

ENVIRONMENTAL DEFENSE FUND, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CHILDHOOD LEAD ACTION PROJECT, CLEAN LABEL PROJECT, CONSUMER REPORTS, DEFEND OUR HEALTH, ENVIRONMENTAL WORKING GROUP, HEALTHY BABIES BRIGHT FUTURES, AND UTAH PHYSICIANS FOR A HEALTHY ENVIRONMENT

December 9, 2020

Division of Dockets Management  
Food and Drug Administration,  
Department of Health and Human Services  
5630 Fishers Lane, rm.1061  
Rockville, MD 20852

Re: Citizens petition requesting that the agency lower the maximum lead allowed in bottled water from five to one parts per billion; explicitly prohibit lead as an additive to food contact articles; and update its existing guidance limiting lead in children's candy, juice, dried fruits, spices, and other ingredients.

Dear Commissioner:

In 2017, the Food and Drug Administration (FDA) announced that it was evaluating the risks posed by lead, arsenic, cadmium and mercury in foods, cosmetics, and dietary supplements because of their presence in many of the foods we eat and because these substances can be especially harmful to children's neurological development.<sup>1</sup> As part of this effort, the agency acknowledged that "some lead contamination in food is unavoidable; however it is a public health priority to lower lead concentrations in food to the extent feasible."<sup>2</sup>

With regard to lead, the most tangible results of the initiative have been:

- Reaffirming there is no safe level of lead in the blood and cutting its interim target for a maximum daily intake limit in half to 3 micrograms of lead per day for children and 12.5 for adults.<sup>3</sup> However, these efforts have not yet been accompanied by actions such as updates to the agency's limits for candy, juice, dried fruits, spices, and other common food ingredients.
- Removing its approval of lead as hair dye, although these products remain available to consumers because the agency reinstated its approval in response to industry objections. Those objections remain unresolved after almost two years.<sup>4</sup>
- Publishing several peer-reviewed research papers assessing young children's exposure to lead and cadmium from food<sup>5</sup> and identifying strategies to reduce cadmium in food.<sup>6</sup>

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<sup>1</sup> FDA, What FDA is Doing to Protect Consumers from Toxic Metals in Foods, accessed on July 24, 2020 at <https://www.fda.gov/food/conversations-experts-food-topics/what-fda-doing-protect-consumers-toxic-metals-foods>.

<sup>2</sup> Flannery BM et al., U.S. Food and Drug Administration's interim reference levels for dietary lead exposure in children and women of childbearing age. 2020. *Regulatory Toxicology and Pharmacology* 110:104516, <https://doi.org/10.1016/j.yrtph.2019.104516>.

<sup>3</sup> *Id.*

<sup>4</sup> FDA, Reinstatement of Color Additive Listing for Lead Acetate, Final Rule, 84 *Federal Register* 12081, April 1, 2019. <https://www.federalregister.gov/documents/2019/04/01/2019-06238/reinstatement-of-color-additive-listing-for-lead-acetate>.

<sup>5</sup> Spungen JH. Children's exposures to lead and cadmium: FDA total diet study 2014-16. 2019. *Food Additives & Contaminants: Part A* 36:893, DOI: 10.1080/19440049.2019.1595170.

<sup>6</sup> Schaefer HR et al. Cadmium: Mitigation strategies to reduce dietary exposure. 2020. *Journal of Food Science* 85:260, DOI: 10.1111/1750-3841.14997.

While helpful, these actions fail to address several important opportunities to protect young children from this potent neurotoxicant,<sup>7</sup> adults from this significant contributor to cardiovascular disease deaths,<sup>8</sup> and everyone from the public from this recognized carcinogen.<sup>9</sup> The agency still allows lead to be added to food contact articles such as metal cans<sup>10</sup> and to brass and bronze components of equipment used to dispense water and brew tea and coffee.<sup>11</sup> These uses are contrary to the Federal Food Drug and Cosmetic Act and need be stopped. In addition, the agency has not updated its 1994 limit of five parts per billion (ppb) of lead in bottled water. At these levels, a child drinking two bottles of water (24 ounces) would exceed the agency's new interim limit for daily lead in the diet.

With this citizens petition, we ask that FDA cut the limit of lead in bottled water fivefold to one ppb; ban lead as an additive to food contact materials and articles; establish a presumption that lead levels over 100 ppm in food contact materials is from its intentional use as an additive rather than contamination; and update its guidance to reflect the evidence that there is no safe level of lead in blood.

### **A. Action requested**

The undersigned submit this petition pursuant to the Section 4 of the Administrative Procedures Act (codified at [5 U.S.C. § 553e\(e\)](#)) and [21 C.F.R. § 10.30](#) requesting that FDA take three specific actions:

1. *Prohibit lead as an additive to food contact articles by promulgating the following new section to [21 C.F.R. Part 189](#) as follows:*

#### **Section 189.240 Lead.**

- (a) Lead has been added to tin, brass, and bronze that become a component of food contact articles and are known to migrate into food.
- (b) Lead has been a common contaminant in zinc, a substance used to galvanize food contact articles. The lead from the zinc is known to migrate into food (including beverages).
- (c) Lead has been added to plastics, inks, and coatings for food contact articles that have the potential to migrate into food.
- (d) Lead in any component of a food contact article with lead levels greater than 100 micrograms per kilogram is presumed to be added.
- (e) Food contact articles that contain any lead added through the process of making the article are deemed to be adulterated in violation of the Federal Food, Drug, and Cosmetic Act unless the agency specifically authorizes the use of the materials as a food contact substance and:
  - (1) The part of the food contact article that contains added lead does not contact food under intended conditions of use; or
  - (2) No lead migrates into food from the food contact article under intended conditions of use.

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<sup>7</sup> FDA, Termination of Listing of Color Additive Exempt From Certification; Lead Acetate, Final Rule, 83 *Federal Register* 54665, October 31, 2018. <https://www.federalregister.gov/documents/2018/10/31/2018-23725/termination-of-listing-of-color-additive-exempt-from-certification-lead-acetate>.

<sup>8</sup> Brown L et al. Developing a Health Impact Model for Adult Lead Exposure and Cardiovascular Disease Mortality. 2020. *Environmental Health Perspectives* 128:097005-1, <https://doi.org/10.1289/EHP6552>.

<sup>9</sup> National Toxicology Program, 14<sup>th</sup> Report on Carcinogens. Lead and Lead Compounds, 2016. See <https://ntp.niehs.nih.gov/whatwestudy/assessments/cancer/roc/index.html> and

<https://ntp.niehs.nih.gov/ntp/roc/content/profiles/lead.pdf>. See also Department of Health and Human Services, Announcement of Availability of the Fourteenth Report on Carcinogens, 81 *Federal Register* 76621, November 3, 2016, <https://www.govinfo.gov/content/pkg/FR-2016-11-03/pdf/2016-26604.pdf>.

<sup>10</sup> See Section B.2 and B.8.

<sup>11</sup> See Section B.9.

- (f) For purposes of this section, food contact articles include:
- (1) Packaging for food or food ingredients;
  - (2) Equipment that processes or handles food or food ingredients (including beverages);
  - (3) Utensils, dinnerware, and cookware used to prepare or serve food to consumers;
  - (4) Components of these articles including inks, coatings, tubing, sealants, gaskets, and valves.

2. *Reduce the allowed level of lead in bottled water from five to one ppb by amending [§ 165.110](#).*

**Sec. 165.110 Bottled water.**

(b) *Quality.*

(4) *Chemical quality.*

- (iii) Having consulted with EPA as required by section 410 of the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration has determined that bottled water, when a composite of analytical units of equal volume from a sample is examined by the methods listed in paragraphs (b)(4)(iii)(E) through (b)(4)(iii)(F), and (b)(4)(iii)(G) of this section, shall not contain the following chemical contaminants in excess of the concentrations specified in paragraphs (b)(4)(iii)(A) through (b)(4)(iii)(D) of this section.

(A) The allowable levels for inorganic substances are as follows:

Contaminant	Concentration in milligrams per liter (or as specified)
Lead	<u>0.005-0.001</u>

3. *Update its existing guidance and other administrative actions setting limits on lead in children's candy, juice, dried fruits, spices, and other ingredients to reflect the latest science on the risks posed by lead and its new Interim Reference Level.<sup>12</sup>*

**B. Statement of grounds**

In the analysis below we provide a detailed explanation of the grounds on which we request that FDA prohibit the lead as additives to food contact materials

1. FDA has prioritized reducing lead in children's diets along with arsenic, cadmium, and mercury since 2017.
2. Our food supply is contaminated with lead from a myriad of sources.
3. The cumulative amount of lead in young children's diet is significant and needs to be reduced.
4. FDA's existing limits of lead in food are outdated and inconsistent and need to be updated.
5. Intentional use of lead is subject to most protective safety standard.
6. Lead has been found to induce cancer and should be prohibited as an additive.
7. There is no longer a reasonable certainty of no harm for any use of lead due to the lack of a safe threshold to prevent irreversible neurodevelopmental harm to young children and to its widespread presence in the food supply.
8. Lead has been and is being added to food contact articles and can migrate into food.
9. Intentional addition of lead, especially to brass and bronze, is unsafe.
10. Lead contamination of materials used to make food contact articles warrant strict limits.
11. The lead limit for bottled water is outdated and needs to be reduced from 5 to 1 ppb.

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<sup>12</sup> See Section B.4. for details.

**B.1. FDA has prioritized reducing lead in children’s diets along with arsenic, cadmium, and mercury since 2017.**

In 2017, FDA convened a Toxic Elements Workgroup to evaluate the risks posed by metals that are present in certain foods. In April 2018, the agency provided an update on the workgroup’s efforts explaining that:

The workgroup is focusing first on metals like lead, arsenic, cadmium, and mercury in foods, cosmetics, and dietary supplements. These naturally occurring contaminants<sup>13</sup> are present in many of the foods we eat, but can be especially harmful to children because of concerns about effects on their neurological development. So we’re looking into the presence of these four metals in foods commonly consumed by children. We’re also concerned about the rest of the population, but our initial focus is on those who are the most vulnerable.<sup>14</sup>

FDA’s workgroup chair, Conrad Choiniere, stated that:

One thing that comes across when I look at the data is that there isn’t one single source we can point to that results in exposure to these metals. Even though the levels of a metal in any particular food is low, our overall exposure adds up because many of the foods we eat contain them in small amounts.<sup>15</sup>

As FDA acknowledged, the cumulative effect of the low levels of these toxic elements can result in an overall exposure that warrants close evaluation.

Consistent with this priority, we ask that the agency undertake the requests we outline in this petition.

**B.2. Our food supply is contaminated with lead from a myriad of sources.**

FDA’s [Total Diet Study](#) (TDS) is an important source of data for both the agency and the public to estimate exposure, track trends, and set priorities for chemicals such as heavy metals in food. In 2017, [EDF analyzed](#) results from samples the agency collected from 2003-13, finding widespread contamination with 20% of baby food samples and 14% for other foods having detectable levels of lead.<sup>16</sup>

Beginning in 2014, FDA upgraded its analytical equipment with inductively-coupled plasma mass spectrometry (ICP-MS) so it could reliably detect lower levels of heavy metals in food. It published a new method based on the equipment with a limit of detection (LOD) for lead between 1 and 3 parts per billion (ppb).<sup>17</sup>

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<sup>13</sup> We cannot explain FDA’s designation of lead, cadmium and mercury as “naturally occurring contaminants” since the agency has also acknowledged that “a lot of [lead] comes from industrial uses and environmental contamination.” FDA, Lead in Food, Foodwares, and Dietary Supplements, accessed on November 11, 2020 at <https://www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements>. According to [21 C.F.R. § 109.3\(c\)](#),”

<sup>14</sup> FDA, What FDA is Doing to Protect Consumers from Toxic Metals in Foods, accessed on July 24, 2020 at <https://www.fda.gov/food/conversations-experts-food-topics/what-fda-doing-protect-consumers-toxic-metals-foods>.

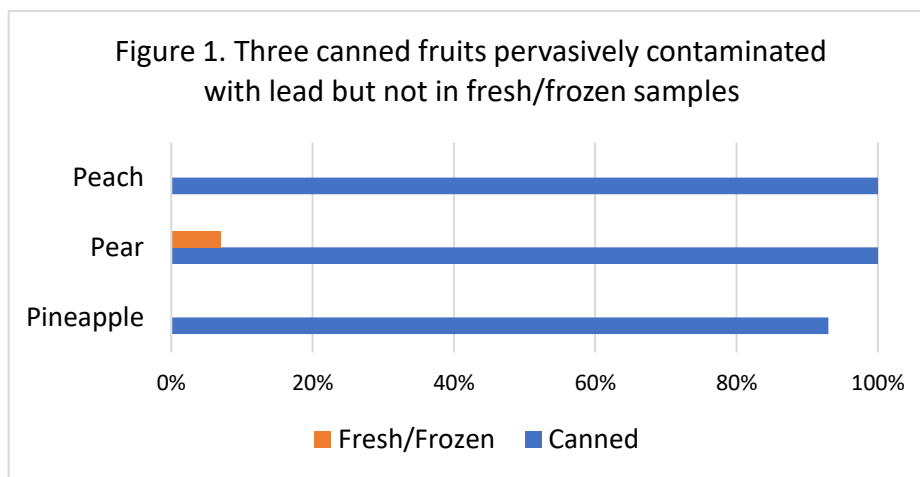
<sup>15</sup> *Id.*

<sup>16</sup> EDF, Lead in food: A hidden health threat, 2017. See [https://www.edf.org/sites/default/files/edf\\_lead\\_food\\_report\\_final.pdf](https://www.edf.org/sites/default/files/edf_lead_food_report_final.pdf).

<sup>17</sup> FDA, Elemental Analysis Manual for Food and Related Products, 4.7 Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic, Cadmium, Chromium, Lead, Mercury, and Other Elements in Food Using

EDF evaluated FDA's [TDS data from 2014-17](#) that had been analyzed using ICP-MS, finding lead detected in 29% of baby food samples and 26% for other foods. Many of the foods with frequent lead detections such as sweet potatoes, grapes, carrots, peaches, squash, and pears could be attributed to contamination in the field where they are grown. However, EDF found that canned food was a significant problem with 48% of 242 samples having detectable lead, including 98% of 70 canned fruit samples (apricot, peach, pear, pineapple and fruit cocktail).<sup>18</sup> The contamination was not limited to fruit; more than half the cans of sweet potato, New England clam chowder, vegetable beef soup, and chili con carne with beans also had detectable lead.

The greater likelihood of a contamination source other than the food itself in canned food was made clear when EDF compared the results for the three fruits for which FDA had sampled both canned and fresh/frozen products – peach, pear, and pineapple. Only 1 of 31 fresh or frozen samples of those fruits had detectable lead compared to 41 of 42 for their canned versions. See Figure 1.



Clearly lead is entering food from the canning process and not from the fruit itself.

### **B.3. The cumulative amount of lead in young children's diets is significant and needs to be reduced.**

Food represents a significant source of lead in the blood of most young children. In 2017, Zartarian and colleagues at the Environmental Protection Agency (EPA) estimated the relative contribution of various sources of lead in young children's blood.<sup>19</sup> For food, they used FDA's TDS results from 2003-13 (before the switch to ICP-MS). Figure 2<sup>20</sup> provides the contribution of four sources of lead – air, food, soil/dust, and water – for toddlers (1 to < 2 year old) and for other young children (2 to < 6 years old) to their blood lead levels after adjusting for the bioavailability of each source. For more than 70% of the children, food is the dominant source – essentially all children but those who live in the 24 million homes with lead-based paint hazards.

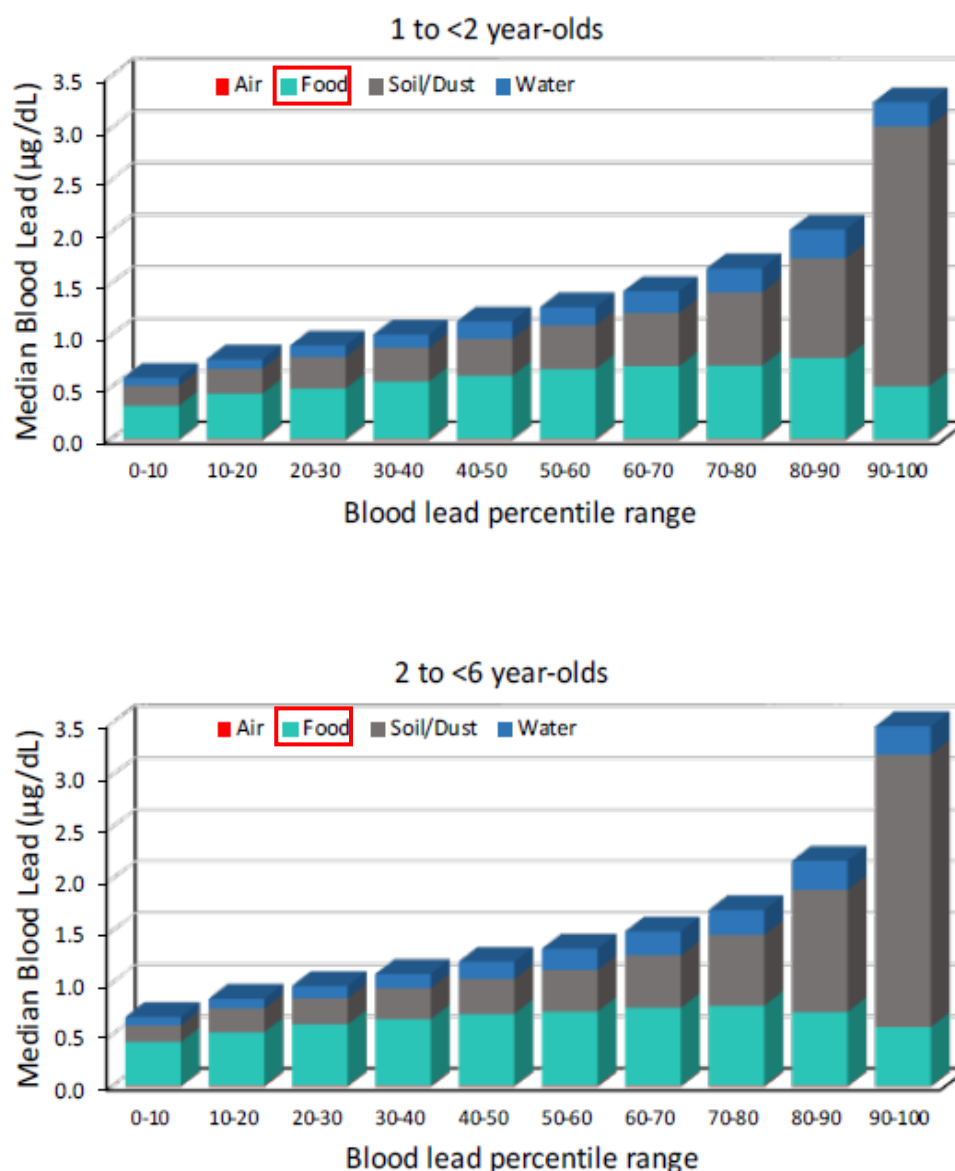
Microwave Assisted Digestion, 2014. See <https://www.fda.gov/media/95170/download>. Based on the Total Diet Study results for 2014-2017, the LOD of bottled water is 0.052 ppb.

<sup>18</sup> EDF excluded food types that were samples as either canned or bottled because FDA did not differentiate the two types in its results.

<sup>19</sup> Zartarian V et al. Children's Lead Exposure: A Multimedia Modeling Analysis to Guide Public Health Decision-Making. 2017. Environmental Health Perspectives 125:097009-1, <https://doi.org/10.1289/EHP1605>.

<sup>20</sup> Zartarian V et al. Supplemental Materials, Figure S5.

Figure 2. Food is a primary source of blood lead in all but the most exposed children ([Zartarian et al., 2017](#)) (Supplemental Materials)



Using these estimates, EDF calculated that eliminating lead from food would save society an estimated \$27 billion annually.<sup>21</sup>

Building on the method used by Zartarian et al., Judith Spungen, an FDA scientist, evaluated lead exposure to children 1 to 6 years old using the TDS data from 2014-16 that was analyzed using ICP-MS method.<sup>22</sup> She found that the 90<sup>th</sup> percentile exposure for these children was 2.9 µg/day using the hybrid

<sup>21</sup> EDF, Lead in food: A hidden health threat, 2017. See [https://www.edf.org/sites/default/files/edf\\_lead\\_food\\_report\\_final.pdf](https://www.edf.org/sites/default/files/edf_lead_food_report_final.pdf).

<sup>22</sup> Spungen JH. Children's exposures to lead and cadmium: FDA total diet study 2014-16. 2019. Food Additives & Contaminants: Part A 36:893, DOI: 10.1080/19440049.2019.1595170.



model, a model that represents the best estimate of exposure. See Table 1. This estimate of exposure is slightly lower than FDA’s “Interim Reference Level” (IRL) of 3 µg of lead/day for children.<sup>23</sup> The IRL is essentially a maximum daily intake limit. With almost 3.8 million children born each year,<sup>24</sup> more than two million young children in this cohort likely exceed FDA’s daily limit.<sup>25</sup>

Table 1. Estimated dietary exposure for young children ([Spungen, 2019](#))

		Dietary Lead Exposure <sup>a</sup>					
		Mean			90 <sup>th</sup> %ile		
Age group	Toxicological Reference Value for Lead	Lower Bound <sup>b</sup>	Upper Bound <sup>c</sup>	Hybrid <sup>d</sup>	Lower Bound <sup>b</sup>	Upper Bound <sup>c</sup>	Hybrid <sup>d</sup>
µg/day							
1–6 years	3 µg/day, <sup>e</sup>	1.2	3.2	1.8	2.0	4.6	2.9
1–3 years	6 µg/day <sup>f</sup>	1.0	3.0	1.7	1.8	4.4	2.6
4–6 years		1.3	3.4	2.0	2.1	4.8	3.1
µg/kg bw/day							
1–6 years	N/A <sup>g</sup>	0.07	0.20	0.11	0.12	0.30	0.17
1–3 years		0.08	0.23	0.12	0.13	0.33	0.20
4–6 years		0.06	0.17	0.10	0.10	0.24	0.15

<sup>a</sup>Data sources: Toxic element concentrations in foods: FDA Total Diet Study, 2014–16 (analysis method: inductively coupled plasma mass spectrometry, or ICPMS), arithmetic mean concentrations. Food consumption: What We Eat In America (WWEIA)/National Health and Nutrition Examination (NHANES) 2009–14. Estimated exposures do not include contributions from breast milk or from tap water.

<sup>b</sup>Values < limit of detection (LOD) set to zero.

<sup>c</sup>Values < LOD set to LOD.

<sup>d</sup>Values < LOD set to zero if there were no detections from 2009–16; otherwise, values < LOD set to 0.5 \* LOD.

<sup>e</sup>Lead Interim Reference Level (IRL), 0 through 6 years developed by FDA (2018c) based on the CDC’s blood Pb “reference value” or clinical intervention level of 5 µg/dL blood lead for children ([CDC] Centers for Disease Control and Prevention 2017).

<sup>f</sup>Lead Provisional Total Tolerable Daily Intake (PTTDI), 0 through 6 years (Carrington and Bolger 1992).

<sup>g</sup>Not applicable because toxicological reference values used by FDA to evaluate lead exposures are expressed in units of µg/day.

With more than two million young children exceeding FDA’s IRL, lead in food must be considered a significant source of exposure to children.

#### B.4. FDA’s existing limits of lead in food are outdated and inconsistent and need to be updated.

FDA has taken a number of regulatory actions to limit lead in some foods and maintains a [webpage](#)<sup>26</sup> summarizing its efforts. All limits were set before the federal government – including FDA – reached a consensus that there is no safe level of lead in the blood of a child that is shown to sufficiently protect children from harmful neurological effect. There is similar evidence for adults for [cardiovascular disease](#).<sup>27</sup>

The most significant rules were promulgated in the mid-1990s. They are:

- **Limit on lead in bottled water** of 5 ppb in 1994 at [§ 165.110](#).<sup>28</sup> The limit was based on the analytical method’s ability to quantify levels of lead in bottled water. In its TDS results for 2014–17 using the ICP-MS equipment, FDA reports a limit of quantification of 0.39 ppb.

<sup>23</sup> *Id.*

<sup>24</sup> Centers for Disease Control and Prevention, National Center for Health Statistics, Births and Natality, accessed November 9, 2020 at <https://www.cdc.gov/nchs/fastats/births.htm>.

<sup>25</sup> 3.8 million \* 6 years in cohort = 2.28 million rounded down to 2 million.

<sup>26</sup> FDA, Lead in Food, Foodwares, and Dietary Supplements, accessed on November 1, 2020 at <https://www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements>.

<sup>27</sup> Brown L et al. Developing a Health Impact Model for Adult Lead Exposure and Cardiovascular Disease Mortality. 2020. Environmental Health Perspectives 128:097005-1, <https://doi.org/10.1289/EHP6552>.

<sup>28</sup> FDA, Beverages: Lead in Bottled Water, Final Rule, 59 *Federal Register* 26933, May 25, 1994.

- **Ban on lead in can solder** in 1995 at [§ 189.240](#). The decision revoked a prior sanction of the use.<sup>29</sup> However, the agency failed to define the term “lead solder” and, unlike similar measures taken in drinking water, FDA did not set a maximum amount of lead that solder could contain.<sup>30</sup>
- **Ban on tin-coated lead foil capsules** for wine bottles in 1996 at [§ 189.301](#). As with can solder, FDA did not set a maximum amount of lead allowed in the replacement foil.

In addition, FDA often sets limits for lead contamination in direct additives to food. The limits range from 100 to 10,000 ppb and appear to be largely based on the specifications provided by the company that sought agency’s approval, rather than the cumulative effect of lead in the diet. For example:

- **Color additives to food:** Lead limits range from 400 ppb (soy leghemoglobin at [§ 73.520](#)) to 10,000 ppb (synthetic iron oxide at [§ 73.200](#)).
- **Direct food additives:** Lead limits range from 100 ppb (glycerides and polyglycerides of hydrogenated vegetable oils at [§ 172.736](#)) to 10,000 ppb (anoxomer preservative at [§ 172.105](#), epoxidized soybean oil at [§ 172.723](#), and sucrose fatty acid esters at [§ 172.859](#)).
- **Direct food substances affirmed as generally recognized as safe:** Lead limits range from 100 ppb (menhaden oil at [§ 184.1472](#), at [§ 172.736](#)) to 10,000 ppb (cocoa butter substitute at [§ 184.1259](#), glyceryl palmitostearate at [§ 184.1329](#), whey at [§ 184.1979](#), reduced minerals whey at [§ 184.1979b](#), and whey protein concentrate at [§ 184.1979c](#)).

Beyond promulgating regulations, FDA has taken less formal action to limit lead in food itself or in food contact articles.

- **Children’s candy:** In 2010 [guidance](#), FDA limited lead in candy to 100 ppb, down from 500 ppb.<sup>31</sup> It also reaffirmed a 1995 limit to lead in printing inks to 10,000 ppb on any portion of the package that directly contacts food and clarified that printing ink on the outer surface of the package and not directly contacting food does not ensure it will not contaminate food.
- **Juice:** In 2004 [guidance](#), FDA limited lead in juice to 50 ppb and was not updated since then.<sup>32</sup>
- **Dried fruits:** In an [import alert](#), FDA limited lead to 100 ppb in dried fruits.<sup>33</sup>
- **Spices:** In an [import alert](#), FDA warned of lead in spices and spice products, but did not set a numerical limit instead stating that a lab analysis needs to demonstrate “that the product does not contain a level of lead that may render it injurious to health.”<sup>34</sup>
- **Ceramic foodware:** In a [compliance policy guide](#), FDA limited lead in ceramic foodware to between 500 ppb in pitchers and mugs, 1,000 in large hollowware, 2,000 ppb in small hollowware other than cups and mugs, and 3,000 ppb in flatware. The levels are based on the

<sup>29</sup> FDA, Lead-Soldered Food Cans, Final Rule, [60 Federal Register 33106](#), June 27, 1995.

<sup>30</sup> In Section 1417 of the Safe Drinking Water Act, Congress limited the amount of lead in solder or flux to 0.2% for new uses in any public water system or any plumbing in a residential or non-residential facility providing water for human consumption, that is not lead free.” Neither Congress or EPA have modified this limit since 1986 when it was enacted. Safe Drinking Water Act Amendments of 1986, [Pub.L. 99-359](#), 100 Stat. 642.

<sup>31</sup> FDA, Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children, 2006. See <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-lead-candy-likely-be-consumed-frequently-small-children>. Accessed on November 30, 2020

<sup>32</sup> FDA, Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, First Edition, 2004. See <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-hazard-analysis-critical-control-point-hazards-and-controls-guidance-first>.

<sup>33</sup> FDA, Import Alert 20-03, accessed on November 1, 2020 at [https://www.accessdata.fda.gov/cms\\_ia/importalert\\_55.html](https://www.accessdata.fda.gov/cms_ia/importalert_55.html).

<sup>34</sup> FDA, Import Alert 28-13, accessed on November 1, 2020 at [https://www.accessdata.fda.gov/cms\\_ia/importalert\\_1143.html](https://www.accessdata.fda.gov/cms_ia/importalert_1143.html).



amount of lead leaching into a 4% vinegar solution allowed to set overnight at room temperature.<sup>35</sup> It was issued in 1980 and updated in 2005.

- **Silver-plated hollowware:** In a [compliance policy guidance](#), FDA limited lead in silver-plated hollowware to 500 ppb if intended for the exclusive use of infants and children or 7,000 ppb for other uses based on the amount of leaching into a 4% vinegar solution allowed to set overnight at room temperature.<sup>36</sup> It was issued in 2005 and was adapted from the 1980 guide for ceramic foodwares without a revised assessment of the risk to health.

In its [Food Code](#) that provides guidance for food establishments, the agency establishes limits for food contact surfaces.<sup>37</sup> These limits include

- Pewter may have 50 ppb of lead;
- Solder and flux may have 200 ppb of lead; and
- Ceramic, china, and crystal utensils, and decorative utensils may have lead leaching levels equal to those for ceramic foodware above.

In summary, the most recent action was in 2010 for children's candy and in 2005 for food contact articles used to serve food. The agency has not updated any limit to reflect the latest scientific evidence on risks posed by lead, especially to young children but also adults. As discussed below, beginning in 2012 federal agencies have uniformly concluded that there is no safe level of lead in the blood of child that has been shown to sufficiently protect children from harmful neurological effect. There is similar evidence for adults for cardiovascular disease.<sup>38</sup>

Therefore, we request that FDA update its standards to reflect the latest evidence on the risks posed by lead.

#### **B.5. Intentional uses of lead are subject to most protective safety standard.**

An additive to food or a food contact article must be safe as that term is defined at [21 C.F.R. § 170.3\(i\)](#), which states:

*Safe or safety* means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use. . . . In determining safety, the following factors shall be considered:

- (1) The probable consumption of the substance and of any substance formed in or on food because of its use.
- (2) The cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet.

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<sup>35</sup> FDA, Compliance Policy Guide Sec. 545.450 Pottery (Ceramics); Import and Domestic - Lead Contamination, 2005. See <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-545450-pottery-ceramics-import-and-domestic-lead-contamination>.

<sup>36</sup> FDA, Compliance Policy Guide Sec. 545.500 Silver-Plated Hollowware - Lead Contamination, 2005. See <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-545500-silver-plated-hollowware-lead-contamination>.

<sup>37</sup> FDA and U.S. Public Health Service, Food Code, 2017. Section 4-101.13. See <https://www.fda.gov/media/110822/download>.

<sup>38</sup> Brown L et al. Developing a Health Impact Model for Adult Lead Exposure and Cardiovascular Disease Mortality. 2020. Environmental Health Perspectives 128:097005-1, <https://doi.org/10.1289/EHP6552>.

- (3) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate.

In addition, Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA)<sup>39</sup> establishes that “no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal . . .” ([21 U.S.C. § 348\(c\)\(3\)\(A\)](#)) This requirement, known as the Delaney Clause in honor of its Congressional author, is a bright line drawn by Congress on what is not safe in food with respect to carcinogens. This statutory requirement for food additives has not been altered in the intervening half-century.

These requirements established a standard of safety for uses of a substance that are more protective than the “any poisonous or deleterious substance which may render it injurious to health” at [21 U.S.C. § 342\(a\)\(1\)](#) that applies to food in general.

#### **B.6. Lead has been found to induce cancer and should be prohibited as an additive.**

In its most recent Report on Carcinogens, the National Toxicology Program (NTP) designates [lead and lead compounds](#) “as a class that is reasonably anticipated to be a human carcinogen” based “on limited evidence of carcinogenicity from studies in humans and sufficient evidence of carcinogenicity from studies in experimental animals.”<sup>40</sup> NTP, FDA’s sister agency, initially made this designation in 2004 in its Congressionally-mandated<sup>41</sup> biennial report listing substances: 1) which are known to be carcinogens or may reasonably be anticipated to be carcinogens; and 2) to which a significant number of persons residing in the United States are exposed.

Petitioners maintain that this conclusion by the agency designated by Congress to evaluate the carcinogenicity of chemicals indicates that the scientific evidence substantiating a direct correlation between lead exposure and human carcinogenicity is sufficiently strong for FDA to conclude that use in food or food contact articles of lead and lead compounds are unsafe pursuant to the Delaney Clause.

#### **B.7. There is no longer a reasonable certainty of no harm for any use of lead due to the lack of safe threshold to prevent irreversible neurodevelopment harm to young children and to its widespread contamination of the food supply.**

In response to a petition requesting that FDA remove its approval of lead acetate as a color additive in hair dyes, the agency said:

**The risks of lead exposure are particularly high *in utero*, infancy, and in early childhood; CDC has stated that there is no safe blood lead level in children, and that even low levels of**

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<sup>39</sup> Codified at [21 U.S.C. § 348\(c\)\(3\)\(A\)](#))

<sup>40</sup> National Toxicology Program, 14<sup>th</sup> Report on Carcinogens. Lead and Lead Compounds, 2016. See <https://ntp.niehs.nih.gov/whatwestudy/assessments/cancer/roc/index.html> and <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/lead.pdf>. See also Department of Health and Human Services, Announcement of Availability of the Fourteenth Report on Carcinogens, 81 *Federal Register* 76621, November 3, 2016, <https://www.govinfo.gov/content/pkg/FR-2016-11-03/pdf/2016-26604.pdf>.

<sup>41</sup> 42 U.S.C. § 241(b)(4).

**lead in blood have been shown to affect IQ, ability to pay attention, and academic achievement** (Ref. 4). As part of its program to prevent childhood lead poisoning, CDC has recommended 5 [micrograms of lead per deciliter of blood ( $\mu\text{g}/\text{dL}$ )]<sup>42</sup> as the reference blood lead level to identify children who have been exposed to lead and who require case management (Ref. 4). )<sup>43</sup> [*Emphasis added*]

In addition, FDA found that **“Lead exposure also poses significant health risks to adults. . . . A growing body of evidence indicates that adults, like children, may experience adverse health impacts from exposure to levels of lead lower than those previously believed to be harmful.”**<sup>44</sup> [*Emphasis added*]. In reaching this conclusion, it referenced the NTP’s 2012 report finding sufficient evidence for decreased glomerular filtration rate (in the kidney) in adults and reduced fetal growth in pregnant women at blood lead levels less than 5  $\mu\text{g}/\text{dL}$ ; increased blood pressure, hypertension, and essential tremor in adults at blood lead levels less than 10  $\mu\text{g}/\text{dL}$ ; and adverse changes in sperm parameters in men, as well as increased time to achieve pregnancy, at blood lead levels greater than or equal to 15–20  $\mu\text{g}/\text{dL}$ .<sup>45</sup>

FDA also noted that the Joint Food and Agriculture/World Health Organization (FAO/WHO) Expert Committee on Food Additives (JECFA) withdrew the previously established Provisional Tolerable Weekly Intake for lead and concluded that it was not possible to establish a new level that would be considered health protective. In addition, FDA noted that the EPA has set the maximum contaminant level goal for lead in drinking water at zero.<sup>46</sup>

While FDA’s conclusions were in response to a petition involving dermal contact with lead as the route of exposure instead of ingestion that would occur with food, in 1993 FDA found a direct correlation between ingested lead and blood lead levels. In that analysis conducted as part of its proposed decision to ban lead-soldered food cans, FDA estimated that a young child’s blood lead level increased 0.16  $\mu\text{g}/\text{dL}$  for each microgram of lead ingested each day; the correlation was 0.4  $\mu\text{g}/\text{dL}$  for each microgram for women of child-bearing age to protect the fetus.<sup>47</sup>

In Flannery et al., published earlier this year, FDA’s scientists [reaffirmed the correlation](#), acknowledging that the agency included a 10-fold uncertainty factor to account for the highly variable conversion of dietary lead to blood lead.<sup>48</sup> The study also reaffirmed that no safe level of lead in blood has been

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<sup>42</sup> FDA used the mc/dL as abbreviation. We use the more common  $\mu\text{g}/\text{dL}$  instead.

<sup>43</sup> FDA, Termination of Listing of Color Additive Exempt From Certification; Lead Acetate, Final Rule, 83 *Federal Register* 54665, October 31, 2018. <https://www.federalregister.gov/documents/2018/10/31/2018-23725/termination-of-listing-of-color-additive-exempt-from-certification-lead-acetate>.

<sup>44</sup> *Id.* at 54668.

<sup>45</sup> NTP, NTP Monograph on Health Effects of Low-level Lead, 2012.

[https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffects/lowlevellead\\_newissn\\_508.pdf](https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffects/lowlevellead_newissn_508.pdf).

<sup>46</sup> FDA, Termination of Listing of Color Additive Exempt From Certification; Lead Acetate, Final Rule, 83 *Federal Register* 54665, October 31, 2018. <https://www.federalregister.gov/documents/2018/10/31/2018-23725/termination-of-listing-of-color-additive-exempt-from-certification-lead-acetate>.

<sup>47</sup> FDA, Lead-Soldered Food Cans, Proposed Rule, 58 *Federal Register* 33860, June 21, 1993 at 38864.

<sup>48</sup> Flannery BM et al., U.S. Food and Drug Administration’s interim reference levels for dietary lead exposure in children and women of childbearing age. 2020. *Regulatory Toxicology and Pharmacology* 110:104516, <https://doi.org/10.1016/j.yrtph.2019.104516>. The authors described two goals: 1) Provide an in-depth explanation of the derivation of the FDA [Interim Reference Level] for children and women of child-bearing age; and 2) confirm through a literature review that except for neurodevelopment, which was not evaluated, no adverse effects of lead consistently occur at the BLL associated with the IRLs (0.5  $\mu\text{g}/\text{dL}$ ). **Neurodevelopment was excluded as an endpoint in the literature review because no safe level with respect to this endpoint has been identified to date.** [*Emphasis added*]

identified for neurodevelopment and concluded that “some lead contamination in food is unavoidable; however, it is a public health priority to lower lead concentrations in food to the extent feasible.”<sup>49</sup>

Recognizing that lead is an all-too-common contaminant in food, FDA established of “Interim Reference Level” (IRL) for lead of 3 µg/day for children and 12.5 µg/day for women of child-bearing age.<sup>50</sup> The IRL for young children was derived from the CDC Reference Level for lead whose purpose is “to identify children who have been exposed to lead and who require case management.”<sup>51</sup> The CDC Reference Level is the blood lead level for the top 2.5 percentile of children aged 1 to 5 years and is designed to be reduced periodically as the nation makes progress towards the goal of eliminating young children’s exposure to lead.<sup>52</sup>

However, it is important to be clear that the CDC Reference Level **is not** a level that is considered safe or where below which the exposure is not harmful to children’s neurodevelopment. Rather, it is a trigger for direct public health intervention to protect the child. For example, when a child exceeds the Reference Level, CDC recommends health departments begin follow-up case management, which often involves education, monitoring, and other interventions.<sup>53</sup> Based on this recommendation for direct public health intervention to help the child, at least 18 states require action.<sup>54</sup> In addition, the U.S. Department of Housing and Urban Development requires intervention if a child living in federally-subsidized housing is above CDC’s Reference Level.<sup>55</sup>

According to Flannery et al., “current estimates of dietary lead exposure for children in the United States are 1.4–1.8 µg/day at the mean exposure and 2.9–3.1 µg/day at the 90th percentile exposure.”<sup>56</sup> Therefore, the probable exposure for the 90<sup>th</sup> percentile of young children is roughly the same as the IRL – a level that is inadequate to protect children from neurodevelopmental harm. And that calculation does not consider the many other substances in the diet such as inorganic arsenic that also contribute to neurodevelopmental harm.<sup>57</sup> When the cumulative effect of these pharmacologically-related substances in the diet are considered, there is clearly no longer a reasonable certainty that no harm will occur from any use of lead as an additive. Therefore, the use of lead is not safe according to Section 409 of the FFDCA and by the FDA’s definition of safety at [21 C.F.R. § 170.3\(i\)](#).

#### **B.8. Lead has been and is being added to food contact articles and can migrate into food.**

Food contact articles consist of anything that contacts food (including beverages). It includes:

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<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> CDC, Blood Lead Reference Level, accessed on October 27, 2020 at <https://www.cdc.gov/nceh/lead/data/blood-lead-reference-value.htm>.

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> CDC, State Blood Lead Testing Laws Requiring 5 ug/dL & CDC Reference Rule, 2018, <https://www.cdc.gov/phlp/docs/laws-bll.pdf>.

<sup>55</sup> [24 C.F.R. Part 35](#).

<sup>56</sup> Flannery BM et al., U.S. Food and Drug Administration's interim reference levels for dietary lead exposure in children and women of childbearing age. 2020. Regulatory Toxicology and Pharmacology 110:104516, <https://doi.org/10.1016/j.yrtph.2019.104516> citing Spungen JH (2019).

<sup>57</sup> FDA, FDA In Brief: FDA Takes Action to Limit Inorganic Arsenic Levels in Infant Rice Cereal, August 5, 2020, accessed on October 27, 2020 at <https://www.fda.gov/news-events/fda-newsroom/fda-brief-fda-takes-action-limit-inorganic-arsenic-levels-infant-rice-cereal>.

- Any article used to produce, manufacture, pack, process, prepare, treat, package, transport, or hold food;<sup>58</sup>
- Food packaging and food processing equipment;<sup>59</sup>
- Utensils, dinnerware, and cookware used to prepare or serve food to consumers;<sup>60</sup> and
- Components of these articles including inks, coatings, tubing, sealants, gaskets, and valves.

For centuries, lead has been intentionally added to components of food contact articles, such as:

- Alloys with copper, tin, and zinc including brass and bronze fittings, pumps, and valves; solders to join metals; and galvanized coatings on steel to prevent corrosion; and
- Ceramics, glass, inks, glazes, plastic, and various coatings and paints to add color or improve durability.<sup>61</sup>

Many of these food contact articles with intentionally added lead continue to be in service today. And, in some cases, such as brass and bronze, lead is being added to new food contact articles made of those food contact materials.

Since FDA has not approved of any use of lead in its rules and has not authorized it through a Food Contact Substance Notification (FCN)<sup>62</sup> or acknowledged it through a Generally Recognized as Safe (GRAS) Notification (GRN),<sup>63</sup> we are left to assume that any of these lead uses were prior-sanctions<sup>64</sup> or self-certified as GRAS without notice to the agency.

Lead is also a common contaminant in food contact articles as a result of environmental, agricultural, industrial, or other contamination, and, in some cases, from natural sources such as the zinc, tin, or silver ore.<sup>65</sup>

### **B.8.1. Brass and bronze.**

Lead has been used in brass and bronze for devices such as faucets, pumps, and valves to make the alloys more easily machinable and resist corrosion. In 1986, Congress limited the maximum amount of lead in these alloys for materials in contact with drinking water to 8%, and, in 2014, Congress further reduced the limit to 0.25% or 2,500 parts per million (ppm).<sup>66</sup> While these uses were focused on drinking water, they apply as well to water used to make or process food (including beverages).

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<sup>58</sup> Section [178.3740](#) for example.

<sup>59</sup> Sections §§ [170.3\(e\)](#) and [174.5](#). See also FDA, List of Indirect Additives Used in Food Contact Substances, accessed on November 11, 2020 at <https://www.fda.gov/food/packaging-food-contact-substances-fcs/list-indirect-additives-used-food-contact-substances>.

<sup>60</sup> FDA, Food Code, 2017, <https://www.fda.gov/food/fda-food-code/food-code-2017>.

<sup>61</sup> Agency for Toxic Substances and Disease Registries, Toxicological Profile for Lead, 2020, <http://dx.doi.org/10.15620/cdc:95222>.

<sup>62</sup> FDA, Inventory of Effective Food Contact Substance (FCS) Notifications, accessed on November 10, 2020 at <https://www.fda.gov/food/packaging-food-contact-substances-fcs/inventory-effective-food-contact-substance-fcs-notifications>.

<sup>63</sup> FDA, GRAS Notice Inventory, accessed on November 10, 2020 at <https://www.fda.gov/food/generally-recognized-safe-gras/gras-notice-inventory>.

<sup>64</sup> Section § [170.3\(l\)](#).

<sup>65</sup> FDA, GRAS Notice Inventory, accessed on November 10, 2020 at <https://www.fda.gov/food/generally-recognized-safe-gras/gras-notice-inventory>.

<sup>66</sup> EPA, Use of Lead Free Pipes, Fittings, Fixtures, Solder, and Flux for Drinking Water, 85 *Federal Register* 54235, September 1, 2020. See <https://www.federalregister.gov/documents/2020/09/01/2020-16869/use-of-lead-free-pipes-fittings-fixtures-solder-and-flux-for-drinking-water>.

Even at levels less than 2,500 ppm, lead has been demonstrated to leach into water from these materials, with greater leaching occurring with longer retention times or higher temperatures.<sup>67</sup> The leaching levels were significant enough that NSF/ANSI/CAN 61,<sup>68</sup> the voluntary consensus standard for drinking water system components, set a leaching limit for endpoint devices such as kitchen faucets.

Under the NSF/ANSI/CAN 61 standard, the leaching limit for faucets was five (5) µg of lead in cold water based on the first draw of water allowed to set in the device overnight. In June 2020, the limit was reduced fivefold to one (1) µg for these devices based on concerns with the health risks posed by lead.<sup>69</sup> The limit was tightened in response to a report by NSF International that demonstrated 23% of more than 500 faucets certified to comply with the standard leached between one and five µg over the three weeks in the test protocol, including one faucet that released 39 µg on the third day of the test.<sup>70</sup>

NSF/ANSI 51<sup>71</sup> is a companion voluntary consensus standard for “materials and finishes used in the manufacture of food equipment and components such as plastic materials, tubing, sealants, gaskets, valves and other items intended for various food equipment and food contact applications.”<sup>72</sup> The purpose of the standard is to establish “minimum public health and sanitation requirements for materials used in the construction of commercial food equipment. The requirements are based on U.S. FDA regulations.”<sup>73</sup>

NSF/ANSI 51 generally prohibits the use of lead as an intentional ingredient. However, it contains an explicit exemption for lead to be added to brass and bronze to prepare or serve tea, coffee, or water up to 2,500 ppb. It says:

Section 4.1.2. Food zone materials shall not contain lead, arsenic, cadmium, or mercury as intentional ingredients. **Brass and bronze materials may contain lead** as permitted under Section 4.2.3.2.

Section 4.2.3.2. Brass and bronze may be used in a food zone or splash zone only where rendered corrosion-resistant or where exposure to food is clearly and specifically limited to tea, coffee, or water.

Section 4.2.3.3 Equipment having brass or bronze components in contact with tea, coffee, or water (as permitted in Section 4.2.3.2), which is intended for human consumption, shall be evaluated for weighted average lead content in accordance with NSF/ANSI 372, *Drinking Water System Components – Lead Content*. **The weighted average lead content of the water contact portion of the equipment shall be ≤ 0.25%.**<sup>74</sup> [Emphasis added]

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<sup>67</sup> EDF Health, Lead from a new “lead-free” brass faucet? More common than you’d hope, November 6, 2018, at <http://blogs.edf.org/health/2018/11/06/nsf-61-lead-from-a-new-lead-free-brass-faucet/>.

<sup>68</sup> NSF/ANSI/CAN 61 – 2019, Section 9. See <https://blog.ansi.org/2020/10/nsf-61-2020-drinking-water-system-components/>.

<sup>69</sup> EDF Health, Revised national standard tightens lead leaching limits for new drinking water fixtures, June 18, 2020, <http://blogs.edf.org/health/2020/06/18/revised-lead-leaching-limits-drinking-water-fixtures/>.

<sup>70</sup> NSF International, Analysis of lead extraction results obtained during Q Statistic evaluations on devices submitted as ‘lead free’ under NSF/ANSI 61, 2018. <http://blogs.edf.org/health/files/2018/10/Experience-with-Lead-Extractions-during-Section-9-under-NSF-61.pdf>.

<sup>71</sup> American National Standards Institute, NSF/ANSI 51-2019: Food Equipment Materials, 2018, accessed on October 27, 2020 at <https://blog.ansi.org/2018/07/nsf-ansi-51-2017-food-equipment-materials/>.

<sup>72</sup> NSF International, NSF/ANSI 51 & NSF/ANSI 61: Covering Your Product Certification Needs from Food to Drinking Water, 2018. See [http://www.nsf.org/newsroom\\_pdf/water\\_nsf\\_ansi\\_51\\_and\\_61.pdf](http://www.nsf.org/newsroom_pdf/water_nsf_ansi_51_and_61.pdf).

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*



While the NSF/ANSI 51 standard sets no limits on the amount of lead leaching that may occur, there is no basis on which to anticipate that the lead intentionally used in brass and bronze does not leach into the water at levels similar to NSF/ANSI/CAN 61 certified devices.

Beyond NSF/ANSI 51, there are other uses of lead in brass or bronze in contact with food that may also migrate into food through leaching or abrasion. For example, pasta extruders are commonly made of these materials in order to give the product a rough texture.<sup>75</sup>

### **B.8.2. Zinc used to galvanize steel.**

Zinc also contains lead. A peer review study<sup>76</sup> in 2015 considered lead in zinc used to galvanized steel pipe noting that it was also a source of cadmium. They used cadmium to fingerprint the zinc as a source of both heavy metals.

[H]istorical research documents that the grade of zinc typically used for galvanizing contains a minimum of 0.5% lead and can itself be a significant long-term source of lead, which may explain some recent lead contamination problems associated with galvanized steel. Surface analysis of various galvanized steel pipes and fittings installed from 1950 to 2008 demonstrated that the concentration of lead in the original zinc coating can range from nondetect to nearly 2%, dependent on the manufacturer and fitting type. **Since cadmium is also present in many zinc coatings, but not in lead pipe, leaded solder, or brass, correlation of zinc concentration to both lead and cadmium concentrations in water was considered as a possible fingerprint implicating the coating on galvanized steel as a lead source;** bench-scale tests of metal leaching from harvested galvanized steel pipes were used to validate this approach. Using profile sampling, individual homes with galvanized steel pipes as a primary lead source were identified in Washington, DC, Providence, RI, Chicago, IL, and a city in Florida.<sup>77</sup> *[Emphasis added]*

We could not find any evidence that zinc used to galvanized steel pipe would be different than the use in food contact articles. Therefore, while lead and cadmium are not added to zinc, the use of zinc to galvanize food contact materials is a potential source of both heavy metals in food.

While NSF/ANSI 51 does not allow the use of galvanized steel in food contact articles, compliance is voluntary.

### **B.8.3. Lead in tin coatings and solder**

Lead has been used in an alloy with tin to make a solder to join metals such as steel or copper. In 1986, Congress limited the maximum amount of lead in solder to 2,000 ppm, designating it as lead-free solder.<sup>78</sup> While these uses were focused on drinking water, they apply as well to water used to make or process food (including beverages).

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<sup>75</sup> LovePasta.org. Best Pasta Extruders and Shapers for Home Use, accessed on November 10, 2020 at <https://lovepasta.org/guidance/best-pasta-extruders-shapers.htm>. See also PastaBiz, Pasta Extruder Dies, accessed on November 10, 2020 at <https://www.pastabiz.com/pasta-machine-accessories/pasta-extruder-dies.html>

<sup>76</sup> Clark BN et al.. Lead release to drinking water from galvanized steel pipe coating. 2015. Environmental Engineering Science. 32:713 <http://doi.org/10.1089/ees.2015.0073>.

<sup>77</sup> *Id.*

<sup>78</sup> EPA, Use of Lead Free Pipes, Fittings, Fixtures, Solder, and Flux for Drinking Water, 85 *Federal Register* 54235, September 1, 2020. See <https://www.federalregister.gov/documents/2020/09/01/2020-16869/use-of-lead-free-pipes-fittings-fixtures-solder-and-flux-for-drinking-water>.

The lead-tin alloy was also commonly used join seams in metal cans until FDA banned lead solder in 1995 at § 189.240. However, FDA did not define the term lead solder or limit the amount of lead allowed in the tin. Given Congress' allowance of 2,000 ppm, we would expect that tin solder still contains some added lead below those levels.

In addition, as described in Section B.2. above, lead appears to be entering food from metal cans with only 3% of fresh or frozen samples of peach, pear and pineapple having detectable levels of lead compared to 98% of the canned variations of those fruits. Metal cans typically have a tin solder and tin coating. And for fruits, a synthetic coating is often not used to prevent migration of lead from the tin.

#### **B.8.4. Lead in ceramic foodware and silver-plated hollowware.**

As described in Section B.4. above, in its compliance policy guides for ceramic foodware and silver-plated hollowware, FDA explicitly allows lead to leach these materials as long as the levels are below 500 to 7,000 ppb in the beverage.<sup>79</sup> These levels would far exceed the 3 µg/day IRL that the agency has established for young children. And inexplicably, the agency does not appear to have considered that the lead is added to the food contact articles, and, therefore, subject to the most-protective safety standard. Rather, because it renders lead a contaminant, it applied the much less protective standard of injurious to health.

#### **B.9. Intentional addition of lead is unsafe.**

As explained in Section B.5. above, the intentional use of lead as an additive to food or a food contact material that migrates into food is not safe because: 1) lead has been found to induce cancer; and 2) without regard to its status as a carcinogen, there is no longer a reasonable certainty of no harm for any exposure to lead due to the lack of safe threshold to prevent irreversible neurodevelopment harm to young children and to the widespread contamination of the food supply. In addition, FDA has acknowledged that arsenic, cadmium, and mercury also have neurodevelopment risks<sup>80</sup> what makes them pharmacologically-related substances in the diet and therefore, their cumulative effect must be considered according to § 170.3(i)(3). In short, there is no doubt that all intentional uses of lead do not meet the safety standard.

Therefore, we ask that FDA explicitly prohibit the intentional use of lead in food contact articles, including components to those articles, by adding a new Section 189.240. The use of lead would only be allowed if it is demonstrated that:

- The part of the food contact article that contains added lead does not contact food under intended conditions of use; or
- No lead or cadmium migrates into food from the food contact article under intended conditions of use.

In addition, we ask that FDA take action to remove explicit and implicit approvals of NSF/ANSI 51 as an American National Standard capable of establishing suitable criteria for the sanitary design of commercial food equipment commonly used in food service and retail food establishments until it removes the

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<sup>79</sup> FDA, Compliance Policy Guide Sec. 545.450 Pottery (Ceramics); Import and Domestic - Lead Contamination, 2005. See <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-545450-pottery-ceramics-import-and-domestic-lead-contamination> and FDA, Compliance Policy Guide Sec. 545.500 Silver-Plated Hollowware - Lead Contamination, 2005. See <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-545500-silver-plated-hollowware-lead-contamination>.

<sup>80</sup> FDA, What FDA is Doing to Protect Consumers from Toxic Metals in Foods, accessed on July 24, 2020 at <https://www.fda.gov/food/conversations-experts-food-topics/what-fda-doing-protect-consumers-toxic-metals-foods>.

exemption for intentional use of lead in brass and bronze. Consistent with this request we ask that FDA revise its 2019 Fact Sheet<sup>81</sup> listing NSF/ANSI 51 as a suitable American National Standards.

**B.10. Lead contamination of materials used to make food contact articles warrant strict limits.**

As noted in the prior section, lead is also a common contaminant in food contact articles as a result of environmental, agricultural, industrial, or other anthropogenic sources of contamination, and, in some cases, from natural sources such as the zinc, tin, or silver ore. Given that FDA has acknowledged, “a lot of it comes from industrial uses and environmental contamination,”<sup>82</sup> this presence meets the definition at [§ 109.3](#) of an “*added poisonous or deleterious substance*” because it “is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase.”

According to [§ 109.6](#), the:

“Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive, will be controlled by a regulation issued under section 409 of the [FFDCA] whenever possible. When such a use cannot be approved under the criteria of section 409 of the act, or when the added poisonous or deleterious substance is not a food additive, a tolerance, regulatory limit, or action level may be established pursuant to the criteria in paragraphs (b), (c), or (d) of this section.”

As we discussed above, a food additive regulation is not possible because: 1) lead has been found to induce cancer; and 2) without regard to its status as a carcinogen, there is no longer a reasonable certainty of no harm for any exposure to lead due to the lack of safe threshold to prevent irreversible neurodevelopment harm to young children and to the widespread contamination of the food supply.

A “tolerance” under [§ 109.6\(b\)](#) is not an option because no amount of lead is sufficient to protect young children from neurodevelopment harm. Therefore, we think a “regulatory limit” under [§ 109.6\(c\)](#) is most appropriate and can serve to distinguish intentionally added lead from contamination. That limit should be 100 ppm consistent with:

- **Federal limits on children’s products:** The [Consumer Product Safety Commission](#) (CPSC) requires that children’s products manufactured in or imported into the United States must not contain more than 100 ppm of total lead content in accessible parts.<sup>83</sup> While food equipment is not a children’s product as the CPSC defines the term, there is an [extensive network](#) of third-party laboratories who routinely evaluate products against that standard.<sup>84</sup> They could easily apply their methods to food contact articles.

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<sup>81</sup> FDA, List of American National Standards for Food Equipment, 2019, <https://www.fda.gov/media/133482/download>.

<sup>82</sup> FDA, Lead in Food, Foodwares, and Dietary Supplements, accessed on November 1, 2020 at <https://www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements>.

<sup>83</sup> Consumer Product Safety Commission (CPSC), Total Lead Content Business Guidance & Small Entity Compliance Guide, accessed on November 2, 2020 at <https://www.cpsc.gov/Business--Manufacturing/Business-Education/Lead/Total-Lead-Content-Business-Guidance-and-Small-Entity-Compliance-Guide>.

<sup>84</sup> CPSC, List of CPSC-Accepted Testing Laboratories, accessed on November 2, 2020 at <https://www.cpsc.gov/cgi-bin/labsearch/>. A search for “lead in children’s products” yielded 380 results.

- **State laws regarding packaging:** [Nineteen states](#) prohibit the intentional use of lead, mercury, cadmium, and hexavalent chromium in any packaging or component of packaging.<sup>85</sup> These components could include brass, bronze, tin, zinc, ceramics, or inks. The states also limit the [incidental presence](#) of these metals to a total of 100 ppm. This limit effectively serves as evidence of intentional use. Packaging manufacturers must provide purchasers with a certificate of compliance and have it on file for inspections.<sup>86</sup> These laws, which have been in place for decades, provide a sound basis on which to establish a presumption for brass and bronze used in food contact articles.

Therefore, we ask that new Section 189.240 prohibiting the use of lead:

- Presume lead levels over 100 ppm are added lead; and
- Provide an exemption if FDA specifically authorizes the use of the materials as a food contact substance.

#### **B.11. The lead limit for bottled water is outdated and needs to be reduced from 5 to 1 ppb.**

As described in Section B4., in 1994, FDA promulgated a limit of 5 ppb lead in bottled water at [§ 165.110](#).<sup>87</sup> The limit was based on the ability to quantify levels of lead in bottled water using the technology available at the time. As noted, that technology has improved and now allows lower levels to be quantified. In its TDS results for 2014-17 using the ICP-MS equipment, FDA reports a limit of quantification for water of 0.39 ppb.

This existing limit is five times greater than the 1 ppb recommended for water by the American Academy of Pediatrics.<sup>88</sup> In addition, with a 5 ppb limit, a young child drinking a liter of bottled water would be well over FDA's IRL of 3 µg/day without considering the contribution of lead from other sources. This change would be especially important in communities where residents depend on bottled water because they lack confidence in the quality of the drinking or well water.

Given this improved analytical capability, we ask that FDA amend the regulation to reduce the compliance limit from 5 to 1 ppb.

### **C. Environmental impact**

This citizens petition is categorically excluded from the need to prepare an Environmental Assessment under 21 CFR § 25.30(h) as an "Issuance, amendment, or revocation of procedural or administrative regulations and guidance documents, including procedures for submission of applications for product development, testing and investigational use, and approval." The requested regulations and guidance documents clarify an existing statutory requirement to ensure compliance.

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<sup>85</sup> Toxics Packaging Clearinghouse, State with Toxics in Packaging Law, accessed on November 2, 2020 at <https://toxicsinpackaging.org/the-clearinghouse/state-members/>.

<sup>86</sup> Toxics in Packaging Clearinghouse, Certificates of Compliance, accessed on November 2, 2020 at <https://toxicsinpackaging.org/certificates-of-compliance/>.

<sup>87</sup> FDA, Beverages: Lead in Bottled Water, Final Rule, 59 *Federal Register* 26933, May 25, 1994.

<sup>88</sup> American Academy of Pediatrics' Council on Environmental Health, Prevention of Childhood Lead Toxicity. 2016. Pediatrics 138:e20161493; DOI: [10.1542/peds.2016-1493](https://doi.org/10.1542/peds.2016-1493)

We have identified no extraordinary circumstances as defined at 21 CFR § 25.21 for the action requested in this petition which would require the submission of an Environmental Assessment.

**D. Economic impact**

Not requested by FDA.

**E. Certification**

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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