COMMENTS SUBMITTED BY

ABLE-Differently • Alaska Community Action on Toxics • Alaska Public Interest Research Group (AKPIRG) • Alliance for the Great Lakes • American Academy of Pediatrics New York, Chapters 1, 2, and 3 • Black Warrior Riverkeeper • Break the Cycle of Health Disparities, Inc. • Cahaba Riverkeeper • California Communities Against Toxics • California League of United Latin American Citizens • California Safe Schools • Cassell Neighborhood Association • Center for Neighborhood Technology • Children's Environmental Health Network • CleanEarth4Kids • Cleveland Lead Advocates for Safe Housing • Climate Resilient Communities • Coalition of Community Organizations (COCO) • Community for a Cause • Detroit Hamtramck Coalition for Advancing Healthy Environments • Earthjustice • Environmental Working Group • Environment America • For Love of Water (FLOW) • Green America • Healthy Schools Network • Immigrants & Minorities Unify Services Association (IMUSA) • Kids for Saving Earth • League of Conservation Voters • Learning Disabilities Association of Alabama • Learning Disabilities Association of America • Learning Disabilities Association of Arkansas • Learning Disabilities Association of California • Learning Disabilities Association of Delaware • Learning Disabilities Association of Georgia • Learning Disabilities Association of Illinois • Learning Disabilities Association of Iowa • Learning Disabilities Association of Maine • Learning Disabilities Association of Michigan • Learning Disabilities Association of Minnesota • Learning Disabilities Association of Nebraska • Learning Disabilities Association of New Jersey • Learning Disabilities Association of New York • Learning Disabilities Association of Oklahoma • Learning Disabilities Association of Pennsylvania • Learning Disabilities Association of South Carolina • Learning Disabilities Association of Tennessee • Learning Disabilities Association of Texas • Learning Disabilities Association of Utah • Learning Disabilities Association of Virginia • Learning Disabilities Association of Wisconsin • Milwaukee Riverkeeper • Missouri Coalition for the Environment • Neighbors for Clean Air • New York Lawyers for the Public Interest • New York League of Conservation Voters • North Carolina Conservation Network • Oregon Physicians for Social Responsibility • Pennsylvania Council of Churches • Physicians for Social Responsibility, Arizona • Physicians for Social Responsibility, Maine • Physicians for Social Responsibility, New Mexico • Physicians for Social Responsibility, Pennsylvania • San Francisco Bay Physicians for Social Responsibility • Seneca Lake Guardian, A Waterkeeper Alliance Affiliate • Seventh Generation • STOP Jet Noise NOW! SFOAK North San Francisco Bay Area • Studio City for Quiet Skies • Texas Physicians for Social Responsibility • The Salvador E. Alvarez Institute for Non-Violence • Toxic Free NC • UproarLA • U.S. Public Interest Research Group (U.S. PIRG) • Waterway Advocates • Water You Fighting For? • WE ACT for Environmental Justice • Women's Voices for the Earth • Zero Waste Washington •

and 41 individuals identified at the conclusion of these comments.

February 1, 2023

Submitted via Regulations.gov

Commissioner Robert Califf
U.S. Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Petition on Lead Levels for Bottled Water, Food Contact Materials, and Certain Foods, Docket No. FDA-2020-P-2276

Dear Commissioner Califf:

The undersigned groups and individuals submit these comments in support of the December 9, 2020 petition filed by 11 organizations committed to protecting the public from lead ("Petitioners"),[1] requesting that the Food and Drug Administration ("FDA" or the "Agency") "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" (the "Petition").[2]

INTRODUCTION

For decades, it has been known that lead exposure causes serious and irreversible health harms, particularly for young children, communities of color, and other overburdened and highly susceptible groups. Despite this, FDA continues to maintain insufficiently protective regulations and guidance on lead levels that put the public at risk. In 2020, 11 organizations filed the Petition requesting that FDA promulgate new regulations on the allowable levels of lead in food contact materials and articles (collectively, "food contact materials"); amend regulations on allowable lead levels in bottled water; and update its guidance on recommended lead levels for children's candies, juice, dried fruits, and spices. However, in the almost two years since these

[1] Petitioners are 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.
[2] Citizen Petition, from Env't Def. Fund, to EPA 2 (Dec. 9, 2020) ("Petition"), https://www.regulations.gov/document/FDA-2020-P-2276-0001 (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).

organizations filed the Petition, the Agency has taken no action to update its regulations or guidance documents. Indeed, FDA has issued only a pro forma statement that it has "not been able to reach a decision on [the] petition within the first 180 days of its receipt because of other agency priorities and the limited availability of resources."[3]

This delay is unacceptable. Lead exposure at every measurable level poses a significant threat to human health, and the harms resulting from lead exposure can affect everyone from babies still developing to adults reaching their advanced years. The cumulative effects of lead and related chemicals from both dietary and non-dietary background exposure sources exacerbate these health harms. Systemic racism also places communities of color disproportionately in harm's way. Every day FDA delays acting to reduce lead exposure results in compounding exposure and continuing risk of serious and irreversible harm.

The Petition presents several legally sound and scientifically grounded approaches to prevent these health harms by limiting lead exposure. These requests include banning lead intentionally added to food contact materials and creating a presumption that when the amount of lead in a product reaches a certain threshold it be considered intentionally added under the law. FDA should implement these requests swiftly to protect public health.

These comments provide additional context and support for four points made in the Petition. First, exposure to any measurable amount of lead causes serious and irreversible health harms. These harms are exacerbated by the cumulative effects resulting from exposure to lead and related chemicals that induce similar health effects via (1) dietary intake and (2) non-dietary background exposure sources. Second, lead exposure disproportionately impacts communities of color and low-wealth communities, making lead exposure an environmental justice issue. Third, pursuant to the Food, Drug, and Cosmetics Act (the "FDCA"), FDA must ban the intentional use of lead in food contact materials because this use fails to meet food additive safety standards. Finally, a legal presumption that lead levels that reach a certain threshold will be considered intentionally added to products has legal precedent and should be implemented.

I. LEAD IS A HIGHLY TOXIC SUBSTANCE.

A. There Is No Safe Level of Lead Exposure.

The devastating harm caused by even low levels of lead exposure is irrefutable. Scientific evidence shows that *all* measurable blood lead levels ("BLLs") present human health hazards.[4] According to the World Health Organization, "[a]t lower levels of exposure that cause no

[3] Interim Response Letter from Mark A. Moorman, Ctr. for Food Safety & Applied Nutrition, FDA, to Tom Neltner, Env't Def. Fund (June 3, 2021), https://www.regulations.gov/document/FDA-2020-P-2276-0011. Attached hereto are several of the studies cited in these comments.

[4] Philippe Grandjean, *Even Low-Dose Lead Exposure Is Hazardous,* 376 Lancet 855 (2010), https://doi.org/10.1016/S0140-6736(10)60745-3.

obvious symptoms, lead is now known to produce a spectrum of injury across multiple body systems."[5]

As stated by Petitioners, FDA drafted its regulations and guidance on lead levels for many of the foods and beverages at issue in the Petition before the Environmental Protection Agency ("EPA"), Centers for Disease Control and Prevention ("CDC"), and FDA itself reached a consensus that there is no safe level of lead in a child's blood.[6] Accordingly, while some agencies set reference levels to identify children with high BLLs, these levels are higher than the lowest levels associated with health harms and should be used only to set priorities for mitigation measures. The ultimate goal of regulations and guidance should be the complete elimination of lead exposures.

---

[5] *Lead Poisoning*, WHO: Newsroom (Aug. 31, 2022), https://www.who.int/en/news-room/fact-sheets/detail/lead-poisoning-and-health.

[6] *See* Petition at 7–8; *e.g.* Beverages: Bottled Water, 60 Fed. Reg. 57,076, 57,126 (Nov. 13, 1995) (codified at 21 C.F.R. § 165.110) (establishing rule on allowable level of lead in bottled water effective May 13, 1996); Lead-Soldered Food Cans, 60 Fed. Reg. 33,106, 33,109 (June 27, 1995) (codified at 21 C.F.R. § 189.240) (prohibiting the use of lead solder in cans); Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children; Recommended Maximum Level and Enforcement Policy, Availability; and Supporting Document: Supporting Document for Maximum Recommended Level for Lead in Candy Likely to Be Consumed Frequently By Small Children; Availability, 71 Fed. Reg. 67, 881, 67,881 (Nov. 24, 2006) (establishing maximum recommended lead level for candy in 2006); Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, First Edition; Availability, 69 Fed. Reg. 10,051, 10,051 (Mar. 3, 2004) (establishing lead levels in juice in 2004).

FDA has recently released draft action levels for lead in juice, but this guidance has not been finalized. Action Levels for Lead in Juice; Draft Guidance for Industry; Availability, 87 Fed. Reg. 25,491 (Apr. 29, 2022); *see also* FDA, Draft Guidance, *Action Levels for Lead in Juice: Guidance for Industry*, (Apr. 2022), https://www.regulations.gov/document/FDA-2019-D-5609-0002.

Drinking Water Regulations for Lead, Section in *Basic Information about Lead in Drinking Water*, EPA, https://www.epa.gov/ground-water-and-drinking-water/basic-information-about-lead-drinking-water (last updated Nov. 15, 2022) ("The fact that there is no safe level of exposure underscores the fact that any action to reduce exposures can have impacts on lives and livelihoods."); FDA, *Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry* (Jan. 2023), www.fda.gov/media/164684/download.

B. Lead Exposure at All Levels Results in Significant Health Harms.

1. Health harms are particularly acute for children.

Children, infants, and the developing fetus are especially vulnerable to harm from lead exposure.[7] Children are also exposed to lead through unique routes and pathways (such as through soil while playing outdoors or through dust lead ingested during hand-to-mouth behavior), increasing the potential for harm (*see infra* Section I.C).[8] Because of their small body masses, fetuses and infants absorb more lead per pound than adults, and absorbed lead has an especially detrimental effect on developing systems.

Thousands of studies have examined the human and environmental effects of lead exposure.[9] This body of evidence includes studies associating early life exposure to even low levels of lead with permanent and irreversible harm to the central nervous system, resulting in impaired cognition, learning, memory, attention, and mental health, and other lifelong impairments.[10] Further, the federal government recognizes "causal" and "likely causal"

---

[7] *Populations at Higher Risk,* CDC, (last updated Oct. 29, 2021), https://www.cdc.gov/nceh/lead/prevention/populations.htm.

[8] *Lead Poisoning*, WHO: Newsroom (Aug. 31, 2022), https://www.who.int/en/news-room/fact-sheets/detail/lead-poisoning-and-health.

[9] *U.S. Air Quality Standards for Lead Now 10 Times Stronger,* EPA: Archive (Oct. 16, 2008), www.epa.gov/archive/epapages/newsroom_archive/newsreleases/8be79c35bcf6f882852574e40051e01d.html.

[10] David C. Bellinger, *Very Low Lead Exposures and Children's Neurodevelopment*, 20 Current Op. Pediatrics 172 (2008), https://doi.org/10.1097/MOP.0b013e3282f4f97b; Bruce P. Lanphear et al., *Cognitive Deficits Associated with Blood Lead Concentrations <10 Microg/dL in US Children and Adolescents*, 115 Pub. Health Reports 521 (2000), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1308622/; Bruce P. Lanphear et al., *Low-level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis*, 113 Env't Health Persps. 894 (2005), https://doi.org/10.1289/ehp.7688; Lisa M. Chiodo et al., *Blood Lead Levels and Specific Attention Effects in Young Children*, 29 Neurotoxicology & Teratology 538 (2007), https://doi.org/10.1016/j.ntt.2007.04.001; Kim N. Dietrich et al., *Lead Exposure and the Cognitive Development of Urban Preschool Children: The Cincinnati Lead Study Cohort at Age 4 Years*, 13 Neurotoxicology & Teratology 203 (1991), https://doi.org/10.1016/0892-0362(91)90012-l; Qing-Song Bao et al., *Behavioural Development of School-Aged Children Who Live Around a Multi-metal Sulphide Mine in Guangdong Province, China: A Cross-sectional Study*, 9 BMC Pub. Health Article No. 217 (2009), https://doi.org/10.1186/1471-2458-9-217; Olivia M. Arnold et al., *Blood Lead Levels ≤10 Micrograms/deciliter and Executive Functioning Across Childhood Development: A Systematic Review*, 80 Neurotoxicology & Teratology Article No. 106888 (2020), https://doi.org/10.1016/j.ntt.2020.106888.

relationships between prenatal and childhood lead exposures and many of these neurological effects.[11]

Ample evidence establishes that all levels of infant and childhood exposure to lead can lead to neurological harm. Even BLLs below 3.5 µg/dL (CDC's current reference level) are associated with behavioral disorders in children, including increased impulsivity, distractibility, and disruptiveness.[12] Children with any measurable level of blood lead also exhibit higher incidences of anxiety, depression, and increased emotional reactivity, when compared to children with no detectable blood lead.[13] Further, the federal government recognizes "causal" and "likely causal" relationships between prenatal and childhood lead exposures and many of these neurological effects.[14]

There is also strong evidence that reducing lead exposure for children with relatively low BLLs can have a significant impact on their health outcomes. In one study, IQ reductions associated with incremental increases in lead exposures in children with lower BLLs were greater than those in children with already high BLLs.[15] This indicates that while neurological harms may be more severe overall at higher exposure levels, the opportunity for harm reduction in children with low BLLs is also significant. Collectively, these studies highlight the urgent need for regulatory agencies to prioritize immediate action for children with *any* detectable level of blood lead.

CDC set a blood lead "reference value" specifically for children, to identify children with BLLs in the top 2.5% of all U.S. children aged one to five years old.[16] CDC's most recent review of its data resulted in a reference level of 3.5 µg/dL. However, it is critical for regulatory agencies to remember that this reference level was developed to identify and focus resources on children with the highest BLLs, and that it was not intended to indicate a safe or acceptable amount of blood lead. Research shows increased risk for health harms in children with BLLs

---

[11] EPA, EPA/600/R-10/075F, *Integrated Science Assessment for Lead*, at lxxxiii–lxxxvi tbl.ES-1 (June 2013) ("Lead ISA"), https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=255721.
[12] Angelica Rocha & Keith A. Trujillo, *Neurotoxicity of Low-level Lead Exposure: History, Mechanisms of Action, and Behavioral Effects in Humans and Preclinical Models*, 73 NeuroToxicology 58 (2019), https://doi.org/10.1016/j.neuro.2019.02.021.
[13] Jianghong Liu et al., *Blood Lead Concentrations and Children's Behavioral and Emotional Problems: A Cohort Study*, 168 JAMA Pediatrics 737 (2014), https://doi.org/10.1001/jamapediatrics.2014.332.
[14] Lead ISA at lxxxiii–lxxxvi tbl.ES-1.
[15] Richard L. Canfield et al., *Intellectual Impairment in Children with Blood Lead Concentrations Below 10 Micrograms Per Deciliter*, 348 New Eng. J. Med. 1517 (2003), https://doi.org/10.1056/NEJMoa022848. This study found that an increase in lifetime mean blood lead from 1 to 10 µg/dL was associated with a reduction of 7.4 IQ points, while an increase from 10 to 30 µg/dL was associated with a reduction of 2.5 IQ points.
[16] *Blood Lead Reference Value*, CDC, www.cdc.gov/nceh/lead/data/blood-lead-reference-value.htm (last updated Dec. 2, 2022).

below 3 µg/dL as well.[17] FDA's guidance and regulations should therefore aim not to decrease food-related exposures so that childhood BLLs remain just below CDC's reference level, but to eliminate food-related exposures entirely.

Preventing all possible exposures is critical to the futures of young generations. Lead exposure presents much more than a health hazard to infants and children: it impacts all areas of quality of life well beyond childhood. The harms caused by lead exposure can influence the trajectory of a person's life, creating major obstacles to educational attainment and financial success.[18] Once absorbed, lead remains in the human body for years—it is stored in bones and tissues, which can then function as internal sources of continual exposure.[19] Most of the life-altering deficits caused by lead exposure persist into old age, and many even worsen over time.[20]

2. Lead exposure poses a continuing health hazard to adults.

Though lead poisoning research and prevention efforts often focus on children (and the adult health impacts of childhood exposure), lead exposure during adulthood also presents a serious health hazard. Adult exposure to relatively low levels of lead is associated with increased rates of heart disease, the leading cause of death in the U.S.[21] In fact, up to 28.7% of cardiovascular disease deaths could be attributable to lead exposure.[22]

Numerous studies have found a correlation between exposure and rates of hypertension in adults, and research shows that kidney function may be altered at even the lowest levels of blood lead examined in these studies.[23] Lead exposure in adults is also associated with reduced fertility, nervous system disorders, and memory loss.[24] Research on young adults with low BLLs suggests

---

[17] Rocha & Trujillo, *supra* note 12.
[18] Aaron Reuben et al., *Association of Childhood Blood Lead Levels with Cognitive Function and Socioeconomic Status at Age 38 Years and with IQ Change and Socioeconomic Mobility Between Childhood and Adulthood*, 317 JAMA 1244 (2017), https://doi.org/10.1001/jama.2017.1712.
[19] B. L. Gulson et al., *Contribution of Tissue Lead to Blood Lead in Adult Female Subjects Based on Stable Lead Isotope Methods*, 125 J. Lab. & Clinical Med. 703 (1995), www.pubmed.ncbi.nlm.nih.gov/7769364/.
[20] Haena Lee et al., *Childhood Lead Exposure Is Associated with Lower Cognitive Functioning at Older Ages*, 8 Sci. Advances Article No. eabn5164 (2022), https://doi.org/10.1126/sciadv.abn5164.
[21] Bruce P. Lanphear et al., *Low-level Lead Exposure and Mortality in US Adults: A Population-based Cohort Study*, 34 Lancet E711 (2018), https://doi.org/10.1016/S2468-2667(18)30025-2.
[22] Lanphear et al., *supra* note 21.
[23] Angela Spivey, *The Weight of Lead: Effects Add Up in Adults*, 115 Env't Health Persps. A30 (2007), https://doi.org/10.1289/ehp.115-a30.
[24] T. Sanders et al., *Neurotoxic Effects and Biomarkers of Lead Exposure: A Review*, 24 Reviews on Env't Health 15 (2009), https://doi.org/10.1515/reveh.2009.24.1.15; Osmel La Llave León &

that even among a sample with a mean BLL of 1.6 µg/dL—a level that is less than half of the CDC reference value—measurable blood lead is linked to increased risk of depression and panic disorders.[25]

Petitioners note that the National Toxicology Program designates lead and lead compounds "as a class that is reasonably anticipated to be human carcinogens" based "on limited evidence of carcinogenicity from studies in humans and sufficient evidence of carcinogenicity from studies in experimental animals."[26] Scientific evidence showing the association between lead exposure and increased risk of lung, stomach, and urinary-bladder cancers supports Petitioners' statements regarding carcinogenicity. Lung and stomach cancers show mild but consistent associations with occupational lead exposures in human studies, suggesting that exposure during adulthood contributes to cancer risk.[27]

3. Lead exposure is detrimental to communities and to society.

Beyond impacts on the individual and family level, lead hazards result in tremendous costs for communities and for society. More than half of children living in the U.S. under the age of six have detectable levels of lead in their blood.[28] Exposure to a neurotoxicant like lead on such a large scale has societal consequences, some of which we may not yet know. Existing data link lead exposure to more than 400,000 deaths in the U.S. each year.[29] Early indications suggest that lead exposure during childhood may lead to earlier onset of dementia during adulthood; as generations that were exposed to lead begin to age, the U.S. could face "an explosion of people seeking support for dementia" that could strain the country's fragile healthcare system.[30]

Lead exposure also affects the educational attainment and financial stability of the population. Minimal lead exposure early in life has significant negative effects on statewide

---

José M. Salas Pacheco, *Effects of Lead on Reproductive Health, in Lead Chemistry* ch.1 (Pipat Chooto ed. 2020), http://doi.org/10.5772/intechopen.87761.

[25] Maryse F. Bouchard et al., *Blood Lead Levels and Major Depressive Disorder, Panic Disorder, and Generalized Anxiety Disorder in US Young Adults*, 66 Archives Gen. Psychiatry 1313 (2009), https://doi.org/10.1001/archgenpsychiatry.2009.164.

[26] Petition at 10; Nat'l Toxicology Program, *Lead and Lead Compounds, in 15th Report on Carcinogens* (2021), https://ntp.niehs.nih.gov/ntp/roc/content/profiles/lead.pdf.

[27] Nat'l Toxicology Program, *Lead and Lead Compounds, in 15th Report on Carcinogens* (2021), https://ntp.niehs.nih.gov/ntp/roc/content/profiles/lead.pdf.

[28] Marissa Hauptman et al., *Individual- and Community-Level Factors Associated with Detectable and Elevated Blood Lead Levels in U.S. Children: Results from a National Clinical Laboratory*, 175 JAMA Pediatrics 1252 (2021), https://doi.org/10.1001/jamapediatrics.2021.3518.

[29] Lanphear et al., *supra* note 21.

[30] Linda Geddes, *Children Exposed to Lead May Experience Symptoms of Dementia Sooner – Study*, Guardian (Nov. 9, 2022), https://www.theguardian.com/society/2022/nov/09/children-exposed-to-lead-may-experience-symptoms-of-dementia-sooner-study; Lee et al., *supra* note 20.

exam scores, in the same order of magnitude as the effects of poverty.[31] Elevated BLLs are associated with an increased risk of not completing high school, which in turn can lead to lowered lifetime earnings.[32] Estimated total net lifetime earnings lost due to cognitive reduction related to lead exposure will fall between $165 and $233 billion for all children who were age six or younger in 2006.[33] These losses in lifetime earnings result in an estimated $25 to $35 billion of lost tax revenue.

Both the neurodevelopmental impairments associated with lead exposure, as well as the associated elevated risk of not completing high school, result in an increased risk of criminal behavior and entrance into the criminal justice system. Indeed, multiple studies have found links between lead exposure rates and entry rates into the criminal justice system.[34]

Eliminating lead exposures will create healthier, safer communities in which people can reach their full potentials. FDA must do its part to remove lead at all levels from our foods, food contact materials, and drinking water.

C. The FDCA Requires FDA Consider the Cumulative Effects of the Dietary Intake of Lead and Other Related Substances.

When determining whether a proposed use of a food additive is safe, the FDCA requires FDA to "consider among other relevant factors . . . the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet."[35] To establish lead levels that are truly health protective, FDA must consider the cumulative effects of lead and other related chemicals which contribute to the same health concerns. Below are ways in which drinking water and food—components of dietary intake—contribute to lead exposure.

---

[31] Marie Lynn Miranda et al., *The Relationship Between Early Childhood Blood Lead Levels and Performance on End-of-grade Tests*, 115 Env't Health Persps. 1242 (2007), https://doi.org/10.1289/ehp.9994.

[32] Elise Gould, *Childhood Lead Poisoning: Conservative Estimates of the Social and Economic Benefits of Lead Hazard Control*, 117 Env't Health Persps. 1162 (2009), https://doi.org/10.1289/ehp.0800408.

[33] *Id.*

[34] Herbert L. Needleman et al., *Bone Lead Levels in Adjudicated Delinquents: A Case Control Study*, 24 Neurotoxicology & Teratology 711 (2002), https://doi.org/10.1016/s0892-0362(02)00269-6; John Paul Wright et al., *Association of Prenatal and Childhood Blood Lead Concentrations with Criminal Arrests in Early Adulthood*, 5 PLoS Med. Article No. e101 (2008), https://doi.org/10.1371/journal.pmed.0050101.

[35] 21 U.S.C. § 348(c)(5)(B).

(1) Drinking Water: Contaminated drinking water systems expose a significant percentage of the public to lead.[36] EPA modeling has shown that drinking water constitutes a significant proportion of lead exposure for infants and children, including up to 80% of daily lead exposure in formula-fed infants.[37] Lead poisoning of children from drinking water has been documented throughout the U.S.,[38] through water systems that EPA has identified as requiring corrective action to address lead levels and through systems which EPA has not pinpointed as in need of action.[39] Further, ineffective and under enforced regulations such as the Lead and Copper Rule, a regulation intended to control lead in drinking water,[40] do little to remediate the exposure to lead from drinking water.[41] Cynthia Giles, the former Assistant Administrator for EPA's Office of Enforcement and Compliance Assurance from 2009 to 2017 asserts that there is a "mountain of evidence that violations of the lead [and copper] rule may be as much as ten times what EPA's data claims," and that widespread violations and underreporting are to be

[36] Kristi Pullen Fedinick, *Millions Served by Water Systems Detecting Lead*, Nat. Res. Defense Council (May 13, 2021), www.nrdc.org/resources/millions-served-water-systems-detecting-lead.
[37] Lindsay W. Stanek et al., *Modeled Impacts of Drinking Water Pb Reduction Scenarios on Children's Exposures and Blood Lead Levels*, 54 Env't Sci. & Tech. 9474 (2020), https://doi.org/10.1021/acs.est.0c00479; Ronnie Levin et al., *The Urban Lead (Pb) Burden in Humans, Animals and the Natural Environment*, 193 Env't Res. Article No. 110377 (2021), https://doi.org/10.1016%2Fj.envres.2020.110377.
[38] *See, e.g.*, Mona Hanna-Attisha et al., *Elevated Blood Lead Levels in Children Associated with the Flint Drinking Water Crisis: A Spatial Analysis of Risk and Public Health Response*, 106 Am. J. Pub. Health 283 (2016), http://doi.org/10.2105/AJPH.2015.303003; Marc Edwards et al., *Elevated Blood Lead in Young Children Due to Lead-Contaminated Drinking Water: Washington, DC, 2001-2004*, 43 Env't Sci. & Tech. 1628 (2009), https://doi.org/10.1021/es802789w; Mary Jean Brown et al., *Association Between Children's Blood Lead Levels, Lead Service Lines, and Water Disinfection, Washington, DC, 1998–2006*, 111 Env't Res. 67 (2011), https://doi.org/10.1016/j.envres.2010.10.003; Simoni Triantafyllidou et al., *Lead Particles in Potable Water*, 99 J. Am. Water Works Ass'n 107 (2007), https://doi.org/10.1002/j.1551-8833.2007.tb07959.x; Rebecca Renner, *Out of Plumb: When Water Treatment Causes Lead Contamination*, 117 Env't Health Persps. A542 (2009), https://doi.org/10.1289/ehp.117-a542.
[39] *See, e.g.*, Hanna-Attisha et al., *supra* note 38; Edwards et al., *supra* note 38; Brown et al., *supra* note 38; Triantafyllidou et al., *supra* note 38; Renner, *supra* note 38.
[40] *See generally* 40 C.F.R. § 141.80.
[41] *Safe Drinking Water Act (SDWA) Alerts,* Section in *Known Data Problems*, EPA: Enf't & Compliance Hist. Online, https://echo.epa.gov/resources/echo-data/known-data-problems#sdwa (last updated Nov. 13, 2022) ("EPA is aware of inaccuracies and underreporting of some data in this system."); *see generally* Adrienne Katner et al., *Weaknesses in Federal Drinking Water Regulations and Public Health Policies that Impeded Lead Poisoning Prevention and Environmental Justice*, 9 Env't Just. 1 (2016), https://doi.org/10.1089/env.2016.0012.

expected from a rule as complicated as the Lead and Copper Rule.[42] These inefficiencies expose more people to lead through drinking water, contributing to the cumulative dietary intake of lead.

(2) Food: EPA modeling indicates that food functions as a primary source of lead exposure for many children.[43] Since the filing of the Petition, which cited evidence that babies were being exposed to lead through baby food,[44] a staff report from the U.S. House of Representatives' Subcommittee on Economic and Consumer Policy was released and reported that "commercial baby foods are tainted with significant levels of toxic heavy metals," including lead.[45] While we appreciate FDA's recent announcement proposing action levels for lead in processed foods intended for young children, these proposed action levels do not address the totality of the issues addressed in the Petition, as they do not address intentional use of lead in food packaging and processing equipment and only address a subset of lead-contaminated foods.[46] Lead in bullets used for hunting can also contaminate game animals, resulting in lead exposures for those who consume animals they hunt themselves. This exposure can also disproportionally affect indigenous communities consuming subsistence diets.[47] These food exposures are *in addition to* the lead exposures from food contact materials and children's candies, juice, dried fruits, and spices.

---

[42] Cynthia Giles, Comment Letter on Proposed Revisions to Lead and Copper Rule in the National Primary Drinking Water Regulations 1 (Feb. 4, 2020), https://www.environmentalprotectionnetwork.org/wp-content/uploads/2020/02/Giles-LCR-comment-2-4-20.pdf.

[43] Tom Neltner, *Children's Lead Exposure: Relative Contributions of Various Sources*, Env't Def. Fund: Blogs (Dec. 15, 2017), https://blogs.edf.org/health/2017/12/15/childrens-lead-exposure/ (explaining that for the average child 1 to 6 years old, food is the largest source of lead exposure).

[44] Petition at 4–5.

[45] Subcomm. on Econ. & Consumer Pol'y, Comm. on Oversight & Reform, U.S. H.R., *Baby Foods Are Tainted With Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury* 2 (Feb. 4, 2021), https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf; *see also* Jesse Hirsch, *Heavy Metals in Baby Food: What You Need to Know,* Consumer Reports (Sept. 29, 2021), https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food-a6772370847/; *Metals in Baby Food,* USDA, https://wicworks.fns.usda.gov/resources/metals-baby-food (last visited Jan. 25, 2023).

[46] FDA, *Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry* 3 (Jan. 2023), https://www.fda.gov/media/164684/download.

[47] Lori A. Verbrugge et al., *Human Exposure to Lead from Ammunition in the Circumpolar North*, *in Ingestion of Lead from Spent Ammunition: Implications for Wildlife and Humans* 126, 132 (Richard T. Watson et al. eds. 2009), http://doi.org/10.4080/ilsa.2009.0110 ("In many cases, elevated blood lead levels in the Arctic have been associated with ingestion of lead from spent ammunition, primarily shot, although lead from fragmented bullets in big game may have been overlooked as a source until recently" (citations omitted)).

These varying exposures to lead through diet must be considered for FDA to establish lead levels that protect the public.

D. Regulations and Guidance on Allowable Lead Levels Must Account for Non-Dietary Background Exposures to Lead and Related Chemical Substances.

FDA's regulations on allowable lead levels in bottled water and food contact materials and its guidance on maximum lead levels for children's candy, juice, dried fruits, spices, and other ingredients fail to protect public health. This stems in part from a failure to properly account for the cumulative effects of the dietary intake of lead and other chemically or pharmacologically related substances, background exposures to lead and other related toxic chemicals, and non-chemical stressors—all of which may increase the severity of harm from exposure.

Consideration of background exposures when determining lead levels for bottled water, food, and food contact materials is essential to public health, and is particularly relevant for individuals who live, work, and play near significant lead emitters (such as airports and lead smelters) who are at increased risk of harm. FDA action is also mandated by statute, as FDA has an obligation to "promote the public health" by ensuring that "foods are safe."[48] It is helpful to identify the various exposure sources, routes, and pathways that contribute to the public's non-dietary background exposures to lead and related toxic chemicals. These include:

(1) Air: A variety of industrial sources currently emit new lead pollution into the air. These emissions contaminate the air people inhale and fall on homes, schools, playgrounds, day care centers, and into drinking water sources contaminating soil and water which people touch and ingest. According to EPA's Toxics Release Inventory, between 2018 and 2021, the reported national industrial releases of lead and lead compounds into the environment totaled nearly 2.4 billion pounds.[49] Industrial sources of these lead emissions include copper smelters, lead acid battery manufacturing, and secondary lead smelters.[50] Lead emissions from integrated iron and steel mills are also estimated to reach more than 80 tons of lead each year from just 11 mills.[51]

---

[48] 21 U.S.C. § 393(b)(1), (2)(A).
[49] *TRI Explorer,* EPA, https://enviro.epa.gov/triexplorer/tri_release.chemical (choose "All of United States" for "Geographic Location"; then choose "Select specific chemical(s)"; then scroll and select "Lead"; then choose "2021" for "Year of Data"; then click "Generate Report"; and then repeat steps for years 2018, 2019, and 2020) (last visited Jan. 25, 2023).
[50] *Air Pollution from Lead,* Tex. Comm'n on Env't Quality, *Air Pollution from Lead*. www.tceq.texas.gov/airquality/sip/criteria-pollutants/sip-lead (last updated June 7, 2022).
[51] *TRI On-site and Off-site Reported Disposed of or Otherwise Released (in Pounds), Trend Report for Facilities in Freeport-McMoRan Miami Inc (TRI ID 85532NSPRTPOBOX) for Lead Compounds Chemical, U.S. 1998-2000*, EPA: TRI Explorer, https://enviro.epa.gov/triexplorer/release_trends?tri=85532NSPRTPOBOX&p_view=TRYR&trilib=TRIQ1&sort=_VIEW_&sort_fmt=1&state=All+states&county=All+counties&chemical=N4

Lead emissions from these mills particularly affect some communities, such as northwestern Indiana where four mills emit more than 35 tons of lead into nearby communities. Much of this lead comes in the form of fugitive emissions that remain completely uncontrolled.

Recent lead air emissions data captured by EPA's National Emissions Inventory ("NEI") indicate that combustion of leaded fuel by piston-engine general aviation aircraft[52] was the single largest source of lead emissions to the air in 2017, contributing about 70% of total lead air emissions that year.[53] Fuel combustion releases lead into the air near the thousands of airports that serve piston engine aircraft, and biomonitoring studies indicate that direct exposures to lead can occur from inhaling contaminated air. For example, multiple studies have demonstrated that children living in close proximity to airports using leaded aviation gas have higher BLLs than children who do not.[54]

20&industry=ALL&core_year=&tab_rpt=1&FLD=AIRLBY&FLD=E1&FLD=E2&FLD=E3&FLD=E4&FLD=E41&FLD=E42&FLD=E5&FLD=E52&FLD=E53&FLD=E53A&FLD=E53B&FLD=E54&FLD=E51&FLD=E51A&FLD=E51B&FLD=TSFDSP&FLD=m10&FLD=m41&FLD=m62&FLD=potwmetl&FLD=m71&FLD=m81&FLD=m82&FLD=m72&FLD=m63&FLD=m64&FLD=m65&FLD=m66&FLD=m67&FLD=m73&FLD=m79&FLD=m90&FLD=m94&FLD=m99&FLD=RELLBY (last visited Feb. 1, 2023).

[52] General Aviation is civilian, non-commercial flight. *See What is General Aviation?*, Smithsonian Inst.: Nat'l Air & Space Museum, https://airandspace.si.edu/what-general-aviation (last visited Jan. 25, 2023).

[53] Proposed Finding That Lead Emissions from Aircraft Engines That Operate on Leaded Fuel Cause or Contribute to Air Pollution That May Reasonably Be Anticipated to Endanger Public Health and Welfare, 87 Fed. Reg. 62,753, 62,757-62,758 (proposed Oct. 17, 2022); Transp. Rsch. Bd., Nat'l Acads. of Scis., Eng'g, & Med. et al., *Options for Reducing Lead Emissions from Piston-Engine Aircraft* 46 (2021), https://www.nap.edu/read/26050/chapter/5 (noting that, in EPA's 2017 National Emissions Inventory, piston-engine general aviation aircraft accounted for "roughly 70 percent of total lead emissions to air in the United States").

[54] *See* Marie Lynn Miranda et al., *A Geospatial Analysis of the Effects of Aviation Gasoline on Childhood Blood Lead Levels*, 119 Env't Health Persps. 1513, 1516 (2011), https://doi.org/10.1289/ehp.1003231 (examining the relationship between proximity to airports in North Carolina where leaded aviation gas is used and blood lead levels in children and finding that "children living within 500 m, 1,000 m, or 1,500 m of an airport had average blood lead levels that were 4.4, 3.8, or 2.1% higher, respectively, than other children"); Sammy Zahran et al., *The Effect of Leaded Aviation Gasoline on Blood Lead in Children*, 4 J. Ass'n Env't & Res. Economists 575 (2017), https://doi.org/10.1086/691686 (examining the blood lead levels of children living within 2 kilometers of airports in Michigan and finding that "the odds that a child's [blood lead levels] will eclipse CDC thresholds for concern increases dose-responsively in proximity to airports, declines measurably in neighborhoods proximate to airports in the months following 9/11" when there was less air traffic, and "increases dose-responsively in the flow of [piston-engine aircraft] traffic"); Mountain Data Grp., *Leaded Aviation Gasoline Exposure Risk at Reid-Hillview Airport in Santa Clara County, California* 37–67 (Aug. 2021), https://news.sccgov.org/sites/g/files/exjcpb956/files/documents/RHV-Airborne-Lead-StudyReport.pdf (explaining that "children proximate to [the general aviation airport] Reid-

Other sources of lead pollution in air, including fuel combustion plants and oil refineries, resulted in nearly 200 tons of reported lead emissions in 2017, according to the NEI.[55] Solid waste incinerators also release lead, with municipal solid waste incinerators polluting at rates that EPA admitted over a decade ago are inconsistent with D.C. Circuit precedent.[56]

(2) Paint and Dust: Millions of people also currently live in homes and other buildings where lead-based paints are in deteriorating condition, causing lead exposure to arise from inhaling, dermally absorbing, or directly ingesting lead contaminated dust, soil, and paint. Dust can be contaminated with lead from various sources including, leaded paint chips, lead that settles from the air, or lead in soil tracked into the house. People are also exposed to lead-contaminated dust during building renovations and demolitions.[57]

(3) Consumer Products: Common household products also still contain lead which poses a particular risk for young children who could ingest lead through mouthing of these items.

Hillview Airport present with systematically higher [blood lead levels], net of other measured sources of lead exposure risk, child demographic characteristics, and observed and unobserved neighborhood conditions," that children who live downwind of the airport had higher blood lead levels than those who did not, and that the blood lead levels "of sampled children increase with exposure to piston-engine aircraft operations at [the airport], net of all other factors" and ultimately "suggesting that child [blood lead levels] increase dose-responsively with [piston engine aircraft] traffic"); *cf.* Won-Ju Park et al., *Blood Lead Level and Types of Aviation Fuel in Aircraft Maintenance Crew*, 84 Aviation, Space, & Env't Med. 1087, 1089 (2013), https://doi.org/10.3357/ASEM.3647.2013 (analyzing the blood lead levels of aircraft-maintenance workers in the Republic of Korea, finding higher blood lead levels among maintenance workers that are based in airports that service propeller driven aircraft and use leaded avgas relative to maintenance workers that are based in airports that service jets, which do not use leaded avgas, and concluding that leaded avgas emissions "could increase the [blood lead levels] of aircraft maintenance crews").

[55] *Data Queries*, Section in *2017 National Emissions Inventory (NEI) Data*, EPA, https://www.epa.gov/air-emissions-inventories/2017-national-emissions-inventory-nei-data#dataq (choose "Lead – 7439921" for "Pollutant"; then leave other fields as default; and then click "Submit" for full data) (last updated Dec. 27, 2022).

[56] *See* Petition for Writ of Mandamus at 16–17, *In re East Yard Cmtys. for Env't Just.*, No. 21-1271 (D.C. Cir. Dec. 12, 2021), ECF No. 1928045, https://earthjustice.org/sites/default/files/files/2021-12-21_petition_for_writ_of_mandamus.pdf.

[57] *See* Emily A. Benfer, *Contaminated Childhood: How the United States Failed to Prevent the Chronic Lead Poisoning of Low-Income Children and Communities of Color*, 41 Harv. Env't L. 493, 529–530 (2017), https://harvardelr.com/wp-content/uploads/sites/12/2017/08/Benfer_final.pdf (referencing regulation established by EPA in response to EPA scientific study that found "that renovation and repair activities that disturb lead-based paint 'have the highest potential for generating lead exposure'" (quotation omitted)); RI Hist. Pres. & Heritage Comm'n, *Guide to Lead Safety in Historic Buildings* 1, 3, https://preservation.ri.gov/media/206/download?language=en (last updated June 14, 2021).

For instance, while there are limits on lead levels in children's toys, many consumer goods that children use do not have such limits.

Further, products which contain lead and are used by pregnant or nursing people present an exposure hazard to fetuses and infants. Also, many products containing lead are sold in dollar stores, which are disproportionally concentrated in low-wealth communities and communities of color, contributing to a serious environmental justice issue.[58]

People can be exposed to lead through each of these pathways and through dermal absorption, ingestion, and/or inhalation routes. In particular, workers who manufacture, process, or dispose of toxic chemicals can be exposed in the workplace via inhalation (breathing in fumes or particles from an item); ingestion (touching an item or lead contaminated soil and then touching their mouth); or dermal absorption (touching the item). Consumers can be exposed to lead through dermal absorption by direct handling of products with lead, through mouthing consumer products, or playing in lead-contaminated soil (a particular concern for children).[59] Inhalation can also happen by breathing in household dust and from lead released into the air from industrial sources and airports. These exposures all compound, so a person can be exposed to the same chemical in three different ways through multiple different exposure pathways, increasing their overall likelihood of harm.

Exposure to lead in combination with other toxic chemicals, particularly those that contribute to similar adverse health effects as lead, can also increase the risk of certain health conditions caused by lead exposure alone. Indeed, when determining if a food additive is safe, the FDCA *requires* that FDA take into account chemically or pharmacologically related substances when considering the cumulative effect of the dietary intake of a food additive like lead.[60] For example, people exposed to multiple chemicals that cause cancer experience a greater likelihood of developing cancer than a person exposed to only one cancer-causing chemical.[61] Non-chemical stressors like nutritional deficiencies or psychosocial stress from experiencing

---

[58] For example, a 2022 report on toxic substances in items sold in dollar stores identified princess wireless headphones sold at Family Dollar containing 656,000 ppm of lead in solder. *See* Campaign for Healthier Sols., *Toxic Chemicals in Dollar Store Products: 2022 Report* 1, 4 (2022), https://www.ecocenter.org/sites/default/files/2022-08/Toxic%20Chemicals%20in%20Dollar%20Store%20Products%202022%20Report.pdf.

[59] Ami R. Zota et al., *Reducing Chemical Exposures at Home: Opportunities for Action*, 71 J. Epidemiology & Cmty. Health 937 (2017), https://pubmed.ncbi.nlm.nih.gov/28756396/; Susanna D. Mitro et al., *Consumer Product Chemicals in Indoor Dust: A Quantitative Meta-Analysis of U.S. Studies*, 50 Env't Sci. & Tech. 10661 (2016), https://pubmed.ncbi.nlm.nih.gov/27623734/.

[60] 21 U.S.C. § 348 (c)(5)(B).

[61] Sydney Evans et al., *Cumulative Risk Analysis of Carcinogenic Contaminants in United States Drinking Water*, 5 Heliyon Article No. E02314 (2019), https://doi.org/10.1016/j.heliyon.2019.e02314; Rachel A. Morello-Frosch et al., *Air Toxics and Health Risks in California: The Public Health Implications of Outdoor Concentrations*, 20 Risk Analysis 273 (2000), https://doi.org/10.1111/0272-4332.202026.

poverty or racial injustice exacerbate this likelihood of harm.[62] Studies examining the cumulative effects associated with exposure to mixtures containing lead and other related heavy metals found an increased likelihood of developing certain chronic health conditions, including obesity, hypertension, and type-2 diabetes in adults,[63] and cognitive dysfunction and behavioral disorders in children.[64] High levels of co-exposures to lead, cadmium, and mercury were additionally linked to higher mortality rates in adults.[65]

Other agencies' failures to factor into their regulatory processes the cumulative effects of lead and related chemicals from both dietary and non-dietary background exposure sources further exacerbate lead exposure-related health harms. Many agencies set lead limits and draft regulations focused only on pathways under their direct purview, without considering the cumulative effects of exposure to lead and other related chemicals from background exposures. The alarming rates of lead exposure across the country are a result of this failure to look at lead exposure holistically. To protect the public, FDA must stop setting lead levels in a vacuum and consider the cumulative effects of lead and related chemicals from dietary intake and non-dietary background exposures before setting maximum lead levels for foods, food contact materials, and bottled water.

II. LEAD EXPOSURE IS AN ENVIRONMENTAL INJUSTICE.

The serious harm that lead exposure causes cannot be disputed. Nor can it be disputed that children from communities of color and low-wealth communities suffer the most. According to EPA, among children with the highest BLLs from 2015-2018, Black children's BLLs were the highest.[66] Children living in homes below the federal poverty line had higher BLLs than children

---

[62] Rachel A. Morello-Frosch et al., *Understanding the Cumulative Impacts of Inequalities in Environmental Health: Implications for Policy*, 30 Health Affs. 879 (2011), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2011.0153; Cliona M. McHale et al., *Assessing Health Risks from Multiple Environmental Stressors: Moving from G×E to I×E*, 775 Mutational Rsch. 11 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5863617/.

[63] Xin Wang et al., *Associations of Cumulative Exposure to Heavy Metal Mixtures with Obesity and Its Comorbidities Among U.S. Adults in NHANES 2003-2014*, 121 Pt. 1 Env't Int'l 683 (2018), https://doi.org/10.1016/j.envint.2018.09.035.

[64] Agency for Toxic Substances & Disease Registry, *Interaction Profile for: Arsenic, Cadmium, Chromium, and Lead* (May 2004), https://www.atsdr.cdc.gov/interactionprofiles/ip-metals1/ip04.pdf.

[65] XuYao et al., *Stratification of Population in NHANES 2009-2014 Based on Exposure Pattern of Lead, Cadmium, Mercury, and Arsenic and Their Association with Cardiovascular, Renal and Respiratory Outcomes*, 149 Env't Int'l Article No. 106410 (2021), https://doi.org/10.1016/j.envint.2021.106410.

[66] *Lead in Children Ages 1 to 5 Years: Median Concentrations in Blood, by Race/Ethnicity and Family Income, 2015-2018 (Indicator B2)*, Table in *ACE: Biomonitoring – Lead*, EPA, www.epa.gov/americaschildrenenvironment/ace-biomonitoring-lead#B2 (last updated June 29, 2022).

living above the poverty line, and Black children living below the poverty line had markedly higher BLLs than children in any other demographic reported.

Non-chemical stressors affect the impact of lead exposure in low-wealth communities and communities of color. One study by the Urban Institute reviewed CDC data from selected counties across the country and found that all five of the counties with the highest lead exposure rates (measured by percentage of children with elevated BLLs) also had child food insecurity rates that exceeded the national average.[67] Considering that nutritional deficiencies can increase the toxicity of lead in the body, these results are particularly troubling—not only are children in low-wealth communities facing both food scarcity and elevated lead exposures, but they are also facing a greater risk of health harms from the combination of these two burdens.[68]

The same inequities that leave families without the resources needed to prevent childhood lead exposure are then exacerbated by lead exposure itself. Lead exposure perpetuates cycles of inequity by creating additional barriers in life: negative effects on intellectual and social development, adverse health conditions, lost earnings, financial burdens of treatment, and higher risk of entry into criminal justice system.[69]

Another cycle of inequity plays out in communities affected by contaminated drinking water. Contaminated drinking water disproportionately burdens communities of color and low-wealth communities.[70] While deprived of safe drinking water from the tap, communities often rely on bottled water as a substitute. However, FDA's current allowable lead level of 5 ppm in bottled water is not sufficiently protective of human health. As a result, families seeking to protect their children from contaminated water may end up unknowingly relying on bottled water contaminated with lead.[71]

---

[67] Elaine Waxman & Megan Thompson, *Poor Nutrition Leaves Kids Vulnerable to Lead Poisoning—and Not Just in Flint*, Urban Inst. (Apr. 8, 2016), www.urban.org/urban-wire/poor-nutrition-leaves-kids-vulnerable-lead-poisoning-and-not-just-flint.

[68] Orville A. Levander, *Lead Toxicity and Nutritional Deficiencies*, 29 Env't Health Persps. 115 (1979), https://doi.org/10.1289/ehp.7929115.

[69] Needleman et al., *supra* note 34; Reuben et al., *supra* note 18; Wright et al., *supra* note 34.

[70] Kristi P. Fedinick, *Watered Down Justice*, Nat. Res. Def. Council (Mar. 27, 2020), www.nrdc.org/resources/watered-down-justice.

[71] Julie Bosman, *Michigan to Pay $600 Million to Victims of Flint Water Crisis*, N.Y. Times (July 29, 2021), www.nytimes.com/2020/08/19/us/flint-water-crisis-settlement.html; Bill Duhart, *After 17 years of Giving Bottled Water to Students, Camden schools to Review Policy*, NJ.com (Nov. 8, 2019), www.nj.com/camden/2019/11/after-17-years-drinking-bottled-water-camden-schools-may-change-110k-lead-policy.html; Ron Fonger, *Ice Mountain Will Continue Flint Water Deliveries Through the End of 2022*, MLive (June 6, 2022), www.mlive.com/news/flint/2022/06/ice-mountain-will-continue-flint-water-deliveries-through-the-end-of-2022.html.

The harm borne from these racial and economic disparities in lead exposure deprives many children of equal protection and of the bright future that all children deserve—increasing the likelihood of developmental delays and related harm, putting them at greater risk of multiple serious health problems, and subjecting them to significant lost earnings over their lifetimes.[72]

Further, lead is just one of many toxic chemicals that are disproportionately concentrated in communities of color and low-wealth communities (*see supra* Section I.C). The health harms associated with these exposures are compounded by non-chemical stressors like income inequality, lack of access to healthcare, and food insecurity.[73] Lead exposures through the media listed in the Petition add to these exposures and to this environmental injustice and can be lessened through the actions recommended by Petitioners.

III. FDA SHOULD PROHIBIT THE INTENTIONAL ADDITION OF LEAD IN FOOD CONTACT MATERIALS.

The Petition requests "that FDA explicitly prohibit the intentional use of lead in food contact articles, including components to those articles."[74] It supports this request by stating that "lead has been found to induce cancer" and even "without regard to its status as a carcinogen, there is no longer a reasonable certainty of no harm for any exposure to lead."[75] Petitioners' request is valid under the FDCA and should be implemented.

Pursuant to the FDCA, lead intentionally added to food contact materials is a "food additive." A material added to food containers and packages is considered a "food additive" "if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container."[76] Lead meets this definition because of its ability to leach out of food packaging into food. Lead can leach out of different types of packaging,

---

[72] Joseph Boyle et al., *Estimated IQ Points and Lifetime Earnings Lost to Early Childhood Blood Lead Levels in the United States*, 778 Sci. Total Env't Article No. 146307 (2021), https://doi.org/10.1016/j.scitotenv.2021.146307.

[73] Gilbert C. Gee et al., *Environmental Health Disparities: A Framework Integrating Psychosocial and Environmental Concepts*, 112 Env't Health Persps. 1645 (2004), https://doi.org/10.1289/ehp.7074; Devon C. Payne-Sturges et al., *Methods for Evaluating the Combined Effects of Chemical and Nonchemical Exposures for Cumulative Environmental Health Risk Assessment*, 15 Int'l. J. Env't Rsch. & Pub. Health Article No. 2797 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6313653/; Kathleen Hibbert & Nicole S. Tulve, *State-of-the-Science Review of Non-Chemical Stressors Found in a Child's Social Environment*, 16 Int'l J. En't Rsch. & Pub. Health Article No. 4417 (2019), https://doi.org/10.3390/ijerph16224417.

[74] Petition at 16.

[75] *Id*.

[76] 21 C.F.R. § 170.3(e)(1).

including for example glass,[77] clay,[78] paper food packaging,[79] and plastic food packaging.[80] EPA itself has acknowledged that "lead used in pottery or other food contact surfaces can leach into foods."[81]

Since lead intentionally added to food contact materials is a food additive, lead can only be added to food contact materials if it is deemed safe under the food additive provisions of the FDCA. Alternatively, if a food additive is deemed unsafe within the meaning under the FDCA, the food contact material is deemed adulterated and cannot be legally sold.[82]

Lead fails to meet two safety standards that would permit its usage as a food additive. First, lead is a likely human carcinogen, and therefore does not meet the requirement that food additives do *not* "induce cancer when ingested by man or animal."[83] Dozens of scientific studies including *in vitro*,[84] animal,[85] and epidemiological studies[86] have demonstrated a link between lead and cancer. The requirement that a food additive not cause cancer, known as the Delaney clause, "is generally intended to prohibit the use of any additives which *under any conditions*

---

[77] P. K. Sinha et al., *Leaching of Lead and Cadmium from Glass Dinnerware*, 49 J. Env't Sci. & Eng'g 58 (2007), https://pubmed.ncbi.nlm.nih.gov/18472562/.
[78] Mona S. El Kutry & El-Sayeda G.E. El-Sahar, *Evaluated the Lead Levels at Boiling Water in Clay Pots and Impact of the Lead Contaminated Diet on Nutritional, Biochemical Status of Male Rats*, 9 Beni-Suef Univ. J. Basic & Applied Scis. Article No. 18 (2020), https://doi.org/10.1186/s43088-020-00043-1.
[79] Se-Jong Park et al., *Migration of lead and Arsenic from Food Contact Paper into a Food Simulant and Assessment of Their Consumer Exposure Safety*, 35 Food Additives & Contaminants 2493 (2018), https://doi.org/10.1080/19440049.2018.1547426.
[80] Paulo Henrique M. Kiyataka et al., *Method for Assessing Lead, Cadmium, Mercury and Arsenic in High-Density Polyethylene Packaging and Study of the Migration into Yoghurt and Simulan*t, 31 Food Additives & Contaminants 156 (2013), https://doi.org/10.1080/19440049.2013.855826; Elizeu Chiodi Pereira et al., *Study of Controlled Migration of Cadmium and Lead into Foods from Plastic Utensils for Children*, 29 Env't Sci. & Pollution Rsch. 52833 (2022), https://doi.org/10.1007/s11356-022-19433-2.
[81] *Lead in Food, Foodwares, and Dietary Supplements*, FDA, www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements (last updated Jan. 24, 2023).
[82] 21 U.S.C. §§ 331(a), 342(a)(1)(c).
[83] *Id.* § 348(c)(3)(A).
[84] J. A. DiPaolo et al., *In Vitro Neoplastic Transformation of Syrian Hamster Cells by Lead Acetate and its Relevance to Environmental Carcinogenesis*, 38 Brit. J. Cancer 452 (1978), https://doi.org/10.1038%2Fbjc.1978.228.
[85] Bożenna Zawirska, *The Role of the Kidneys in Disorders of Porphyrin Metabolism During Carcinogenesis Induced with Lead Acetate*, 24 Env't Rsch. 391 (1981), https://www.sciencedirect.com/science/article/abs/pii/0013935181901687.
[86] Kyle Steenland et al., *Cancer Incidence Among Workers with Blood Lead Measurements in Two Countries*, 76 Occupational & Env't Med. 603 (2019), https://doi.org/10.1136/oemed-2019-105786.

induce cancer in any strain of test animal."[87] Further, Congressman Delaney's bill, later incorporated into the Delaney clause, was "intended to ensure that no carcinogens, no matter how small the amount, would be introduced into food."[88] The evidence supports the statement that lead can cause cancer under some conditions, therefore under the Delaney clause lead cannot be permitted as a food additive in food contact materials.

However, even if FDA deems the Delaney clause inapplicable to intentionally added lead, because lead cannot be deemed safe, it must be banned from food contact materials. To be deemed safe as a food additive, FDA must determine that there "is a reasonable certainty in the minds of competent scientists that [a] substance is not harmful under the conditions of its intended use."[89] FDA must consider three factors when determining safety: "(1) [t]he probable consumption of the substance and of any substance formed in or on food because of its use"; "(2) [t]he cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet"; and "(3) [s]afety 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."[90] FDA simply cannot make the claim that lead is not a harmful substance when ingested as part of food or water, due to the evidence outlined *supra* in Section I.

IV. FDA SHOULD PRESUME THAT LEAD IN FOOD CONTACT MATERIALS IS INTENTIONALLY ADDED WHERE IT EXCEEDS A PREDETERMINED THRESHOLD.

The Petition requests that FDA set a threshold above which lead will be presumed to be intentionally added to food contact materials.[91] We support the promulgation of a threshold-based presumption for lead and urge FDA to adopt a threshold that is the most protective of public health.

As discussed *supra*, exposure to lead through food contact materials represents a serious threat to public health, and FDA must address this source of harm by promulgating a regulation which bans the intentional addition of lead to food contact materials. However, to further protect public health, FDA must also regulate lead currently classed as a contaminant.[92] Under the FDCA, FDA has a duty to regulate lead because it is an added poisonous and deleterious substance. Because lead is added to food contact materials as a "result of environmental, agricultural, industrial, or other contamination" as opposed to being a naturally occurring constituent of food, lead at any level meets the definition of an added poisonous or deleterious

---

[87] *Bell v. Goddard*, 366 F.2d 177, 181 (7th Cir. 1966) (emphasis added).
[88] *Les v. Reilly*, 968 F.2d 985, 989 (9th Cir. 1992) (holding that the Delaney clause has no *de minimis* exemption for food additives).
[89] 21 C.F.R. § 170.3(i); 21 U.S.C. § 348(a)(3).
[90] 21 C.F.R. § 170.3(i)(1)–(3).
[91] Petition at 17–18.
[92] *Id.* at 17.

substance.[93] Since lead meets this definition and FDA asserts it cannot be avoided,[94] the Agency has a duty to "promulgate regulations limiting the quantity therein or thereon [food contact materials] to such extent as [the Agency] finds necessary for the protection of public health."[95]

An effective way to meet its duty to regulate lead exposure is to establish a presumption for what qualifies as an "intentionally added" toxic substance. Presumptions are a well-accepted approach to ensuring the safety of consumer products and would provide increased transparency for regulated entities regarding how FDA defines intentionally added as it relates to food additives. Various states regulate toxic chemicals by presuming that a chemical is intentionally added where it is detected in a product covered by the relevant regulation.

In December 2022, Washington's Department of Ecology proposed a rule that regulates toxic substances and includes a presumption.[96] First, the rule bans the intentional addition of certain chemicals to specified products.[97] For instance, the regulation would prohibit manufacturers from intentionally adding ortho-phthalates to fragrances in beauty and personal care products or per- and polyfluoroalkyl substances ("PFAS") to carpets and rugs.[98] Second, the proposed rule establishes that the detection of covered chemicals in certain products satisfies the definition of intentionally added (within certain parameters). For example, the proposed rule states that the presence of ortho-phthalates in a product in which ortho-phthalates are not on the ingredient list means they were intentionally added.[99]

California law also effectively creates a presumption that certain levels of a toxic substance be deemed intentionally added.[100] California law prohibits distributing or selling any

---

[93] 21 C.F.R. § 109.3(c), (d).
[94] Petitioners and commenters reject the notion that lead cannot be removed from the food supply but acknowledge that this is FDA's position so are operating under that premise.
[94] *Lead in Food, Foodwares, and Dietary Supplements*, FDA, https://www.fda.gov/food/environmental-contaminants-food/lead-food-foodwares-and-dietary-supplements (last updated Jan. 24, 2023); *see also* 21 C.F.R. § 109.6.
[95] 21 U.S.C. § 346.
[96] Safer Products Restrictions and Reporting, WAC 173-337-110(3)(c)(ii) (proposed Dec. 7, 2022) (to be codified at WAC Ch. 173-337), https://ecology.wa.gov/Regulations-Permits/Laws-rules-rulemaking/Rulemaking/WAC-173-337 (click on "Proposed rule language" under "Rule proposal documents") ("Ecology presumes the detection of total fluorine indicates the intentional addition of PFAS.").
[97] *See, e.g.,* Safer Products Restrictions and Reporting, WAC 173-337-110(1)(c)(i) (proposed Dec. 7, 2022) (to be codified at WAC Ch. 173-337) (banning the intentional addition of PFAS to aftermarket stain and water resistance treatments for textiles and leather).
[98] Safer Products Restrictions and Reporting, WAC 173-337-111(1)(c)(i), 173-337-110(2)(c)(i) (proposed Dec. 7, 2022) (to be codified at WAC Ch. 173-337).
[99] Safer Products Restrictions and Reporting, WAC 173-337-111(1)(c)(ii) (proposed Dec. 7, 2022) (to be codified at WAC Ch. 173-337).
[100] Cal. Health & Safety Code § 109000 (West 2022). California passed a similar statute regulating PFAS in textiles in 2022. *Id.* §§ 108970(g)(2), 108971(a) (West 2022).

food packaging containing "regulated [PFAS]."[101] The statute defines "regulated PFAS" as either PFAS that a manufacturer has intentionally added to a product or PFAS in a product at or above 100 ppm.[102] The statute recognizes that when a PFAS is present in a product at a concentration greater than a specified threshold, it should be understood to be intentionally added. This presumption structure mirrors the Petitioners' request.

Congress has charged FDA with protecting the public from toxic chemicals in food.[103] The FDCA requires FDA to "protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled."[104] Creating a presumption that lead that reaches a certain threshold in a food contact material be considered intentionally added is a reasonable and efficient way to address the dangers posed by lead and to provide clarity to regulated entities about how much lead is permissible in food contact materials. The presumption-based approaches in Washington and California showcase that this method of regulation is not novel, but an established and efficient tool. FDA should ban the intentional addition of lead in food contact materials and set a threshold above which lead in food contact materials will be presumed intentionally added.

V. REDUCING FDA'S PERMISSIBLE LEAD LEVELS IN BOTTLED WATER WOULD IMPROVE PUBLIC HEALTH.

The Petition requests FDA reduce the permissible level of lead in bottled water from five ppb to one ppb.[105] This request presents a simple mechanism for reducing a source of lead exposure, would improve public health, and should be implemented.

VI. CONCLUSION

FDA must act now to lessen the burdens the public faces from unrelenting lead exposure. As detailed in these comments, lead exposure at every measurable level poses a significant threat to human health. Even low levels of exposure from the media outlined in the Petition (bottled water; food contact materials; and children's candies, juice, dried fruits, and spices) can cause irreversible health harms, particularly for the developing neurological systems of infants and children. The cumulative effects of lead and related toxic chemicals from both dietary intake and non-dietary background exposures add to these health harms. Further, communities of color and low-wealth communities face disproportionately high exposure levels, exacerbating cycles of economic and social inequity.

---

[101] Cal. Health & Safety Code § 109000(b).
[102] *Id*. § 109000(a)(3).
[103] 21 U.S.C. § 393(b)(2)(A).
[104] *Id.* § 393(b).
[105] Petition at 2.

Under the FDCA, FDA must ban the intentional use of lead in food contact materials because this use fails to meet food additive safety standards. In addition, a legal presumption that lead levels at or above a certain threshold will be considered intentionally added to products has legal precedent and should be implemented. Setting such a threshold would also help regulated industries to comply more readily with FDA's lead regulations. We respectfully submit these comments to urge FDA to meet its legal mandate to protect the public health[106] by eliminating these sources of lead exposure. If you would like to discuss any aspect of these comments, please feel free to contact Lakendra Barajas, Senior Associate Attorney, Toxic Exposure & Health Program, Earthjustice, lbarajas@earthjustice.org.

Organizations

ABLE-Differently

Alaska Community Action on Toxics

Alaska Public Interest Research Group (AKPIRG)

Alliance for the Great Lakes

American Academy of Pediatrics New York, Chapters 1, 2, and 3

Black Warrior Riverkeeper

Break the Cycle of Health Disparities, Inc.

Cahaba Riverkeeper

California Communities Against Toxics

California League of United Latin American Citizens

California Safe Schools

Cassell Neighborhood Association

Center for Neighborhood Technology

Children's Environmental Health Network

CleanEarth4Kids

[106] 21 U.S.C. §393(b)(2)(A).

Cleveland Lead Advocates for Safe Housing

Climate Resilient Communities

Coalition of Community Organizations (COCO)

Community for a Cause

Detroit Hamtramck Coalition for Advancing Healthy Environments

Earthjustice

Environmental Working Group

Environment America

For Love of Water (FLOW)

Green America

Healthy Schools Network

Immigrants & Minorities Unify Services Association (IMUSA)

Kids for Saving Earth

League of Conservation Voters

Learning Disabilities Association of Alabama

Learning Disabilities Association of America

Learning Disabilities Association of Arkansas

Learning Disabilities Association of California

Learning Disabilities Association of Delaware

Learning Disabilities Association of Georgia

Learning Disabilities Association of Illinois

Learning Disabilities Association of Iowa

Learning Disabilities Association of Maine

Learning Disabilities Association of Michigan

Learning Disabilities Association of Minnesota

Learning Disabilities Association of Nebraska

Learning Disabilities Association of New Jersey

Learning Disabilities Association of New York

Learning Disabilities Association of Oklahoma

Learning Disabilities Association of Pennsylvania

Learning Disabilities Association of South Carolina

Learning Disabilities Association of Tennessee

Learning Disabilities Association of Texas

Learning Disabilities Association of Utah

Learning Disabilities Association of Virginia

Learning Disabilities Association of Wisconsin

Milwaukee Riverkeeper

Missouri Coalition for the Environment

Neighbors for Clean Air

New York Lawyers for the Public Interest

New York League of Conservation Voters

North Carolina Conservation Network

Oregon Physicians for Social Responsibility

Pennsylvania Council of Churches

Physicians for Social Responsibility, Arizona

Physicians for Social Responsibility, Maine

Physicians for Social Responsibility, New Mexico

Physicians for Social Responsibility, Pennsylvania

San Francisco Bay Physicians for Social Responsibility

Seneca Lake Guardian, A Waterkeeper Alliance Affiliate

Seventh Generation

STOP Jet Noise NOW! SFOAK North San Francisco Bay Area

Studio City for Quiet Skies

Texas Physicians for Social Responsibility

The Salvador E. Alvarez Institute for Non-Violence

Toxic Free NC

UproarLA

U.S. Public Interest Research Group (U.S. PIRG)

Waterway Advocates

Water You Fighting For?

WE ACT for Environmental Justice

Women's Voices for the Earth

Zero Waste Washington

Individuals Affiliated with Project TENDR

Jerry P. Abraham, MD MPH CMQ
President-Elect, Los Angeles County Medical Association (LACMA)
Director & Chief Vaccinologist, CDU-KEDREN Mobile Street Medicine Program
TENDR Representative, National Hispanic Medical Association (NHMA)
Family & Community Medicine Physician, Global Injury Epidemiologist, Medical Quality Specialist, NHMA

Linda S. Birnbaum, Ph.D.
Scientist Emeritus and Former Director
National Institute of Environmental Health Sciences and National Toxicology Program
Scholar in Residence, Nicholas School of the Environment, Duke University

Carla Campbell, MD, MS
Retired Pediatrician and Public Health Professor

Department of Public Health of the University of Texas at El Paso

Aimin Chen, MD, PhD
Professor, University of Pennsylvania

Kristie Ellickson, PhD
Kendall Fellow, Center for Science and Democracy, Union of Concerned Scientists

Arthur Lavin, MD
Pediatrician, Akron Children's Hospital

Melanie A. Marty, PhD
Retired Toxicologist, California Environmental Protection Agency

Heather Patisaul, PhD
Associate Dean for Research and Professor, College of Sciences,
Center for Human Health and the Environment, WM Keck Center for Behavioral Biology
NC State University

Frederica Perera, DrPH, PhD
Professor of Public Health, Department of Environmental Health Sciences
Mailman School of Public Health, Columbia University

Devon Payne-Sturges, DrPH, MPH, MEngr
Associate Professor, University of Maryland School of Public Health

Tanya Khemet Taiwo PhD, MPH
Assistant Professor, Department of Midwifery, Bastyr University

R. Thomas Zoeller, PhD
Professor Emeritus, Department of Biology, University of Massachusetts
Visiting Professor, Örebro University, Sweden

Individuals

Nadia Ahmad
Associate Professor of Law, Barry University School of Law

Louis Allen, MD, MPH, AAP
Able Differently

Serena Alvarez, Esq.
Executive Director, The Salvador E. Alvarez Institute for Non-Violence

Chair, CA LULAC State Health Committee

Christine Armer, PhD
Entomology

Mona Hanna-Attisha, MD MPH
Director and Professor, Department of Public Health and Pediatrics, Michigan State University
Director, Pediatric Public Health Initiative

Scott Wilson Badenoch, Jr., Esq., MDR
Attorney/Visiting Attorney, Environmental Law Institute

Deborah Bennett, PhD
Professor, Public Health Sciences, University of California, Davis

Joseph M. Campbell, DC
President, Executive Director, Seneca Lake Guardian

Linda S. Birnbaum, PhD, DABT, ATS
Science Emeritus and Former Director, National Institute of Environmental Health
Stephanie Coates, MPP, MSW

Kathleen A. Curstin, LPN
Founding Director, Moms for a Nontoxic New York

Lon Goldstein, MA, MS
Instructional Designer

Jennifer M. Hadayia, MPA
Executive Director, Air Alliance Houston

Aria Kovalovich
Resident of Washington, DC

Vanessa Kranz
J.D. Candidate, Vermont Law & Graduate School

Bruce P. Lanphear, MD, MPH
Simon Fraser University

Judy Levin, MSW
Environmental Advocate
Consultant

Peter S Millard, MD, PhD
Professor, Public Health, University of New England

Heather Patisaul, PhD
Professor, Center for Human Health and the Environment, NC State University

Jerome A. Paulson, MD, FAAP
Professor Emeritus of Pediatrics and of Environmental & Occupational Health George Washington University School of Medicine and Health Sciences and George Washington University Milken Institute School of Public Health

Susan Schantz, PhD
Professor Emerita, University of Illinois at Urbana-Champaign
Beckman Institute for Advanced Science and Technology

Charlie Schlinger, Ph.D., P.E., R.G., C.P.G.
Principal Engineer and Scientist
Consulting Engineer and Scientist

Teresa Tse
Citizen of Hillsboro, OR
Member of OregonAviationWatch.org

Rick White
Former Chair Person, Western Broome Environmental Stakeholders Coalition (WBESC)

Charlene Willey
Former Member, Save Our Skies Alliance
Community Advocate

**Affiliations are provided for identification purposes only and do not imply institutional endorsement or support.*