaminated sweet potatoes and carrots for products specifically produced for babies and young children, while industry also strives to reduce heavy metal contamination across the whole sweet potato and carrot markets.

#### **A. FDA Should Establish Explicit Public Health Goals to Use in Deriving Action Levels for Lead in Foods and Beverages Consumed by Children in the Context of the Whole Diet**

As authority for setting the proposed action levels for lead in food intended for babies and young children, FDA cites regulation 21 CFR 109.6, which authorizes 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.”<sup>14</sup> Action level development should therefore start with an explicit public health goal. With a goal established, action levels for the product should then be set to achieve that goal. Considerations of achievability should then be considered as mitigating factors.

In its draft guidance, FDA states that it took into account four considerations when developing action levels, two of which pertain to exposure:

- “the action level should minimize the likelihood that a consumer will be exposed to lead levels exceeding the IRL;
- as appropriate, there should be a limited number of unique action levels for simplicity;

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<sup>13</sup> FDA, Draft Food Guidance. p. 10; FDA. Draft Juice Guidance Support Document, p. 9.

<sup>14</sup> 21 CFR 109.6; 21 USC 346.

- 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.”<sup>15</sup>

Thus, the agency is framing exposure as a key consideration alongside (or even following) achievability and simplicity. However, achievability is the only consideration for which FDA includes a quantitative metric of success. The agency did not define in quantitative terms what it means by “minimize the likelihood that a consumer will be exposed to lead levels exceeding the IRL” and it failed to prescribe a target level of exposure reduction. This leaves us uncertain as to whether the agency actually had a specific public health target in mind as it developed these goals.

It must be noted that the IRL, which is based on the Centers for Disease Control and Prevention Blood Lead Reference Value of 3.5µg/dL<sup>16</sup>, is not necessarily the most appropriate metric to use in this case because even exposure at the IRL is damaging, considering that no level of lead exposure is safe. Ideally, the Closer to Zero plan will drive exposure levels considerably lower than the IRL. It would be better for FDA to determine a level of harm reduction it aims to achieve based on health outcomes and a resultant target exposure level rather than exposure (see Section D below). Nonetheless, using a measure of exposure (i.e., the IRL) is preferable to using achievability as the basis of action levels.

Despite FDA framing this as an exposure-driven approach to setting action levels, it is not clear from the draft guidance that exposure was the starting point from which proposed action levels were derived. If FDA had taken an exposure-driven approach, we would have expected the agency to: (1) assess total dietary exposure to lead in children in the U.S, (2) determine the proportion of children currently exceeding the IRL, (3) identify which components of the diet contribute to dietary lead exposure (especially in children exceeding the IRL), (4) identify action levels on individual foods that would ensure no children exceed the IRL, and (5) then assess whether these ideal action levels are achievable. Thereafter, if need be, FDA could refine the action levels to provide temporary flexibility to allow industry time to develop and implement best practices to meet the objectively determined ideal action levels.

It does not seem that this is the approach FDA has implemented. Instead, the agency’s approach, as described in the draft guidance, does not enunciate a clear exposure goal. Instead, the guidance outlines an approach that seems to arbitrarily presuppose that 10 ppb is the ideal action level for most foods. The agency does not indicate why 10 ppb was chosen as the starting point, state whether other action levels were considered (except in the case of 10 ppb for root vegetables), nor specify the criteria it used to determine whether the action level(s) considered produced the desired impact in an achievable way. We have attempted to infer such information from the details provided in the draft guidance.

**i. Possible presupposition of 10 ppb as the ideal action level**

In the first portion of its assessment, Section III, *Lead Levels Found in Food Intended for Babies and Young Children*, FDA concludes with this statement:

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<sup>15</sup> FDA, Draft Food Guidance. p.8

<sup>16</sup> Centers for Disease Control and Prevention. Childhood Lead Poisoning Prevention: Blood Lead Reference Value. <https://www.cdc.gov/nceh/lead/data/blood-lead-reference-value.htm#print>. Accessed 15 March 2023.

“FDA’s review of data indicates that different types of food intended for babies and young children exhibit different lead concentrations (Tables 2 and 3). In addition, for the TEP and survey data, 85 percent of samples had lead levels lower than 10 ppb, while for the TDS data 97 percent of samples had lead levels lower than 10 ppb. The mean lead levels for the categories of food intended for babies and young children were below 10 ppb (Tables 2 and 3) except for root vegetables (Table 3).”<sup>17</sup>

This survey of current products appears to be the basis from which 10 ppb was established as the starting point for action levels. However even here, FDA does not indicate why 10 ppb was used as a benchmark.

Notably, this presupposition was not extended to all foods. For dry infant cereals, FDA merely proposed an action level of 20 ppb without explanation.

## **ii. Consideration of other action levels**

FDA proposes to set action levels on three categories of foods, but it only reports considering more than one possible action level for one category: root vegetables. In Section IV, *FDA’s Action Levels for Lead in Food Intended for Babies and Young Children*, FDA states:

“Moreover, at an action level of 10 ppb (the action level provided in this guidance for other vegetable products), root vegetable achievability was only 71%. For root vegetables, we expect that an action level of 20 ppb will help minimize the likelihood of significant exposure to lead, while also considering achievability. At the action level of 20 ppb, root vegetables have an achievability rate of 88%. Root vegetables are a source of several nutrients important in growth and development for babies and young children, and a lower action level could reduce the availability of single-ingredient root vegetable foods on the market intended for infants and young children. Therefore, we consider it appropriate to place single-ingredient root vegetables in their own category.”<sup>18</sup>

For the other categories of food, FDA does not discuss considering more than one action level.

## **iii. Criteria for determining whether action levels produced the desired impact**

As noted above, FDA took two exposure considerations into account when deriving these action levels:

- “the action level should minimize the likelihood that a consumer will be exposed to lead levels exceeding the IRL;
- the action levels should result in a reduction in exposure to lead;”<sup>19</sup>

FDA does not specify quantitative criteria it used in assessing whether action levels achieved these goals, but such criteria can potentially be inferred.

In describing its exposure assessment, FDA stated that exposures from these three categories of

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<sup>17</sup> FDA, Draft Food Guidance. p. 8.

<sup>18</sup> Ibid. p. 9.

<sup>19</sup> Ibid. p. 8

food already fall below the IRL at 90<sup>th</sup> percentile consumption,<sup>20</sup> meaning inherently, exposure from these three categories after setting action levels will also fall below the IRL. In raising this point, the agency might be implying that any reduction in levels of exposure from these categories of food would be sufficient. These potential implications are flawed for several reasons.

First, according to an FDA assessment of Total Diet Study data from 2014-2016, mean and 90<sup>th</sup> percentile upper bound dietary lead exposures in children aged 1-6 years old exceed 2.2 µg/day,<sup>21</sup> suggesting that current levels of dietary lead exposure are not acceptable because young children are exceeding the IRL, contrary to FDA's goal to minimize the likelihood of that occurring.

Second, the IRL is inclusive of the whole diet. Therefore, the fact that exposures from an individual food category, or even a group of categories, fall below the IRL does not necessarily mean that children's overall dietary exposure to lead would be below the IRL. As such, it is important to contextualize lead exposure from individual foods within the whole diet. FDA determined in 2016 which components of the diet contribute most to lead exposure in children aged 1-6 years old, reporting that grains, fruits (including juices), dairy, and mixture products are the main contributors in this demographic.<sup>22</sup> As such, the question FDA should address is whether the proposed action levels, in addition to those proposed for juice, properly target the main contributors to lead exposure in infants and young children and collectively ensure that children do not exceed the IRL. However, neither this guidance nor last year's draft guidance on juice took a whole-diet approach to assessing adequacy of proposed action levels.

Third, exposures were estimated using the 90<sup>th</sup> percentile of consumption. However, the agency acknowledges "(t)he 90<sup>th</sup>, 95<sup>th</sup> and 97.5<sup>th</sup> percentile intakes are used by various regulatory bodies in the world to represent 'high level' consumers."<sup>23</sup> To truly minimize the likelihood of consumers exceeding the IRL, FDA would need to consider exposures at higher levels of consumption.

To assess attainment of its second goal, exposure reduction, FDA estimated the percent reduction in lead exposure from each category at 90<sup>th</sup> percentile consumption that these action levels would produce. For the category "fruits, vegetables [excluding single-ingredient root vegetables], mixtures [including grain and meat-based mixtures], yogurts, custards/puddings, and single ingredient meats" the proposed 10 ppb action level would reduce lead exposure by 26% at 90<sup>th</sup> percentile consumption with 96% achievability. For root vegetables, an action level of 20 ppb would produce a 27% reduction in lead exposure at 90<sup>th</sup> percentile consumption with 88% achievability. For dry infant cereals, exposure would be reduced by 24% at 90<sup>th</sup> percentile

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<sup>20</sup> FDA, Draft Food Guidance, p. 9, "As shown in Table 4, for Scenario A, the 90th percentile dietary exposures for babies and young children are below the IRL for lead of 2.2 µg/day for children."

<sup>21</sup> Spungen JH. Children's Exposures to Lead and Cadmium: FDA Total Diet Study 2014-16. Food Addit Contam Part A Chem Anal Control Expo Risk Assess. 2019 Jun;36(6):893-903. doi: 10.1080/19440049.2019.1595170. Epub 2019 Apr 15. PMID: 30985263.

<sup>18</sup> Spungen, 2019, p. 7.

<sup>23</sup> U.S. Food and Drug Administration. Guidance for Industry: Estimating Dietary Intake of Substances in Food. August 2006. Accessed 2 March 2023. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-estimating-dietary-intake-substances-food>

consumption by an action level of 20 ppb with 90% achievability. Thus, it appears that FDA sought to reduce exposure by approximately 25% in these categories, though the agency has not stated that this was an explicit goal. If it was, FDA has offered no explanation as to why it selected this specific goal. Therefore, while FDA has estimated that dietary lead exposures will be reduced to some degree through these action levels, the agency has not presented convincing evidence that these action levels truly minimize the likelihood that a consumer will not exceed the IRL nor has it explained why the level of exposure reduction offered by these levels is acceptable.

#### **iv. Criteria for determining whether action levels are achievable**

FDA states that, “for those baby foods where lead levels are already relatively low, the action levels should be established where achievability is in the 90<sup>th</sup>-95<sup>th</sup> percentile range.”<sup>24</sup> We are pleased that the agency is no longer limiting achievability to the arbitrary limit of 95%, like it did when proposing action levels for juice, but the 90<sup>th</sup>-95<sup>th</sup> percentiles are equally arbitrary and equally lacking scientific basis or public health rationale.

FDA rejected a 10 ppb action level for root vegetables on the basis of low achievability (71%) relative to the proposed action level of 20 ppb (88% achievability).

Achievability is defined as a “manufacturers’ ability to achieve the action levels for lead”<sup>25</sup>, but, as we demonstrate below, the baby food industry only needs to source 0.25% and 0.23% of the carrots and sweet potatoes, respectively, to meet the demands of children 24 months old and younger (see Section B below). By implementing better sourcing practices (i.e., testing of raw crops prior to use in manufacturing baby food and only using those with non-detectable levels of lead), we suspect industry could accomplish near 100% achievability while almost entirely eliminating lead from manufactured root vegetable baby food.

### **B. The Baby Food Industry Accounts for less than Two Percent of the Sweet Potatoes and Carrots Available on the US Market**

The role of nutrition within the Closer to Zero Action Plan was discussed at length at several events hosted by the FDA, USDA and NIH in recent years.<sup>26</sup> At these meetings, concerns were raised by industry representatives and health advocates as well as FDA and USDA staff that the imposition of action levels for toxic heavy metals in baby foods could result in the elimination of nutritionally important baby food products from the US market. For example, at the November 2021 Closer to Zero meeting, Dr. Susan Mayne, Director of the Center for Food Safety and Applied Nutrition at the FDA stated, “It is crucial to ensure that measures we take to limit toxic elements in foods do not have unintended consequences like eliminating from the marketplace the nutritious,

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<sup>24</sup> FDA, Draft Food Guidance, p. 8

<sup>25</sup> Ibid. p. 10

<sup>26</sup> A public meeting was hosted by the FDA on November 18th, 2021 titled, “Closer to Zero Action Plan: Impacts of Toxic Element Exposure and Nutrition at Different Crucial Developmental Stages”; another public meeting was hosted by the USDA and FDA on April 27th, 2022 titled, “U.S. Department of Agriculture Public Meeting—Closer to Zero: Impacts of Toxic Element Exposure and Nutrition in the Food System”; and a two-day workshop was hosted by the National Institute of Child Health and Human Development, National Institutes Health (NICHD/NIH) on February 9-10, 2023 titled, “Bridging the Biological and Communication Sciences on Nutrients and Environmental Contaminants in Foods to Support Child Development.”

affordable foods that many families rely on for their children or increase costs in ways that could limit availability or that efforts to reduce the presence of one toxic element in a food inadvertently increase another.”<sup>27</sup> At the same meeting, Dr. Aparna Bole, a pediatrician who spoke on behalf of the American Academy of Pediatrics (AAP) commented that in, “...addressing potential unintended consequences of measures to reduce toxic metal exposures...if policy changes designed to promote safety in packaged baby food inadvertently drive parents to exclusively use homemade baby foods, we know these... in some cases may not be nutritionally adequate.”<sup>28</sup>

CSPI agrees that ensuring children have access to nutritious and affordable foods is essential to protecting public health. However, action levels will only cause shortages if the U.S. agricultural commodities market does not have, or cannot generate, supplies of crops with sufficiently low levels of contamination to allow the baby food industry to maintain current production levels. If the supply of crops with low levels of heavy metal contamination exceeds demand by the baby food industry, then the focus of the Closer to Zero plan should be to identify means through which these less-contaminated crops can be prioritized for use in baby food production. Conversely, if supply were insufficient to meet demand, additional efforts would need to be made to increase the availability of crops with sufficiently low levels of heavy metal contamination, and shortages might occur if the new standard is enforced before such availability is increased.

At the FDA Webinar on the Draft Guidance for Lead in Food on March 2, 2023, Dr. Paul South, Director of the Division of Plant Products and Beverages, Office of Food Safety, commented “It is also possible in some cases where manufacturers who have found elevated levels in food or food ingredients intended for babies and young children to source food or food ingredients with low or no detectable lead levels. Manufacturers could consider increased testing of ingredients or finished products that are historically known to contain elevated lead levels. This is important for ingredients or finished products for food intended for babies and young children.”<sup>29</sup> Dr. Conrad Choiniere, Director of the Office of Analytics and Outreach, noted “...we anticipate we will routinely do surveillance of the industry by way of testing and sampling a product, as well as doing inspections. Including the specific evaluation of the supply chain controls.”<sup>30</sup>

Fortunately, according to our analysis for two categories of baby foods, sweet potatoes and carrots (detailed below and in the attached appendix), the demands of the baby food industry for raw carrots and sweet potatoes are minute relative to the overall supply on the US market. As such, through development and use of responsible sourcing practices (e.g., testing crops for heavy metals and selecting those with undetectable, or low, levels of heavy metals; or sourcing crops from geographic areas that generally have low levels of heavy metals in soil) industry should be able to produce enough root vegetable baby foods to meet the demand for sweet potatoes and carrots of children while simultaneously complying with a highly protective standard. We focused on sweet potatoes and carrots for the same reason that FDA has proposed

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<sup>27</sup> U.S. Food and Drug Administration. Transcript for “Closer to Zero Action Plan: Impacts of Toxic Element Exposure and Nutrition at Different Crucial Developmental Stages for Babies and Young Children; Public Meeting Docket No. FDA-2021-N-0966”. 18 November 2021. p. 20. (reported by Stacie Dorsey, Notary Public). Accessed 14 March 15, 2023.

<sup>28</sup> Ibid. p. 179,181.

<sup>29</sup> U.S. Food and Drug Administration. Transcript for “FDA Webinar: Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance”. 2 March 2023. p. 6. (compliments of Birnbaum Interpreting Services). Accessed 14 March 15, 2023.

<sup>30</sup> Ibid. p. 14



to set action levels on root vegetables, specifically (i.e., because evidence suggests these are among the foods with the highest level of lead contamination). Sweet potatoes and carrots were among the few specific crops discussed at the April 2022 USDA meeting (also discussed were rice and spinach) because it is well established that heavy metals accumulate in the edible portions of these plants.

Carrots<sup>31</sup> and sweet potatoes<sup>32</sup> are high in vitamin A, potassium, and other vitamins and minerals and are commonly consumed by children under two,<sup>33</sup> making them nutritionally important for young children. Hence concern over the possibility that strict action levels could cause a shortage.

CSPI estimates that only 0.23% of all sweet potatoes and 0.25 % of all carrots available for human consumption in the U.S. are needed to manufacture enough baby foods to meet children's (ages 0-24 months) demands (methodology in Appendix A). We are optimistic that at least 0.23% and 0.25% of the sweet potatoes and carrots, respectively, currently available on the US market should contain very low levels of heavy metals. However, we do not have adequate data on the distribution of lead in raw sweet potatoes and carrots to confirm this. FDA, USDA, and other researchers should collaborate to more comprehensively monitor the U.S. sweet potato and carrot markets for other heavy metal contaminants and thereby determine the fraction of these crops containing undetectable levels of heavy metals. However, the Total Diet Study (TDS) for fiscal years 2018-2020 provides some reassurance. All 27 samples of raw baby carrots had no detectable lead (100% non-detects). Eight out of 27 samples of baked sweet potatoes with peel removed had no detectable lead (29.6% non-detects)<sup>34</sup>. Although sample sizes are small—and thus likely not representative of the whole market—and the data for sweet potatoes is for the cooked, versus raw, food, these numbers suggest that the current availability of carrots and sweet potatoes with no detectable levels of lead is sufficient to meet the demand needed to produce enough carrot and sweet potato baby foods for children aged 0-24 months. In order to identify an adequate supply of carrots and sweet potatoes meeting specifications, baby food manufacturers would need to enhance testing of raw crops and identify sourcing techniques to funnel the least contaminated 0.25% and 0.23% of sweet potatoes and carrots into processed baby foods.

Our analysis also helps demonstrate how standards set under the Closer to Zero initiative for baby food will not negatively impact the overall food supply for older children and adults in any substantial way. Diverting the least contaminated 0.23% and 0.25% of sweet potatoes and carrots for use in baby food, an expected outcome of FDA setting standards for these products, is unlikely to appreciably impact the contamination levels within the remaining supply.

As new health-protective standards in baby food incentivize innovation of new crop cultivation and product manufacturing methods minimize heavy metal uptake by crops and reduce heavy metals in finished products, we hope that over time, the proportion of crops with very low levels of lead is likely to increase. These efforts will open up opportunities to decrease lead levels

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<sup>31</sup> USDA. FoodData Central: Carrots, cooked, boiled, drained, without salt. April 1, 2019. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/170394/nutrients>. Accessed December 15, 2021.

<sup>32</sup> USDA. FoodData Central: Sweet potato, cooked, boiled, without skin. April 1, 2019. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/168484/nutrients>. Accessed December 15, 2021.

<sup>33</sup> United States Department of Agriculture (USDA). Food Pattern Modeling: Under 2 Years of Age. July 15, 2020. [https://www.dietaryguidelines.gov/sites/default/files/2020-07/FoodPatternModeling\\_Report\\_Under2Years.pdf](https://www.dietaryguidelines.gov/sites/default/files/2020-07/FoodPatternModeling_Report_Under2Years.pdf). Accessed December 15, 2021.

<sup>34</sup> U.S. Food and Drug Administration. FDA Total Diet Study (TDS) FY2018-FY2020 Report Supplement: Summary of Analytical Results. July 2022. <https://www.fda.gov/media/159751/download>. Accessed 27 February 2023.

across the food supply, which will benefit children who consume foods prepared at home rather than processed baby foods. FDA should consider setting action levels on a broader suite of products consumed by children in addition to baby food to further incentivize progress across the whole market. At the USDA meeting last year, speakers from the USDA Agricultural Research Service presented recent and ongoing research suggesting that heavy metal contamination of various edible crops could potentially be limited by altering where and how crops are grown (e.g., growing crops in regions with low levels of heavy metals in soil) and through selective breeding of cultivars that absorb heavy metals at lower levels.<sup>35</sup> Setting strict health-protective standards for baby food will create economic incentives to further develop such methods, which will increase the proportion of crops with low levels, resulting in a more general reduction in lead in crops produced for the general population.

Moreover, even if the market for baby food is temporarily impacted by the new standards, it will not negatively impact early childhood nutrition because carrots and sweet potatoes are not the sole sources of vital nutrients for this age group.

Sweet potatoes and carrots are a source of Vitamin A and potassium. Vitamin A content is noteworthy because there are very few unfortified foods that can equal the high vitamin A content of carrots (200% of the Daily Value for children 1-3 years [DV] per 70 g boiled and drained serving)<sup>36</sup> and sweet potatoes (180% DV per 70 g boiled and drained serving).<sup>37</sup> However, there are other vegetables common in commercially available baby food that are also rich sources of vitamin A, such as butternut squash (130% DV per 70 g baked serving)<sup>38</sup> and pumpkin (70% DV per 70 g boiled and drained serving).<sup>39</sup> Vitamin A is also not under-consumed by toddlers and young children.

For potassium, the current underconsumption of potassium by infants and toddlers could pose a public health challenge, captured by the 2020 DGA Committee Scientific Report, which

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<sup>35</sup> US Department of Agriculture. Agenda for “U.S. Department of Agriculture Public Meeting—Closer to Zero: Impacts of Toxic Element Exposure and Nutrition in the Food System.” April 27, 2022.

<sup>36</sup> US Department of Agriculture, Agricultural Research Service. FoodData Central: Carrots, cooked, boiled, drained, without salt. April 1, 2019. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/170394/nutrients>. Accessed May 11, 2022; U.S. Food and Drug Administration. Reference Amounts Customarily Consumed: List of Products for Each Product Category: Guidance for Industry. February 2018. <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/guidance-documents-regulatory-information-topic-food-and-dietary-supplements>. Accessed 23 March 2023; U.S. Food and Drug Administration. A Food Labeling Guide: Guidance for Industry. January 2013. [www.fda.gov/FoodLabelingGuide](http://www.fda.gov/FoodLabelingGuide). Accessed 23 March 2023; U.S. Food and Drug Administration. Frequently Asked Questions for Industry on Nutrition Facts Labeling Requirements. <https://www.fda.gov/media/99069/download>. Accessed 23 March 2023.

<sup>37</sup> US Department of Agriculture, Agricultural Research Service. FoodData Central: Sweet potato, cooked, boiled, without skin. April 1, 2019. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/168484/nutrients>. Accessed May 11, 2022 (Note: We used USDA’s database because few packaged baby foods voluntarily disclose vitamin A content on Nutrition Facts labels); FDA, Reference Amounts Guidance for Industry, 2018; FDA, Food Labeling Guide, 2013; FDA, Nutrition Facts Labeling FAQs.

<sup>38</sup> US Department of Agriculture, Agricultural Research Service. FoodData Central: Squash, winter, butternut, cooked, baked, without salt. April 1, 2019. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/169296/nutrients>. Accessed May 11, 2022; FDA, Reference Amounts Guidance for Industry, 2018; FDA, Food Labeling Guide, 2013; FDA, Nutrition Facts Labeling FAQs.

<sup>39</sup> US Department of Agriculture, Agricultural Research Service. FoodData Central: Pumpkin, cooked, boiled, drained, without salt. April 1, 2019. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/168449/nutrients>. Accessed May 11, 2022; FDA, Reference Amounts Guidance for Industry, 2018; FDA, Food Labeling Guide, 2013; FDA, Nutrition Facts Labeling FAQs.

reported that, “For Americans ages 1 year and older, dietary intake distributions, along with biological endpoints, clinical indicators, and prevalence of health conditions measured through validated surrogate markers, suggest that current underconsumption of...potassium is of public health concern.”<sup>40</sup> Sweet potatoes<sup>41</sup> and carrots<sup>42</sup> each contain 6% DV per 70 g boiled and drained serving and so, like many vegetables, contribute modest amounts of potassium to overall diets. Likewise, many fruits found in baby foods can provide amounts of potassium similar to that of sweet potatoes and carrots, such as bananas,<sup>43</sup> peaches,<sup>44</sup> and apricots.<sup>45</sup> CSPI suggests that FDA work with USDA’s Food Pattern Modeling team<sup>46</sup> to explore the impact of these alternatives on the typical diets of infants and toddlers.

### **C. FDA’s Approach Should Be Based on What is Achievable with the Most Advanced Technology, Not Current Industry Practice**

As we noted in our comments on the draft guidance for action levels for lead in juice, the FDA’s current approach seems to place undue emphasis on what is achieved under current industry practice, and resembles the approach taken by the Codex Alimentarius Commission<sup>47</sup>, in setting standards for contaminants in food.<sup>48</sup> While this approach might be considered desirable by stakeholders who seek to minimize efforts by industry, the U.S. Occupational Health and Safety Administration (OSHA) demonstrates that public health-centered approaches can be implemented without placing industry concerns front and center. 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,

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<sup>40</sup> Dietary Guidelines for Americans (DGA). Scientific Report of the 2020 Dietary Guidelines Advisory Committee. July 2020. P. 3. <https://www.dietaryguidelines.gov/2020-advisory-committee-report>. Accessed December 15, 2021.

<sup>41</sup> USDA, FoodData Central, Sweet potato (168484), 2019; FDA, Food Labeling Guide, 2013; FDA, Nutrition Facts Labeling FAQs.

<sup>42</sup> USDA, FoodData Central, Carrots (170394), 2019; FDA, Food Labeling Guide, 2013; FDA, Nutrition Facts Labeling FAQs.

<sup>43</sup> US Department of Agriculture, Agricultural Research Service. FoodData Central: Bananas, ripe and slightly ripe, raw. April 1, 2019. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/1105314/nutrients>. Accessed May 12, 2022; FDA, Reference Amounts Guidance for Industry, 2018; FDA, Food Labeling Guide, 2013; FDA, Nutrition Facts Labeling FAQs

<sup>44</sup> US Department of Agriculture, Agricultural Research Service. FoodData Central: Peaches, yellow, raw. April 1, 2019. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/169928/nutrients>. Accessed May 12, 2022; FDA, Reference Amounts Guidance for Industry, 2018; FDA, Food Labeling Guide, 2013; FDA, Nutrition Facts Labeling FAQs

<sup>45</sup> US Department of Agriculture, Agricultural Research Service. FoodData Central: Apricots, raw. April 1, 2019. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/171697/nutrients>. Accessed May 12, 2022; FDA, Reference Amounts Guidance for Industry, 2018; FDA, Food Labeling Guide, 2013; FDA, Nutrition Facts Labeling FAQs

<sup>46</sup> See, DGA. Food Pattern Modeling for the 2020 Dietary Guidelines Advisory Committee. <https://www.dietaryguidelines.gov/advisory-committee-approaches-to-examine-the-evidence/food-pattern>. Accessed December 15, 2021.

<sup>47</sup> The Codex Alimentarius Commission is an international organization that works to develop international food standards under the Joint FAO/WHO Food Standards Program. Joint FAO/WHO Expert Committee on Food Additives (JECFA). [https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-\(jecfa\)/about](https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-(jecfa)/about). Accessed 14 March 2023.

<sup>48</sup> Food and Agriculture Organization of the United Nations World Health Organization. CXS 193-1995. General Standard for Contaminants and Toxins in Food and Feed. Codex Alimentarius International Food Standards. 2019. [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B193-1995%252FCXS\\_193e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B193-1995%252FCXS_193e.pdf). Accessed 15 February 2023.

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, potentially resulting in a standard somewhat less protective than public health considerations would require.<sup>49</sup>

OSHA is not required to set standards based first on what is achievable with standard technology and practices and 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.”<sup>50</sup> While OSHA must, “show that the standard will not cause massive economic dislocations within, or imperil the existence of, affected industries,” for economic feasibility it, “need not guarantee the continued viability of individual firms that historically have lagged other regulated firms in providing safe places of employment.”<sup>51</sup> OSHA is prohibited from using a direct benefit-cost analysis for setting health standards.

In contrast, FDA interprets achievability based on current levels of lead contamination found in baby foods across the whole industry. In the preferable alternative, action levels should be based on producers or manufacturers who have successfully implemented methods to reduce lead contamination in raw crops, particularly when crop requirements to satisfy a given public health need are low. If no such producers or manufacturers can be identified, setting aggressive action levels would further incentivize efforts to develop practices to reduce lead contamination in raw agricultural crops. The FDA should adopt a “health first” approach modeled on that used by OSHA rather than continue its current approach to develop the draft action levels for lead in foods intended for babies and young children.

#### **D. FDA and Manufacturers Need to Increase Testing Efforts**

FDA based its exposure and achievability assessment on data collected as part of their Toxic Element Program (TEP) between fiscal year (FY) 2008 and 2021, FDA surveys from FY 2013/2014 and 2021, and the Total Diet Study (TDS) from FY 2014-2020.<sup>52</sup> While these data provide a suitable baseline for assessing the impact of the current proposal, FDA should dramatically expand its monitoring efforts to ensure the data used to generate the proposed action levels accurately reflect contamination in the current market and that these action levels and others developed as part of the Closer to Zero plan produce the intended effect of driving levels of toxic heavy metal contamination in foods and beverages closer to zero. Additionally, manufacturers in the baby food market will need to implement enhanced testing methods to identify crops with low levels (or no detectable levels) of lead.

#### **E. Conclusion**

CSPI commends FDA’s commitment to reducing lead contamination in foods, especially those

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<sup>49</sup> 29 USC 655

<sup>50</sup> U.S. Congress, Office of Technology Assessment. Gauging Control Technology and Regulatory Impacts in Occupational Safety and Health—An Appraisal of OSHA’s Analytic Approach, OTA-ENV-635 (Washington, DC: U.S. Government Printing Office, September 1995). Box 2-1, p. 18-19. Available at: <https://repository.library.georgetown.edu/bitstream/handle/10822/708168/9531.PDF>

<sup>51</sup> Ibid.

<sup>52</sup> FDA, Draft Food Guidance, p.6-; TDS data was not used in the achievability analysis.



intended for babies and young children. As the FDA has noted, we understand this effort is an iterative process. With additional refinement to ground the guidance and the overall Closer to Zero action plan in public health protection, the agency could help ensure that children's dietary exposures to lead and other heavy metals are as low as possible.

We thank the agency for the opportunity to comment and its continued commitment to protecting our children's health. Questions related to this comment can be directed to Thomas M. Galligan, PhD, Principal Scientist for Food Additives and Supplements at Center for Science in the Public Interest, [tgalligan@cspinet.org](mailto:tgalligan@cspinet.org).

Sincerely,

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## Appendix A

We sought to estimate the fraction of all sweet potatoes and carrots that the baby food industry would need to meet current consumption of sweet potatoes and carrots by children aged 0-24 months.

### **Estimating mass (kg) of raw sweet potatoes and carrots required for the U.S. baby food market in 2020**

We estimated the masses (kg) of raw edible sweet potatoes and carrots consumed as baby food (i.e., the annual demand) by US children aged 0-24 months in 2020 using the following formula:

$$D = C * p * k * j * P_{0,24} * 365 \text{ days}$$

Where  $D$  is annual demand (kg),  $C$  is the daily per capita consumption rate of red/orange vegetables by infants and children (ounce equivalents per person per day),  $p$  is the proportion of red/orange vegetable consumption comprised of cooked sweet potato or cooked carrot,  $k$  is the number of grams per ounce cooked,  $j$  is the ratio of cooked mass to raw mass (g raw/g cooked), and  $P_{0,24}$  is the estimated population of children aged 0-24 months in 2020. Multiplying by 365 days annualizes the daily consumption rate. We performed this calculation independently for sweet potatoes and carrots.

According to the data analysis supplement used by the 2020 Dietary Guidelines Advisory Committee (DGAC), from 2007-2016, infants 6-11 months old consumed an average of 0.21 ounce equivalents per day of total red/orange vegetables, while toddlers 12-23 months old consumed an average of 0.18 ounce equivalents per day of total red/orange vegetables.<sup>53</sup> To ensure our calculations are conservative, erring toward overestimation of consumption by babies, we assumed all children ages 0-24 months consumed red/orange vegetables at the higher rate. Thus we set  $C$  at 0.21 ounce equivalents per day.

The USDA 2020 DGAC Food Pattern Modeling Report for Under 2 Years of Age indicates that 15.5% and 26.8% of the red/orange vegetables subgroup consumed by children ages 6-24 months is made up of cooked sweet potatoes/orange yams and cooked carrots, respectively. We therefore set  $p$  at 0.155 for sweet potatoes and 0.268 for carrots.<sup>54</sup>

We set  $k$  using the conversion factor of 0.028 kilograms per ounce (28.35 g/oz).

We converted cooked mass to raw mass based on caloric density, which we assumed would be a good approximation of mass ratios. In its Standard Reference Dataset, USDA's FoodData Central database includes two sweet potato baby food entries (babyfood, vegetables, sweet potatoes

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<sup>53</sup> US Department of Agriculture & US Department of Health and Human Services. Infants and Toddlers: Food Group and Nutrient Intakes, 2020 Dietary Guidelines Advisory Committee Supplementary Data Analysis. July 15, 2020. [https://www.dietaryguidelines.gov/sites/default/files/2020-07/DA\\_Supplement\\_Infants\\_and\\_Toddlers\\_0.pdf](https://www.dietaryguidelines.gov/sites/default/files/2020-07/DA_Supplement_Infants_and_Toddlers_0.pdf). See Table 3 and 4.

<sup>54</sup> US Department of Agriculture. Food Pattern Modeling: Under 2 Years of Age. 2020 Dietary Guidelines Advisory Committee Food Pattern Modeling Report. July 15, 2020. [https://www.dietaryguidelines.gov/sites/default/files/2020-07/FoodPatternModeling\\_Report\\_Under2Years.pdf](https://www.dietaryguidelines.gov/sites/default/files/2020-07/FoodPatternModeling_Report_Under2Years.pdf). See Table 4.1.

strained [57 kcal per 100g];<sup>55</sup> babyfood, vegetables, sweet potatoes, junior [60 kcal per 100 g]<sup>56</sup> and three carrot baby food products (babyfood, carrots, toddler [21 kcal per 100g];<sup>57</sup> babyfood, vegetables, carrots, strained [26 kcal per 100g];<sup>58</sup> babyfood, vegetables, carrots, junior [32 kcal per 100 g]<sup>59</sup>). We assumed these foods only contained a single caloric ingredient—sweet potato or carrot—meaning the full caloric value could be attributed to the vegetable. To be conservative, we used the highest of the listed caloric values for each vegetable. According to USDA’s FoodData Central, raw unprepared sweet potatoes contains 86 kcal per 100 g,<sup>60</sup> and raw carrots contain 41 kcal per 100 g.<sup>61</sup> Thus, the ratio of raw to cooked vegetable ( $j$ ) is:

$$j_{\text{sweet potato}} = \frac{60 \text{ kcal}}{g, \text{cooked}} * \frac{g, \text{raw}}{86 \text{ kcal}} \approx \frac{0.70 \text{ kg, raw}}{\text{kg, cooked}}$$

$$j_{\text{carrot}} = \frac{32 \text{ kcal}}{g, \text{cooked}} * \frac{g, \text{raw}}{41 \text{ kcal}} \approx \frac{0.78 \text{ kg, raw}}{\text{kg, cooked}}$$

Finally, According to the Centers for Disease Control and Prevention (CDC; HHS), the number of births that occurred in the US among citizens and residents in 2019 and 2020 were 3,747,540 and 3,613,647<sup>62,63</sup> respectively for a total ( $P_{0,24}$ ) of 7,361,187 persons.

Bringing this all together, we estimate the demand for raw sweet potatoes and carrots by the U.S. baby food industry in 2020 was:

$$D_{\text{sweet potato}} = \frac{0.21 \text{ oz equivalents}}{\text{day} * \text{person}} * 0.155 * \frac{0.028 \text{ kg}}{\text{oz equivalents}} * \frac{0.70 \text{ kg, raw}}{\text{kg, cooked}} * 7,361,187 \text{ persons} * 365 \text{ days}$$

$$D_{\text{sweet potato}} \approx 1,700,000 \text{ kg}$$

$$D_{\text{carrot}} = \frac{0.21 \text{ oz equivalents}}{\text{day} * \text{person}} * 0.268 * \frac{0.028 \text{ kg}}{\text{oz equivalents}} * \frac{0.78 \text{ g, raw}}{\text{g, cooked}} * 7,361,187 \text{ persons} * 365 \text{ days}$$

$$D_{\text{carrot}} \approx 3,300,000 \text{ kg}$$

## Estimating the mass (kg) of raw edible sweet potatoes and carrots available to U.S. baby

<sup>55</sup> US Department of Agriculture, Agricultural Research Service. FoodData Central: Babyfood, vegetables, sweet potatoes strained. April 1, 2019. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/172276/nutrients>. Access: May 11, 2022/

<sup>56</sup> US Department of Agriculture, Agricultural Research Service. FoodData Central: Babyfood, vegetables, sweet potatoes, junior. April 1, 2019. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/172277/nutrients>. Accessed: May 11, 2022.

<sup>57</sup> US Department of Agriculture, Agricultural Research Service. FoodData Central: Babyfood, carrots, toddler. April 1, 2019. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/169871/nutrients>. Accessed: May 11, 2022.

<sup>58</sup> US Department of Agriculture, Agricultural Research Service. FoodData Central: Babyfood, vegetables, carrots, strained. April 1, 2019. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/173506/nutrients>. Accessed: May 11, 2022.

<sup>59</sup> US Department of Agriculture, Agricultural Research Service. FoodData Central: Babyfood, vegetables, carrots, junior. April 1, 2019. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/173507/nutrients>. Accessed: May 11, 2022.

<sup>60</sup> US Department of Agriculture, Agricultural Research Service. FDC ID: 168482, FoodData Central. 2019. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/168482/nutrients>.

<sup>61</sup> US Department of Agriculture, Agricultural Research Service. FDC ID: 170393, FoodData Central. 2019. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/170393/nutrients>.

<sup>62</sup> US Centers for Disease Control. User Guide to the 2019 Natality Public Use File. 2019. Available at: [https://ftp.cdc.gov/pub/Health\\_Statistics/NCHS/Dataset\\_Documentation/DVS/natality/UserGuide2019-508.pdf](https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Dataset_Documentation/DVS/natality/UserGuide2019-508.pdf). See page 7.

<sup>63</sup> US Centers for Disease Control. User Guide to the 2020 Natality Public Use File. 2020. Available at: [https://ftp.cdc.gov/pub/Health\\_Statistics/NCHS/Dataset\\_Documentation/DVS/natality/UserGuide2020.pdf](https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Dataset_Documentation/DVS/natality/UserGuide2020.pdf). See page 7.

## food manufacturers in 2020

The USDA Economic Research Service (ERS) reports annual crop availability on a per capita basis, and crop availability does not account for yield (i.e., the proportion of the unprocessed crop that is consumed after culinary processing). Therefore, we estimated the mass (kg) of raw sweet potatoes and carrots available to U.S. baby food manufacturers in 2020 using the following formula:

$$A_{total} = A_f * Y * P_{total}$$

Where  $A_{total}$  is the mass of the vegetable available,  $A_f$  is the per capita availability of raw sweet potato or carrot in the U.S. on a farm weight basis (kg per person),  $Y$  is the yield (i.e., the edible proportion of the farm weight), and  $P_{total}$  is the total US population in 2020. We performed this calculation independently for sweet potatoes and carrots.

The USDA ERS calculates per capita availability as the difference between supply (i.e., sum of production, imports, and beginning stocks if available) and nonfood use (i.e., exports, other use, and ending stocks if available). According to ERS data, in 2020 the annual per capita availability of sweet potatoes and carrots was 6.69 pounds per capita and 10.7 pounds per capita, respectively (i.e.,  $A_{f, \text{sweet potato}} = 3.035 \text{ kg per person}$ ;  $A_{f, \text{carrot}} = 4.853 \text{ kg per person}$ ).<sup>64</sup>

The Book of Yields is a culinary reference of standard values that estimates the proportion of an unprocessed vegetable that is consumable after culinary processing. For sweet potatoes and carrots, yield ( $Y$ ) is 0.75 and 0.813, respectively.<sup>65</sup>

The US Bureau of the Census (DOC) estimates there were 331,753,003 residents in the US on December 1, 2020 (i.e.,  $P_{total} = 331,753,003 \text{ persons}$ ).<sup>66</sup>

Thus, we estimate:

$$A_{total, \text{ sweet potato}} = \frac{3.035 \text{ kg}}{\text{person}} * 0.75 * 331,753,003 \text{ persons}$$

$$A_{total, \text{ sweet potato}} \approx 755,000,000 \text{ kg}$$

$$A_{total, \text{ carrot}} = \frac{4.853 \text{ kg}}{\text{person}} * 0.813 * 331,753,003 \text{ persons}$$

$$A_{total, \text{ carrot}} \approx 1,309,000,000 \text{ kg}$$

## Estimating the proportion of available raw edible sweet potato and carrot necessary to meet U.S. baby food industry demand in 2020

We then divided the mass of sweet potato and carrot needed for babies (D) by the mass of the

<sup>64</sup> US Department of Agriculture. Vegetables and Pulses Yearbook Tables, Table 1d-PerCapitaAvail (09-20). July 30, 2021. Available from: <https://www.ers.usda.gov/data-products/vegetables-and-pulses-data/vegetables-and-pulses-yearbook-tables/>.

<sup>65</sup> Lynch, Francis T. The Book of Yields: Accuracy in Food Costing and Purchasing: 8th Edition. John Wiley & Sons, Inc. 2012.

<sup>66</sup> US Bureau of the Census. Monthly Population Estimates for the United States: April 1, 2020 to December 1, 2022 (NA-EST2021-POP). Available at: <https://www.census.gov/data/datasets/time-series/demo/popest/2020s-national-total.html>.



vegetable available for consumption ( $A_{\text{total}}$ ):

$$X_{\text{sweet potato}} = \frac{1,700,000 \text{ kg}}{755,000,000 \text{ kg}} = 0.23\%$$

$$X_{\text{carrot}} = \frac{3,300,000 \text{ kg}}{1,309,000,000 \text{ kg}} = 0.25\%$$

Therefore, we estimate that US infants and children aged 0-24 months consumed **0.23%** of the available edible sweet potatoes and **0.25%** of the available edible carrots as store-bought baby food in 2020.

These quantities are **overestimates** of the actual percentage consumed by babies as baby food for the following reasons:

- Infants do not typically begin consuming solid foods until 4-6 months of age. Our consumption estimates included all children aged 0-24 months.
- Although the DGA reports estimated that children 12-23 months ate less red/orange vegetables (0.18 ounce equivalents per day) than children 6-24 months (0.21 ounce equivalents per day), our estimates used the higher rate (0.21 ounce equivalents per day) for all age ranges (0-24 months).
- We assumed that all sweet potato/orange yams and carrots consumed by children aged 0-24 months were consumed in the form of manufactured sweet potato or carrot baby food, as opposed to foods prepared at home or in restaurants.
- We assumed all sweet potato and carrot baby foods had the highest caloric density of those listed in the USDA's FoodData Central database to calculate  $j$ . This led to higher estimated consumption rates.