ESTIMATION OF LEAD EXPOSURE FROM WATER SOURCES: UPDATE TO THE DEFAULT VALUE FOR THE INTEGRATED EXPOSURE UPTAKE BIOKINETIC MODEL FOR LEAD IN U.S. CHILDREN

OVERVIEW

Since 1994, the Office of Land and Emergency Management (OLEM), formerly known as the Office of Solid Waste and Emergency Response (OSWER), has recommended the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model) as a risk assessment tool to support environmental cleanup decisions at current and future anticipated residential sites (U.S. EPA, 1994a,b). The IEUBK model predicts blood lead levels (PbB) in young children (birth to 7 years of age[1]) exposed to lead from several sources of exposure and routes. The IEUBK model uses more than 100 input parameters that are initially set to default values. Of these, there are 46 parameters that may be input, or modified, by the user; the remainder are internal variables that are unavailable for modification (U.S. EPA, 1994a).

The IEUBK model uses empirical data from numerous scientific studies of lead uptake and biokinetics, contact and intake rates of children with contaminated media, and data on the presence and behavior of environmental lead to predict a plausible distribution centered on the geometric mean (GM) of PbB for a hypothetical child or population of children (EPA, 2020).[2] The relative variability of PbB concentrations around the GM is defined as the geometric standard deviation (GSD). The GSD encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability.[3] From this distribution, the IEUBK model estimates the risk (*i.e.,* probability) that a child's or a population of children's PbB concentration will not exceed a certain PbB level (U.S. EPA, 1998, 1994a; White et al., 1998).

The default value for the *Lead Concentration in Drinking Water* variable in the IEUBK model (v. 1.1, build 11)represents a national central tendency estimate for lead concentration in drinking water (PbW). This value was derived from a combination of PbW data reported by the American Water Works Service Company, Inc. (AWWSC, 1988) and a quantitative analysis performed by Marcus (1989).[4]

The purpose of this document is to provide the technical basis for an analysis of the currently available data on lead in U.S. drinking water to support an updated *Lead Concentration in*

[1] To better align the CDC recommendation and the risk predictions for lead exposure at Superfund sites, the TRW Lead Committee recommends that the default age range in IEUBK model be modified to match the 1-5 year age range (12-72 months).

[2] The GM represents the central tendency estimate (*e.g.,* mean, 50th percentile) of PbB concentration of children from a hypothetical population (Hogan et al., 1998). If an arithmetic mean (or average) is used, the model provides a central point estimate for risk of an elevated PbB level. By definition a central tendency estimate is equally likely to over- or under-estimate the lead-intake at a contaminated site. Upper confidence limits (UCLs) can be used in the IEUBK model; however, the IEUBK model results could be interpreted as a more conservative estimate of the risk of an elevated PbB level. See U.S. EPA (1994a) for further information.

[3] The IEUBK model uses a log-normal probability distribution to characterize this variability (U.S. EPA, 1994a). The biokinetic component of the IEUBK model output provides a central estimate of PbB concentration, which is used to provide the geometric standard deviation (GSD). In the IEUBK model, the GSD is not intended to reflect variability in PbB concentrations where different individuals are exposed to different media concentrations of lead. The recommended default value for GSD (1.6) was derived from empirical studies with young children where both blood and environmental lead concentrations were measured (White et al., 1998).

[4] The AWWSC (1988) performed a survey of the trace element concentrations and characteristics of 1,484 locations throughout the United States (U.S. EPA, 1994a,b).

*Drinking Water (*PbW) value in the IEUBK model (Table 1). The updated PbW value was derived as a population-weighted, average estimate of high end exposure data[5] from the U.S. EPA's Second Six-Year Review of National Primary Drinking Water Regulations, or "Six-Year Review" (US EPA, 2010a,b).[6] The intended audience for this document is risk assessors who are familiar with using the IEUBK model. For further background information on the use of the IEUBK model in Superfund lead risk assessment, refer to U.S. EPA (1994a) or the Technical Review Workgroup for Lead (TRW) website https://www.epa.gov/superfund/lead-superfund-sites-guidance.

Table 1. Comparison of water lead concentrations for use in the IEUBK model

Source	Constant Water Lead Concentration (µg/L)	Basis for Age-Specific Value
IEUBK Model (v. 1.1, Build 11) Default[a]	4	Methodology Marcus, 1989 Central tendency estimate Water Lead Concentration Data American Water Works Service Company, Inc. (AWWSC, 1988)
IEUBK Model (v. 2) Updated Drinking Water Lead Concentration Value[b]	0.9	Methodology Population-weighted, average estimate of high end exposure data Water Lead Concentration Data 1998-2005 Six-Year Review-Information Collection Request (ICR) Dataset (U.S. EPA, 2010a)

[a] IEUBK model (v. 1.1, build 11).
[b] IEUBK model (v. 2). Value is intended to be a nationally representative, population-weighted, estimate of high end water lead concentration found in tap water in the U.S. This value does not represent filtered or bottled water consumption. Order of operations: Calculated mean population per sample: 22,022 observations; all samples multiplied by population weight factor: value * (population / mean population); mean of all samples by location; mean of all means by location.

INTRODUCTION

The IEUBK model predicts PbB in young children (birth to 7 years of age) exposed to lead from several sources of exposure and routes. The IEUBK model uses more than 100 input parameters that are initially set to default values. Of these, there are 46 parameters that may be input, or modified, by the user; the remainder are locked (U.S. EPA, 1994a). Default values represent national averages or other central tendency values derived from empirical data in the open literature. Default values include: a) lead concentrations in exposure media (*e.g.*, diet representative of national food sources); b) contact and intake rates (*e.g.*, soil/dust ingestion); and c) exposure durations (White et al., 1998). The representativeness of IEUBK model output

[5] The Six-Year Review are not designed to assess mean exposure. Rather, the sampling is intended to detect elevated levels of lead if they are occurring in a water system to trigger additional actions to reduce lead and copper exposure.
[6] Due to ongoing analyses of lead in drinking water, the lead dataset was not published as part of the Six-Year Review of National Primary Drinking Water Regulations (U.S. EPA, 2010a). The lead concentration in drinking water dataset obtained from the 1998-2005 National Compliance Monitoring Information Collection Request Dataset (*i.e.,* "Six-Year Review-ICR Dataset"), however, was delivered by U.S. EPA Office of Groundwater and Drinking Water to the TRW for this review. For more information see http://water.epa.gov/scitech/datait/databases/drink/sdwisfed/howtoaccessdata.cfm.

is wholly dependent on the representativeness of the data (often assessed in terms of completeness, comparability, precision, and accuracy [U.S. EPA, 1994a]).

Representative site-specific data are essential for developing a risk assessment (as well as cleanup goals) that reflect the current or potential future conditions. The most common type of site-specific data is media-specific lead concentration information (air, water, soil, dust). Until recently, an inexpensive, EPA validated method[7] (U.S. EPA 2017) to estimate bioavailability of lead in soil or dust was not available. Receptor data (e.g., age, body weight, breathing rate, or soil ingestion rate) does not typically vary due to site-specific factors.

To promote defensible and reproducible site investigations and decision making, while maintaining flexibility needed to respond to different site conditions, EPA recommends the Data Quality Objectives process (U.S. EPA, 2006). Data Quality Objectives provide a structured approach to collecting environmental data that will be sufficient to support decision-making: http://www.epa.gov/QUALITY/dqos.html.

TECHNICAL ANALYSIS

The TRW identified information on PbW from seven sources (Clayton et al. 1999; Moir et al., 1996; U.S. EPA, 2006a, 2007, 2008, 2010a,c).

U.S. EPA (2008, 2010c) and the National Ambient Air Quality Standards (NAAQS) analysis (U.S. EPA, 2006a, 2007) suggest that a constant mean water lead concentration of 4.61 µg/L is appropriate based on data from two studies of residential water concentrations in U.S. and Canadian homes (Clayton et al., 1999, Moir et al., 1996).

Clayton et al. (1999) based PbW estimates on the results of the National Human Exposure Assessment Survey (NHEXAS) Phase I field studies conducted by the Research Triangle Institute and the Environmental and Occupational Health Sciences Institute. Phase I was conducted in six states in U.S. EPA Region 5 (Ohio, Michigan, Illinois, Indiana, Wisconsin, and Minnesota) between July 1995 and May 1997. The study included a series of questionnaires of personal exposure and onsite physical samples of residential water (both first-draw and flushed).[8] Clayton et al. (1999) reported the arithmetic mean drinking water concentration for the Region 5 areas as follows: first-draw (n=444) water 3.92 µg/L (95% CI: 3.1 to 4.8) and flushed water (n=443) 0.84 µg/L (95% CI: 0.6 to 1.1) (see Table 2).

Moir et al. (1996) summarized data on PbW from 36 single-family homes serviced by municipal water drawn from a lake in Halifax, Nova Scotia, Canada. Two tap water samples over two separate occasions were collected from each location in April and June 1987. Moir et al. (1996) noted that many of the homes sampled were serviced by lead pipe mains, and that 70% and 25% of the first-draw and flushed water samples, respectively, from the homes sampled had lead concentrations that exceeded 10 µg/L. The mean lead concentration for first-draw water was 16 µg/L (maximum=51 µg/L), and for flushed water was 8 µg/L (maximum=70 µg/L) (see Table 2).

Amendments to the Safe Drinking Water Act require U.S. EPA to review each National Primary Drinking Water Regulations (NPDWR) every six years. This process, or "Six-Year Review" is a

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[7] Method 1340 *In Vitro* Bioaccessibility Assay for Lead in Soils, https://www.epa.gov/hw-sw846

[8] The NHEXAS study was a federal interagency research effort coordinated by the U.S. EPA Office of Research and Development (ORD). NHEXAS was implemented in three phases: Phase I, scoping studies using probability-based sampling designs; Phase II, a full national exposure survey; and Phase III, a series of focused characterization modules (Pellizzari et al. 1995). Pellizzari et al. (1995) and Clayton et al. (1999) provide further detail the scope and design of Phase I of the NHEXAS study.

comprehensive assessment of drinking water quality that measures the state of water treatment capabilities, as well as current laboratory analytical methods for the regulated contaminants (U.S. EPA, 2010b).[9] As described by U.S. EPA (2010d), during the Six-Year Review process, public water systems must sample homes or other sites with plumbing materials expected to contain lead or copper (*i.e.*, homes connected to water mains by lead pipes, etc.) to detect elevated levels of chemicals (*e.g.*, lead). In addition, drinking water samples must be first draw following a 6-hour stagnation period to allow for corrosion effects to accumulate. The findings of the sampling efforts are reported to the respective Primacy Agency (*i.e.*, states and tribes with primary enforcement authority under the Safe Drinking Water Act) in accordance with 40 CFR 141.90 of the Lead and Copper rule, and additional actions are taken if elevated levels of lead are present (U.S. EPA, 2010d). See Table 2 for a comparison of constant lead concentrations in drinking water values derived from the identified sources and the current default water lead concentration.

[9]A national database for receiving and storing public water system data has not been established, and the Six-Year Reviews rely on voluntary reporting of data from the states, territories and tribes (U.S. EPA, 2010b).

Table 2. Comparison of constant lead concentration in drinking water values

Source	Constant Water Lead Concentration (µg/L)	Basis for Value	
IEUBK (v. 1.1, Build 11) Model Default[a]	4	Marcus, 1989	American Water Works Service Company, Inc. (AWWSC, 1988)
IEUBK Model (v. 2) Updated Value[b]	0.9	U.S. EPA, 2010a Population-weighted, arithmetic mean estimate of high end exposure data	1998-2005 Six-Year Review-ICR Dataset
Current Analysis	4.89	U.S. EPA, 2010a Arithmetic mean estimate of high end exposure data	1998-2005 Six-Year Review-ICR Dataset
	0.89	U.S. EPA 2010a Population-weighted, arithmetic mean estimate of high end exposure data	1998-2005 Six-Year Review-ICR Dataset
U.S. EPA, 2010b	4.61	U.S. EPA, 2008 U.S. EPA, 2007 U.S. EPA, 2006a Clayton et al., 1999 Moir et al., 1996 Geometric mean	1995-1997 NHEXAS Phase I Field Study, U.S. EPA Region 5[c] 1987 Sampling efforts in Halifax, Nova Scotia, Canada[d]
Clayton et al., 1999	3.92	Mean first-draw tap water	1995-1997 NHEXAS Phase I Field Study, U.S. EPA Region 5[c]
	0.84	Mean flushed tap water	
Moir et al., 1996	16	Mean first-draw tap water	1987 Sampling Efforts in Halifax, Nova Scotia, Canada[d]
	8	Mean flushed tap water	

[a] IEUBK model (v. 1.1, Build 11).

[b] IEUBK model (v. 2). Value represents the population-weighted arithmetic mean estimate of high end exposure data rounded to one significant figure. Value is intended to be a nationally representative water lead concentration found in tap water in the U.S. This value does not represent filtered or bottled water consumption.

[c] Values represent 444 and 443 samples for first-draw and flushed tap water, respectively. Data were collected in U.S. EPA Region 5 from the six states (Illinois, Indiana, Ohio, Michigan, Minnesota, and Wisconsin) between July 1995-May 1997.

[d] Values represent 36 samples collected from single-family homes in the city of Halifax, Nova Scotia, Canada between April and June 1987.

Data obtained from the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a) consisted of 45 States and Primacy Agencies that comprised of 44,257 individual sample monitoring records.[10] On average, 883 water suppliers voluntarily contributed data from each state. The number of suppliers varied from one in Tennessee to 5,557 in Texas. The frequency distribution of lead concentration reported by water suppliers is presented in Figures 1 and 2. From the 44,257 individual sample monitoring records, the calculated mean population per sample is 22,022 observations of PbW for the six-year period. These PbW data were used for this analysis. The order of operations was as follows: (1) all samples multiplied by population (e.g., the reported number of people served by the water supply) weight factor, (i.e., each reported *value * (population / mean population))*; (2) the mean of all samples by location is calculated; and (3) the mean of all means by a population – weighted estimate in the report for all location is calculated (see Table 2). The calculated geometric mean PbW was 4.89 µg/L (95% CI= 4.38 to 5.39 µg/L; see Table 3). In addition, a population-weighted mean PbW of 0.89 µg/L (95% CI= 0.78 to 1.0 µg/L) was calculated based on the population served by each water supplier (see Table 4).

Table 3. Summary statistics for arithmetic mean water lead concentration (µg/L) based on data reported by the U.S. EPA Office of Groundwater and Drinking Water 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a)[a]

Mean	StDev	Min	Max	N	SEM
4.89	54.4	$1x10^{-5}$	$56.3x10^{3}$	44257	0.26

Confidence Limit	T	MinCL (µg/L)	MaxCL (µg/L)
50%	0.674	4.71	5.06
60%	0.842	4.67	5.1
70%	1.036	4.62	5.15
80%	1.282	4.55	5.22
90%	1.645	4.46	5.31
95%	1.960	4.38	5.39
98%	2.326	4.28	5.49
99%	2.576	4.22	5.55

Mean: arithmetic mean water lead concentration; StDev: standard deviation; Min: minimum water lead concentration; Max: maximum water lead concentration, N: number of samples; SEM: standard error of the mean; T: t statistic; MinCL: minimum confidence limit; MaxCL: maximum confidence limit
[a]See U.S. EPA (2010a) for detailed information such as analytical sensitivity, laboratory QA/QC methods, etc.

[10]The monitoring records were voluntarily obtained from 45 States and Primacy Agencies (including two Tribal Nations located in U.S. EPA Region 8 and Region 9), and represented approximately 250 million people nationally. The database did not include data from Kansas, Louisiana, Maryland, Mississippi, New Hampshire, Pennsylvania, and Washington state.

Table 4. Summary statistics for population-weighted arithmetic mean water lead concentration (µg/L) based on data reported by the U.S. EPA Office of Groundwater and Drinking Water 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a)

Mean[a]	StDev	Min	Max	N	S.E.M.
0.89	12.4	7.95×10^{-8}	1.56×10^{3}	44257	5.9×10^{-2}

Confidence Limit	T	MinCL (µg/L)	MaxCL (µg/L)
50%	0.674	0.85	0.93
60%	0.842	0.84	0.94
70%	1.036	0.83	0.95
80%	1.282	0.82	0.97
90%	1.645	0.79	0.99
95%	1.960	0.78	1.01
98%	2.326	0.75	1.03
99%	2.576	0.74	1.04

Mean: population-weighted arithmetic mean lead concentration; StDev: standard deviation; Min: minimum water lead concentration; Max: maximum water lead concentration, N: number of samples; SEM: standard error of the mean; T: t statistic; MinCL: minimum confidence limit; MaxCL: maximum confidence limit

[a]Order of operations: Calculated mean population per sample: 22,022 observations; all samples multiplied by population weight factor: value * (population / mean population); mean of all samples by location; mean of all means by location.

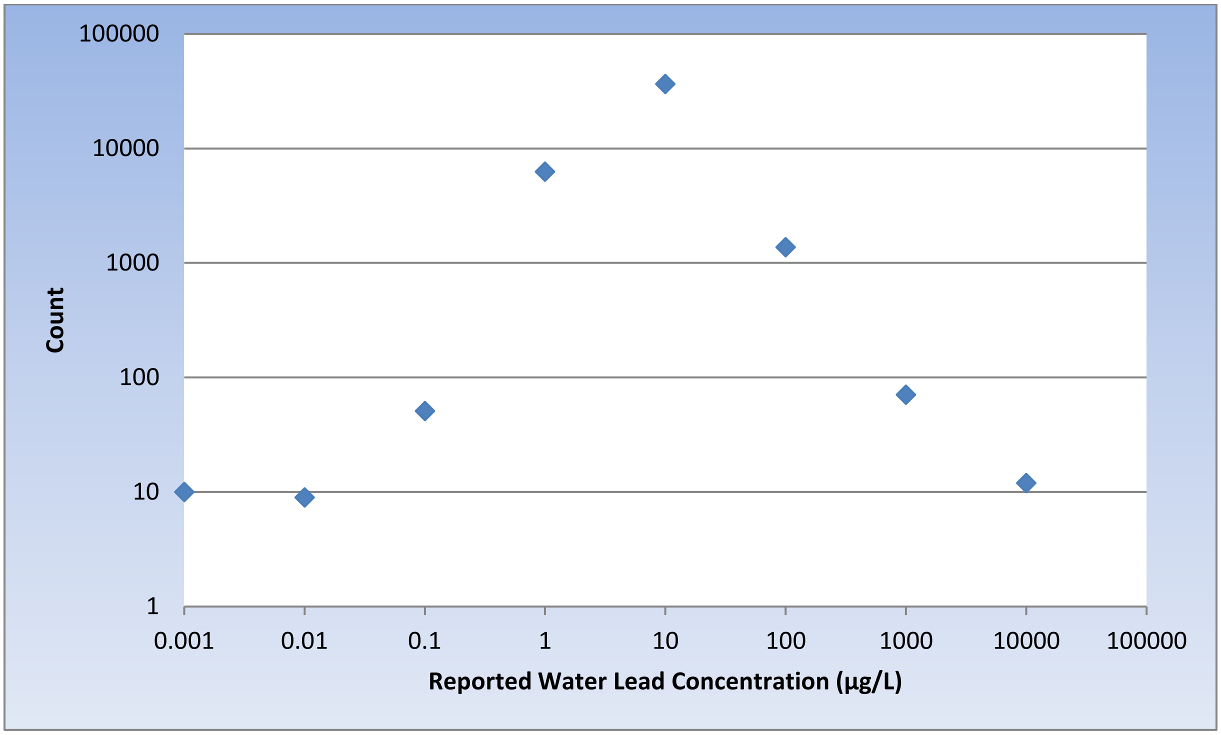

Figure 1. Frequency distribution of arithmetic mean water lead concentration (μg/L) as reported by water suppliers in the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a).

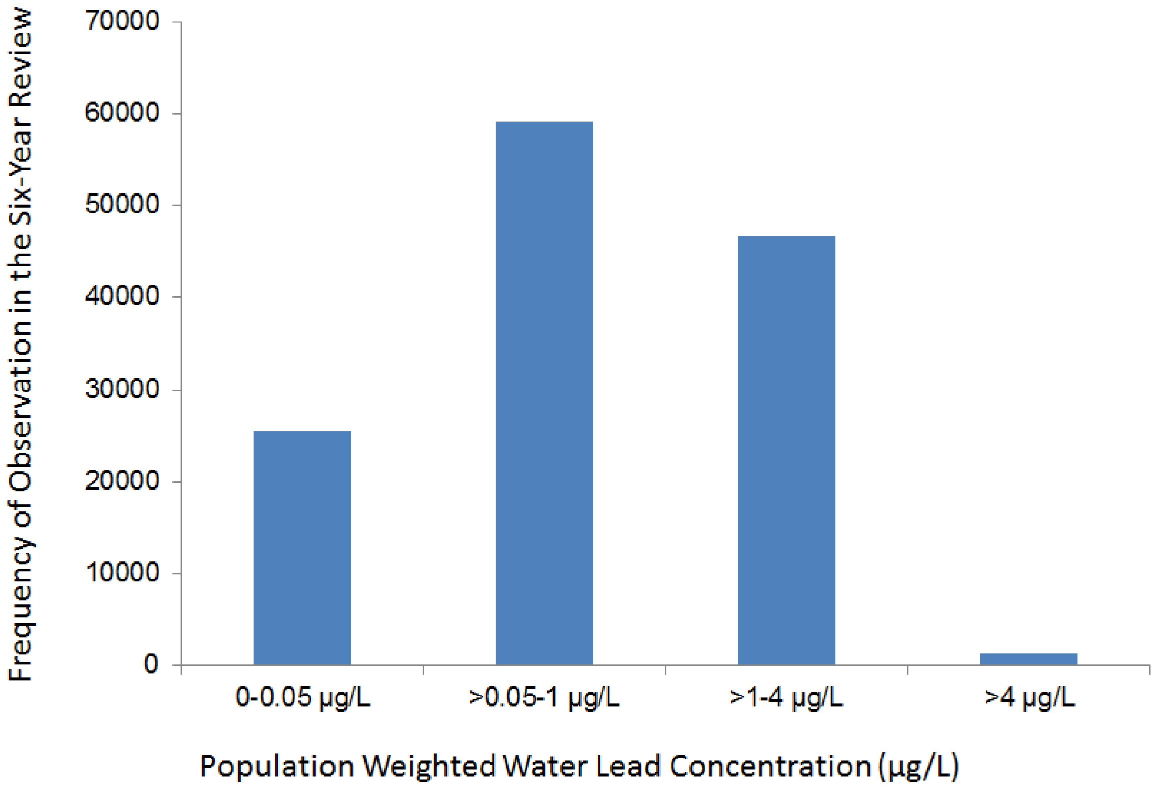

Figure 2. Frequency distribution for the population-weighted water lead concentrations (µg/L) as reported by water suppliers in the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a).

UNCERTAINTY

The lead and copper sampling requirements in the Six-Year Review are not designed to assess mean exposure. Rather, the sampling is intended to detect elevated levels of lead and copper for compliance monitoring purposes. The presence and occurrence of elevated lead and copper in a water system may trigger additional actions to reduce lead and copper exposure. These data likely represent the higher levels of lead found in homes served by public water systems throughout the United States. Further, EPA's Office of Water did not conduct quality assurance activities on the data voluntarily submitted by the states and primary agencies to identify anomalies such as incorrect units, and duplicate samples.

RECOMMENDATIONS FOR THE IEUBK MODEL

As described in U.S. EPA (2006a, 2007, 2008, 2010a,c), the range of values (0.84 to 16 µg/L) observed in Clayton et al. (1999) and Moir et al. (1996) was considered at the time to be representative of randomly sampled residential water in houses constructed since lead pipe and solder were banned for residential use. The mean water lead concentration of 4.61 µg/L value, however, does not address elevated background exposures encountered in homes with Pb piping and/or very corrosive water.[11] The Six-Year Review is considered the "largest and most comprehensive contaminant occurrence dataset ever compiled and analyzed by EPA's Drinking Water Program" in the United States and territories (U.S. EPA, 2010b). The TRW considers this dataset an appropriate source of information to serve as the basis for updating the default water lead concentration variable in the IEUBK model. Based on the analysis outlined in this document, the TRW recommends updating the default *Lead Concentration in Drinking Water* variable in the IEUBK model using the population-weighted mean estimate derived from the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a). This default value is considered appropriate for all applications of the IEUBK model where current and future residential scenarios are being assessed if site-specific information on water lead concentration is not available.

The recommended value for Superfund lead site risk assessment is based on the Office of Water six-year Review data set (see Table 3). The updated default value for water lead concentration, 0.9 µg/L, is shown in Table 1. This default value is to be used when site-specific information is not available.

The TRW recommends replacing the default with site-specific information if representative site-specific information is available that meet the Data Quality Objectives of the site.[12] For example, site-specific data may include water lead concentration sampling or local water compliance monitoring data which report 90^{th} percentile values. Although site-specific measures will best represent drinking water exposure at properties at a site, there may be scenarios where site-specific water concentrations are not available. There may be a need to run exposure scenarios (e.g., future – use scenarios) in the absence of site-specific data (i.e., a default value is necessary for some uses of the IEUBK model). Further information on collecting site-specific water lead concentration data can be found at https://www.epa.gov/superfund/lead-superfund-sites-guidance.

IMPACT ON THE IEUBK MODEL PREDICTIONS

When applying the recommended default water lead concentration value to the IEUBK model (v. 2), together with default values for all other parameters, the geometric mean blood lead concentration for children (0-84 months of age[13]) will decrease from 2.7 to 2.3 µg/dL. Table 5 presents the lead soil PRG values derived from the IEUBK model using the recommended default water lead concentration value with default values for all other parameters. The blood lead levels in Table 5 are used to illustrate the impact when developing a screening level for lead in soil.

[11] The IEUBK model (v. 1,1, build 11) default value (4 µg/L) would be within the confidence limits on the estimate (3.31 to 4.19 µg/L) derived from Clayton et al. (1999). However it was based on one geographical area (i.e., Ohio, Michigan, Illinois, Indiana, Wisconsin and Minnesota) and a relatively minimal sample size (i.e., n = 444) of residential water samples. The data reported in Moir et al. (1996) does not represent a statistically robust sample of the lead concentrations in U.S. drinking water, for the following reasons: (1) the relatively small sample size (n=36); (2) limited geographic area of the sample (one area of Nova Scotia); and (3) the potential contribution of lead from lead pipe mains to the water in the sample. In addition, neither of these sources represent national estimates of lead in drinking water.

[12] To promote defensible and reproducible site investigations and decision making, while maintaining flexibility needed to respond to different site conditions, U.S. EPA recommends the Data Quality Objectives process (U.S. EPA, 2006b). Data Quality Objectives provide a structured approach to collecting environmental data that will be sufficient to support decision-making.

[13] To better align the CDC recommendation and the risk predictions for lead exposure at Superfund sites, the TRW Lead Committee recommends that the default age range in IEUBK model be modified to match the 1-5 year age range (12-72 months).

The proposed default value water lead concentration value is based on the national population-weighted mean estimate derived from the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a); however, this value may not represent subpopulations of children at sites. The IEUBK model will continue to allow for input of site-specific water concentration information (e.g., first-draw, flushed, water fountains) that meet the Data Quality Objectives of the site.

Table 5. Comparison of the IEUBK model output for selected lead concentrations in drinking water

Parameter	Age Range (months)								GM (µg/dL)	P_{10} (%)	PRG for 5% NTE (ppm)	
	0 < 12	12 < 24	24 < 36	36 < 48	48 < 60	60 < 72	72 < 84	12 -71[c]			5 µg/dL (ppm)	10 µg/dL (ppm)
IEUBK Model Default Value (4 µg/L)[a]												
Lead uptake from water (µg/day)	0.375	0.929	0.976	1.004	1.059	1.123	1.146	0.91	2.7	0.3	153	418
Calculated Total Lead Uptake (µg/day)	5.586	8.368	8.593	8.651	7.045	6.720	6.592	7.5				
Calculated Geometric Mean Blood Lead Concentration (µg/dL)	3.0	3.5	3.2	3.0	2.5	2.1	1.9	2.8				
Updated IEUBK Model Default Value (0.9 µg/L)[b]												
Lead uptake from water (µg/day)	0.085	0.210	0.221	0.227	0.239	0.254	0.259	0.20	2.3	0.09	200	605
Calculated Total Lead Uptake (µg/day)	5.311	7.693	7.879	7.911	6.252	5.873	5.725	6.3				
Calculated Geometric Mean Blood Lead Concentration (µg/dL)	2.9	3.2	2.9	2.8	2.3	1.9	1.7	2.6				

GM: Geometric mean blood lead concentration (µg/dL) for 0-84 month age range; P10: Probability of the predicted GM blood lead concentration ≤ 10 µg/dL; PRG: preliminary remediation goal; NTE: not to exceed. The GM, P10 and PRGs are for the 0-84 month age range. To better align the CDC recommendation and the risk predictions for lead exposure at Superfund sites, the TRW Lead Committee recommends that the default age range in IEUBK model be modified to match the 1-5 year age range (12-72 months).

[a] IEUBK Model (v. 1.1, build 11)
[b] IEUBK Model (v. 2) value based on the analysis of the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a) performed for this review.
[c] To better align the CDC recommendation and the risk predictions for lead exposure at Superfund sites, the TRW Lead Committee recommends that the default age range in EPA's tool for determining risk from lead exposure (the Integrated Exposure Uptake Biokinetic Model for Lead in Children; IEUBK model) be modified to match the 1-5 year age range (12-71 months). The values shown are approximate for the 12-71 month age range.

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