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WASHINGTON, D.C. 20460

OFFICE OF
LAND AND EMERGENCY
MANAGEMENT

formerly

OFFICE OF
SOLID WASTE AND
EMERGENCY RESPONSE

MAY 17 2017

MEMORANDUM:

OLEM Directive 9285.6-56

SUBJECT: Transmittal of Update to the Adult Lead Methodology's Default Baseline Blood Lead Concentration and Geometric Standard Deviation Parameters

FROM: Schatzi Fitz-James, Acting Director
Assessment and Remediation Division
Office of Superfund Remediation and Technology Innovation

TO: Superfund National Policy Mangers, Regions 1-10

The purpose of this memorandum is to transmit the document, *Update of the Adult Lead Methodology's Default Baseline Blood Lead Concentration and Geometric Standard Deviation Parameters and the Integrated Exposure Uptake Biokinetic Model's Default Maternal Blood Lead Concentration at Birth Variable.* The recommendations in this document provide the technical basis for updating the default baseline blood lead concentration and default geometric standard deviation input parameters of the Adult Lead Methodology and maternal blood lead concentration in the Integrated Exposure Uptake Biokinetic Model. This document is primarily intended for Regional risk assessors and others involved in assessing risk to lead at residential and non-residential sites.

The Adult Lead Methodology (ALM) is used to assess lead risks from the soil for non-residential Superfund site scenarios. The Integrated Exposure Uptake Biokinetic Model (IEUBK) is used to assess lead risks from soil at residential Superfund site scenarios. The baseline blood lead concentration input parameter of the ALM represents the geometric mean blood lead concentration in women of child-bearing age and the geometric standard deviation (GSD) input parameter is a measure of the inter-individual variability in these concentrations. The *Mother's Blood Lead Concentration at Childbirth* (MatPb) allows the user to consider the impact of lead transferred from the mother to the fetus *in utero*.

Default values for these input parameters were originally derived from an analysis of blood lead data for U.S. women 17-45 years of age, from Phase I (1988 to 1991) of the Third National Health and Nutrition Examination Survey (NHANES III) as well as consideration of available site-specific data on blood lead concentrations and GSD values. EPA prepared updated estimates for these two parameters in 2002 (using data from NHANES 1988 to 1994) in 2009 (using data from NHANES 1999 to 2004) and again in 2016 (using data from NHANES 2007 – 2012). The proposed updated estimates for the ALM and IEUBK are based on the most recent six years of PbB data (using data from NHANES 2009-2014).

This document and other efforts related to addressing lead in soil can be found on the Internet at https://www.epa.gov/superfund/lead-superfund-sites-guidance. If you have any questions, please contact me or have your staff contact Michele Burgess (Burgess.Michele@epa.gov).

Attachment

1. "Update of the Adult Lead Methodology's Default Baseline Blood Lead Concentration and Geometric Standard Deviation Parameters and the Integrated Exposure Uptake Biokinetic Model's Default Maternal Blood Lead Concentration at Birth Variable"

cc:

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FAQ:

Concerning appropriate use of the new NHANES values (May 2017) for the Adult Lead Methodology (ALM) and Integrated Exposure Uptake Biokinetic Model, this FAQ provides some important caveats for using the updated values.

OLEM recognizes adverse health effects at blood lead concentrations below 10 µg/dL[1]. Accordingly, OLEM is updating the soil lead strategy to incorporate this new information. However, the release date for the updated strategy is pending.

In the interim, the TRW Lead Committee is recommending the following considerations for all non-residential risk assessments where lead is a contaminant of concern:

1. The updated NHANES values are appropriate for lead risk assessments for residential and non-residential exposures both in assessing risk and in developing preliminary remediation goals (PRGs) for your site.
2. Lead risk assessments should include a discussion of the most current toxicity information and Centers for Disease Control and Prevention Reference level[1].
3. Consistent with risk management bests practices, caution should be applied when implementing cleanup levels based on the updated NHANES values for non-residential scenarios (PRGs are greater than 2000 ppm using default values). Ineffective controls or incorrect land use assumptions could have potentially greater health consequences on children who are exposed (*e.g.*, by visiting, trespassing, or tracking the material to the residence) to these high concentrations (especially given the new toxicity information).

Users are encouraged to contact the technical support hotline, TRW Lead Committee, or regional risk assessor with any questions.

[1] See 2006 Air Quality Criteria Document for Lead (AQCD), 2012 Federal Advisory Committee on Childhood Lead Poisoning Prevention to the Centers for Disease Control and Prevention (ACCLPP), 2012 National Toxicology Program (NTP) Monograph: Health Effects of Low Level Lead, and 2013 Children's Health Protection Advisory Committee (CHPAC) Letter to Acting Administrator Perciasepe concerning Childhood Lead Poisoning Prevention

UPDATE OF THE ADULT LEAD METHODOLOGY'S DEFAULT BASELINE BLOOD LEAD CONCENTRATION AND GEOMETRIC STANDARD DEVIATION PARAMETERS AND THE INTEGRATED EXPOSURE UPTAKE BIOKINETIC MODEL'S DEFAULT MATERNAL BLOOD LEAD CONCENTRATION AT BIRTH VARIABLE

OVERVIEW

Since 1994, the Office of Land and Emergency Management (OLEM) (formerly known as the Office of Solid Waste and Emergency Response) 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 residential sites. The IEUBK model uses data from a variety of scientific studies of lead biokinetics, contact rates of children with contaminated media, and data on the presence and behavior of environmental lead to predict a plausible distribution or geometric mean (GM) of blood lead (PbB) for a hypothetical child or population of children. From this distribution, the IEUBK model estimates the risk (*i.e.*, probability) that the PbB concentration of an individual child or a population of children will exceed a specified blood lead level.

Studies have demonstrated that there is no significant placental/fetal barrier for lead, since fetal blood lead values are either equal to or slightly less than maternal blood lead values (Goyer, 1990). The *Mother's Blood Lead Concentration at Childbirth* (MatPb) variable in the IEUBK model allows the user to consider the impact of Pb transferred from the mother to the fetus *in utero*. The Pb that is stored in the tissues of the newborn child in the IEUBK model is calculated by entering the maternal PbB value at the time of birth.

In 1996, the Technical Review Workgroup for Lead (TRW) recommended the use of the Adult Lead Methodology (ALM) (U.S. EPA, 1996) for assessing risks to adults from exposures to lead in soil at non-residential Superfund sites.

The background blood lead concentration (PbB_0) parameter in the ALM represents the geometric mean (GM) blood lead concentration (PbB) (μg/dL) in US women of child-bearing age[1]. The geometric standard deviation parameter (GSD_i) is a measure of the inter-individual variability in blood lead concentrations in a population whose members are exposed to the same non-residential environmental lead levels. Default values for both PbB_0 and GSD_i were originally derived from an analysis of blood lead data for U.S. women 17–45 years of age, from Phase 1 (1988 to 1991) of the Third National Health and Nutrition Examination Survey

[1] The estimates do not include institutionalized women (e.g., residents of nursing homes; https://wwwn.cdc.gov/Nchs/Data/Series/sr02_162.pdf)

(NHANES), as well as consideration of available site-specific data on PbBs and GSDs (U.S. EPA, 1996). The TRW prepared updated estimates for these two parameters in 2002, 2009, and 2016 using data from Phase 1 and 2 (1988 to 1994; 1999 to 2004; 2007 to 2012) of NHANES (U.S. EPA, 2002, 2009, 2016 respectively).

The purpose of this report is to provide updated estimates for the PbB_o and GSD_i variables in the ALM, as well as to identify an updated estimate for the MatPb variable in the IEUBK model using more recent NHANES survey data. The Centers for Disease Control (CDC) releases data from the continuous NHANES in 2-year cycles; however, it is recommended to use four or more years of data when estimating parameters for demographic sub-domains (Johnson et al., 2013). The current estimates for the ALM and IEUBK model are based on the most recent six years of PbB data (2009-2014) from the National Health and Nutrition Examination Survey (NHANES) (CDC, 2012a,b, 2014a,b) and are presented in Table 1.

Table 1. Updated estimates of the PbB_o and GSD_i for 17-45 year old women based on NHANES (2009-2014).

Parameter[a]	Estimate	90% Confidence Interval	
		Lower Confidence Limit	**Upper Confidence Limit**
GM (PbB_o)	0.64	0.62	0.66
GSD (GSD_i)	1.80	1.76	1.85

[a]Forty-seven (1.3% of the sample) of the blood lead measurements were below the detection limit of 0.25 µg/dL and were assigned values of ½ the detection limit (0.125 µg/dL). The 2013-2104 data used an updated detection limit of 0.07 µg/dL and all were detections.

This document provides the technical basis for updating the PbB_o and GSD_i parameters in the ALM and the MatPb variable in the IEUBK model. This document details how the updated estimates for the parameters were calculated. The intended audience for this document is risk assessors who are familiar with using the ALM and IEUBK model. For background and further detail on the use of the ALM or the IEUBK model in Superfund lead risk assessment, please refer to U.S. EPA (2003, 1994, respectively) or the TRW website (https://www.epa.gov/superfund/lead-superfund-sites-software-and-users-manuals).

Technical Analysis

Information on PbB for non-institutionalized U.S. women 17–45 years of age was extracted from the NHANES database (CDC, 2012a, 2012b, 2014a, 2014b, 2017a, 2017b). Data from three 2-year cycles of the continuous NHANES (2009-2014) were used in this analysis in accordance with CDC recommendations (Johnson et al., 2013).

Estimates for MatPb, PbB_0 and GSD_i were calculated using SAS® software, Version 9.4 of the SAS System for Microsoft Windows[2]. Parameter estimates used the sample weights provided in the NHANES demographic data files (CDC, 2012b, 2014b, 2017b). Standard errors for the GM (MatPb and PbB_0) and GSD were estimated using the sample weights and the masked variance units (*i.e.*, pseudo-strata and pseudo-primary sampling units which are also provided in the NHANES demographic files). The sample weights account for the unequal probabilities of selection of survey participants, the non-response of some participants, and are adjusted to population controls. The masked-variance units account for the multistage sampling design and are necessary to estimate accurate standard errors for parameter estimates. Standard errors for the estimates of the GM were estimated using the Taylor linearization method in the *SURVEYMEANS* procedure in SAS. The standard errors for the GSD were estimated using a SAS macro[3] that implements a jackknife method.

The detection limit for the NHANES 2013-2014 survey cycle data is 0.07 µg/dL; the 2013-2014 data do not include any non-detects. The detection limit for the 2009-2012 data is 0.25 µg/dL. Results in the 2009-2012 data reported at less than the detection limit were assigned a value of ½ the detection limit (0.125 µg/dL). To evaluate the effect of the method used to handle non-detects on the estimates, the PbB_0 and GSD_i were also calculated using two alternate methods for handling non-detects: assigning non-detects (1)¼ the detection limit and, (2) the detection limit. The effect on the PbB_0 was approximately 0.005 µg/dL while the effect on the GSD_i was less than 0.05. An extensive sensitivity analysis performed with the 1999-2004 NHANES PbB data showed the estimated PbB_0 and GSD_i were not sensitive to the method that was used to treat the non-detects (U.S. EPA, 2009). Given the rate of non-detects in the 2009-2014 PbB data (1.3%) is substantially lower than the rate of non-detects in the 1999-2004 PbB data (2.2%), additional effort is not necessary to conclude that the method used to treat the non-detects will not have a substantial effect on the estimates of the PbB_0 and GSD_i.

The PbB data were reviewed for the possible presence of extreme sampling weights, which could have an undue influence on the estimates of the PbB_0 and GSD_i. The maximum sampling weight in the 2009-2014 NHANES PbB data was less than 5 multiples of the interquartile range greater than the median and less than 5 times the average sampling weight; therefore, there does not appear to be any need to truncate (trim) the sampling weights (Chowdhury et al., 2007).

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[2]SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc. in the USA and other countries.

[3]Confidence limits for the GM and GSD were estimated with a SAS macro that employs the 'leave one out' jackknife method (*e.g.*, Sarndal, et al. 1991).

IMPLICATIONS FOR THE ADULT LEAD METHODOLOGY (ALM)

The PbB_0 and GSDi are estimated to be 0.6 µg/dL, and 1.8, respectively. Table 2 presents the updated estimates as well as the estimates from the previous analyses.

Table 2. Geometric mean baseline blood lead concentration (PbB_0, µg/dL) and geometric standard deviation (GSD_i) estimates and ALM calculation of Preliminary Remediation Goals (PRGs) for the 5% probability that a fetus' blood lead level will not exceed a 5 µg/dL blood lead level [$P(PbB_{fetal}>PbB_t)$] compared to estimates from the previous analyses.

NHANES Data (ALM)	N	Detection Limit	PbB_0 (µg/dL)	GSD_i	ALM Output: $P(PbB_{fetal}>PbB_t)$	ALM Output: Soil PRG for PbB_t = 5 µg/dL (ppm)
1988-1991 [a]	-	-	1.7-2.2 (1.95)[f]	1.8-2.1 (1.95)	5%	n/a
1988-1994 [b]	5,016	1.0	1.5	2.1	5%	97
1999-2004 [c]	4,589	0.3	1.0	1.8	5%	773
2007-2012 [d]	4,256	0.25	0.7	1.7	5%	1126
2009-2014[e]	3,683	0.07, 0.25[g]	0.6	1.8	5%	1050

[a]U.S. EPA, 1996
[b]U.S. EPA, 2003
[c]U.S. EPA, 2009
[d]U.S. EPA, 2015
[e]Current Update

[f]Values in parentheses represent the midpoint between the upper and lower values.

[g]Detection limits for 2009-2012 and 2013-2014 are 0.25 µg/dL and 0.07 µg/dL, respectively (the 2013-2014 data do not include any non-detects).

Implications for the IEUBK Model

The proposed geometric mean value for the MatPb variable is estimated to be 0.6 µg/dL. The update for the IEUBK model recommends that the IEUBK model be used for the 12-71 month age range, so changes to the MatPb variable have little impact on results.

Uncertainty

As blood lead levels continue to decline in the U.S. population, the number of non-detects in the NHANES data has the potential to become an important source of uncertainty in estimates of PbB and GSD. However, the detection limit for measuring lead concentration in blood has also decreased from 1.0 µg/dL (1988–1994 NHANES) to 0.3 µg/dL (1999-2004 NHANES) and to the current levels of 0.25 µg/dL and 0.07 µg/dL (2007-2012 and 2013-2014 NHANES, respectively). In addition, the rate of non-detects in the 2007-2012 NHANES data (1.1%) and the 100% detection rate in the 2013-2014 NHANES are much lower than the rate of non-detects in the 1999-2004 and 1988–1994 NHANES data (~2 and ~21%, respectively). The lower detection limit and lower-rates of non-detects removes a considerable source of uncertainty that was present in previous estimates of the GM (U.S. EPA, 2009).

RECOMMENDATIONS FOR THE ALM

Consistent with U.S. EPA (2009), estimates of the PbBo and GSDi are provided for the population of non-institutionalized U.S. women 17–45 years of age. Like the earlier analysis, the TRW Lead Committee continues to recommend using a single national estimate. Based on the analysis of the NHANES 2009-2014 data, the updated values for the PbB_o and GSD_i parameters, 0.6 µg/dL and 1.8, respectively, are recommended for all applications of the ALM where current and future use scenarios are assessed (see Table 3).

Table 3. Current and previous PbB_o and GSD_i parameter values shown in the ALM *PRG calculation* tab of the ALM spreadsheet. Calculations of PRGs 5% probability that a fetus' blood lead level will not exceed a 5 µg/dL blood lead target level.

Variable	**Description of Variable**	**Units**	**Current** **GSDi and PbB_o from Analysis of NHANES: 2009-2014**	**Previous** **GSDi and PbB_o from Analysis of NHANES 1999-2004**
$PbB_{fetal, 0.95}$	95th percentile PbB in fetus	µg/dL	5	5
$R_{fetal/maternal}$	Fetal/maternal PbB ratio	--	0.9	0.9
BKSF	Biokinetic Slope Factor	µg/dL per µg/day	0.4	0.4
GSD_i	Geometric standard deviation PbB	--	1.8	1.8
PbB_o	Baseline PbB	µg/dL	0.6	1.0
IR_S	Soil ingestion rate (including soil-derived indoor dust)	g/day	0.050	0.050
$AF_{S, D}$	Absorption fraction (same for soil and dust)	--	0.12	0.12
$EF_{S, D}$	Exposure frequency (same for soil and dust)	days/yr	219	219
$AT_{S, D}$	Averaging time (same for soil and dust)	days/yr	365	365
PRG	**Preliminary Remediation Goal Soil Lead Concentration where PbB_t = 5 µg/dL**	**ppm**	**1050**	**773**

Recommendations For the IEUBK Model

Based on the analysis of the NHANES 2009-2014 data, 0.6 µg/dL is recommended as the updated value for the *Mother's Blood Lead Concentration at Childbirth* (MatPb) variable. This default value is appropriate for all applications of the IEUBK model where current and future residential scenarios are being assessed (see Figure 1). The TRW Lead Committee does not recommend changing this value unless representative site-specific information is available that meet the Data Quality Objectives of the site.

The empirical validation effort for the IEUBK model did not include data specific to the disposition of maternally supplied lead in a young child, and the IEUBK model predictions during the first few months of life related to this should be interpreted with caution.

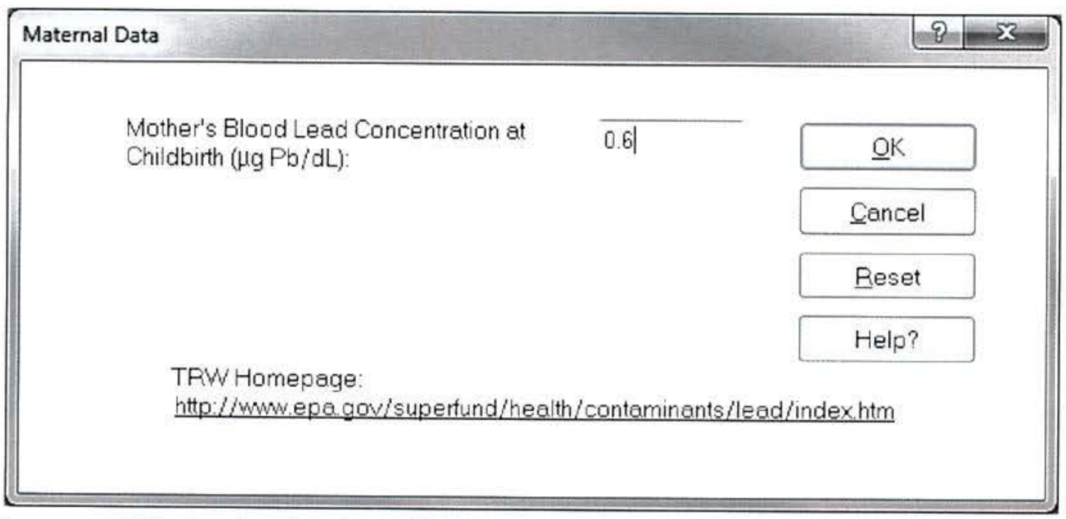

Figure 1. Proposed *Mother's Blood Lead Concentration at Childbirth* (MatPb) default value for the IEUBK model.

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