#### ESTIMATION OF AGE-SPECIFIC SOIL AND DUST INGESTION RATES FOR U.S. CHILDREN: UPDATE TO THE DEFAULT VALUES 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 or 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) exposed to lead from several sources 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 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 (U.S. EPA, 2020).<sup>1</sup> 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.<sup>2</sup> From the 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 concentration (U.S. EPA, 1998, 1994a; White et al., 1998).

Ingestion of fine soil and dust particulates, especially by young children, is the dominant route of exposure for lead. (Laidlaw et al., 2014; Landrigan et al., 1975; Lanphear et al., 1998, 2003). Childhood soil and dust ingestion occurs via multiple pathways, including hand-to-mouth transfer, mouthing of objects, and contaminated food. The rate at which soil and dust is ingested are dependent on a child's age, individual behaviors, exposure time, total dust and soil accessible and environmental conditions (Zahran et al., 2013a,b). Age-specific estimates of the soil and dust ingestion rate pathway are needed to assess children's exposures in the home or play environment, and to make informed cleanup decisions.

<sup>&</sup>lt;sup>1</sup> The GM represents the central tendency estimate (*e.g.*, mean, 50<sup>th</sup> 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.

<sup>&</sup>lt;sup>2</sup> 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 blood lead concentration along with the distribution of possible blood lead concentrations in a population of similarly exposed children. In the IEUBK model, the GSD encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability. The GSD is **not** intended to reflect variability in blood lead concentrations where different individuals are exposed to substantially **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).

The soil and dust ingestion rate is one of the most influential variables in the IEUBK model for lead in children (U.S. EPA, 1994a).

Early estimates of soil and dust ingestion rate in children were based on studies of trace elements in soil and feces (Battelle, 2005; Doyle et al., 2010; Sedman and Mahmood, 1994; U.S. EPA, 2011, 2012). The default values for the Age-Dependent Soil and Dust Ingestion Rate variable in the IEUBK model (v. 1.1, build 11) represent age-specific central tendency estimates for lead intake from soil and dust for children (6 to 84 months of age). The default values (v.1.1, build 11) are based on these tracer studies from a literature review and analysis performed during a review of the National Ambient Air Quality Standards (NAAQS) for lead (U.S. EPA, 1989, pp. A-16). The default soil and dust ingestion rate values are based on a study of soil ingestion in children (Sedman et al., 1989). This study utilized trace elements to quantify soil ingestion rates. The initial calibration of the IEUBK model employed these default values, and the results of a validation study performed in the early 1990s showed reasonably close agreement between model estimates using these intake values and empirical blood lead measurements (Hogan et al., 1998). The study that formed the basis for the existing default values did not, however, account for several factors that should be considered when designing a soil dust ingestion study (e.g., sieve to the currently recommended size fraction<sup>3</sup>, sample household dust, soil outside of individual vards or the bioavailability of the lead in ingested soil or dust).

The purpose of this document is to provide the technical basis for an analysis of the currently available published literature to support an updated *Age-Dependent Soil and Dust Ingestion Rate (IRsd)* variable in the IEUBK model (Table 1). The updated age-specific soil and dust ingestion rate estimates for the *Age-Dependent Soil and Dust Ingestion Rate* variable in the IEUBK are based on soil and dust ingestion rates from scenario 3 of von Lindern et al. (2016). As described below in the Technical Analysis Section, this study was selected because it was determined that the approach employed by the authors provides the best central tendency estimate of age-specific soil and dust ingestion rates for use in the IEUBK to support risk assessments conducted under CERCLA or RCRA corrective action authority. The soil-dust ingestion rates from Scenario 3 results in soil-dust ingestion rates that are supported by other independent analyses that use dermal transfer to estimate soil and dust ingestion rate, specifically the modeled estimates from Ozkaynak et al. (2011) and Wilson et al. (2013) (see Table 2).

Soil/dust ingestion studies reviewed for this effort are not intended to specifically represent soildust ingestion for children who engage in pica behavior. The intake estimates for soil pica behavior would be greater than intake estimates for incidental ingestion of soil-dust, but reliable data for pica ingestion rates or frequency are not available<sup>4</sup>.

The intended audience for this document is human health risk assessors familiar with using the IEUBK model in support of CERCLA and RCRA corrective action risk assessments. For further background information on both this variable and 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).

<sup>&</sup>lt;sup>3</sup> Particle size should be similar to the fraction that adheres to skin to reflect the particles that are incidentally ingested during hand-to-mouth activity.

<sup>&</sup>lt;sup>4</sup> See Chapter 5 of US EPA Exposure Factors Handbook for more information on pica.

			Basis for Age-					
Source	0<12	12<24	24<36	36<48	48<60	60<72	72<84	Specific Value
IEUBK Model Defaultª	85	135	135	135	100	90	85	<u>Methodology</u> U.S. EPA, 1989 <u>Data Source</u>
Revised Soil/Dust Ingestion Rate	86	94	67	63	67	52	55	<u>Methodology</u> von Lindern et al., 2016 Ozkaynak et al., 2011 Wilson et al., 2013 <u>Data Source</u> von Lindern et al., 2016

Table 1. Recommended revision to default age-specific soil/ dust ingestion rates (mg/day) in the IEUBK model

<sup>a</sup>IEUBK model v. 1.1, build 11.

#### **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 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, validated method 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 from site to site.

To promote defensible and reproducible risk assessments and cleanup plans, while maintaining flexibility needed to respond to different site conditions, U.S. 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 initial default IEUBK total soil and dust ingestion rates were used in the development of the NAAQS (U.S. EPA, 1989). Rather than adding new data, many of the published studies since the initial default values were adopted in 1994 were reanalyzed data from previous studies. Moreover, the TRW identified a number of limitations of the re-analyses of the data that were published after 1994. For example, Stanek and Calabrese (2000) included estimates of daily soil ingestion that were significantly negative, biased by large negative values in the data. The decision to include the negative values and their consequent impact on the results was never addressed by the authors (Stifelman 2006). We have identified several newer and relevant studies on soil/dust ingestion from seven sources: Arnot et al., 2010; Bierkens and Cornelis, 2006; Jang et al., 2014; Ozkaynak et al., 2011; Stanek et al., 2012a,b; von Lindern et al., 2016; Wilson et al., 2013.

To evaluate these studies, the TRW Lead Committee used a data quality objective (DQO) approach (see Attachment 1). This approach (working through the first four steps of the DQO process) allowed the Committee to focus on identifying studies that provided information that would support a revision of the default age-specific soil-dust ingestion rates for use in the IEUBK model for assessing lead exposure at CERCLA and RCRA corrective action sites. Table 2 provides a summary of these literature sources.

The following studies were evaluated to support a revision to the soil and dust ingestion rate default parameter in the IEUBK. Arnot et al. (2010) described the Farfel Exposure Model (FHX) employed by Health Canada, which uses a soil/dust ingestion rate of 65 mg/day for children age 5-11 years, and 100 mg/day for toddlers (age 6-60 months). Bierkens and Cornelis (2006) derived a range of soil/dust ingestion values (23.2 to 116 mg/day assuming an 8-hour waking and outdoor period [alternate values for 12-hour waking and outdoor period shown in Table 2]) based on probabilistic modeling of other mouthing frequency and hand loading publications. A 4-day fecal study of Korean children age 0 to 84 months, using the limiting tracer method, calculated an arithmetic mean soil/dust ingestion rate of 118 mg/day and a geometric mean of 29.3 mg/day (Jang et al., 2014; tracer-specific data not provided in study). Ozkavnak et al. (2011) estimated a mean soil/dust ingestion rate for children 3 to 6 years of age (as compared to the age range of the IEUBK model which is children <72 months old) using stochastic human exposure and dose simulation (SHEDS) modeling, using activity diaries to estimate hand-tomouth, and object-to-mouth contact rates. Stanek et al. (2012a,b) conducted a meta-analysis of their earlier four mass balance studies using stochastic modeling of the most reliable tracers of children from Amherst, Massachusetts; Anaconda, Montana; and Washington State. Soil pica data were excluded from their analysis. Soil/dust ingestion rates for children in specific age classes are shown in Table 2; an overall mean soil/dust ingestion rate of 25.5 mg/day (95<sup>th</sup> percentile 79.4 mg/day) was estimated. Similar to Ozkaynak et al. (2011), Wilson et al. (2013) calculated soil and dust ingestion rates using a mechanistic model including parameters for particle loading on skin, transfer to hands, hand surface area, mouthing surface area, hand-tomouth frequency, saliva dissolution, and exposure time using deterministic and probabilistic methods. Results, which are dependent on exposure time, were calculated separately for soil and dust, then summed for a daily soil/dust ingestion rate.

In addition, the information available on soil and dust ingestion rate values in EPA's Exposure Factors Handbook (U.S. EPA, 2017) was also considered as part of this effort but was not included in the peer review of this document (which preceded the release of the Exposure Factors Handbook update). The difference between the soil and dust ingestion rate values in the Exposure Factors Handbook (U.S. EPA, 2017) and those proposed herein was addressed by the Office of Research and Development evaluation of the IEUBK model. (U.S. EPA, 2020).

The study by von Lindern et al. (2016) satisfies many of the evaluation criteria described in the TRW Lead Committee's DQOs (see Attachment 1). The authors of that study used environmental information collected at the Bunker Hill Mining and Metallurgical Complex Superfund Site (BHSS) site in Idaho to compare archived soil and dust samples from the BHSS to children's blood lead levels monitored from 1989 through 2002 to calculate soil/dust ingestion rates using the IEUBK model. Over 15 years of active cleanup, the Lead Health Intervention Program amassed approximately 5,400 blood lead observations (referred to as the parent database) from nearly 2,340 children (ages 0-9 and with a >50% participation rate) and yielding 2,176 records of blood/soil/dust lead concentrations. The study by von Lindern et al. (2016) used measured peak blood leads, community soil, neighborhood soil, yard soil concentration, house dust concentration and bioavailability information with IEUBK model defaults for Air, Water, and Diet to estimate soil-dust ingestion rates (IRs<sub>D</sub>) under different Structural Equations Modeling (SEM) scenarios.

In the Bunker Hill study, four variables were used to quantify soil and dust exposures: house dust, yard soil, neighborhood soil (the mean of all yard soils within 200, 500, and 1000 feet of the home, excluding the home's yard), and community soil (the mean of all yard soils within the community, excluding the home's yard and neighborhood). The 271 samples (193 house dust samples, 73 yard soil samples and 5 quality control samples) were sieved to 80 mesh (to account for the particle size that would likely adhere to a child's hands) and analyzed for total lead and bioavailability.

The default assumption for the IEUBK model is that the source of soil ingested is 55% dust and 45% yard soil (U.S. EPA, 1994b). Structural Equations Modeling (SEM) was used to evaluate three different scenarios of yard soil to dust, neighborhood soil, and community soil:

- 1. 55% house dust/45% yard soil (as currently in the IEUBK model),
- 2. 40% house dust/30% yard soil/30% community soil, (alternatively using arithmetic or geometric means for community soil) and
- 3. 50% house dust/25% yard soil/10% neighborhood soil/15% community soil (alternatively using arithmetic or geometric means for neighborhood and community soil).

	Soil/Dust Ingestion			
~	Rate			
Source	(mg/day)	Age Range	n	Summary of Evaluation
IEUBK Model	85-135	Children 0-84	77	Existing IEUBK model soil-dust ingestion rates Based on technical analysis to
Default		months (yearly		support the NAAQS for Lead (U.S. EPA, 1989).
Values <sup>a</sup>		values)		
Arnot et al.,	100	Children 6 60	n/a <sup>b</sup>	Is not considered a support document for revising the soil/dust ingestion rate
2010		months (age		because these are assumed input parameters for an exposure model using
		range)		exposure factors for the general population of Canada. They are based on Health
	65	Children age 5 to		Canada 1998, which is based on Binder et al., (1986), Clausing et al. (1987),
		144 months (age		Calabrese et al. (1989), and Van Wijnen et al. (1990). Farfel Exposure Model
		range)		(FHX) and Health Canada. 1998. <sup>b</sup>
Bierkens and	23.2-116	Children 12-84	5,000 (model	Supportive study based on the limited number of observations Ranges of
Cornelis,		months (age	runs)	ingestion rates derived from probabilistic modeling of data from other
2006 <sup>c</sup>		range)		publications reporting mouthing frequency and hand loading (Holmes et al.,
		8-hr awake and		1999; AuYeung et al., 2003; and U.S. EPA exposure factors, 2017).
		outdoors		
	34.8-174	Children 12-84		
		months (age		
		range)		
		12-hr awake and		
		outdoors		
Ozkaynak et	68	Children 36-72	1,000 (model	Supportive study based on lack of new observation data. The estimates are based
al., 2011		months (age	runs)	on modeling using SHEDS and hand-to-mouth and object-to-mouth contacts.
		range)		
		Mean value		
Jang et al.,	118	Children 0-96	58 samples	New tracer data based on Korean children. Estimates based on aluminum. The
2014		months		publication lacked details of the study. Only feces and soil-dust collected. 5
		Arithmetic mean		children were used as control group to compensate for exposure from other
	29.3	Children 0-96	58 samples	sources.
		months Geometric		
		mean		

# Table 2. Data summary of average soil/dust ingestion rates in children from selected studies.

	Soil/Dust			
	Ingestion			
	Rate			
Source	(mg/day)	Age Range	n	Summary of Evaluation
Stanek et al.,	3.8	Children 12 to	39 samples	Meta-analysis of four existing mass balance studies. The reanalysis of existing data is not
2012a,b		36 months old		a direct measurement and is not considered a candidate for supporting a revised default
	20.6	Children 24 to	55 samples	age-specific soil-dust ingestion rate
		36 months old		
	32.2	Children 36 to	47 samples	
		60 months old		
	40.9	Children 48 to	75 samples	
		108 months		
		old		
U.S EPA	40 - 90	Children < 6	241 in key	The overall rating was low based on criteria of Soundness, Applicability and Utility,
Exposure		months, 6	tracer studies,	Clarity and Completeness, Variability and Uncertainty, and Evaluation and Review.
Factors		months to $< 1$ ,	2,599	
Handbook		1 to <2 years,	biokinetic	
(2017)		2 to <6 years,	modeling	
		1  to  < 6  years,	studies,	
		6  to < 12  years	modeled	
			estimates of	
			1,000	
			individuals and	
			individuals and	
von Lindom	50.04d	Children 10 to	200,000 trials.	Poonalyzic of archived soil and dust data from Punker Hill Superfund Site, available
ot al 2016	5 <b>2-</b> 94"	70 months old	PbB and	information includes bioavailability data, particle size and children's blood load lovels
et al., 2010		(vearly values)	environmental	monitored (in some cases longitudinal data) from 1088-2002. Evaluated various
		(yearly values)	values used for	combinations of dust vard soil neighborhood soil and community soil Accurately
			model runs)	predicted peak annual blood lead from children representing greater than 50% of all
			model runs)	resident children for 15 consecutive years
Wilson et	61	Toddlers 7 to	200,000	The study is considered a supportive study due to new modeled data. This study models
al., 2013	-	60 months	(model runs)	soil/dust ingestion rates in Canada using hand-to-mouth transfer.
	55	Children 60 to		, , , , , , , , , , , , , , , , , , , ,
		144 months		

<sup>a</sup>IEUBK model v. 1.1, build 11.

<sup>b</sup>Health Canada values based on data from Binder et al., 1986; Clausing et al., 1987; Calabrese et al., 1989; and Van Wijnen et al., 1990.

<sup>c</sup>Study reports values in units of mg/hr. The range (2.9-14.5 mg/hour) was converted to mg/d assuming both an 8-hour and a 12-hour waking and outdoor period. <sup>d</sup>Results of Structural Equations Modeling (SEM) assuming 50% dust, 25% yard soil, 10% neighborhood soil, and 15% community soil.

<sup>e</sup> von Lindern et al. (2016) employed a hybrid approach that measured peak blood leads, particle size, community soil concentration, neighborhood soil concentration, yard soil concentration, as well as house dust concentration, and used IEUBK Modeled defaults for Air, Water, and Diet to estimate IRs under different SEM scenarios to select the model which best fit the empirical distribution of blood leads, representative of over 50% of the community for 15 consecutive years.

<sup>f</sup> 985 is the sum of 12-72 month old children in the 50/25/10/15 partition from Table S-1 of Supplemental Material to von Lindern et al. (2016).

The authors selected the model that provided the best fit to the empirical distribution of blood leads, which represented over 50% of the community for 15 consecutive years. Though ingestion rates for all three scenarios were similar, scenario 3 above had the lowest sum of squared error (SSE) in the statistical evaluation<sup>5</sup>. For this scenario, the authors derived age-specific, arithmetic mean soil/dust ingestion rates ranging from 52 to 94 mg/day for children age 1 to 6 years, with 95% confidence intervals ranging from 47 to 106 mg/day (Table 3). The other two scenarios were less acceptable because they did not fit the data as well.

Table 3. Soil/dust ingestion rates for the 50% house dust/25% yard soil/10% neighborhood soil/15% community soil scenario for the 12-71 month age range that is used in the IEUBK model (von Lindern et al., 2016).

		AvgIR	Percentiles						
Agea	n	(95% CI) <sup>b</sup>	5	10	25	50	75	90	95
0-12	54	86 (66, 105)	17	27	38	72	94	165	221
13-24	174	94 (82, 106)	16	22	42	69	123	188	250
25-36	202	67 (59, 75)	10	19	28	53	82	140	178
37-48	209	63 (55, 72)	10	14	26	47	76	130	156
49-60	192	67 (59, 75)	11	15	32	53	86	122	182
61-72	208	52 (47, 57)	10	12	23	41	74	102	126
73-84	218	55 (48,62)	7	11	21	41	68	116	171

<sup>a</sup> Months

<sup>b</sup>AvgIR (95% CI) = arithmetic mean ingestion rate (95% confidence intervals)

After evaluating the available literature using the DQOs (see Attachment 1), the TRW Lead Committee recommends the age-specific soil-dust ingestion rates from scenario 3 of von Lindern et al. (2016) as the basis for revising the default age-specific soil-dust ingestion rates in the IEUBK model for CERCLA and RCRA corrective action risk assessments. As described above, this study was selected because it was determined that the approach employed by the authors most closely fits the DQOs established by the TRW Lead Committee for this effort; the study by von Lindern et al. (2016) provides the best estimate of age-specific soil and dust ingestion rates for use in the IEUBK model at CERCLA and RCRA 5,400 blood lead observations from nearly 2,340 individuals, yielding 2,176 records of blood/soil/dust lead concentrations over a 15 year timeframe with a >50% participation rate. In total, 271 samples (193 house dust samples, 73 yard soil samples and 5 quality control samples) sieved to 80 mesh (the particle size that adheres to a child's hand and most likely to be ingested by children) were analyzed for total lead and *in vitro* bioaccessibility. Community mean absolute bioavailability values (ABS) for unremediated vards soils and house dust, and site-wide ABS means for postremediation soils were integrated into the database. Annual site-wide ABS means were calculated using a weighted average of bioavailable lead from remediated and unremediated yards. Aggressive LHIP education and intervention programs may have resulted in a temporary reduction in soil-dust intake rates by children, although this conclusion is not supported by multiple systematic reviews (Nussbaumer-Streit, Yeoh et al. 2016). Alternatively, elevated dust loadings caused by flooding and construction activities may have exacerbated soil-dust ingestion rates in the middle years of the BHSS cleanup. However, SEM and IEUBK model sensitivity analysis suggested that variation in calculated ingestion rates may be an artifact of the source partitions, nature of the data, or progression of the cleanup. The data collected at the BHSS best represents conditions at most CERCLA and RCRA corrective action sites during the Remedial

<sup>&</sup>lt;sup>5</sup> Sum of Squared Error (SSE) is a statistical measure of the discrepancy between empirical values and the estimation model results. Lower SSE means better model prediction

Investigation and Feasibility Study phase of the remedial process. The soil-dust ingestion rates from Scenario 3 of von Lindern et al. (2016) results in soil-dust ingestion rates for the IEUBK model that are supported by other independent analyses, specifically the modeled estimates from Ozkaynak et al. (2011) and Wilson et al. (2013) (see Table 2).

#### **UNCERTAINTY**

Several studies published since 1994 were not applicable to this variable; for example, they contained only adult data, evaluated sediment ingestion rates rather than soil ingestion rates, or were review papers summarizing or reanalyzing other studies. Among recent publications that provide new data for young children (see Table 2), the TRW Lead Committee considered the study by yon Lindern et al. (2016) to provide the relevant age-specific estimates of soil-dust ingestion rates for young children because it satisfied the most evaluation criteria (see Attachment 1) compared with the other studies. The TRW Lead Committee acknowledges that the data used by von Lindern et al. (2016) are site-specific and consideration was given to whether the Bunker Hill site was representative of other hazardous waste sites in the US. The data collected for that study were from an area of known lead contamination and could represent higher levels of lead than found in some areas. Also, as these data were collected from a site where EPA and other authorities were actively engaged in public outreach to reduce exposure, the soil-dust ingestion rates could be lower than in communities lacking public education efforts to limit exposure to soil and dust and thus may not necessarily be appropriate as an estimate for the general population, although the effectiveness of education has not been demonstrated in any of the Cochrane systematic reviews (Nussbaumer-Streit et al., 2016). Alternatively, elevated dust loadings caused by flooding and construction activities may have exacerbated soil-dust ingestion rates in the middle years of the BHSS cleanup. However, SEM and IEUBK model sensitivity analysis suggested that variation in calculated ingestion rates may be an artifact of the source partitions, nature of the data, or progression of the cleanup. The TRW Lead Committee notes that these conditions would likely occur at any CERCLA or RCRA corrective action site where USEPA was engaged in a risk assessment and therefore this limitation may be considered a strength (in that the data are possibly a better fit for the intended purpose than soil-dust ingestion rates collected from a naïve population would be). Furthermore, the information from this study is supported by two independent studies (Ozkaynak et al., 2011; Wilson et al., 2013). Thus, in the absence of other high-quality information the estimates from yon Lindern et al. (2016) shown in table 3 are likely to be most representative of soil dust ingestion rates for young children at CERCLA and RCRA corrective action sites. The TRW Lead Committee did not, as part of this review process, define study acceptance criteria (aside from using the DQOs to guide the evaluation), conduct a systematic review, or conduct quality assurance activities on the published data to identify anomalies such as incorrect units, duplicate samples, etc. Consideration of additional studies published in the future could inform further refinement of age-specific soil and dust ingestion rates.

#### **RECOMMENDATIONS FOR THE IEUBK MODEL**

Results from several new studies provide information on average soil dust ingestion rates from children 0-84 months old. In general, these studies support an average combined soil/dust ingestion rate from 50 to 100 mg/day for children younger than 84 months old that could be applied to children residing near a CERCLA or RCRA corrective action site. For example, the two supporting studies Ozkaynak et al. (2011) and Wilson et al. (2013) result in values of 68 mg/day and 55-61 mg/day, respectively. These values are consistent with the recommended age-specific soil-dust ingestion rates for some of the similar age groupings from von Lindern et al.

(2016). The age-specific soil/dust ingestion recommended as the default soil/dust ingestion rates in the IEUBK model are shown in Table 4.

IEUBK model.		
Age (years)	Age-specific, Average Soil/Dust Ingestion Rate (mg/day)	Basis for Age-Specific Value
0-1	86	Age-specific arithmetic mean ingestion rates
1-2	94	based on the best fit model from von Lindern
2-3	67	et al., 2016 and supported by modeled
3-4	63	estimates from Ozkaynak et al., 2011; Wilson

67

52

55

<u>4-5</u> 5-6

6-7

et al., 2013

Table 4. Recommended change to soil/dust ingestion rates for use in the IEUBK model.

Based on the evaluation described in this document and many factors specific to CERCLA and RCRA corrective action sites, these soil-dust ingestion rates are appropriate for assessing exposure at contaminated areas where the IEUBK model is frequently used. The TRW Lead Committee recommends updating the default *Age-Dependent Soil and Dust Ingestion Rate* variable in the IEUBK model to the age-specific average soil/dust ingestion rates based on von Lindern et al. (2016) (Table 3). These default values are considered appropriate for all applications of the IEUBK model where current and future residential scenarios are being assessed for CERCLA and RCRA corrective action risk assessment. The updated age-specific soil-dust ingestion rates are incorporated into the IEUBK model as shown in Figure 1.

Constant Value     Z00     Variable Values	Indoor Dust Lead Concentration (µg/g) Constant Value 200 Variable Values Multiple Source Analysis Set Multiple Source Avg: 150					<u>C</u> ance <u>R</u> ese Help?	
Soil/Indoor Dust Concentratio	on (µg/g)		AG	iE (Years)			
0.44-0.211-0.41-0.41	0-1	1-2	2-3	3-4	4-5	5-6	6-7
Uutdoor Soil Lead Leveis:	200	200	200	200	200	200	200
Indoor Dust Lead Levels:	150	150	150	150	150	150	150
Amount of Soil/Dust Ingested	d Daily (g/da	ay)	A	GE (Years)			
	0.1	1.2	2-3	3-4	4-5	5-6	6-7
	0-1						

# Figure 1. IEUBK Model Site Specific Soil Dust Data Entry Window with the Updated Soil/Dust Ingestion Rates.

### **IMPACT ON THE IEUBK MODEL PREDICTIONS**

Using current IEUBK model (v.2) defaults for all parameters while implementing the proposed soil-dust rates will increase the preliminary remediation goal (PRG). Table 5 presents the updated estimates as well as the estimates from the previous analyses.

The PRGs in Table 5 are used to illustrate the impact when developing a screening level for lead in soil. As examples, the PRGs corresponding to PbBs of 10  $\mu$ g/dL and 5  $\mu$ g/dL are presented for illustrative purposes.

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Study	Age Range	IRsd	P10 PRG <sup>†</sup>	P5 PRG <sup>‡</sup>
IEUBK Model (v1.1	0-1 yr	85 mg/d		
build 11) default values	1-2 yrs	135 mg/d		
	2-3 yrs	135 mg/d		
	3-4 yrs	135 mg/d	418 ppm	153 ppm
	4-5 yrs	100 mg/d		
	5-6 yrs	90 mg/d		
	6-7 yrs	85 mg/d		
Proposed Update (based	0-1 yr	86 mg/d		
on von Lindern et al.	1-2 yrs	94 mg/d	605 ppm	200 ppm
	2-3 yrs	67 mg/d		

Table 5. Effects of changing the Soil-Dust Ingestion Rate (mg/day) in the IEUBK model

Study	Age Range	IRsd	P10 PRG <sup>†</sup>	P5 PRG <sup>‡</sup>
[2016]) using IEUBK v.2	3-4 yrs	63 mg/d		
default values	4-5 yrs	67 mg/d		
	5-6 yrs	52 mg/d		
	6-7 yrs	55 mg/d		

<sup>†</sup> P10 PRG is the preliminary remediation goal for soil lead based on no more than 5% probability of exceeding a blood lead concentration of 10  $\mu$ g/dL using IEUBK (v1.1. build 11) with default values for the 0-84 month age range.

<sup>‡</sup> P5 PRG is the preliminary remediation goal for soil lead based on no more than 5% probability of exceeding a blood lead concentration of 5  $\mu$ g/dL using IEUBK (v1.1. build 11) with default values for the 0-84 month age range.

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## ATTACHMENT 1. DATA QUALITY OBJECTIVES FOR THE SOIL-DUST INGESTION RATE LITERATURE EVALUATION

- 1. State the Problem
  - a. Current IEUBK Model soil-dust ingestion rates do not reflect recent studies, which have addressed many of the problems of previous studies
    - i. Age-specific rates
    - ii. Dust rates
    - iii. Confidence limits
    - iv. Analytical uncertainty
      - 1. ČV
      - 2. Negative values
    - v. Study duration
      - 1. 5-20 days
    - vi. Untested tracer bioavailability assumptions
    - vii. Biomarkers
    - viii. Sampling uncertainty
      - 1. Particle size
      - 2. Dust
      - 3. Exposure area
    - ix. Number of subjects
    - x. Transparency
      - 1. Stanek & Calabrese Data was not shared, despite requests & assurances
    - xi. Consistency with other studies
      - 1. Multiple analyses of single datasets produce multiple estimates
    - xii. Potential Conflict (or appearance) of interest
      - 1. PRP funding
- 2. Identify the Decisions
  - a. IEUBK default
    - i. Age-specific values
    - ii. CTE values
- 3. Identify Inputs to the Decision
  - a. Literature search
  - b. Evaluation criteria
  - c. Peer review
- 4. Define the Study Boundaries
  - a. Timing
  - b. Schedule
  - c. Review process
  - d. Impacts to programs & agencies

FMI see <u>https://www.epa.gov/fedfac/guidance-systematic-planning-using-data-quality-objectives-process</u>

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