**COMMENTS BY THE TEXAS COMMISSION ON ENVIRONMENTAL QUALITY REGARDING 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**

**EPA DOCKET ID NO. EPA-HQ-OW-2016-0686**

## I. Summary of Proposed Action

On January 19, 2017, the United States (US) Environmental Protection Agency (EPA) published a *Federal Register* notice (82 FR 6546) of a public comment period (ending March 6, 2017) for the "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." Among the peer review materials released for public comment was the January 2017 draft report entitled, "Proposed Modeling Approaches for a Health-Based Benchmark for Lead in Drinking Water." This draft report provides several possible approaches for deriving lead drinking water values corresponding to "health-based benchmarks" for public comment.

## II. TCEQ Comments on the Draft Report

### The January 2017 draft report and the January 19, 2017, notice should be withdrawn in their entirety.

The new leadership team of the EPA should be granted an opportunity to study the health-based benchmarks and determine whether and to what extent they accord with the Executive Branch's enforcement of the Clean Water Act.

### The EPA names its derived household action levels as "health-based benchmarks," but the term is not accurate and thereby unnecessarily confuses the public. The EPA should revise this terminology to accurately depict the derivation and intended use of the value, or provide the necessary documentation to justify a health-based benchmark in a separate document made available for public and peer review.

The EPA uses the term "health-based benchmark" to refer to the concept of defining the relationship between lead levels in drinking water and blood lead levels (BLLs), particularly for sensitive life stages such as formula-fed infants and children up to age 7 (pp. 5-6 of the draft report). However, this term is a misnomer, as the EPA-referenced concept is simply a modeling exercise (i.e., toxicokinetic) as opposed to referring to a true health-based childhood blood lead benchmark that is derived using health studies and a generally accepted chemical risk assessment process. As such, use of this term in the draft report is misleading and does not reduce confusion, which was the stated goal (p. 7 of the draft report). The draft report does not discuss or propose any benchmark that is in fact health-based. For example, the current reference value of 5 micrograms per deciliter (µg/dL) established by the Centers for Disease Control and Prevention (CDC) is not a health-based benchmark, but rather simply is a reference value corresponding to the 97.5$^{th}$ percentile of the blood lead distribution in children ages 1-5 years based on two National Health and Nutrition Examination Surveys (NHANES 2007-2008 and 2009-2010). The draft report later acknowledges (p. 41) that the CDC reference levels used (whether 3.5 or 5 µg/dL) are not health-based in any way, "but rather based on a statistical

approach considering BLLs at the national level." Not even this much can be said of the small increases in BLLs used in Approach 1 or 2 in the draft report since a health (or even statistical) basis for these small increases (0.5 or 1 µg/dL increases) is absent.

In the absence of any truly health-based benchmark in the draft report, the TCEQ notes that the most recent EPA guidance on deriving soil lead cleanup values (EPA 2016) recommends that EPA Regions work within the framework of existing policy and references no more than a 5% chance of exceeding the blood action level of 10 µg/dL as the historical criterion for calculating a health-protective concentration in environmental media (i.e., surface soil). The guidance does not identify *any* lower alternative BLL criteria (e.g., CDC reference values or small BLL increases are not even mentioned) or recommend any value other than 10 µg/dL. If the EPA does not intend to use this health-based benchmark of concern, the TCEQ recommends that EPA develop an appropriate health-based value in a separate draft document made available for public and peer review and comment.

Alternatively, the TCEQ emphasizes that EPA's National Drinking Water Advisory Council's (NDWAC) Lead and Copper Rule Working Group was established to inform the EPA Administrator on recommendations to strengthen public health protections of the Lead and Copper Rule (LCR). In December 2015, the NDWAC provided specific recommendations to the EPA Administrator for LCR revisions related to, among other things, the establishment of a household action level. The NDWAC specifically recommended that this level be "based on the amount it would take an infant to have a blood lead level (BLL) greater than five micrograms per deciliter (µg/dL) based on consumption by an average, healthy infant of infant formula made with water" (p. 5 of the draft report). In the absence of a new health-based BLL, the EPA's own experts recommend that the EPA use 5 µg/dL as a benchmark BLL in evaluating the potential need for any revisions to the LCR. While not a true health-based benchmark, this BLL (5 µg/dL) is very conservative as it simply represents the upper end of the US childhood BLL distribution.

Although recommended by NDWAC, the TCEQ cautions the EPA against tying an action level or the LCR to an ever-moving target such as the 97.5$^{th}$ percentile of the US childhood BLL distribution. This level is not a health-based benchmark, therefore it tells the public nothing with regard to the risk of adverse health effects. Further, population BLLs change over time, so a static benchmark based on this target will quickly be out of date.

**Of the options presented in the draft report, the TCEQ recommends that the EPA use the 37/72 µg/g (ppm) geometric mean background soil/dust lead concentrations to satisfy the NDWAC's request.**

Generally, the current draft evaluates three age groups (i.e., 0-6 month formula-fed infants, 1-2 year olds, and 0-7 year olds) using three approaches:

- Approaches based on a modeled individual child using the EPA's Integrated Exposure Uptake Biokinetic (IEUBK) model include:
  - Approach 1 - Estimate the concentration of lead in drinking water that would result in a 1 or 5% increase in the probability of a child having a BLL above 3.5 or 5 µg/dL.
  - Approach 2 - Estimate the concentration of lead in drinking water that would result in a 0.5 or 1 µg/dL increase in a child's mean BLL.
- Approach based on a modeled population of children using EPA's Stochastic Human Exposure and Dose Simulation (SHEDS) and IEUBK models:
  - Approach 3 - Estimate the amount of lead in drinking water that would result in a target population of children's predicted distribution of BLLs having the 95$^{th}$ or 97.5$^{th}$ percentile BLL of 3.5 or 5 µg/dL.

As indicated above, the NDWAC specifically recommended that any household action level be "based on the amount it would take an infant to have a BLL greater than five micrograms per deciliter (μg/dL) based on consumption by an average, healthy infant of infant formula made with water" (p. 5 of the draft report). Additionally, the TCEQ notes that a 5% increase in the probability of exceeding 5 μg/dL is: (1) consistent with that used historically by the EPA for assessing acceptable lead exposures (i.e., no more than a 5% chance of exceeding 10 μg/dL for children's surface soil impacted by historic Superfund sites); (2) more meaningful in terms of actual risk; and (3) consistent with a more stringent (yet reasonable) probability criterion that may be used by EPA for more serious effects in benchmark dose modeling (i.e., a benchmark response of 5% as opposed to 10%). Finally, as the "average" infant recommended by the NDWAC would be exposed to central tendency soil/dust lead concentrations, based on options in the current draft report, the TCEQ would recommend a household action level be derived at the 37/72 μg/g (ppm) geometric mean concentrations (Exhibits 7 and 8). Thus, based on current draft report options, the scenario corresponding to the NDWAC (i.e., formula-fed infant, BLL of 5 μg/dL) and TCEQ recommendations (i.e., 5% increase in the chance of exceeding the benchmark BLL, with soil/dust lead concentrations of 37/72 μg/g) is contained in Exhibit 47 of Appendix A (p. 74 of the draft report). Based on results reported in Exhibit 47, the drinking water concentration that results in a 5% increase in the probability of exceeding 5 μg/dL for formula-fed infants (with soil/dust lead concentrations of 37/72 μg/g) is 15.4 μg/L. This value happens to be essentially identical to the current lead action level of 0.015 mg/L or 15 μg/L. The same is true for all 0-6 month old infants using 5 μg/dL as the BLL criterion as recommended by the NDWAC. Exhibits 37 and 38 of the draft report (p. 58) show that 15-17 μg/L protects infants at 5 μg/dL considering aggregate exposure to lead. Thus, based on the options currently in the draft report, it appears the current action level (15 μg/L) that is based on the technical feasibility of corrosion control is also health protective for the formula-fed, average infant scenario recommended by EPA's own NDWAC (as well as all infants combined).

**The EPA should revise its soil ingestion, soil/dust concentration, and outdoor air input parameters, as they currently include higher-end exposures.**

The draft report (p. 19) indicates that, "The input parameters used in this analysis do not represent high-end exposures." However, various analyses in the draft report as well as Appendix A do incorporate higher-end exposure inputs. For example, although not point source-oriented, the outdoor lead air concentration used for all analyses (0.01 μg/m$^3$) was based exclusively on air monitoring data from 50 urban areas. More specifically, it was based on the average of the highest rolling 3-month average for the 50 urban sites in 2013 (p. 21 of the draft report). Consequently, the resulting air concentration is not representative of typical childhood exposure (whether 0-6 months or 0-7 years) but rather worst-case, high-end, relatively short-term urban exposure.

In regard to soil concentrations, the draft report explicitly uses soil sample results from homes built prior to 1950 (soil lead geometric mean concentration of 221 μg/g (ppm); Exhibit 7) for various analyses, thereby incorporating high-end exposure to soil/dust lead at homes with lead-based paint (Section A.2 of the draft report). This same comment applies to dust concentrations for homes built prior to 1950 (dust lead geometric mean concentration of 134 μg/g (ppm); Exhibit 8). More importantly, even the mean concentrations used in the draft report appear to represent high-end exposures for Texas. For example, while the draft report uses a mean soil concentration of 160 μg/g (ppm; Exhibit 7) based on the American Healthy Homes Survey (AHHS) (US Department of Housing and Urban Development (HUD) 2011), Table 7-2 of the AHHS shows that the mean for southern states actually ranges from 67-83 ppm with a 95% confidence interval upper bound of 91-109 ppm. Thus, even the "mean" soil concentration used

in the draft report would represent high-end exposure in Texas[1] and other southern states. It follows that the same is likely to be true for the geometric mean soil/dust lead concentrations used in the draft report based on all homes (37/72 µg/g), as opposed to those in southern states.

Lastly, the central tendency soil/dust ingestion rates may overestimate mean exposure and represent higher-end exposure. Based on the meta-analysis of soil ingestion studies in children by Stanek et al. (2012), the mean soil ingestion rate in the draft report (Exhibit 9) for children 0-2 years (43.9 mg/day) may overestimate exposure by more than an order of magnitude, and may actually exceed the 95$^{th}$ percentile (see Table II of Stanek et al. 2012). Additionally, the mean used for children 2-3 years (45.2 mg/day) may overestimate exposure by more than 2-fold and soil/dust ingestion may be overestimated by more than an order of magnitude for the formula-fed infant scenario that was of the most importance to the NDWAC. Thus, certain analyses in the draft report may be biased towards high-end exposure, contrary to the statement that, "The input parameters used in this analysis do not represent high-end exposures" (p. 19).

**Given the complexity of the issue and supporting documentation, the EPA should have planned on providing more than 45 days for the public to comment on this draft.**

The length of the comment period should be commensurate with the importance of the issue (e.g., it has great implications in regulatory and public health contexts) and the complexity inherent in the draft report. The EPA initially provided 45 days for the public comment period. Approximately two weeks prior to the end of the comment period, the EPA provided notice that the comment period would be extended by 30 days. The original 45-day period is insufficient for regulatory agencies and others to provide the most thorough and meaningful comments possible based on an in-depth review and analysis of the draft report. However, the belated extension to a more reasonable comment period does not help organizations conduct a more thorough analysis. There is great complexity associated with multiple issues relevant to the assessment of lead health hazard from drinking water, and while the draft report itself is relatively short, background information relevant to the approaches utilized in the draft report is voluminous. In order to meet the original deadline, organizations would have already shifted their focus to a few key issues, rather than critically reviewing the draft report and more specifically, the procedures, calculations, underlying assumptions, and supporting contentions employed by EPA therein. There is no time to restart the analysis in a more holistic fashion. Consequently, the TCEQ comments are based on a superficial review of the draft report that is limited by the original comment period provided.

**EPA should carefully consider and respond to public comments.**

The TCEQ acknowledges the significant agency effort and resources required to produce draft reports/assessments, review public comments, and make any scientifically justified revisions and additions. The public deserves regulatory agencies that make good risk management decisions using realistic assessments. Consequently, for this and other draft reports and assessments, the TCEQ urges EPA to give thoughtful scientific and common-sense consideration to these and other comments (e.g., the NDWAC) that support or contradict key decisions and procedures employed by EPA in the draft report. The issuance of a final report necessarily implies that EPA agrees with its ability to reasonably predict actual risk at commonly encountered environmental doses and with the unavoidable conclusions about public health that will naturally follow.

[1] The TCEQ further notes that the Texas-specific surface soil lead data available from United States Geological Survey (USGS 2013) provide Texas-specific and US medians of approximately 13 and 18 µg/g (ppm), respectively.

References

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