DRAFT Supporting Document for Establishing FDA's Action Levels for Lead in Juice

DRAFT-NOT FOR IMPLEMENTATION

April 2022

[FDA-2019-D-5609]

Table of Contents

I. Introduction

Lead is toxic to humans and can affect people of any age or health status. Lead is especially harmful to vulnerable populations, including infants, young children, pregnant women and their fetuses, and others with chronic health conditions. 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 (HHS/NTP, 2012). Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time (Flannery et al., 2020).

Lead is widely present in the environment due to its natural occurrence and human activities that have introduced it into the environment. Because lead may be present in environments where food crops used to make juices are grown, juices may contain unavoidable but small amounts of lead. Potential sources of lead in juice include contaminated soil where the crops are grown, contaminated water, old lead-containing equipment, processing aids, and atmospheric deposition from industrial activities. It may be possible in some cases for manufacturers who have found elevated lead in sources of fruit or fruit juice to choose sources of fruit or fruit juice concentrate with lower lead levels or no detectable lead. It may be possible, in some cases, for manufacturers who have found lead in water used to dilute concentrates to reduce or limit levels of lead in ready-to-drink juice by examining and controlling lead levels in water used for dilution of juice concentrate. Recent research by FDA shows that the use of some filter aids to remove sediments in juice can contribute to elevated lead levels. Changing or treating filter aids may reduce the levels of lead in filtered juices (Wang et al., 2017; Redan et al., 2020).

The purpose of this document is to present the background and rationale for the Food and Drug Administration's (FDA's) action level of 10 micrograms/kilogram (µg/kg) or 10 parts per billion (ppb) for lead in single-strength (ready-to-drink) apple juice[1] and action level of 20 µg/kg or 20 ppb for lead in all other single-strength juices, including juice blends that contain apple juice. The action levels for lead in juice are included in an FDA draft guidance entitled, "Action Levels for Lead in Juice: Guidance for Industry." FDA considers the action levels for lead in juice to be achievable by industry when control measures are taken to minimize the presence of this contaminant.

[1] Juice includes both liquid and puree forms (21 CFR 120.1(a)).

II. Overview of FDA Activities Addressing Lead in Food

In 1979, FDA stated that it intended to expand its programs to monitor and reduce lead levels in the food supply with the objective of reducing consumers' lead exposure to the lowest level that can be practicably obtained (44 FR 51233, Jan. 2, 1979). FDA's earliest lead reduction actions, some originating a century ago, focused on limiting the potential for lead to become a component of food as a consequence of intentional uses of lead-containing substances in agriculture and food processing, e.g., lead-based pesticides and lead-containing solder in food cans (58 FR 33860, June 21, 1993).

The goal of limiting lead contamination of food was facilitated by the development and implementation of the use of welded (non-soldered) food cans during the 1980s. This development and the concurrent prohibition of the use of lead-containing gasoline in the U.S. are largely responsible for dramatic decreases in measured lead levels in the U.S. diet beginning in the 1980s (Bolger et al., 1996).

In 2021, FDA initiated the *Closer to Zero* action plan that identifies actions we will take to reduce exposure to toxic elements, including lead, from foods eaten by babies and young children (FDA, 2021b). The plan outlines an iterative approach for achieving continual improvements over time, reducing children's exposure to lead and other toxic elements from food through activities such as setting action levels. FDA will identify interim reference levels (IRLs) for certain toxic elements as appropriate and may use these IRLs to help inform the development of action levels. The plan commits to consulting with stakeholders, including on the achievability of reducing toxic element levels, and notes the importance of minimizing the potential for unintended consequences on the availability of nutritious foods for children.

FDA's past and current regulatory activities intended to reduce or limit lead levels in food have addressed a variety of products, including, bottled water, wine, juice, candy, food cans, candy wrappers, and lead-glazed ceramic ware and other housewares. In addition, FDA has established Import Alerts and/or taken enforcement actions against a variety of violative food products found to have lead levels that posed health concerns, including dietary supplements, spices, juices, dried fruits, and candies.

III. FDA Actions Addressing Lead in Juice

In 1993, FDA established an emergency action level of 80 ppb for lead in juice packed in lead soldered cans (58 FR 17233, April 1, 1993) as an interim public health measure to limit the presence of lead in juice while undertaking necessary rulemaking to revoke the prior sanction for lead soldered cans and ultimately prohibit their use for packing food.

In 1999, the Joint World Health Organization (WHO)/Food and Agriculture Organization (FAO) Expert Committee on Food Additives (JECFA) released a toxicological assessment for lead which maintained the provisional tolerable weekly intake (PTWI) for lead of 25 micrograms per kilogram body weight (µg/kg bw) but noted that foods with high levels of lead remain in commerce. In 2001, the Codex Alimentarius Commission (Codex), an international food standards organization, established a maximum level (ML) of 50 ppb for lead in ready-to-drink fruit juices, including fruit nectars, that are in international trade. FDA concurred with the Codex ML and adopted 50 ppb as the recommended level not to be exceeded for lead in juice in the Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance (Juice HACCP Guidance), First Edition (FDA, 2004).

In 2011, JECFA reassessed the safety of lead and withdrew the PTWI for lead. JECFA further concluded that "it was not possible to establish a new PTWI [for lead] that would be considered to be health protective" (JECFA, 2011). JECFA concluded that in populations with prolonged dietary exposures to higher levels of lead, measures should be taken to identify major contributing sources, and if appropriate, to identify methods for reducing dietary exposure that are commensurate with the level of risk reduction (JECFA, 2011).

In 2012, Codex initiated work to reevaluate the previously established MLs for lead in multiple commodities in the Codex General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) (Codex Stan 193-1995) (CAC 2021), prioritizing review of MLs for foods (such as juice) that are highly consumed by children. Because no safe level of lead exposure from food had been identified by JECFA, the focus of the Codex Committee on Contaminants in Foods (CCCF) (a subsidiary body of Codex) was to review data to determine what percentage of samples could meet proposed new MLs. CCCF's approach has been to recommend reductions in MLs when more than 95% of the samples traded internationally, as reflected by data provided by Codex member countries, had lead concentrations at or below proposed new MLs.

This work, led by the U.S., as a member of the CCCF, resulted in the reduction of the lead ML for fruit juices in general from 50 ppb to 30 ppb and for grape juice from 50 ppb to 40 ppb. The ML for fruit juices made from berries and other small fruits was retained at 50 ppb. Therefore, current Codex MLs for all juices including apple juice (30 ppb) and for grape juice (40 ppb) are lower and therefore more health protective than the 2004 FDA Juice HACCP guidance level for all juices (50 ppb).

Because no safe level of lead exposure has been identified for children's health, in 2018, FDA developed interim reference levels (IRLs) for dietary lead to replace FDA provisional tolerable total daily intakes (PTTDIs) which had been developed in the early 1990's (Flannery et al., 2020). FDA used the Centers for Disease Control and Prevention (CDC) reference value of 5 µg/deciliter (dL) blood lead[2] level, the level at which public health interventions should be initiated for children, and dietary conversion factors calculated by the Environmental Protection Agency to derive IRLs of 3 µg/day for children and 12.5 µg/day for women of child-bearing age (WOCBA), respectively. The IRL for WOCBA is protective against possible fetal lead exposure in women who are not yet aware that they are pregnant (Flannery et al., 2020).

In response to the 2011 JECFA conclusion, the Codex adoption of lower MLs for fruit juices based on achievability, as well as FDA's development of lead IRLs and the *Closer to Zero* plan, FDA reevaluated the 50 ppb lead level recommended in the current Juice HACCP Guidance (FDA, 2004). Given that no safe level of lead exposure from food has been identified by JECFA, FDA's reevaluation has focused on the review of U.S. data to determine if lower levels were achievable and if lower levels would reduce lead exposure in vulnerable populations.

IV. Lead Levels Found in Juice

Products and data included in the reevaluation of the lead in juice guidance level

FDA's reevaluation considered data for juice products subject to the Juice HACCP regulation found in Title 21 of the Code of Federal Regulations, part 120 (21 CFR part 120). The juice HACCP regulation defines juice 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" (21 CFR 120.1(a)).

FDA has been routinely monitoring lead in juice through its Toxic Elements in Food and Foodware and Radionuclides in Food – Import and Domestic Compliance Program (the Toxic Elements Program or TEP)[3] and the Total Diet Study (TDS)[4]. The TEP is a targeted monitoring program that monitors levels of certain toxic elements, including lead, in foods and foodware. Foods selected for analysis include those that are suspected to have elevated levels of toxic

[2] The reference value of 5 µg/deciliter (dL) blood lead was updated in 2021 by the CDC. Additional information is available at: https://www.cdc.gov/media/releases/2021/p1028-blood-lead.html.
[3] https://www.fda.gov/food/chemical-contaminants-food/toxic-elements-foods-and-foodware.
[4] https://www.fda.gov/food/science-research-food/total-diet-study.

elements based on historical data or other information available to FDA. For lead analysis under the TEP, particular emphasis is placed on foods consumed by children, who are the most sensitive to lead's adverse health effects. The TDS is a market basket study in which about 280 table-ready foods representative of the U.S. diet are analyzed for certain pesticide residues, industrial chemicals, radionuclides, nutrients, and toxic elements, including lead.

As the first step in our reevaluation, we examined TEP and TDS data to determine if industry generally can manufacture juice with lead levels lower than the 50 ppb lead level adopted in 2004 in FDA's Juice HACCP guidance (FDA, 2004). We used TEP and TDS data collected since fiscal year (FY) 2005, after FDA published the 50 ppb level; specifically, TEP data collected between FY 2005 and FY 2018[5] and TDS data collected between FY 2005 and FY 2016.

Toxic Elements Program data

From FY 2005 to FY 2018, FDA analyzed 1,640 juice samples (FDA, 2021a). These juices included U.S. domestic and imported products, consumer and bulk products, and ready-to-drink juice and juice concentrates. All included data were expressed on a single strength (ready-to-drink) basis for this analysis. Approximately 35 percent of juices sampled were apple juice, the most commonly consumed juice type by children in the U.S. (CDC, 2014; Herrick et al., 2015).

TEP data were analyzed using the empirical bootstrap method (Efron and Tibshirani, 1993) to estimate the lead concentrations at 95th percentiles with 80% confidence intervals for individual juice types with at least 30 samples, for the category "other juices" (juice types with less than 30 samples each), and for all juice types (Table 1). Statistical analyses were performed using the R language version 3.5.1[6].

Analysis of the TEP data suggests that most juice samples have lead levels well below the recommended level of 50 ppb in the current Juice HACCP Guidance (Figures 1 and 2; FDA, 2021a). The 95th percentile lead concentration for all juices is estimated at 13 ppb; however, differences were observed among juice types (Table 1). Grape juice, pomegranate juice, and juices from berries have relatively higher lead concentrations than other juice types, with the estimated 95th percentile lead concentrations at 25, 28, and 28 ppb, respectively (Figure 2 and Table 1). For apple juice, carrot juice, mixed-type juices, pear juice, and prune juice, the estimated 95th percentile lead concentrations ranged from approximately 10 to 20 ppb (Figure 2 and Table 1). Orange juice, coconut water, mango juice, and pineapple juice have relatively

[5] For FY 2018, results listed in the table were obtained from the FDA database as of May 21, 2018.
[6] R language version 3.5.1 is available at https://www.r-project.org/.

lower lead concentrations, with the estimated 95th percentile lead concentrations below 10 ppb (Figure 2 and Table 1).

Total Diet Study data

FDA publishes TDS results online[7]. From FY 2005 to FY 2016, FDA collected and analyzed 643 juice samples under the TDS program, each sample being a composite of three juices collected at retail in the domestic market. The types of juices analyzed under the TDS program during that period included mixed-type juices, apple juice, grape juice, pear juice, prune juice, tomato juice, pineapple juice, and grapefruit juice. All juice samples collected during FY 2005 to FY 2016 under the TDS program had lead levels well below 50 ppb (Figure 3). About 62% of the samples had non-detectable[8] levels of lead and about 36% had trace levels[9] of lead (Figure 4). Eight samples had lead concentrations above the limit of quantification of 20 ppb and the values ranged from 20 to 29 ppb. Due to the composite nature of the TDS data,[10] lead concentrations at the 95th percentile were not statistically estimated.

Summary of FDA data

Different types of juices exhibit different lead concentration distributions (Figures 2 and 3 and Table 1). FDA's review of data indicates that industry can generally manufacture juice with lead levels much lower than the 50 ppb lead level currently recommended in FDA's Juice HACCP guidance (FDA, 2004).

V. FDA's New Action Levels for Lead in Juice

After determining that industry generally can manufacture juice with lower lead levels (Section IV), we then considered different approaches to establish action levels under 21 CFR 109.6 for lead in juices based on data described below. We examined the estimated lead exposure, considering the IRL for lead of 3 µg/day for children, and the current industry achievability. All of these analyses were based on the TEP dataset (import and domestic), which contains a wider range of juice types and a greater number of samples per juice type than the TDS dataset.

The first approach FDA considered was to establish a single lower action level for lead (i.e., lower than the 50 ppb recommended lead level established in 2004). For this approach,

[7] https://www.fda.gov/food/total-diet-study/analytical-results-total-diet-study.
[8] Below the method limit of detection.
[9] Trace levels are levels at or above the method limit of detection but below the limit of quantification.
[10] TDS samples are composite samples and exhibit the features of zero inflated negative binomial distribution.

following the Codex model, FDA considered establishing an action level based on the juice type with the highest estimated lead concentration that would allow for at least 95% of those samples to be at or below the new level. For grape juice, pomegranate juice, and juices from berries, the 95th percentile lead concentrations were 25, 28, and 28 ppb, respectively. Therefore, under this first approach, FDA would establish an action level of 30 ppb for all juice types. However, FDA rejected this single action level approach because it relied on achievability for the juice types with the highest 95th percentile lead concentrations and did not consider achievability for other juice types with lower lead concentrations. Based on FDA TEP data, the majority of juice types had 95th percentile lead concentrations at or below approximately 20 ppb (Table 1).

The second approach FDA considered was to establish a single action level for all juices at 20 ppb. Although easier to implement than multiple action levels, it did not consider the relative consumption of different juice types.

The third approach that FDA considered was to establish one level for all juices other than apple juice and a lower level for apple juice. We considered apple juice separately because it is the most commonly consumed juice type by young children in the U.S. (CDC, 2014; Herrick et al., 2015). Under the TEP, FDA sampled 586 apple juice samples during the 14-year period, which included imported and domestic products, consumer and bulk products, and ready-to-drink juice and concentrates. The large sample size coupled with the variety of products sampled provides confidence in FDA's estimation of the lead concentration in apple juice. About 95% of the apple juice sampled under FDA's TEP program had lead concentrations at or below approximately 10 ppb (Table 1).

Exposure assessment

To examine the effect of a proposed 10-ppb action level for apple juice on lead exposure, FDA compared the concentration of lead in apple juice and dietary exposure to lead from apple juice for children (consumers only, 0-6 years old) with and without the action level.[11] As shown in Table 2, the mean concentration of lead in apple juice is 2.4 ppb (µg/kg) and the 90th percentile (representing an upper bound) dietary exposure for children (consumers only, 0-6 years) is 0.79 µg/day (Scenario A) which is below the IRL for lead of 3 µg/day for children. The upper bound percentile was chosen as a health protective measure to account for children who consume larger amounts of juice and would therefore have higher exposures. Removing all apple juice samples

[11] Exposure estimates were calculated based on lead concentration data from the TEP and on juice consumption data from What We Eat in America (WWEIA) 2003-2018, the food consumption portion of the National Health and Nutrition Examination Survey (NHANES). The 90th percentile lead exposures for consumers are based on 2-day average juice intakes.

with lead concentrations > 10 ppb from the dataset (simulating complete compliance with an action level of 10 ppb) results in a decrease in the estimated mean lead concentration in apple juice to 1.3 ppb, and a decrease in the 90th percentile dietary exposure for children consuming apple juice to 0.43 µg/day (Scenario B). An action level of 10 ppb for lead in apple juice is estimated to result in a 46% reduction in lead exposures from consumption of apple juice at the 90th percentile consumption level for children.

For all other fruit and vegetable juice types**,** we examined a higher proposed action level, 20 ppb. The consumption-weighted mean concentration of lead in this category of juice is 2.9 ppb[12] and the 90th percentile dietary exposure for children is 0.78 µg/day, which is below the IRL for lead of 3 µg/day for children (Scenario A). Removing all other fruit and vegetable juice samples with lead concentrations > 20 ppb from the dataset (simulating complete compliance with an action level of 20 ppb) results in a decrease in the mean lead concentration to 2.4 ppb, corresponding to a decrease in the 90th percentile dietary exposure for children consuming juice to 0.64 µg/day (Scenario B). An action level of 20 ppb for lead in other fruit and vegetable juice types is estimated to result in a 19% reduction in lead exposures from consumption of other fruit and vegetable juice types at the 90th percentile consumption level for children. Information on the effects of removing samples above the proposed action levels on lead exposure from consumption of individual juice types is presented in Table 3.

Achievability assessment

To assess achievability, or manufacturers' ability to achieve the action levels for lead, FDA determined the percentage of juice samples that fell at or below the proposed action levels of 10 ppb (apple juice) or 20 ppb (fruit and vegetable juices other than apple juice). For apple juice, the achievability was 95%. For all other juices combined, the achievability was 97% on a consumption-weighted basis (Table 2). Achievability estimates for individual juice type are presented in Table 3.

In summary, an action level of 10 ppb for apple juice reduces dietary exposure to lead for children by 46% at the 90th percentile consumption level and has an achievability of 95%. An action level of 20 ppb for all other fruit and vegetable juices reduces dietary exposure to lead for children on average by 19% at the 90th percentile consumption level (Tables 2 and 3) and has an achievability of 97%, on a consumption-weighted basis. Although an action level of 20 ppb results in lower achievability rates for certain juice types (Table 3), the FDA considers that lowering lead levels in children is important given the FDA's priority for reducing lead

---

[12] Mean concentrations for fruit/vegetable juices other than apple were calculated using TEP concentrations for each juice, weighted by mean per capita consumption of each juice type.

exposures in children (FDA 2021b). These lower action levels for apple juice and other fruit and vegetable juices were established in consideration of FDA's IRL for lead for children.

Therefore, FDA is including in its draft guidance entitled "Action Levels for Lead in Juice: Guidance for Industry" a 10 ppb action level for lead in single-strength (ready-to-drink) apple juice and a 20 ppb action level for lead in all other single-strength juice types, including juice blends that contain apple juice. These action levels will encourage manufacturers to maintain lead levels in juices below the action levels and will result in benefits to public health with less lead intake from a person's diet.

Consideration of the IRL and achievability in the establishment of these action levels for lead in juice is consistent with FDA's longstanding policy of reducing consumers' lead exposure. The action is focused on juice, a product consumed frequently by children, who are also more sensitive than adults to the neurodevelopmental effects of lead. The action levels differ from international levels established by Codex, as the action levels reflect data from samples collected in the U.S. (from both import and domestic products in the workplace), while Codex levels are based on international data.

VI. Conclusion

The action levels are part of the Agency's efforts under the *Closer to Zero* plan to reduce exposure to toxic elements from foods eaten by babies and young children to the lowest possible levels. Action levels were established in consideration of FDA's IRLs for dietary lead and are achievable by industry when control measures are taken to minimize the presence of lead, a substance for which no known safe level has been established. The action levels for lead in juice are included in a draft FDA guidance titled "Action Levels for Lead in Juice: Guidance for Industry." Consistent with 21 CFR 109.4, these action levels define the levels of lead contamination that may cause the juice products described in this guidance to be regarded as adulterated. We intend to consider these action levels, in addition to other factors, when considering whether to bring enforcement action in a particular case. When this draft guidance is finalized, the Juice HACCP Guidance (FDA 2004) will be updated to reflect the new action levels.

FDA recommends that the juice industry continue to work to lower the lead concentrations in juices to the extent possible under current good manufacturing practices. As part of our *Closer to Zero* plan, FDA intends to further engage with stakeholders on proposed action levels, including the achievability of such levels, and the feasibility of further reducing the presence of lead in food. After action levels are finalized, we plan to monitor the levels of lead in food and children's exposures to lead from food to assess whether to further adjust the action levels for lead in juice.

VII. References

Bolger, P. M., Yess, N. J., Gunderson, E. L., Troxell, T. C., and Carrington, C. D., 1996. Identification and reduction of sources of dietary lead in the United States. Food Additives and Contaminants, 13: 53-60.

Centers for Disease Control and Prevention (CDC), 2014. National Health and Nutrition Examination Survey, 2011-2012 and 2013-2014. Available at https://www.cdc.gov/nchs/nhanes/index.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fnchs%2Fnhanes.htm.

Codex Alimentarius Commission (CAC). General Standard for Contaminants and Toxins in Food and Feed (GSTCFF). Codex Stan 193-1995. Updated 2021. Available athttps://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B193-1995%252FCXS_193e.pdf.

Delignette-Muller, M.L. and Dutang, C. 2015. Fitdistrplus: An R package for fitting distributions. Journal of Statistical Software, 64(4): 1-34.

Efron, B. and Tibshirani, R. 1993. An Introduction to the Bootstrap. Chapman & Hall/CRC Monographs on Statistics & Applied Probability.

FDA, 2004. Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, First Edition; Final Guidance. Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-hazard-analysis-critical-control-point-hazards-and-controls-guidance-first.

FDA, 2021a. Lead Levels in Juice Sampled under the FDA's Toxic Elements in Food and Foodware and Radionuclides in Food – Import and Domestic Compliance Program, FY 2005 to FY 2018. Available at https://www.fda.gov/media/157533/download.

FDA, 2021b. Closer to Zero: Action Plan for Baby Foods. Available at https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods.

Flannery B.M., L.C. Dolan, D. Hoffman-Pennesi, A. Gavelek, O.E. Jones, R. Kanwal, B. Wopert, K. Gensheimer, S. Dennis, S. Fitzpatrick, 2020. U.S. Food and Drug Administration's interim reference levels for dietary lead exposure in children and women of childbearing age. Reg. Toxicol. Pharmacol. 110:1-20.

Herrick, K. A., Rossen, L. M., Nielsen, S. J., and Branum, A. M., 2015. Fruit consumption by youth in the United States. Pediatrics. 136: 664-671.

HHS, National Toxicology Program, 2012. NTP Monograph on Health Effects of Low-Level Lead. Available at: https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffectslowlevellead_newissn_508.pdf.

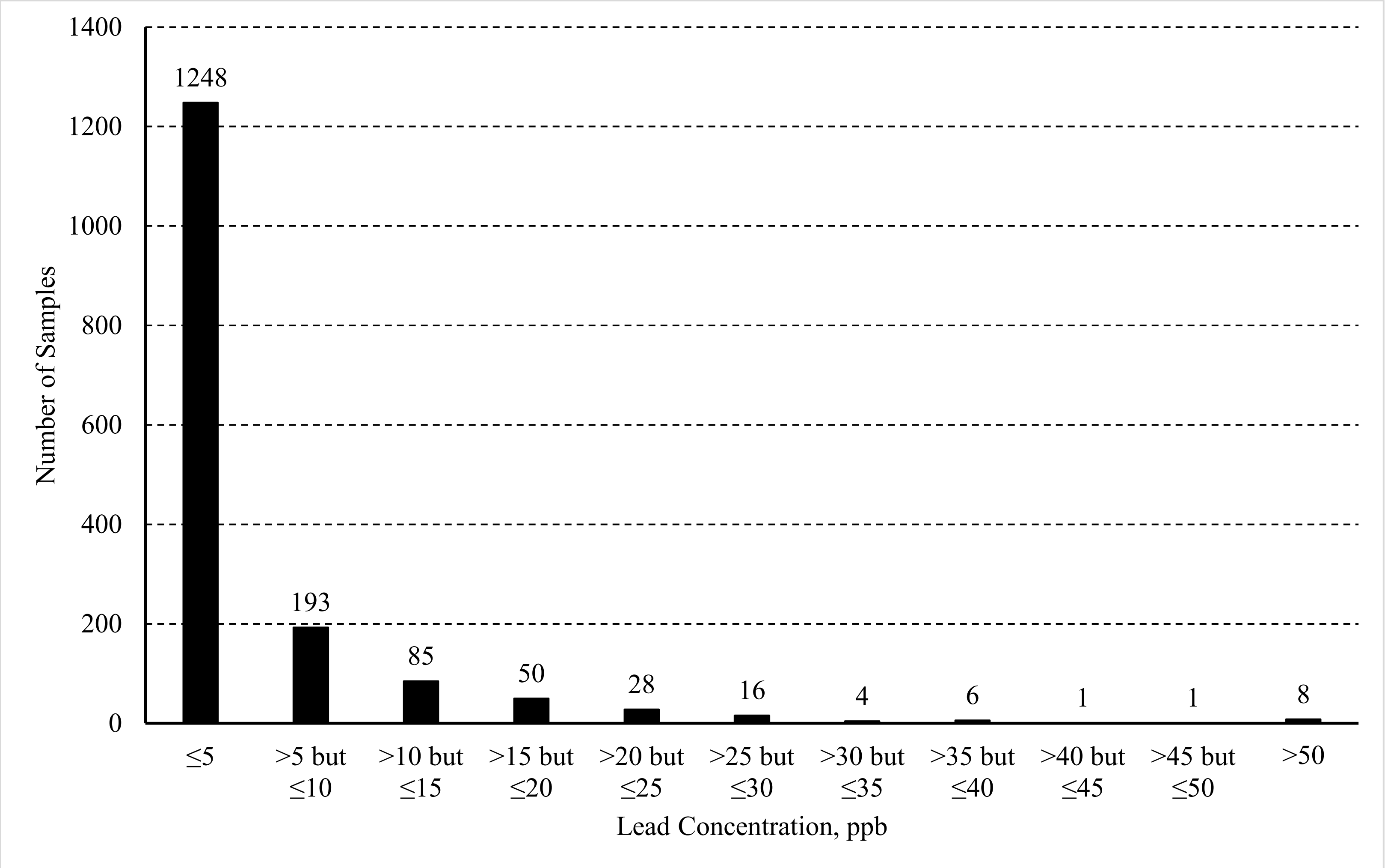
Redan, B.W., 2020. Processing aids in food and beverage manufacturing: potential source of elemental and trace metal contaminants. Journal of Agricultural and Food Chemistry. 68(46):13001-13007.

Wang, Z., Jackson, L.S., Jablonski, J.E., 2017. Factors affecting the levels of heavy metals in juices processed with filter aids. Journal of Food Protection. 80(6):892-902.

WHO/FAO Joint Expert Committee on Food Additives (JECFA), 2011. Evaluation of Certain Contaminants in Food, 73rd Report of the World Health Organization/Food and Agriculture Organization of the United Nations Joint Expert Committee on Food Additives. WHO Technical Report Series 960. Available at https://apps.who.int/iris/bitstream/handle/10665/44515/WHO_TRS_960_eng.pdf?sequence=1.

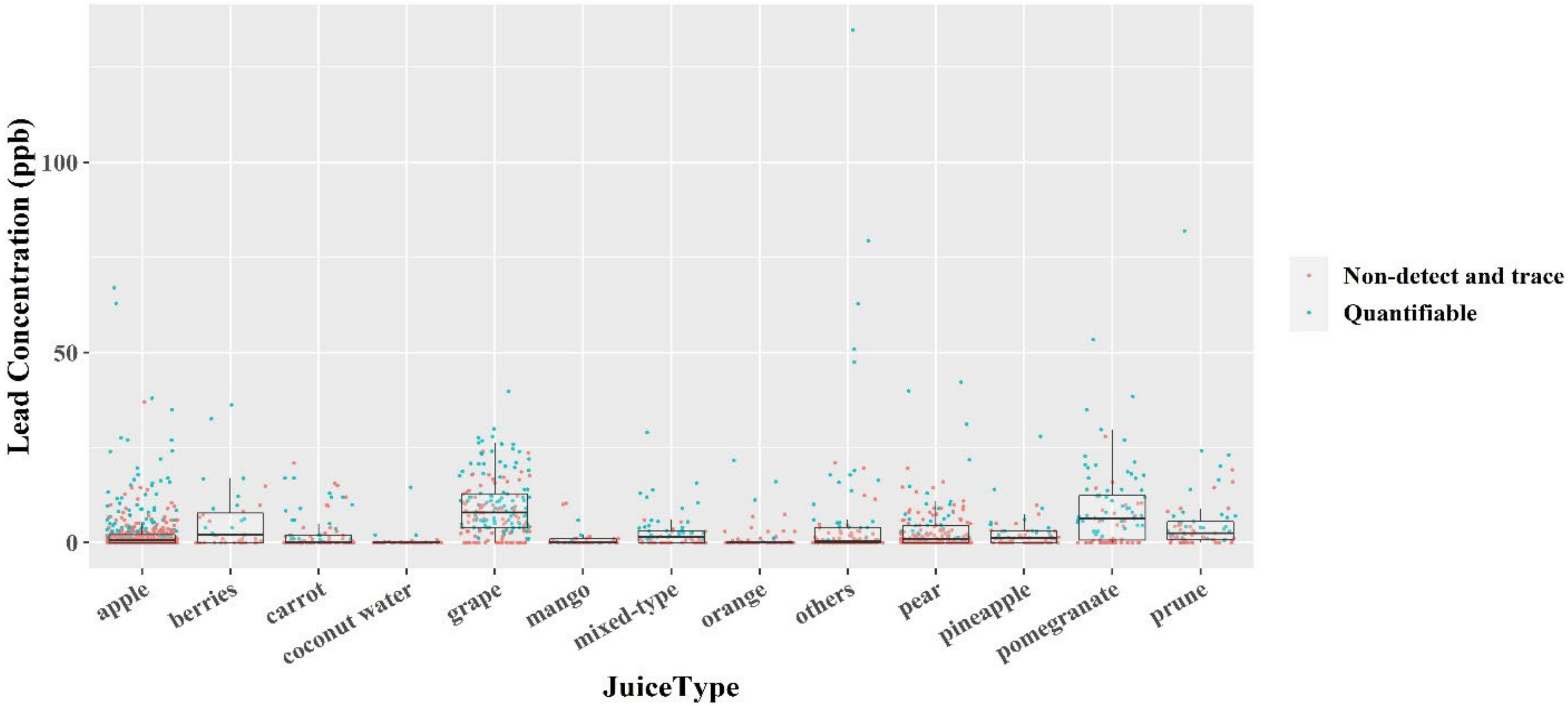
VIII. Figures and Tables

Figure 1. Lead concentrations for all juice types sampled under the Toxic Elements in Food and Foodware, and Radionuclides in Food – Import and Domestic Compliance Program, between FY 2005 and FY 2018 (total samples: 1,640)



[1]For FY 2018, results were obtained from the FDA database as of May 21, 2018.

Figure 2. Box plot and data points for lead concentrations by juice type for samples analyzed under the Toxic Elements in Food and Foodware, and Radionuclides in Food – Import and Domestic Compliance Program, between FY 2005 and FY 2018 (total samples: 1,640)



[1]For FY 2018, results were obtained from the FDA database as of May 21, 2018.

[2]Data points are overlaid on boxplots to show 1,640 lead sample concentrations. For each juice type, the center box represents data between the first (Q1) and third (Q3) quartiles (the 25th and 75th percentiles). The line within the box represents the median value. The whiskers represent the minimum and maximum values.

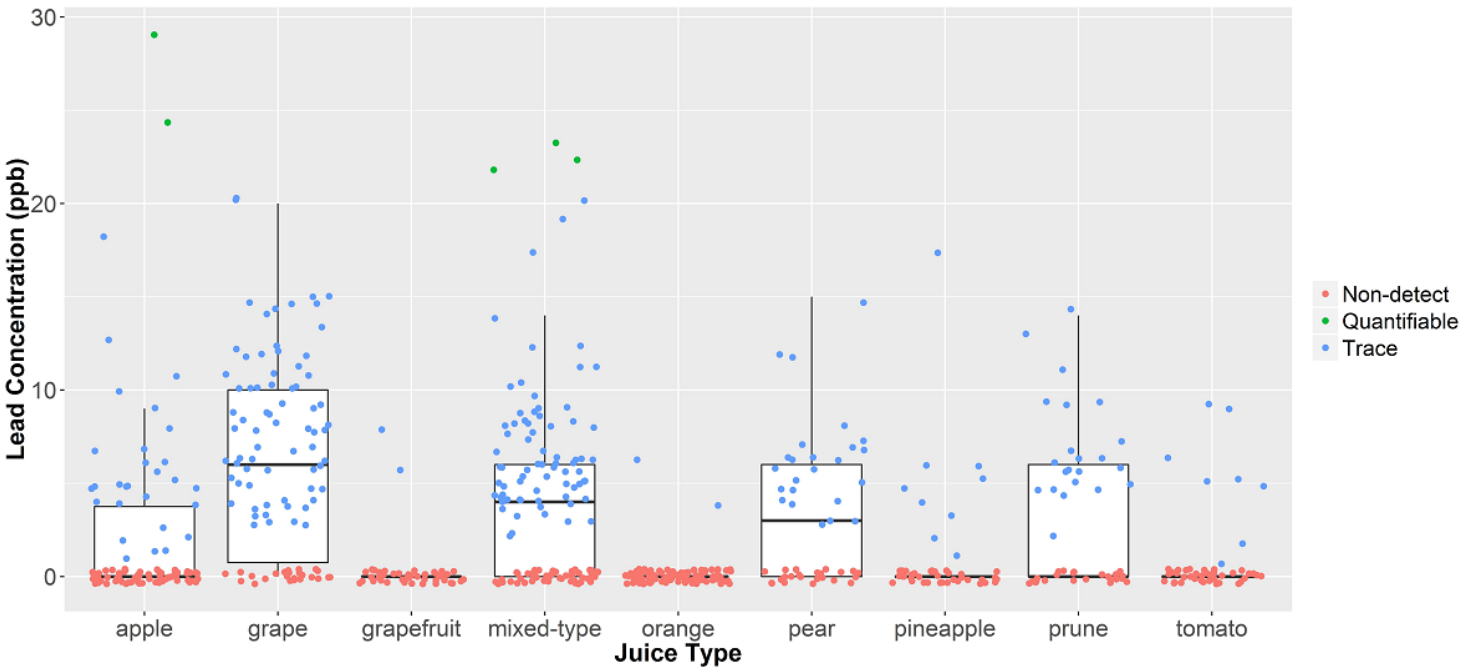
[3]Quantifiable levels are levels at or above the method limit of quantification (LOQ). LOQ values ranged from 0.1 to 50 ppb. Non-detects and trace values in the figure represent all values below the LOQ. Non-detect levels are levels below the method limit of detection (LOD) (not reported). Trace levels are levels at or above the LOD but below the LOQ.
[4]Juice from berries includes juice made exclusively from blueberries, blackberries, cranberries or other berries, but not grape.
[5]Mixed-type juice is juice made from more than one type of fruit and/or vegetable.
[6]The "others" category includes the juices of various types that have less than 30 samples per juice type.

Table 1. Estimated lead concentrations at the 95th percentile for both individual juice types with at least 30 samples and for all juices collected under the Toxic Elements in Food and Foodware, and Radionuclides in Food – Import and Domestic Compliance Program between FY 2005 and FY 2018 (total samples: 1,640)[1]

Juice types	Number of samples	Estimated juice lead concentrations (ppb) at 95th percentile with 80% confidence interval[2]
Apple	586	12 [9, 14]
Berries[3]	39	28 [15, 35]
Carrot	99	14 [12, 17]
Coconut water	40	2 [1, 10]
Grape	191	25 [24, 26]
Mango	37	9 [2, 10]
Mixed-type[4]	71	13 [9, 16]
Orange	72	8 [3, 16]
Pear	182	14 [11, 16]
Pineapple	64	9 [6, 14]
Pomegranate	89	28 [22, 36]
Prune	70	21 [16, 24]
Other juices (each with <30 samples)	100	38 [18, 59]
All juices	1,640	13[5] [12, 15]

[1]For FY 2018, results were obtained from the FDA database as of May 21, 2018.
[2]Data were analyzed using the empirical bootstrap method (Efron and Tibshirani, 1993).
[3]Berries include juice made exclusively from blueberries, blackberries, cranberries or other berries, but not grape.
[4]Mixed-type juice is made from more than one type of fruit and/or vegetable.
[5]95th percentile concentration for "All juices" was calculated using Toxic Elements Program (TEP) concentrations for each juice weighted by mean per capita consumption of each juice for children (0-6 years old).

Figure 3. Box plot and data points for lead concentrations by juice type for samples collected under the Total Diet Study between FY 2005 and FY 2016 (total samples: 643)

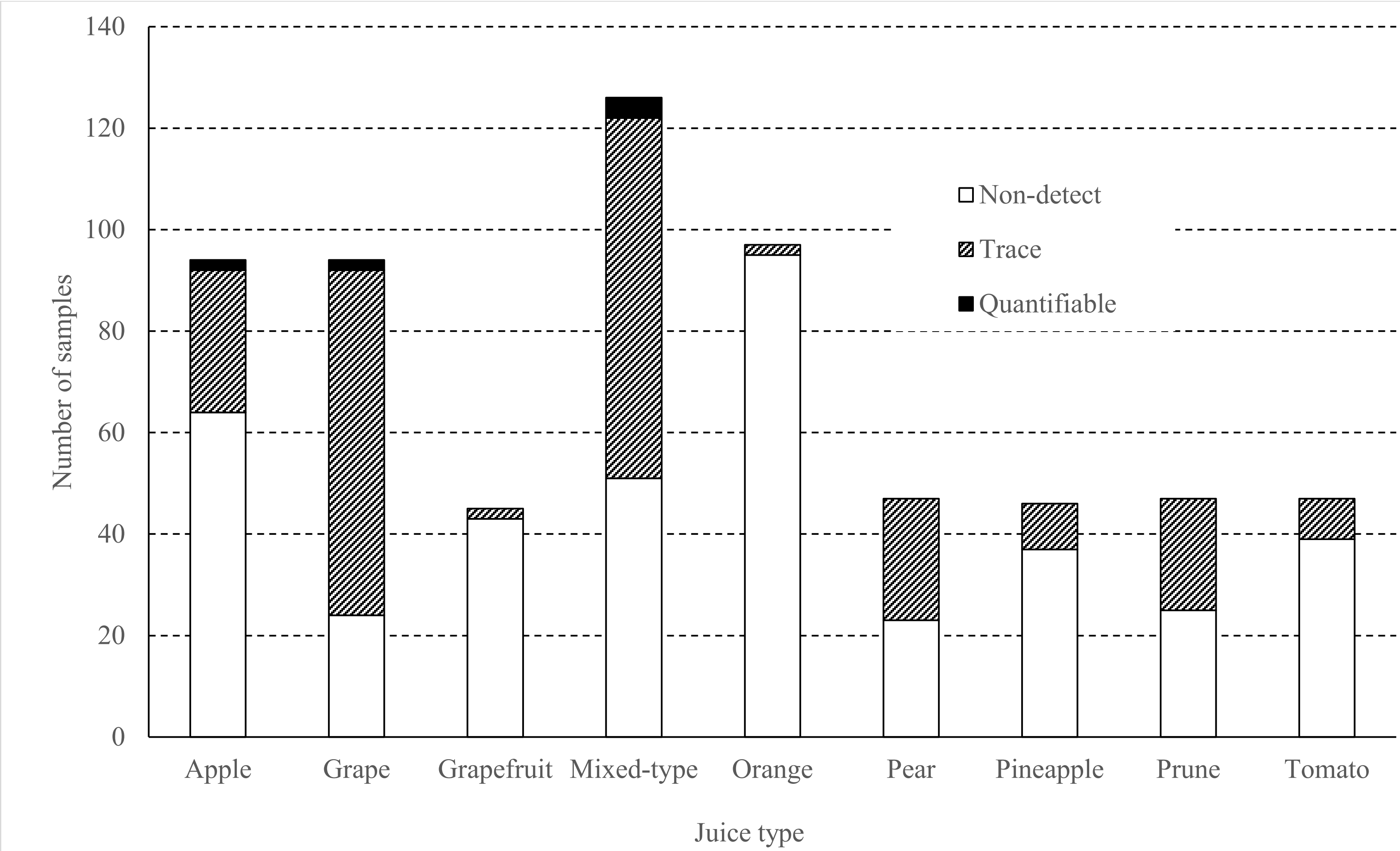


[1] Data points are overlaid on boxplots to show 643 lead samples. For each juice type, the center box represents data between the first (Q1) and third (Q3) quartiles (the 25th and 75th percentiles). The line within the box represents the median value. The whiskers represent the minimum and maximum values.

[2]Non-detect levels are levels below the method limit of detection (LOD). Trace levels are levels at or above the LOD but below the method limit of quantification (LOQ). Quantifiable levels are levels at or above the LOQ. (LODs ranged from 1-5 ppb and LOQs ranged from 10-30 ppb).

[3]Mixed-type juice is juice made from more than one type of fruit and/or vegetable.

Figure 4. Number of Total Diet Study juice samples with lead concentration at non-detect, trace, and quantifiable levels. Samples were collected between FY 2005 and FY 2016 (total samples: 643)



[1]Non-detect levels are below the method limit of detection (LOD). Trace levels are at or above the LOD but below the method limit of quantification (LOQ). Quantifiable levels are at or above the LOQ. (LODs ranged from 1-5 ppb and LOQs ranged from 10-30 ppb.)
[2]Mixed-type juice is made from more than one type of fruit and/or vegetable.

Table 2. Summary data for apple and fruit and vegetable juices (other than apple): mean lead concentrations, 90th percentile lead exposures from juice consumption for children (0-6 years old) with and without action levels, and achievability

Juice	Action Level	Achievability	Scenario A: No Action Level		Scenario B: With Action Level		Reduction in exposure at 90th %ile[4]
			Estimated mean lead concentration	Estimated lead exposure from juice at 90th %ile[2]	Estimated mean lead concentration[3]	Estimated lead exposure from juice at 90th %ile[2]	
	ppb	%	ppb	µg/day	ppb	µg/day	%
Apple	10	95	2.4	0.79	1.3	0.43	46
Fruit/vegetable juices other than apple	20	97[1]	2.9[1]	0.78	2.4[1]	0.64	19

[1]Mean concentrations for fruit/vegetable juices other than apple were calculated using Toxic Elements Program (TEP) concentrations for each juice, weighted by mean per capita consumption of each juice.

[2]Exposure estimates were calculated based on lead concentration data from the TEP and on juice consumption data from What We Eat in America (WWEIA), the food consumption portion of the National Health and Nutrition Examination Survey (NHANES), 2003-2018. Estimates are for consumers only. The 90th percentile lead exposures (representing an upper bound) from juice for NHANES/WWEIA respondents were calculated as the sum of the products of the 90th percentile 2-day average consumption of each type of juice and the mean lead concentration in that juice. For fruit/vegetable juices other than apple, the exposure value is weighted by mean per capita consumption of each juice. 90th percentile 2-day average consumption values for each type of juice are provided in Table 3. Calculations are based on unrounded data.

[3]Mean lead concentrations in Scenario B were calculated after removal of TEP data for samples with a concentration above the action level.

[4]Calculated as [(lead exposure under Scenario A - lead exposure under Scenario B)/lead exposure under Scenario A] * 100. Calculations are based on unrounded data.

Table 3. Mean lead concentrations, and 90th percentile lead exposures from juice consumption for children (0-6 y) with and without action levels for all juices including apple

Juice	Action Level	Achievability	Consumption at the 90th %ile		Scenario A: No Action Level		Scenario B: With Action Level		Reduction in exposure at 90th %ile[6]
					Estimated mean lead concentration	Estimated lead exposure from juice at 90th %ile[4]	Estimated mean lead concentration[5]	Estimated lead exposure from juice at 90th %ile[4]	
	ppb	%	g/day	oz/ day[3]	ppb	µg/day	ppb	µg/day	%
Apple	10	95	324[1]	11	2.4	0.79	1.3	0.43	46
Fruit/vegetable juices other than apple:									
Berries	20	95	193[2]	6	5.6	1.08	4.1	0.78	28
Carrot	20	99	122[2]	4	2.5	0.3	2.3	0.28	8
Coconut water	20	100	285[2]	10	0.5	0.15	0.5	0.15	0
Grape	20	88	249[2]	8	9.3	2.32	7.2	1.8	23
Mango	20	100	227[2]	8	1	0.24	1	0.24	0
Mixed-type[7]	20	99	305[1]	10	3	0.9	2.6	0.79	13
Orange	20	99	242[1]	8	1.2	0.29	0.9	0.22	24
Pear	20	98	153[2]	5	3.4	0.52	2.7	0.41	20

Pineapple	20	98	222[2]	7	2.4	0.53	2	0.44	17
Pomegranate	20	89	115[2]	4	8.7	1	6.1	0.7	30
Prune	20	94	152[2]	5	5.6	0.86	3.7	0.57	34
Other (juices with <30 samples)	20	94	190[2]	6	6.4	1.22	2.6	0.49	60

[1]Juice consumption estimate based on data from What We Eat in America (WWEIA), the food consumption portion of the National Health and Nutrition Examination Survey (NHANES), 2009-2018. Estimates are based on 2-day averages for consumers only.
[2]Juice consumption estimate based on data from What We Eat in America (WWEIA), the food consumption portion of the National Health and Nutrition Examination Survey (NHANES), 2003-2018. Estimates are based on 2-day averages for consumers only. For juices other than grape, 90th percentile consumption (representing an upper bound) was estimated as 2 * mean intakes by juice consumers due to small sample size (< 165).
[3]Based on one ounce (oz) = 30 g.
[4]Exposure estimates were calculated based on lead concentration data from the Toxic Elements Program (TEP) and on juice consumption data from WWEIA/NHANES. 90th percentile lead exposures from juice for NHANES/WWEIA respondents were calculated as the products of the 90th percentile 2-day average consumption of each juice type and the mean lead concentration in that juice. Calculations are based on unrounded data.
[5]Mean lead concentrations in Scenario B were calculated after removal of TEP data for samples with a concentration above the action level.
[6]Calculated as [(lead exposure under Scenario A - lead exposure under Scenario B)/lead exposure under Scenario A]*100. Calculations are based on unrounded data.
[7]Mixed-type juice is made from more than type of fruit and/or vegetable.