LEAD IN DRINKING WATER MODELING
EXTERNAL PEER REVIEW
CHARGE TO REVIEWERS

The U.S. Environmental Protection Agency's (EPA) Office of Water is considering revisions to the National Primary Drinking Water Regulations for Lead and Copper (LCR) to improve public health protection by making changes to rule requirements under the Safe Drinking Water Act. EPA has engaged stakeholder groups and the public to inform revisions to the LCR. As part of this work, the EPA's National Drinking Water Advisory Council's (NDWAC) Lead and Copper Rule Working Group was formed to provide advice to the Administrator on recommendations to strengthen public health protections of the LCR.

In December 2015, the NDWAC provided a number of specific recommendations to the EPA Administrator for LCR revisions, one recommendation is the establishment of a *household action level* "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" (Lead and Copper Rule Working Group, 2015, p. 37). The NDWAC recommended that water systems be required to notify the consumer, the state drinking water program and the local public health agency if this level were exceeded, with the expectation that individuals and local health officials will use this information to take prompt actions at the household level to mitigate lead risks. To reduce confusion with the existing LCR system-wide "action level," EPA will use the terminology health-based benchmark to refer to this concept.

While EPA has not yet determined the specific role of a health-based benchmark for lead in drinking water in the revised LCR, the Agency sees value in providing states, drinking water systems and the public with a greater understanding of the potential health implications for vulnerable populations of specific levels of lead in drinking water. EPA anticipates that the proposed rule will consider the health-based benchmark approach recommended by the NDWAC, but this value could also help to inform other potential elements of a revised rule – including public education requirements, prioritization of households for lead service line replacement (LSLR) or other risk mitigation actions at the household level, and potential requirements related to schools.

EPA has developed three potential scientific modeling approaches to define the relationship between lead levels in drinking water and BLLs, particularly for sensitive life stages such as formula fed infants and children. These modeling approaches, as described in the draft document "Proposed Modeling Approaches for a Health-Based Benchmark for Lead in Drinking Water," are the subject of this peer review, which will inform future consideration of a health-based benchmark for the LCR revisions. Note that the modeling approaches are intended to provide scientific understanding for the LCR rulemaking, but do not anticipate or prejudge those policy decisions.

EPA is considering three approaches that model lead in drinking water's effect on BLLs using a range of exposure scenarios. All the approaches employ the Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children. Approaches 1 and 2 are individual-based approaches that look at the increase in the probability that a child would have an elevated BLL (EBLL) and a child's incremental increase in BLL, respectively. Approach 3 is a population-based probabilistic approach that evaluates the drinking water lead concentrations that would keep BLLs at particular percentiles of a simulated national distribution of different aged children. It uses the probabilistic Stochastic Human Exposure and Dose Simulation (SHEDS) Multimedia model coupled with IEUBK.

The values applied in the approaches and the results derived from the models are for illustrative purposes only.

They do not indicate EPA policy decisions and are not, in and of themselves, the focus of this peer review.

EPA is seeking comments on the scientific aspects of these potential modeling approaches to associate lead in drinking water with BLLs.

1. MODEL SCENARIOS
   Please comment on the strengths and weaknesses associated with the decision to model three life stages: 0-6 months, 1-2 years, and 0-7 years. Please comment on whether there are additional life stages that should be considered by EPA. Please also comment on the strengths and weaknesses of the modeling scenarios conducted, i.e., exposure scenarios for drinking water only and all pathways, and target BLLs (3.5 ug/dL and 5 ug/dL at several upper tail percentiles of the population). Please identify additional scenarios that would add utility.

2. MODEL INPUTS
   Please comment on the strengths and weaknesses, including suggestions for improving the input parameters (i.e., point estimates and distributions) for the IEUBK and SHEDS-IEUBK modeling approaches. Please identify any data gaps or additional data related to the various input parameters that could improve the exposure and BLL estimates. Please comment on the appropriateness of the water consumption rate based on NHANES data for this modeling effort, and on soil/dust ingestion rate and other key factors.

3. MODELING APPROACHES
   EPA demonstrated three modeling approaches. The first two are individual-based deterministic (with central tendencies) approaches using IEUBK modeling, and the third is a population-based probabilistic approach using SHEDS-Multimedia coupled with the IEUBK model. "Approach 1" determines the concentration of lead in drinking water associated with a percentage increase in the probability of an individual "representative" child experiencing an elevated BLL. "Approach 2" determines the concentration of lead in drinking water that would result in a 0.5 µg/dL or 1 µg/dL increase in a child's mean BLL for an individual "representative child" exposed to lead in drinking water. "Approach 3" determines drinking water lead concentrations that would keep particular percentiles of simulated national BLL distributions of different aged children below a defined benchmark BLL.

   a. Compare and contrast each approach and comment on the strengths, weaknesses, and uncertainties of each as well as the utility of the different ways the outputs are presented.
   b. Please comment on the strengths and weaknesses of using the IEUBK model to predict drinking water concentrations that may result in specific increases in BLLs and/or increased probability of elevated BLLs.
   c. Please comment on the potential utility of using the SHEDS-IEUBK approach (currently used in Approach 3) to develop an estimate of the concentration of lead in drinking water associated with a percentage increase in the probability of an individual child experiencing an elevated BLL as is done in Approach 1 (using only IEUBK). Please also comment on the utility of using the SHEDS-IEUBK approach to identify the concentration of lead in drinking water associated with a specified increase in the geometric mean (GM) BLL for a population exposed to lead in drinking water as is done in Approach 2 (using only the IEUBK).

4. MODEL EVALUATION AND MULTIMEDIA EXPOSURE PATHWAY/SENSITIVITY ANALYSES
   Please comment on the strengths and weaknesses of the three approaches considering existing blood lead data. Please also comment on the strengths and weaknesses associated with the approach to modeling the relative contributions by exposure pathway. Please comment on what type of sensitivity analysis would be useful to analyze aggregate lead exposures and identify key model inputs, and on the sensitivity analyses conducted for Approach 3.

5. How could each of these approaches be improved for the purposes of evaluating drinking water concentrations associated with increased/elevated BLLs? For each of these approaches, how could one account for the variability of drinking water concentrations measured at homes during sampling, in research studies, or predicted using modeling techniques.?