



**ENVIRONMENT
& HEALTH**

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TECHNICAL COMMENTS ON JANUARY 2024 USEPA UPDATED RESIDENTIAL SOIL LEAD GUIDANCE

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ACRONYMS AND ABBREVIATIONS

AHHS:	American Healthy Homes Survey
BLL:	blood lead level
BTV:	background threshold value
CDC:	Centers for Disease Control
CERCLA:	Comprehensive Environmental Response, Compensation, and Liability Act
FDA:	U.S. Food and Drug Administration
GSD:	geometric standard deviation
GOF:	goodness-of-fit test
HUD:	U.S. Department of Housing and Urban Development
IEUBK:	Integrated Exposure Uptake Biokinetic
IRL:	interim reference level
KM:	Kaplan-Meier analysis
LOD:	limit of detection
LOQ:	limit of quantitation
MSD:	mass soil-to-dust transfer factor
NCI:	National Cancer Institute
NHANES:	National Health and Nutrition Examination Survey
ND:	non-detect
NPL:	National Priority List
OFAS:	Office of Food Additive Safety
OLEM:	Office of Land & Emergency Management
RCRA:	Resource Conservation and Recovery Act
RSL:	regional screening level
SHEDS:	Stochastic Human Exposure and Dose Simulation Model
TDS:	Total Diet Study
UCL:	upper confidence limit of the mean concentration
UPL:	upper prediction limit
USEPA:	United States Environmental Protection Agency
UTL:	upper tolerance limit
µg/dL:	micrograms per deciliter
µg/m ³ :	micrograms per cubic meter

µm:	micrometers
mg/kg:	milligram per kilogram
mm:	millimeter

1. INTRODUCTION

The U.S. Environmental Protection Agency (USEPA) Office of Land & Emergency Management (OLEM) recently issued updated guidance addressing lead in residential soils at Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) sites and Resource Conservation and Recovery Act (RCRA) corrective action facilities (USEPA 2024a). The guidance, *Updated Residential Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities*,¹ released on January 17, 2024 (previous USEPA soil lead guidance was issued in 1994), results in lower regional screening levels (RSLs) for lead (Pb) in residential soils and therefore increases the number of residential properties where the level of soil lead contamination may be high enough to warrant further investigation at new sites, at open active sites, and at sites that have previously undergone remediation and closure. The Guidance directs regions to conduct further site-specific evaluations in these situations to identify local exposure levels and achievable cleanup levels. Additionally, the new guidance may impact both current and future land-use decisions and remediation costs.

Several of the assumptions used by OLEM in the Integrated Exposure Uptake Biokinetic (IEUBK) model to derive the RSLs are outdated, overly conservative, and inconsistent with those used by other USEPA programs. It is our opinion that the calculated RSLs are far lower than needed to achieve the desired target blood lead levels. In this memorandum, we present alternate assumptions that more accurately reflect current scientific knowledge and are more consistent with assumptions used by USEPA in other lead programs. Notably, the use of these alternate assumptions yields an RSL of 435 milligrams per kilogram (mg/kg) for a target blood lead level of 5 micrograms per deciliter (µg/dL) and an RSL of 253 mg/kg for a target blood lead level of 3.5 µg/dL, far higher than the RSLs of 200 and 100 mg/kg, respectively, in the new guidance. We believe that these alternate RSLs will achieve the level of health protection sought by USEPA.

We also provide comments on the future application of cleanup levels derived based on the new blood lead targets, as well as suggestions for how to derive anthropogenic background levels for sites. Both the RSLs and site-specific cleanup levels should be applied to the average concentrations for an exposure unit such as a residential property and should not be considered as not-to-exceed levels. OLEM should provide additional guidance to ensure consistency in the application of the RSLs and site-specific cleanup levels. The OLEM guidance also notes that cleanup levels will not be set below natural or anthropogenic background. We provide comments showing that anthropogenic soil levels will exceed the new RSLs for any community that has older housing. As shown by the U.S. Department of Housing and Urban Development (HUD; 2021), the U.S. average soil lead concentration for homes built prior to 1940 is 405 mg/kg, more than double the single source RSL. We provide an example of how national datasets, such as the data from HUD, could be used to derive site-specific anthropogenic soil lead values based on house age distribution at sites where site-specific natural or anthropogenic background lead concentrations cannot be determined.

OLEM's updated residential soil lead guidance is likely to result in substantial environmental assessment and remediation activities and costs. While the update on protective blood lead levels (BLLs) is important to protect human health, it is critical that the IEUBK model be updated to reflect the latest science, issues with the lower blood lead target (3.5 µg/dL) be adequately addressed, methods for characterizing anthropogenic background be provided, and implementation strategies be

¹https://www.epa.gov/system/files/documents/2024-01/olem-residential-lead-soil-guidance-2024_signed_508.pdf

expanded to accommodate achievable remediation strategies while still meeting remedial or corrective action goals.

2. THE UPDATED SOIL GUIDANCE SHOULD INTEGRATE RECENT RESEARCH

For the revised guidance, OLEM uses the IEUBK model to generate RSLs for lead in soil based on a blood lead target of 5 µg/dL when only one source of lead has been identified at a site or 3.5 µg/dL when multiple sources have been identified. As described above, OLEM has used several out-of-date input parameters that result in RSLs far lower than needed to achieve the target blood lead levels. These input parameters should be updated to reflect the most recent science. In the following sections, we comment on the current background dietary lead intakes, soil ingestion, and mass soil-to-dust transfer factor (MSD) parameters included in the IEUBK model and provide suggestions for updating these parameters based on recent peer-reviewed scientific publications. Updating these parameters is consistent with USEPA's Lead Strategy, which states that, "EPA expects that this strategy will be updated to ensure that we continue to engage with stakeholders, to rely on the best available science." (USEPA 2022a, pg. 13). Despite OLEM's acknowledgement of the importance of using "Best Available Science and Data" OLEM actually fails to do so by ignoring the more recent studies described in the comments. We urge OLEM to take action to correct these deficiencies promptly.

2.1 Background Dietary Lead Intakes Should Be Consistent with Those Used by USEPA In Other National Rulemaking Efforts for Lead

The background lead dietary intake values for U.S. children incorporated in the IEUBK model, version 2.0 and used by OLEM to derive the revised RSLs are much higher than recent dietary intakes estimated by the U.S. Food and Drug Administration (FDA; Spungen 2019) and USEPA's Office of Research and Development (Zartarian et al. 2017). The dietary lead intakes used in the IEUBK v 2.0 and those in recent studies (Zartarian et al 2017, Spungen 2019) are summarized in Table 1. The Zartarian et al. (2017) values are particularly helpful because dietary lead intakes are provided for the same age ranges used in IEUBK. The more recent Spungen (2019) dietary intakes are for broader age ranges (1-3 years and 4-6 years) and are even lower.

The difference in the dietary intakes is driven primarily by higher food consumption rates assumed by OLEM with potential compounding of the overestimates by OLEM's use of half the limit of detection (LOD) for non-detected results. Additionally, the Zartarian et al. (2017) and Spungen (2019) analyses are based on more recent data and are more fully documented. USEPA has used the Zartarian et al. (2017) dietary intakes to support other national rulemaking efforts for lead, specifically the proposed Lead and Copper Rule revisions (USEPA 2023a) and the reconsideration of the dust-lead hazard standards and dust-lead post-abatement clearance levels (USEPA 2023b). Applying different background dietary lead intakes in the IEUBK model at residential soil lead sites is inconsistent on USEPA's part, misrepresents background lead exposures, and ultimately leads to the calculation of lower soil lead screening levels than are needed to protect public health. The IEUBK dietary lead values are inconsistent with current, best available scientific data.

Table 1. Dietary Lead Intakes from IEUBK v 2.0, Zartarian et al. (2017), and Spungen (2019)

Age Range (months)	IEUBK v 2.0 Dietary Lead Intake (µg/day)	Zartarian et al. (2017) Dietary Lead Intake (µg/day, Geometric Mean)	Spungen (2019) Dietary Lead Intake (µg/day, Hybrid Mean) ^a
0 to <12	2.66	0.65	NA
12 to <24	5.03	2.00	1.7
24 to <36	5.21	2.85	
36 to <48	5.38	2.98	
48 to <60	5.64	3.00	2.0
60 to <72	6.04	3.31	
72 to <84	5.95	3.29	

Notes:
^a To calculate the hybrid mean, values less than the limit of detection (LOD) were set to zero if there were no detections from 2009–16; otherwise, values less than the LOD were set to 0.5 * LOD, consistent with Zartarian et al. (2017) approach.
 IEUBK = Integrated Exposure Uptake Biokinetic; NA = not analyzed

The OLEM memorandum *Estimation of Dietary Lead Exposure: Update to the Default Values for the Integrated Exposure Uptake Biokinetic Model for Lead in U.S. Children* describes the dietary lead intake values used in version 2 of the IEUBK model, (USEPA OLEM DIRECTIVE 9200.1-149). The OLEM memo does not provide adequate rationale for adjustment in the dietary intakes. Specifically, a detailed description of how the food consumption data from the National Health and Nutrition Examination Survey (NHANES) and food concentration data from the FDA Total Diet Study (TDS) was used to determine the input data for the National Cancer Institute (NCI) method is needed to better understand the dietary intake estimate. OLEM did not use the most recent NHANES and TDS data. OLEM, Zartarian, et al. (2017), and Spungen (2019) all rely on food consumption data from NHANES and food concentration data from the TDS, but Spungen (2019) and Zartarian et al. (2017) use more recent data than OLEM (Table 2).

The treatment of non-detected results in the TDS data also impacts the results. OLEM's analysis set all data less than the LOD to one-half the LOD. This approach incorrectly increases the assumed lead intake for foods where lead was not detected in the product in any of the years of TDS data used. Both Zartarian et al. (2017) and Spungen (2019) evaluate three different methods for the treatment of non-detects. Zartarian et al. (2017) observed over-prediction with half LOD for all non-detects; under-prediction with zero for all non-detects; and good model evaluation using a 'hybrid' approach from Xue et al. (2010). In the hybrid approach, foods that were never detected in the TDS data are set to zero, otherwise values less than the LOD with at least one detection are set to one-half the LOD. The hybrid approach is consistent with guidance in the FDA document entitled *Guidance for Industry: Estimating Dietary Intake of Substances in Food* (FDA 2018), which discusses the use of undetected analytical results in dietary analyses stating:

The concentrations of constituents in foods will generally fall on a distribution curve. The values falling below an analytical LOD are typically reported as "non-detects." Concentrations of zero, one half the LOD, the LOD, the LOQ [limit of quantitation], or some other derived distribution of values have been reported as non-detects.[12] [Office of Food Additive Safety] OFAS has used all of these options, selecting the most appropriate in each case on the basis of the quality and quantity of data available. To gauge the effect of the selection of a non-detect value on an intake assessment, the intake estimate may be performed twice: once using zero as the non-detect level to determine the low end of the estimate range and again using the LOD as the non-detect level to determine the high end of the estimate range. The spread in this range is useful as a guide in assessing the importance of non-detect concentration values for a given intake estimate. [Bracketed text added to quote]

Moreover, in the 2022 FDA TDS *FY2018-FY2020 Report Supplement: Summary of Analytical Results Tables* where a constituent is never detected, all remaining statistics are identified as not available or not applicable (i.e., N/A) or non-detect (ND) and the reporting limit is provided (e.g., see arsenic in whole milk on page 1). This would indicate that statistical analysis of these data was not applicable. It is reasonable to assume that where a food is well studied and lead was never detected, it should not be included in a summary at half the detection limit.

The USEPA (2022b) ProUCL version 5.2 software for calculating the upper confidence limit (UCL) on the mean concentration for use in risk assessment also stresses the importance of not relying on one-half of the detection limit in analysis of non-detect data stating specifically:

"9.14.1 Avoid the Use of the DL/2 Substitution Method to Compute UCL95

Based upon the results of the report by Singh, Maichle, and Lee (2006), it is recommended to avoid the use of the DL/2 substitution method when performing a GOF [goodness of fit] test, and when computing the summary statistics and various other limits (e.g., UCL, UPL [upper prediction limit], UTL [upper tolerance limit]) often used to estimate the EPC [exposure point concentration] terms and BTVs [background threshold values]. Until recently, the substitution method has been the most commonly used method for computing various statistics of interest for data sets which include NDs. The main reason for this has been the lack of the availability of the other rigorous methods and associated software programs that can be used to estimate the various environmental parameters of interest. Today, several methods (e.g., using KM [Kaplan-Meier] estimates) with better performance, including the Chebyshev inequality and bootstrap methods, are available for computing the upper limits of interest. Several of those parametric and nonparametric methods are available in ProUCL 4.0 and higher versions. The DL/2 method is included in ProUCL for historical reasons as it had been the most commonly used and recommended method until recently (EPA 2006b)." [Bracketed text added to quote]

The use of more robust analytical methods in the USEPA ProUCL software lends further weight to the use of a hybrid approach in considering non-detect data in analysis of lead in the diet.

Table 2. Basis of Dietary Lead Intake Derivation from OLEM IEUBK v 2.0, Zartarian et al. (2017), and Spungen (2019)

Analysis	Dietary Intake (NHANES Consumption Data Survey Years)	Dietary Lead Concentration (FDA TDS Years)	Treatment of Non-detects^a
OLEM IEUBK v 2.0	2003 - 2006	1995 - 2005	All values < LOD set to 0.5 * LOD
Zartarian et al. (2017)	2009 - 2014	2007 - 2013	Hybrid approach: Foods that were never detected in TDS data set to zero, values < LOD with at least one detection were set to 0.5 * LOD
Spungen (2019)	2009 - 2014	2014 - 2016	Hybrid approach: Foods that were never detected in TDS data set to zero, values < LOD with at least one detection were set to 0.5 * LOD
Notes: ^a For values shown in Table 1. FDA = U.S. Food and Drug Administration; IEUBK = Integrated Exposure Uptake Biokinetic; LOD = limit of detection; NHANES = National Health and Nutrition Examination Survey; OLEM = USEPA Office of Land and Emergency Management; TDS = Total Diet Study			

Zartarian et al. (2017) used the Stochastic Human Exposure and Dose Simulation (SHEDS) model for multimedia, multi-pathway chemicals (SHEDS-Multimedia), a physiologically based probabilistic Monte Carlo exposure model that can simulate aggregate or cumulative exposures over time via dietary and residential routes for a variety of multimedia environmental chemicals using real-world data (i.e., human activity diaries, measured concentration data, exposure factors) for model inputs. This method also uses the regression equations derived from the IEUBK model as part of the process. The approach described by Zartarian et al. (2017) has a number of advantages over the OLEM analysis:

- Use of more current data: NHANES 2009-2014, TDS 2007-2013
- Verification: It compares the estimations made to the measured data from NHANES
- Treatment of non-detect results: Use of a hybrid approach, which properly updates prior 0.5 * LOD default
- Transparency: All the code and data used to derive the information in this publication are available on the USEPA's website²

FDA's analysis (Spungen 2019) relies on TDS data from 2014 – 2016 and produces even lower dietary intakes than Zartarian et al., suggesting dietary lead intakes continue to decline. In addition to mean intakes, Spungen also produces 90th percentile intakes, which range from 2.6 to 3.1 µg/day when the hybrid approach is used. These values are similar to the geometric mean estimates from Zartarian et al. (2017). OLEM's dietary lead intakes exceed all of the estimates produced by Spungen (2019), including the 90th percentile upper bound estimate (where non-detects set to LOD, range of 4.4. to

² <https://catalog.data.gov/dataset/blood-pb-prediction-with-sheds-mm-witth-ieubk>

4.8 µg/day). Also of note, in 2022, the FDA updated the interim reference level (IRL) for lead in food to 2.2 µg/day for young children (0-6 years). In the IRL publication, FDA scientists (Flannery and Middleton 2022) cite the work of Spungen (2019), Carrington et al. (2019), and Parker et al. (2022) which report mean dietary lead intakes in young U.S. children below the IRL. They also note the work of Wong et al. (2022), which estimated lead exposure from foods to be 0.11 µg/kg body weight/day for a 1-year-old child (11.1 kg body weight), corresponding to an intake of 1.2 µg/day, increasing to 2.7 µg/day when water ingestion is included.

The number of food types found to be a consistent source of lead (i.e., lead was detected in 100% of the food types) were similar between 2014-2016 and 2018-2020. In 2014-2016, the FDA reported 18/268 (7%) food items having lead concentrations at or above the LOD in every sample. In 2018-2020, lead was at or above the LOD in 24/307 (8%) types of food. Nevertheless, lead concentration data from the 2018-2020 TDS suggest lead concentrations in foods continue to decline. In the 2014-2016 TDS, the FDA reported lead levels at or above the LOD in 799/2,923 (27%) of samples. This number was roughly half as much in 2018-2020, where the FDA detected lead in 475/3,276 (14%) samples.³ Additionally, lead was detected at least once in 173/268 (65%) food items sampled in the FDA's 2014-2016 TDS, compared to 113/307 (37%) samples in the FDA's 2018-2020 study.

2.1.1 Conclusions and Recommendation

Considering the FDA's recent analyses, the current IEUBK dietary intakes used by OLEM overestimate background dietary lead exposures in young children. The Zartarian et al. (2017) dietary intake values may still overestimate dietary intakes but would provide a more reasonable yet conservative estimate of background diet in the IEUBK model. Impacts to the soil lead RSLs meeting the 5 and 3.5 µg/dL blood lead targets when the Zartarian et al. (2017) and Spungen (2019) intakes are used, with all other model inputs being equal, are shown in Table 3.

Table 3. Soil Lead Concentrations Meeting 5 and 3.5 µg/dL Blood Lead Targets Accounting for Updated Dietary Lead Intakes

Target blood lead level (µg/dL)	Current RSLs (mg/kg)	Alternate Using Zartarian et al. (2017)	Alternate Using Spungen (2019)
5	200	272	294
3.5	100	157	179
Notes: RSL = regional screening level			

In keeping with USEPA's commitment to use the best science, at a minimum, OLEM should immediately adopt the Zartarian et al. (2017) dietary lead intake estimates for use of the IEUBK model in deriving soil lead RSLs consistent with use of these updated data in the proposed Lead and Copper Rule revisions (USEPA 2023a), recognizing that FDA (Spungen 2019) recommends even lower dietary intakes. USEPA should also carefully review the newest lead concentration data from the 2018-

³In the 2014-2016 TDS FDA analyzed lead content in a total of 2,923 samples across 268 food types. The 2018-2020 TDS included 3,276 samples from 307 different types of foods.

2020 TDS that suggest lead concentrations in foods continue to decline and incorporate an updated analysis into all applications of the IEUBK model in the near future.

2.2 Recent Studies Support Lower Soil Ingestion Rates for Use in IEUBK

In IEUBK v2, the OLEM updated the soil+dust ingestion rates based on an analysis of soil, indoor dust, and blood lead concentration data from the Bunker Hill Superfund Site (von Lindern et al 2016). However, more recent analyses by USEPA scientists considering soil and dust intake (Ozkaynak et al. 2022) and cumulative lead exposure (Zartarian et al. 2017; 2023) suggest that central tendency intakes of soil and dust by young children may be lower than the von Lindern et al. (2016) estimates for the youngest age groups. Table 4 summarizes the central tendency soil+dust ingestion rates used in IEUBK v2 and from Ozkaynak et al. (2022).

Table 4. Comparison of Soil+Dust Ingestion Rates Used in IEUBK Model with Ozkaynak et al. (2022)

Age Range (years)	IEUBK Model	Ozkaynak et al. (2022) ^a
1-<2	94	48
2-<3	67	52
3-<4	63	59
4-<5	67	59
5-<6	52	59
Notes: ^a Mean values for 'dust plus soil ingestion' in Table 2 of Ozkaynak et al. (2022). IEUBK = Integrated Exposure Uptake Biokinetic		

Ozkaynak et al. (2022) use the Stochastic Human Exposure and Dose Simulation Soil and Dust (SHEDS-Soil/Dust) model to estimate soil and dust ingestion rates. The SHEDS-Soil/Dust model predicts soil and dust ingestion by pathway, source type, population group, geographic location, and other factors, which offers a better characterization of exposures relevant to health risk assessments (Ozkaynak et al 2011). It incorporates information on children's activity and behavioral patterns (i.e., activities that add soil/dust to hands and those that remove soil/dust from hands), which can be used to more accurately estimate separate ingestion rates for outdoor soil and indoor dust. For example, Ozkaynak et al. (2022) included modifications in their model to account for pacifier-related dust exposures and blanket use.

Ozkaynak et al. (2022) present mean and standard deviation values for soil+dust ingestion for 7 categories within the age group of 0 to <6 years: 0 to <1 month, 1 to <3 months, 3 to <6 months, 6 months to <1 year, 1 to <2 years, 2 to <3 years, and 3 to <6 years. IEUBK includes individual soil ingestion rates for 3 to <4 years, 4 to <5 years, and 5 to <6 years, so having only one rate representing 3 to <6 years adds potential uncertainty. However, the Ozkaynak et al. (2022) estimate for 3 to <6 years (59 milligrams per day [mg/day]) is similar to the von Lindern et al. (2016) rates for this age group (52 to 67 mg/day). The larger differences lie in the younger age groups, especially the 1 to <2-year age range, where the von Lindern et al. (2016) rates are nearly two times as high. Ozkaynak et al. (2022) suggest that differences in their soil ingestion rates compared to von Lindern

et al. (2016) may result from several factors including the von Lindern et al. study being conducted using maximum seasonal blood lead concentrations, smaller sample sizes used for young children, and the geographic focus of von Lindern et al. (2016) at a former lead Superfund site.

Zartarian et al. (2017; 2023) use the SHEDS model coupled with IEUBK to assess relationships between lead in environmental media and children's blood lead levels. Zartarian et al. (2017) found that using the von Lindern et al. (2016) soil+dust ingestion rates for 1 to <2-year-olds caused their model to overestimate background blood lead levels for U.S. children (from the National Health and Nutrition Examination Survey). Because of this issue, Zartarian et al. (2017) opted to use soil ingestion rates from Ozkaynak et al. (2011) in their model. Ozkaynak et al. (2022) is an update to the 2011 study. Zartarian et al. (2023) used the soil+dust ingestion rates from Ozkaynak et al. (2022) in their modeling analysis, noting their selected model inputs 'provide the most accurate representation of what children are exposed to at a national scale.' Of note, they also evaluated soil ingestion rates from von Lindern et al. (2016) and the USEPA Exposure Factors Handbook update (2017) but opted not to use these values. Considering this research by other USEPA offices, the Ozkaynak et al. (2022) soil ingestion rates more accurately represent soil ingestion than the current soil ingestion rates in the IEUBK model.

2.2.1 Conclusions and Recommendations

In keeping with USEPA's commitment to use the best science, at a minimum, OLEM should immediately adopt the Ozkaynak et al. (2022) soil ingestion estimates in the IEUBK model for use in deriving soil lead RSLs. The Ozkaynak et al. (2022) values have been validated by other USEPA scientists (Zartarian et al. 2023) in lead exposure assessment studies. The USEPA should continue to monitor the literature to assess if further changes in the soil ingestion estimates are needed.

2.3 The MSD Used in the IEUBK Model Should be 0.4 or Less

Soil ingestion rates used to estimate exposure typically are assumed to include combined intake from soil and indoor dust; however, data on indoor dust metal concentrations are rarely available. For that reason, assumptions must be made about the concentration of soil-derived metals in indoor dust. USEPA derived a factor to account for soil track-in from yard soils, referred to as MSD. An MSD of 0.7 has been used for the past 25 years as the default assumption in the IEUBK model used to estimate blood lead levels in children (USEPA 1998). More recent studies indicate that the IEUBK default MSD markedly overestimates the influence of yard soil on indoor dust metal concentrations. Use of a more representative MSD results in much higher RSLs.

In 1991, researchers from the University of Canterbury in New Zealand summarize a series of studies and estimate that the fraction of metals in dust attributable to soil is 33% to 44% (e.g., an MSD would be 0.33 to 0.44) (Fergusson and Kim (1991). Based on a multi-element analysis of soil-to-dust ratios from the literature (including their own studies) for metals without indoor sources, Fergusson and Kim (1991) report a ratio of 0.44 (standard deviation 0.06) for nine elements (Hf, Th, Sc, Sm, Ce, La, V, Al and K)⁴, and a ratio of 0.33 (standard deviation 0.09) for Mn, Fe, La, Sm, Hf, Th, V, Al, Sc and Ce⁵. A particular strength of the studies summarized by Fergusson and Kim is that they also examined the role of outdoor street dust on indoor dust. Most studies conducted since these studies assess metals that have indoor, as well as outdoor sources, and thus require analyses that attempt to discern the

⁴The elements, listed in order: Hydrogen fluoride, thorium, scandium, samarium, cerium, lanthanum, vanadium, aluminum, and potassium.

⁵The elements, listed in order: Manganese, iron, lanthanum, samarium, hydrogen fluoride, thorium, vanadium, aluminum, and cerium.

relative influence of indoor and outdoor sources. In the sections below, we provide a critique of the studies used to derive an MSD default of 0.7, summarize recent studies of similar sites that provide more reliable MSDs, and finally, address a methodological question about sample sieve size.

2.3.1 Critique of Studies Relied Upon to Derive the Default 0.7 MSD

To support the current MSD default of 0.7 used for the past 25 years, USEPA interpreted data from four studies of mining and smelting communities as indicating that 70% of dust was attributable to soil (USEPA 1994a). Significant limitations in the studies relied upon by USEPA may have contributed to overestimates of soil track-in from yards and the associated MSD. The MSDs derived by USEPA (1994a) were 0.85 (0.81 and 0.89) for the East Helena, Montana smelter site; 0.70 (0.68, 0.72) for the Midvale, CO smelter site; 0.26 for the historic mining town of Butte, Montana; and 0.09 for Kellogg, Idaho. USEPA does not provide information on the datasets used to derive the MSDs for these sites such as sample size, dates collected, depth of soil samples, nature, and location of dust samples, and if the samples were bulk or were sieved. They also do not explain the statistical method they used to calculate the 0.70 value (USEPA 1994a). One of the most crucial questions regarding the datasets is whether smelters were operating at the time the studies were conducted. When a large air source such as a smelter is operating, the impact of ongoing particulate fallout from the air releases on outdoor surface dust is likely to have significantly increased the MSD because track-in would be influenced by much higher concentrations of metals in (more recently deposited) outdoor surface dust that would not be captured in soil concentration data. In addition, metal-containing airborne dust may infiltrate the houses directly through windows, doors, and other openings. We have been able to glean information about site conditions and methods for one of these datasets by reviewing historical documents.

The highest MSD reported by USEPA was for the East Helena smelter (0.85). In contrast, in 2011 a USEPA scientist and consultant reported an MSD for the E. Helena site of 0.25 (Brattin and Griffin 2011). This smelter closed in 2001 and was actively operating through the mid-1990s (USEPA East Helena Site). The soil and dust samples were collected by the Centers for Disease Control and Prevention (CDC) while the smelter was operating as part of a 1983 exposure study that included 396 children living in three areas at varying distances from the smelter (CDC 1986), with Area 1 being directly adjacent to the smelter and Area 3 being farthest from the smelter. During the study, air lead concentrations over a three-month period were 3 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$) or greater at four stations in Area 1, 0.3 to 2 $\mu\text{g}/\text{m}^3$ at three stations in Area 2, and 0.2 $\mu\text{g}/\text{m}^3$ in Area 3. The current default air concentration assumed by USEPA in the IEUBK model is 0.1 $\mu\text{g}/\text{m}^3$, meaning that the East Helena air concentrations during the CDC study were 3 to 30 times higher than those currently assumed by USEPA in the two areas closest to the smelter. These data suggest that outdoor dust concentrations may also have been elevated compared with soil concentrations.

USEPA suggests that soil-to-dust coefficients may decrease over time at sites where major sources of soil lead deposition are no longer active (USEPA 1994a). Three factors at East Helena may have contributed to the very high MSD estimate of 0.85 that would not be applicable today, including high lead in airborne dust that could infiltrate houses directly, higher lead in outdoor dust as compared with yard soil, as well as sources of soil around the community with very high metal concentrations from smelting wastes that could be tracked into homes by residents.

This overestimate may have been further magnified by the sampling method used. Indoor dust was collected from vacuum cleaner bags. CDC (1986) reports collecting 179 grab samples of vacuum cleaner dust. Vacuum bags will reflect all areas of a house that have been vacuumed, regardless of

the amount of time people spend in each area. Vacuum cleaner dust samples are likely to overrepresent entryways that accumulate the most tracked-in soil and may result in overestimation of the metal concentrations in areas of the house where children play. Current recommended dust sampling protocols specify indoor dust sampling should be conducted in defined areas within residences using a high-volume vacuum method. Geometric mean lead concentrations in the East Helena vacuum-bag samples were reported to be twice the concentrations in yard soil samples for Areas 1 and 2, while in Area 3 vacuum-bag lead levels were reported to be more than four times the yard soil levels. These findings could reflect indoor sources of lead or could reflect the track-in of outdoor dust with concentrations much higher than yard soil concentrations. Nevertheless, it is not clear from this information how USEPA derived an MSD of 0.85 for this site. It is noteworthy that the CDC (1986) found that in a fully parameterized regression model, soil lead was not a significant contributor to blood lead levels. It is also worth noting that initial IEUBK model validation efforts by USEPA used the CDC East Helena exposure study dataset (Hogan et al. 1998). All of these factors indicate that the Brattin and Griffin (2011) MSD estimate for E. Helena of 0.25 is more applicable for sites that are not operating smelters.

The decrease in MSDs that occurs over time after major sources of soil lead deposition are no longer active may also be a factor in the reported decline in the MSD estimate for the Midvale Slag site. The 446-acre Midvale Slag site is located in Midvale City and Murray City, Utah. Five lead and copper smelters operated at the site between 1871 and 1971 (USEPA Midvale Slag Site).

While USEPA's 1994 MSD estimate was 0.7 for Midvale, Brattin and Griffin (2011) report MSD values of 0.04 and 0.09 for Midvale Slag Operable Units 1 and 2, respectively. We were not able to find the sample dates associated with the data used by USEPA (1994a). Brattin and Griffin relied on data reported by ISSI (1998) after substantial remediation had been completed, suggesting that as smelter fallout impacts decline and the highest areas of contamination are cleaned up, apparent soil track-in values also will decline.

In contrast, in Butte, where smelting began in the 1800s and ended with World War II (mining continued to the present), estimated MSDs have remained more stable over time. USEPA (1994a) reported an MSD of 0.26, and Brattin and Griffin (2011) reported a value of 0.20. As described below, we have also analyzed these data using a different method of identifying outliers and derived an MSD of 0.14.

Review of historical documents provided other insights applicable to understanding methodological issues associated with earlier MSD estimates. In a 1998 publication (Hogan et al. 1998) USEPA researchers describe a comparison of the IEUBK model blood lead outputs with results of a 1991 multisite study of lead exposure and blood lead in three historical smelter communities: Palmerton, Pennsylvania, Madison County, Illinois, and Jasper County, Missouri (which includes Galena, Kansas) (ATSDR 1995). The methods used in this study were more consistent with methods used in more recent exposure studies to obtain representative yard surface soil concentrations and indoor dust samples collected from defined areas within residences using a vacuum sampler designed for dust sampling. However, some significant differences in the locations of dust samples across the studies may have affected their reliability for exposure assessment and IEUBK model validation. According to Hogan et al. (1998) the Palmerton, Pennsylvania and Madison County, Illinois composites included dust collected from entries, which is also included in the ASTM Method D-5438; however, the Madison County samples included dust from window wells and sills. Lead concentrations in windowsills are typically much higher than concentrations on floors when lead-based paint and other exterior lead

contamination is present, and these samples would not be representative of soil track-in. Thus, dust samples from this study would not be useful for validating the soil-to-dust coefficient in the IEUBK model. Windowsills were not included in the dust samples from the other sites.

2.3.2 Summary of Recent Studies That Provide More Reliable MSDs

Since 1994, a number of investigations of lead-contaminated sites have included paired yard soil and indoor dust samples from multiple residences. In contrast to the older studies described above, sampling protocols used in the studies included in Brattin and Griffin (2011), USEPA (2016), and Tu et al. (2020) are more likely to produce representative estimates of soil track-in. In these studies, indoor dust was generally collected with a sampling vacuum over one square meter area in three living areas within a residence, most commonly entries, living rooms, kitchens, and bedrooms. Soil samples were generally surface soil samples (usually, 0 to 1 inch or 0 to 2 inches) collected as composites from multiple yard components such as front yard, back yard, gardens, play areas, and drip lines. None of these sites were active smelters, and most had no recent history of smelting or mining. For many of the sites, some remediation of the most contaminated areas within the community had already begun, limiting the potential for higher concentration soil from outside the yard to be tracked in. Thus, these studies comply with USEPA guidance for house dust and residential soil sampling (USEPA 2008) and are more applicable to the general public than the studies relied on for the 0.7 MSD.

Brattin and Griffin (2011), a USEPA consultant and Region 8 toxicologist, report MSDs for lead ranging from 0.04 to 0.34 for nine paired soil and dust datasets from sites with historical mining and smelting activity in the U.S. Rocky Mountain region (Table 5). An additional MSD of 0.36 was reported for the Colorado Smelter Superfund Site in Pueblo based on analysis of 102 data pairs (USEPA 2016).

The findings of Brattin and Griffin (2011) and USEPA (2016) have been confirmed by a more recent analysis by Ramboll scientists of residential yard soil and indoor dust datasets from eight communities near historical mining, smelting, and refining operations (Tu et al. 2020). Regression analyses were used to derive slopes that represent MSDs for each site. The treatment of outliers was a significant methodological factor affecting the slope of the regressions. Covariates that could affect soil track-in, such as the amount of bare soil in the yard or having pets, were examined by multivariate regression analysis when available. MSDs for ordinary linear regression models with a good to moderate fit range from 0.14 to 0.47 for lead (Table 6).

Substantial variability is expected among soils at residences due to both physical characteristics of each property and the ways in which residents interact with their home. Survey data providing information on various factors affecting soil track-in helps to refine MSD estimates. For three of the datasets, covariate data were available that improved model fit by multivariate or stratified linear regression analysis. The results of this study are consistent with prior studies suggesting that MSDs for lead are generally 0.4 or less.

Table 5. Soil–Dust Relationships for Lead (Brattin and Griffin 2011)

Location	Number of data pairs	Number of data pairs fitted ^a	Linear regression parameters		
			Slope (MSD)	Intercept	R ²
Walkerville, MT	196	192	0.20 (0.13–0.26) ^c	280 (197–363) ^c	0.14
Leadville, CO	200	196	0.14 (0.11–0.17)	565 (491–639)	0.35
East Helena, MT	30	29	0.25 (0.12–0.39)	181 (74–288)	0.35
Eureka, UT	55	54	0.14 (0.07–0.20)	467 (329–606)	0.23
Midvale, UT	40	40	0.04 (–0.13–0.21)	289 (210–368)	0.01
Midvale, UT	90	88	0.09 (–0.01–0.20)	139 (123–156)	0.03
Murray, UT	22	21	0.19 (0.03–0.36)	174 (39–309)	0.24
Sandy, UT	165	161	0.12 (0.09–0.14)	122 (93–151)	0.37
Denver, CO	74	72 ^b	0.34 (0.17–0.51)	150 (91–210)	0.18
Notes: ^a Outliers characterized as values ± 3 standard deviation of the mean were excluded. ^b Second outlier emerged after repeating the outlier analysis excluding the first outlier. ^c Values in parentheses represent the 95% confidence intervals around the mean. MSD = mass soil-to-dust transfer factor					

Table 6. Linear Regression Soil-Dust Relationships for Lead (Tu et al. 2020)

Location	Number of data pairs	Number of data pairs fitted ^a	Linear regression parameters ^b		
			Slope (MSD)	Intercept	R ²
			Estimate	Estimate	
Anaconda, MT	34	34	0.43 (0.25, 0.61)	52 (-41.0, 146)	0.43
Bartlesville, OK	59	57	0.47 (0.38, 0.56)	115 (74.5, 155)	0.678
Bingham Creek, UT	716	648	0.34 (0.31, 0.36)	(83.1, 91.3)	0.496
Black Eagle, MT	30	29	0.29 (0.15, 0.43)	49 (-6.83, 106)	0.397
Walkerville, MT	196	181	0.14 (0.11, 0.18)	266 (224, 307)	0.264
Pueblo, CO	102	93	0.36 (0.25, 0.47)	27 (-8.5, 62.4)	0.320
Notes: ^a Outliers characterized as values ± 3 standard deviation of the mean were excluded. The process was repeated on the datasets until no more outliers were identified. ^b Lower and upper 95%ile confidence limits are shown in parenthesis.					

2.3.3 USEPA Has Used a Soil-Dust Coefficient of 0.48 in Other Lead Evaluations

USEPA's Office of Research and Development (Zartarian et al. 2017, Zartarian et al. 2023) used 0.48 as the lead dust-soil correlation coefficient based on data from the American Healthy Homes Survey I (AHHS I; HUD 2011).⁶ The soil and dust data from HUD (2011) were used as the soil and dust concentrations in Zartarian et al. 2017. According to the supplemental material, the authors initially used the default IEUBK MSD of 0.7 to estimate dust concentrations based on HUD (2011) soil lead concentrations but opted not to use the 0.7 MSD in their final analysis following peer consult. The authors provide the following information on the derivation of the 0.48 soil-dust coefficient, "The data were stratified and weighted by house age pre-and post-1950, and a correlation coefficient of 0.48 between dust and soil [lead] concentrations was assigned in SHEDS based on the HUD/AHHS data" (Zartarian et al. 2017, pg. S5). As described in Section 1.1, the Zartarian et al. (2017) analysis was used to support two national rulemaking efforts for lead.

2.3.4 Conclusions and Recommendations

Taken together, the body of research conducted since 1994 provides powerful evidence for using a much lower MSD than the poorly documented and supported 0.7 default value. The default value is

⁶ Zartarian et al. (2023) states they used a dust-soil lead coefficient of 0.5 based on data from the National Human Exposure Assessment Survey (NHEXAS, citing Clayton et al. (1999). We believe this citation to be an error because Clayton et al. (1999) does not provide a dust-soil lead coefficient.

not based on any statistical analysis or comprehensive review of the literature and other relevant data. In addition, now-available evidence strongly indicates that the historical data relied upon to derive the default were not collected using methods consistent with those currently recommended by USEPA for collecting dust data. In contrast, the best available science supports an MSD no higher than 0.4. In keeping with USEPA's commitment to use the best science, at a minimum, OLEM should immediately adopt a default MSD no higher than 0.4 in deriving the RSLs.

2.4 USEPA Should Acknowledge Uncertainties in Geometric Standard Deviation

The probabilistic feature of IEUBK allows estimates that "represent the median values for a lognormal distribution of values that would occur in a population that was subject to fixed lead concentrations in the input media (soil, dust, air, water) equal to those input to the model" (NRC 2005). A key assumption in using the IEUBK for remedial decisions is the application of the geometric standard deviation (GSD) to identify the 95th percentile of the predicted blood lead distribution which is used to set soil cleanup levels.

Blood lead data are generally found to be lognormally distributed. Such data include both environmental variability and biological variability. As noted by USEPA, use of the IEUBK to identify soil cleanup levels should be based on a geometric standard deviation (GSD) that includes only the biological variation, such as individual behaviors and toxicokinetics variation among individuals. The default GSD of 1.6 is stated to represent the biological variability, while a GSD for combined variability for environmental and biological variability is thought to be approximately 1.9 (Zartarian et al. 2017).

The current IEUBK default GSD is based on a 1994 analysis (USEPA 1994a) that may be out of date, and no recent studies appear to have identified a population with sufficiently uniform exposures to provide an update or verification of the 1994 biological GSD derivation. The method suggested by USEPA (1994a) to stratify the blood lead data by soil concentration misses the point that most elevated BLLs are caused by sources other than soil and house dust. Many such sources are identified when home evaluations are conducted for children with elevated BLLs. These additional sources are likely to be driving the lognormal distributions commonly noted for blood lead datasets. It is noteworthy that a blood lead dataset for the community of La Oroya in Peru was found to have a normal distribution (Integral 2005). One dominant source affected this community, producing extremely elevated BLLs and very few other sources were identified. This raises the possibility that biological variation in BLLs may not always be lognormally distributed.

As noted by the National Research Council (2005): "The standard deviation (or geometric standard deviation [GSD]) of the lognormal distribution was derived based on observations of exposed populations of children. EPA (1994) stated that the default value of the GSD is based on analyses at Midvale, Utah; Baltimore, Maryland; and Butte, Montana. The analyses are not available for review" (NRC 2005). OLEM should acknowledge the assumed precision around any hypothetical "community" and their (assumed lognormally distributed) blood lead measurements is an input in the IEUBK model that has not been validated.

Furthermore, OLEM should transparently describe the impacts of the significant uncertainty in the assumed biological GSD of 1.6. The impact of uncertainty is greatest at the upper end of the distribution. One way for USEPA to address the uncertainty in the GSD would be to reduce the risk target from no more than a 95% chance of an individual exceeding the blood lead target, to no more than a 90% chance of exceeding the blood lead target. For example, applying a risk target of no more than a 90% chance of exceeding a blood lead target in the IEUBK model results in a calculated soil

lead concentration of 273 mg/kg associated with the 5 µg/dL blood lead target (as opposed to soil lead concentration of 200 mg/kg based on a 95% chance of exceeding the target), and a soil lead concentration of 135 mg/kg associated with the 3.5 µg/dL blood lead target (as opposed to soil lead concentration of 85 mg/kg). Alternatively, presenting cleanup levels based on several such assumptions would allow the uncertainty to be quantified.

2.5 Impact of IEUBK Parameters on Soil Lead Concentrations Meeting 5 and 3.5 µg/dL Blood Lead Targets

Individually and together, the recommended updates to background dietary lead intake, soil ingestion, and soil-to-dust transfer have significant impacts on the soil lead concentrations calculated by IEUBK to meet the 5 and 3.5 µg/dL blood lead targets (Table 7). The update to dietary intake has the largest individual impact to soil lead concentration goals for both the 5 and 3.5 µg/dL blood lead targets. Of note, updates to soil ingestion and soil-to-dust transfer have little individual impact on the soil lead concentration meeting the 3.5 µg/dL blood lead target, indicating that other background sources of lead dominate lead exposure at this target. The influence of soil increases when background dietary intakes are decreased. When all three parameters are updated, a soil lead concentration of 435 mg/kg meets the 5 µg/dL blood lead target, and a soil lead concentration of 253 mg/kg meets the 3.5 µg/dL blood lead target. If the risk target was adjusted to no more than a 90 percent chance of exceeding the target blood lead level (recognizing the likelihood that the biological GSD is overestimated), these soil concentrations would be significantly higher. Specifically, a cleanup level of 552 mg/kg is likely to ensure blood lead levels of individual children do not exceed 5 µg/dL and a cleanup level of 331 mg/kg is likely to ensure blood lead levels of individual children do not exceed 3.5 µg/dL.

Table 7. Soil Lead Concentrations Meeting 5 and 3.5 µg/dL Blood Lead Targets

Target blood lead level (µg/dL)	Current RSLs (mg/kg)	Soil lead concentration calculated by IEUBK accounting for parameter updates (mg/kg)			
		Diet ^a	Soil ingestion ^b	Soil-to-dust transfer (0.4) ^c	All
5	200	272	257	249	435
3.5	100	157	111	106	253

Notes:
^a From Zartarian et al. (2017)
^b From Ozkaynak et al. (2022)
^c From Tu et al. (2020)
 IEUBK = Integrated Exposure Uptake Biokinetic; RSL = regional screening level

3. OTHER LEAD SOURCES SHOULD BE DELETED AS IEUBK INPUTS FOR TARGET BLL OF 3.5 µg/dL

The updated OLEM residential soil lead guidance recommends that an alternate blood lead target of 3.5 µg/dL be used if an additional source of lead is identified (USEPA 2024a). Additional sources of lead provided as examples in the guidance include lead water service lines, lead-based paint, and non-attainment areas where air lead concentrations exceed National Ambient Air Quality Standards. USEPA's attempt to provide extra protection to communities vulnerable to multiple sources of lead exposure via more stringent control on soil lead concentrations is an inaccurate, ineffective and inefficient approach. Further reductions in soil lead concentrations, alone, will not measurably reduce blood lead levels and control of other sources is needed to reduce blood lead levels. As such, reducing the target blood lead level in the IEUBK model is not an effective means of controlling lead exposures. The alternate blood lead target is problematic in several ways.

First, the recommendation of two different blood lead targets is confusing and will be difficult to communicate to communities. Having two blood lead targets makes it difficult for risk assessors to justify either one. Second, the use of an alternate target blood lead level (BLL) of 3.5 µg/dL is not necessary when the IEUBK model already has functionality to account for other sources of lead exposure, including air, water, and lead-based paint. The IEUBK model is designed to include site-specific air and water lead concentrations when these data are available. Lead-based paint can also be included in the model via the multiple source analysis menu or alternate source intake menu, though quantifying specific lead exposures via lead-based paint is less straightforward. The specific lead exposure menus in IEUBK should be adjusted to account for site-specific exposures rather than relying on a lower blood lead target to account for these exposures. Third, the RSL based on a target BLL of 3.5 µg/dL is 100 mg/kg, which will likely be below anthropogenic background in many communities with lead-based paint exposure. This is discussed further in Section 4. Also of note, the IEUBK model has not been validated at a target BLL of 3.5 µg/dL.

If USEPA continues to recommend application of the lower blood lead target for communities with additional lead exposures, then additional lead exposure pathways, including dietary intake, should be zeroed out in the model to account for the lower blood lead target. In other words, the target blood lead should apply only to soil exposures. This concept is discussed in USEPA's Superfund Residential Lead Sites Handbook (2024b) overview of preliminary remediation goals, which states "Any consideration to take a CERCLA response action at a residence that factors in the increased risk from sources other than outdoor soil needs to be a site-specific risk management determination taking into consideration CERCLA statutory limitations on response." Table 8 shows the influence of zeroing out IEUBK exposure pathways that account for other sources of lead exposure on the soil lead concentration calculated by IEUBK that meets the 3.5 µg/dL blood lead target. Soil lead concentrations calculated incorporating updated soil ingestion and MSD discussed in Section 1 are also provided for reference.

Table 8. Updated Soil Lead Concentrations Accounting for Adjustment of IEUBK Model when 3.5 µg/dL Blood Lead Target Applied

Soil Ingestion and MSD Assumptions	Current RSL (mg/kg)	Soil lead concentration calculated by IEUBK accounting for lead exposure pathway removal (mg/kg)			
		Air Removed	Water Removed	Diet Removed	Air, Water, and Diet Removed
IEUBK default	100	100 ^a	100 ^b	230	254
Using Ozkaynak et al. (2022) soil ingestion, 0.4 MSD	NA	154	159	369	405
Notes: ^a IEUBK calculates a soil lead concentration of 97 mg/kg. The RSL of 100 mg/kg meeting the 3.5 µg/dL blood lead target recommended in USEPA (2024a) is rounded up from 85 mg/kg calculated by IEUBK. ^b IEUBK calculates a soil lead concentration of 98 mg/kg. The RSL of 100 mg/kg meeting the 3.5 µg/dL blood lead target recommended in USEPA (2024a) is rounded up from 85 mg/kg calculated by IEUBK. IEUBK = integrated exposure uptake biokinetic model; MSD= mass soil-to-dust transfer factor; NA= not analyzed; RSL = regional screening level					

We also note that use of a lower blood lead target may not achieve improved measures of lead health effects. Van Landingham et al. (2020) have shown that epidemiology study results used to demonstrate low-dose (<5 µg/dL) effects of lead exposure are influenced by uncontrolled confounding by multiple variables and call into question the conclusions of earlier analyses indicating that adverse effects are evident at these lower doses.

4. CLEAN-UP LEVELS SHOULD BE APPLIED ON AN EXPOSURE UNIT-WIDE BASIS

Clean-up levels meeting blood lead targets should be applied on an exposure unit-wide basis. USEPA's Superfund Residential Lead Sites Handbook (2024b) states the exposure unit is, "...generally determined by the receptor and exposure scenario in the geographic area in which individuals are randomly exposed to a contaminated medium for some relevant exposure duration (i.e., receptors have an equal probability of being anywhere in an exposure unit over the exposure duration)" (USEPA 2024b, pg. 50). At many residential sites, the residential property is the exposure unit. The original soil lead guidance documents (USEPA 1994b; 1998) recommend the individual residence be used as the primary exposure unit of concern. The 2024 guidance does not update this recommendation. Clean-up levels based on the lower blood lead targets should similarly be applied on a property-wide basis (as opposed to individual component-level basis, such as for a front yard, back yard, side yard, or individual sub-components of a property).

Application of clean-up levels on an exposure unit-wide basis allows for more efficient remediation while still meeting remediation goals and is consistent with the way people are exposed to lead in residential soil. As described in USEPA's Superfund Residential Lead Sites Handbook (2024b), lead concentrations across all sampled components (e.g., sub-components or sub-exposure areas of a property) are averaged and compared to the clean-up goal. Activity or area-weighting can be applied when appropriate (USEPA 2024b). If the exposure unit-wide average concentration exceeds the clean-up level, the component (sub-area) with the highest lead concentration is selected for remediation. Then, the exposure unit-wide average is recalculated using the backfill concentration for the remediated component. If the exposure unit-wide average still exceeds the clean-up level, the component with the next highest soil lead concentration is selected for remediation. The process repeats until the exposure unit-wide average no longer exceeds the clean-up level.

This approach, often in combination with a 'not to exceed' level, is part of the selected remedy in the Record of Decision for several National Priority List (NPL) sites, including the Colorado Smelter (Region 8) and ACM Smelter and Refinery Operable Unit 1 (Region 8). At these sites, the residential property is defined as the exposure unit. Residential components exceeding a not-to-exceed level (a higher concentration than the property-wide clean-up level) are targeted for remediation, and additional components are remediated as needed until the property-wide clean-up level is achieved.

A few examples of the impact of applying exposure unit-wide clean-up goals are illustrated in Table 9. Assuming a clean-up goal of 200 mg/kg and backfill concentration of 40 mg/kg, the number of properties and individual property components requiring remediation is vastly reduced when clean-up goals are applied on an exposure unit-wide basis while achieving appropriate risk reduction.

Table 9. Application of a 200 mg/kg Clean-up Goal on an Exposure Unit-wide Basis

Exposure Unit	Pre-remediation		Post-remediation	
	Component Lead Concentration (mg/kg)	Exposure Unit-wide Concentration (mg/kg) ^a	Component Lead Concentration (mg/kg)	Exposure Unit-wide Concentration (mg/kg) ^a
Property A	173	176	NA – no remediation required	NA – no remediation required
	140			
	216			
Property B	262	227	262	137
	110		110	
	307*		40 ^b	
Property C	99.3	214	99.3	174
	155		155	
	224		224	
	176		176	
	224		224	
	247		247	
	397*		40 ^b	
	205		205	
	197		197	

Notes:

Individual components (sub-areas) with lead concentrations greater than 200 mg/kg are shaded.

Component with highest lead concentration slated for remediation identified with an asterisk (*).

^a Simple averaging applied across components.

^b Assumes a backfill concentration of 40 mg/kg.

NA = not analyzed

5. CLEARER GUIDANCE MUST BE PROVIDED ON ANTHROPOGENIC BACKGROUND

OLEM's recommendation to lower the residential soil lead RSLs and apply lower blood lead targets will make characterization of anthropogenic background a key factor at many residential clean-up sites. According to USEPA (2024a), "Consistent with the Role of Background in the CERCLA Cleanup Program [USEPA 2002], cleanup levels should not be set at values below natural or anthropogenic background. When the IEUBK-derived cleanup level is lower than site-specific background, the cleanup level should be set at background" (USEPA 2024a, pg. 7). For many sites, anthropogenic and site sources are comingled, making it difficult to distinguish anthropogenic impacts from site source impacts. In this section, we provide an approach to using data from the HUD residential soil lead surveys combined with site-specific house age data to generate site-specific anthropogenic background estimates.

5.1 Anthropogenic Background Must Be Considered at All Sites

It is well documented that the historical uses of leaded gasoline and lead-based paints have contributed significantly to soil lead concentrations in many areas across the United States. Soil near roadways, older housing structures (particularly pre-1940s buildings), and older urban areas where these two factors are often combined have been documented to have high soil lead concentrations that far exceed natural background and the new RSLs (ATSDR 2020). Many residential soil lead NPL sites are located in such areas.

The updated residential soil lead guidance states that if an additional source of lead is identified, such as lead-based paint, an RSL of 100 mg/kg based on a blood lead target of 3.5 µg/dL should be applied. However, in areas where older housing structures are prevalent, anthropogenic soil lead background is likely to be well above 100, 200, and even 400 mg/kg.

Characterizing site-specific anthropogenic background at NPL sites is a challenge. The updated guidance states that site-specific soil lead background should, "...include consideration of the conceptual site model, natural geological lead sources for the locality, and historical/current anthropogenic activities unrelated to site releases of lead" (USEPA 2024a, pg.7). However, at many residential soil lead sites, it is challenging and resource intensive to characterize anthropogenic lead activities unrelated to the site because the entire residential area falls within the site-impacted boundary.

At present, USEPA Region 4 appears to be the only USEPA region that has characterized anthropogenic lead background for urban soils. USEPA Region 4 (2018) conducted an urban background study for lead and other metals in multiple Region 4 cities with the goals of 1) developing a robust, regional dataset representative of anthropogenic background, and 2) developing a data collection and analysis process that can be consistently applied in Region 4 states and other interested USEPA regions (USEPA 2018). While of interest, this regional approach may not offer sufficient density for determining anthropogenic background for a particular site. Region 4's sampling was completely on public properties and may not adequately represent residential properties where anthropogenic sources may be different (e.g., lead-based paint is more likely to be present on a residential property than a public property).

5.2 HUD (2021) Data Can Be Used to Calculate Anthropogenic Background When Site-Specific Anthropogenic Background Cannot be Estimated

The HUD 2011 and 2021 American Healthy Homes Surveys (AHHS I and II) provide a rich dataset of residential soil lead concentrations in residential areas across the United States segregated by house age, region, and other demographic factors. These datasets capture background lead sources that contribute to soil lead concentrations around the U.S., particularly lead-based paint, but presumably also contributions from historical leaded gasoline, natural geology, etc. where relevant. At sites where site-specific anthropogenic background datasets cannot be generated, residential soil lead data from HUD may be able to be used to generate anthropogenic background estimates based on the distribution of house ages in the affected neighborhoods. The HUD American Healthy Homes Survey II (AHHS II) sampled 703 housing units for lead from March 2018 to June 2019 (HUD 2021). Of these, 595 housing units were sampled for soil and 393 included bare soil.⁷ Housing units were sampled in regions across the U.S. designated as either Northeast, Midwest, South, or West. As described in Appendix A of the AHHS II, at each dwelling unit a maximum of 6 composite soil samples were collected to a ½ inch depth ideally from bare soil (HUD 2017). Composite soil samples were collected from four different locations at each dwelling unit: the main entry, foundation/dripline, mid-yard area, and play areas. To analyze for lead, soil was later dried at room temperature, sieved to <2 millimeters (mm), sub-sampled, then sent to USEPA for laboratory analysis.

The HUD sampling approach is similar to residential soil lead sampling programs under CERCLA. Both use composite sampling of multiple components on the residential property to account for soil lead concentrations at a residence. Both sample soil at depths relevant for human exposure (surface soil). Additionally, both programs sieve the soil samples, although HUD sieved to the <2 mm particle size fraction whereas USEPA currently recommends sieving to <150 micrometers (µm) at residential soil lead sites (USEPA 2016b). If HUD had sieved to <150 µm, soil lead concentrations would likely be higher.⁸ Thus, the HUD (2021) results potentially underestimate soil lead concentrations analyzed in accordance with the USEPA residential soil handbook (USEPA 2024b).

The percent of housing units with bare soil lead greater than 200 and 400 mg/kg by region and construction year is shown in Table 10. HUD (2021) does not present this information for soil lead greater than 100 mg/kg, but the percentage of housing units exceeding 100 mg/kg would be even higher. The HUD (2021) data suggest that a significant portion of housing units in the United States exceed the updated RSLs, and even the old RSL of 400 mg/kg. The percent exceeding RSLs varies by region and house construction year. For example, 29.7% of all homes in the Northeast are estimated to have soil lead above 200 mg/kg, compared with 6.5% in the South. Of note, over 65% of homes constructed before 1940 across the United States are estimated to have soil lead greater than 200 mg/kg and over 45% have soil lead greater than 400 mg/kg.

Summary statistics presented in AHHS II for lead in bare soil by construction year are summarized in Table 11. This information can be used to generate distributions needed for background soil datasets. Notably, for houses built prior to 1940, the median soil lead concentration is 239 mg/kg and the 90th percentile is 841 mg/kg. Whenever a residential neighborhood has many older homes, the anthropogenic background will exceed the RSLs. We recommend deriving site-specific expected anthropogenic background by using these data to generate distributions. For example, if a community

⁷HUD (2021) provides summary statistics for bare soil most consistently throughout the report, so statistics for bare soil areas are presented here.

⁸Juhasz et al. (2011) found soil lead concentrations increased as particle sizes decreased in an analysis of lead in four soil particle size fractions (<2 mm, <250 µm, <100 µm, and <50 µm).

has 50% of homes built before 1940 and 50% built between 1940 and 1959, the expected mean concentration would be 246 mg/kg (i.e., the average of 405 and 87 mg/kg). The 90th percentile would be 511 mg/kg. Clearly, the anthropogenic background for such a site exceeds the RSLs, and use of this data informs meaningful and reasonable site assessment and risk management decision-making.

Table 10. Percent Housing Units (HU) with Bare Soil Lead Greater Than 200 and 400 mg/kg – AHHS II

HU Characteristic	Estimated % of HUs with Bare Soil Lead $\geq$ 200 mg/kg	Estimated % of HUs with Bare Soil Lead $\geq$ 400 mg/kg	HUs in Sample
Region			
Northeast	29.7%	20.1%	58
Midwest	28.0%	16.7%	106
South	6.5%	4.2%	149
West	9.6%	6.9%	80
House Construction Year			
1978-2017	5.0%	3.6%	134
1960-1977	5.2%	4.2%	118
1940-1959	22.1%	8.2%	89
Before 1940	65.5%	46.4%	52
Notes: Values from HUD "American Health Homes Survey II – Lead Findings" Tables 7-10 and 7-11 HU = housing unit			

Table 11. Bare Soil Lead Concentrations (mg/kg) – AHHS II

House Construction Year	Mean	Median	90 th Percentile	HUs in Sample
1978-2017	41	15	56	134
1960-1977	51	26	84	118
1940-1959	87	49	181	89
Before 1940	405	239	841	52
Notes: Values from HUD "American Health Homes Survey II – Lead Findings" Tables 7-2 and 7-9 HU = housing unit				

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