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Submitted via Regulations.gov
U.S. Environmental Protection Agency
Office of Ground Water and Drinking Water
Standards and Risk Management Division (Mail Code 4607M)
1200 Pennsylvania Avenue NW.
Washington, DC 20460

RE: PUBLIC COMMENTS ON EPA'S DRAFT REPORT TITLED "PROPOSED MODELING APPROACHES FOR A HEALTH BASED BENCHMARK FOR LEAD IN DRINKING WATER"

The following comments are submitted in response to EPA's request for input on its draft report setting forth three modeling approaches proposed for peer review, one or more of which would potentially be used to derive a "health-based benchmark" for lead in water (hereafter "Draft Report").[1] This letter explains why we have overarching concerns about the concept of a "health-based" or household-level benchmark. It also identifies shortcomings in the proposed model scenarios and model inputs, which raise a risk that the models would underestimate either the intake of lead in water by the most vulnerable populations, or the effects of lead in water upon blood lead levels ("BLLs") of infants, pregnant women, and other sensitive populations.

We understand that EPA has not yet decided whether to propose a benchmark and has not yet decided how it would use a benchmark. We therefore reserve our right to take a final position on the wisdom of this benchmark idea at such time as EPA articulates a specific proposal. In the meantime, we support EPA's decision to seek peer review of the potential modeling approaches it might use to derive a benchmark or provide public information. Rigorous peer review is needed, at a minimum, to determine whether the models are capable of deriving a conservative value that reliably reflects both potential exposure and effects of exposure on BLLs in the most vulnerable populations.

GENERAL CONCERNS

While we are cautiously optimistic about EPA's efforts to better characterize the health effects of lead in water on blood lead levels, we have grave concerns about the benchmark concept EPA is contemplating. In particular, such a benchmark is inherently likely to create or further entrench a false sense of security about the healthfulness or safety of water that tests below the benchmark in any one-time sampling. This is crucial since, as the Draft Report notes, "[b]ecause there is no known threshold for the developmental effects of lead in children, *any increase in lead exposures can potentially place a child at risk for adverse health effects*."[2]

EPA's authority and reputation is such that any "health-based benchmark" for lead in water other than zero will be seen by the public, health professionals and even other researchers as the holy grail of health-based waterborne lead standards, whether it is meant to represent that or not. Regardless of EPA's intentions on how the Agency will interpret and implement this value (which is a concern because

[1] US EPA. 2017. Proposed modeling approaches for a health-based benchmark for lead in drinking water. Doc. ID: EPA-HQ-OW-2016-0686-0002; US EPA, Request for Nominations for Peer Reviewers and for Public Comment on Peer Review Materials To Inform the Derivation of a Water Concentration Value for Lead in Drinking Water, 82 Fed. Reg. 6546 (Jan. 19, 2017).

[2] Draft Report at 50 (emphasis added).

EPA's description of how this value might be used is vague), EPA should acknowledge that this benchmark is likely to be misunderstood or misused as a threshold below which exposures to lead are "safe," or require no remedial attention.

This is exacerbated by the fact that EPA has chosen to call the concept a "health-based benchmark" for lead in water, as opposed to a "household action level" which was recommended by the EPA's National Drinking Water Advisory Council (NDWAC).[3] We understand that EPA is attempting to differentiate the concept of a benchmark derived from estimates of health effects (i.e. increase in BLLs), from the lead action level which is based on what was thought to be feasible in a system using corrosion control.[4] Nonetheless, because there is no known "healthy" level of lead, and health effects have been detected at even very low doses, the term "health-based" is inherently misleading and ripe for misinterpretation and misapplication.

Indeed, we continue to see this sort of misuse occur even with the lead action level of 15 parts per billion (ppb). Even though EPA acknowledged that the action level was not heath-based, the Centers for Disease Control (CDC) *still* recommends that public health officials disregard water sampling in the homes of lead poisoned children if one-time tap water sampling results are lower than the 15 ppb lead action level and there is no other known source of lead in the home.[5] This has led to a gap in data for a critical direct and chronic exposure pathway for lead which can accumulate in the body over time. It has set into motion a false sense of security, which has needlessly undermined public health investigations and interventions for more than two decades. From speaking with residents in cities across the country, we know that households and schools are using the 15 ppb action level as a (false) measure of the safety of their water, or to evaluate the need for remediation. We therefore strongly urge EPA to drop its use of the word "health" in naming, characterizing or applying any benchmark, and to keep these concerns in mind as it evaluates the potential modeling approaches and the decision whether to propose a benchmark value at all.

MODEL SCENARIOS

Lack of consideration for fetal exposures

It does not appear that consideration is given to deriving a water benchmark that considers fetal exposure. This is a serious concern, given the susceptibility of this overlooked population. Maternal BLLs as low as <1 ug/dL have been associated with a decrease in birth weight and gestational age.[6] At the very least, if EPA is to use one of the models to "provid[e] states, drinking water systems, and the public

[3] Draft Report at 7-8.

[4] Id. at 7.

[5] U.S. Centers for Disease Control and Prevention (CDC). 2002. Managing elevated blood lead levels among young children: Recommendations from the Advisory Committee on Childhood Lead Poisoning Prevention. Atlanta, GA: CDC. Accessed: April 4, 2017, http://www.cdc.gov/nceh/lead/CaseManagement/caseManage_main.htm. In listing "Common Sources of Lead Exposure to Consider in an Environmental Investigation," (Table 2.3), that document recommends only that investigators consider drinking water samples of 15 ppb or higher. See also CDC, Lead Prevention Tips for water, https://www.cdc.gov/nceh/lead/tips/water.htm (accessed April 4, 2017) (stating: "You should begin by asking your water authority these questions: 1. Does my water have lead in it above EPA's action level of 15 parts per billion (ppb)? If the answer is no, no action is needed. . . .").

[6] Rabito, et al., Changes in low levels of lead over the course of pregnancy and the association with birth outcomes, Reprod Toxicol. (Dec. 2014).

with a greater understanding of the potential health implications for vulnerable populations of specific levels of lead in drinking water," as is EPA's stated goal, there should be a disclaimer about the population groups that the model-derived value may not account for.

Lack of consideration for lead intake from cooking

Exposure to lead from tap water through uptake by cooked food is not considered according to the information presented by EPA in this review. It is unclear whether IEUBK can be modified to consider the accumulation of lead in food through cooking. Food like boiled vegetables, pasta and potatoes can absorb 90% or more of the lead present in water.[7] This may be a weakness in the modeling exercises that could grossly underestimate the effects of lead in water on BLLs. We strongly suggest that any model used incorporate uptake from cooked food. If it does not, there should be a disclaimer about the serious limitation of any resulting benchmark.

Lack of consideration for the inherent variability in lead release and water use patterns, and uncertainties about the presence and nature of lead-bearing plumbing in homes, daycares, and schools

Research has shown that lead release from any single tap can be so highly variable that: (1) to calculate average lead from one tap to within 20% of the true mean, collection of over 1,200 samples might be necessary, and (2) collecting single samples from consumer taps can falsely suggest that, "a water is safe while repeated measurements can demonstrate extreme hazards."[8]

We struggle to see how associations between lead-in-water measurements and health effects can be derived from existing lead-in-water data, which do not capture accurately the concentrations of lead flowing out of consumer taps. If EPA is to proceed with the development of a household-level (or "health-based") benchmark, it must first defend the scientific validity of extrapolating estimates of human exposure (and health harm) from data that does not accurately represent actual lead-in-water levels and human exposures. Similarly, EPA must also disclose the fact that for many of the lead-in-water measurements available, there is a dearth of information about the plumbing in the buildings from which these measurements came, and the highly variable ways by which consumers in these buildings use the water – factors that also influence lead-in-water exposures and health harm.

These limitations are especially relevant to EPA's benchmark concept, since EPA appears to be contemplating applying the benchmark to specific residences following a one-time test involving a single sample. Especially if EPA should continue to characterize the benchmark as "health-based," its application could systematically misinform members of the public and residents in individual households, which could prolong health harms.

[7] Moore M.R., Richards W.N, Sherlock J.G. 1985. Successful abatement of lead exposure from water supplies in the west of Scotland. Environ. Res. 38:67-76.

[8] Masters, S., J. Parks, A. Atassi, and M. A. Edwards. 2016. Inherent Variability in Lead and Copper Collected During Standardized Sampling. Environ Monit Assess 188:177; Masters, S., J. Parks, A. Atassi, and M. A. Edwards. 2017. Inherent Variability in Lead and Copper Collected During Standardized Sampling [Power Point presentation]. AWWA 2017 International Symposium on Inorganics, Detroit, MI, March 21-22.

MODEL INPUTS

Drinking water intake parameter for bottle-fed infants

Exposure assumptions used for bottle-fed infants consuming tap water-reconstituted formula demand particular attention, as infants' high water intake on a body weight basis, and high absorption rate for lead (an estimated 50% of total lead intake for children, compared to an estimated 20% for adults)), makes them very susceptible to water contaminants.[9] About 90% of the diet for infants fed reconstituted formula comes from water.[10] The static intake assumptions used in the proposed models will have a critical influence on estimates of lead exposure, and on the resulting benchmark EPA may define. Water intake values for infants used in the proposed models are lower than both: (a) the World Health Organization's (WHO) default for water intake by bottle-fed infants (0.75 L/day),[11] and (b) EPA's own exposure guidelines which range from 0-1.6 L/day for infants, with a 90th percentile of 0.88 L/day, and 95th percentile of 1 L/day.[12] Given the considerable influence of drinking water intake on the outcome of this modeling exercise, EPA should obtain higher quality exposure data or otherwise make appropriate adjustments to the assumptions used in the proposed models for bottle-fed infants.

Consideration of uncertainties

Uncertainties such as absorption factors, which can be influenced by variables such as disease diagnosis, genetics, nutrition and health care, and the variability of lead leaching and lead-scale release, do not appear to be addressed. And there is still much uncertainty surrounding the kinetics of lead transfer across the placenta and in breast milk. If this value is to be based on reliable estimates of the effects of waterborne lead on BLLs, we urge the EPA to consider reviewing data from empirical epidemiological or biomonitoring/exposure studies, especially those which consider cumulative impacts of chronic exposures to low-dose waterborne lead. One such study by Ngueta et al (2016) estimated that 1 ug/L of lead in water could increase childhood blood lead levels by 35% after 5 months of exposure.[13] Fertmann et al (2004) estimated that water lead levels as low as 5 ug/L significantly increased BLLs in young women, and that excluding tap water from their daily intake resulted in a 37% drop in BLL.[14] Cal-OEHHA's documentation in support of its Public Health Goal for lead in water for fetuses and infants (0.2

[9] Draft Report at 20, citing Triantafylidou, et al. 2012. Lead (Pb) in tap water and in blood: implications for lead exposure in the United States. Critical Reviews in Environmental Science and Technology, 42(13), 1297–1352. https://doi.org/10.1080/10643389.2011.556556.

[10] Sherlock J.C., Quinn M.J. 1986. Relationship between blood lead concentrations and dietary lead intake in infants: The Glasgow duplicate diet study 1979-1980. Food Addit. Contam. 3:167-176.

[11] World Health Organization. 2011. Lead in drinking water: Background document for development of WHO guidelines for drinking-water quality. WHO/sde/WSH/03.04/09/Rev/1.

[12] US EPA. 2011. Exposure Factors Handbook.

[13] Ngueta G, Abdous B, Tardiff R, St. Laurent J, Levallois P. 2015. Use of a cumulative exposure index to estimate the impact of tap-water lead concentration on blood lead levels in 1- to 5-year old children (Montreal, Canada). Environ Health Perspect. Advance online publication. DOI: 10.1289/ehp.1409144.

[14] Fertmann, et al., Lead exposure by drinking water: an epidemiologial study in Hamburg, Germany.Int J Hyg Environ Health. 2004 Jul;207(3):235-44.

ppb) also merits attention.[15] These and other studies and reviews should be taken into consideration and highlighted, at the very least to disclose the limitations of any modeled value EPA derives. Deriving a household-level benchmark solely on the basis of models with their inherent uncertainties is not only inadequate but dangerous.[16]

Thank you for the opportunity to comment on this matter.

Should you have any questions, please contact Jennifer C. Chavez at jchavez@earthjustice.org, or 202-667-4500, ext. 5208.

Sincerely,

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[15] CAL-OEHHA. 2009. Public health goals for chemicals in drinking water: Lead. Available at: https://oehha.ca.gov/media/downloads/water/chemicals/phg/leadfinalphg042409_0.pdf

[16] US EPA. 2017. Proposed modeling approaches for a health-based benchmark for lead in drinking water.