ESTIMATION OF LEAD BIOAVAILABILITY IN SOIL AND DUST: EVALUATION OF THE DEFAULT VALUE FOR THE INTEGRATED EXPOSURE UPTAKE BIOKINETIC MODEL FOR LEAD IN U.S. CHILDREN

OVERVIEW

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

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

The current default value for the *Absorption Fraction,* or absolute bioavailability (ABA), for lead in soil and indoor dust for children (birth to 7 years) in the IEUBK model (v. 1.1, build 11) is a central tendency estimate for lead in soil or dust that is absorbed from a child's gastrointestinal tract into the systemic circulation of blood (U.S. EPA 1994a, b). Soluble lead in water and food is

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

[2]The GM represents the central tendency estimate (e.g., mean, 50th percentile) of PbB concentration of children from a hypothetical population (Hogan et al., 1998). The TRW recommends that the soil contribution to dust lead be evaluated by comparing the average or arithmetic mean of soil lead concentrations from a representative area in the child's yard (U.S. EPA, 1994a). If an arithmetic mean (or average) is used, the model provides a central point estimate for risk of an elevated PbB concentration. By definition, a central tendency estimate is equally likely to over- or under-estimate the soil/indoor dust RBA at lead-contaminated sites. 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 concentration. See U.S. EPA (1994b) for further information.

[3]The IEUBK model uses a log-normal probability distribution to characterize this variability (U.S. EPA, 1994a). The biokinetic component of the IEUBK model output provides a central estimate of PbB concentration, which is used to provide the geometric standard deviation (GSD). The GSD encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability. In the IEUBK model, the GSD is intended to reflect variability in PbB concentrations where different individuals are exposed to different media concentrations of lead. The recommended default value for GSD (1.6) was derived from empirical studies with young children where both blood and environmental lead concentrations were measured (White et al., 1998).

estimated to have an ABA of 0.5 (50%) based on the bioavailability of soluble lead acetate (*i.e.,* the standard reference material). The default value for ABA for lead in soil and dust is 0.3 or 30%. This value corresponds to a relative bioavailability (RBA) of 0.6 or 60% (60%; *i.e.*, $RBA=ABA_{soil\ or\ dust}/ABA_{soluble\ lead\ acetate}= 0.3/0.5$). The IEUBK model assumes that indoor dust is derived predominately from soil using a default mass fraction of soil in indoor dust variable (MSD) of 70%. The RBA of lead in outdoor soil applies to lead in indoor dust. The default values were originally derived from an absorption algorithm based on data from lead mass balance and feeding studies in human infants and children (U.S. EPA 1994a).

The purpose of this document is to review and analyze the data and published literature that is currently available on the lead bioavailability of soil and dust and to provide the technical basis to retain the IEUBK model (v. 1.1, build 11) default value for the soil and dust ABA as the central tendency value of 30% (Table 1). U.S. EPA performed a literature search for data on soil lead bioavailability (January 2000–August 2010) and queried U.S. EPA Regions for relevant data through August 2010.

The TRW continues to recommend and encourage the use of the accurate and inexpensive measures of site-specific bioavailability using the SW-846 1340[4] EPA - validated *in vitro* method (U.S. EPA, 2017, 2007a,b; 1989). Reliable, site-specific data on the bioavailability of lead in soil, dusts, or other soil-like waste material can be used to improve the accuracy of lead absorption and resulting blood lead levels predicted for the sites. EPA strongly encourages IEUBK model users to obtain representative site-specific *in-vitro* bioaccessibility data to estimate bioavailability in soil with EPA SW-846 Method 1340. EPA SW-846 Method 1340 is a reliable, cost-effective and widely available laboratory method to improve the accuracy of exposure and risk calculations. Consequently, site-specific information related to the bioavailability of a contaminant in the exposure medium may be as important as the concentration of the contaminant in that medium.
There may be site-specific situations where the project team may determine that collecting site-specific bioavailability is not warranted.

Table 1. Comparison of current and recommended estimates for the Absorption Fraction variable in the IEUBK model

	Absorption Fraction	
Parameter	**IEUBK Model (v. 1.1, build 11) CTE[a] Default**	**Recommended IEUBK Model (v. 2) CTE[a] Default**
Soil	30	30
Dust	30	30

[a]Central Tendency Estimates

This document provides the technical basis for the *Absorption Fraction* variable in the IEUBK model. The intended audience is risk assessors familiar with using the IEUBK model. For further background information on both this variable and use of the IEUBK model in Superfund

[4] https://www.epa.gov/hw-sw846/sw-846-test-method-1340-vitro-bioaccessibility-assay-lead-soil

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).

INTRODUCTION

The IEUBK model 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).

Depending on the chemical and physical characteristics of lead, less than 100% of lead entering the body is readily absorbed into systemic circulation (*i.e.*, bioavailability). The term bioavailability can be expressed either in absolute terms (absolute bioavailability) or in relative terms (relative bioavailability). U.S. EPA (2007a) defines absolute bioavailability (ABA) as the ratio of the amount of the chemical absorbed to the amount ingested (*i.e.*, ABA = Absorbed Dose/Ingested Dose). Relative bioavailability is indexed by measuring the bioavailability of a particular substance relative to a standard reference material, such as lead acetate (*i.e.*, RBA = $ABA_{\text{test material}}/ABA_{\text{reference material}}$) (U.S. EPA, 1994a). For example, if 100 µg of lead in soil were ingested and 30 µg were absorbed[5] into the body, the ABA for soil would be 0.30 (30%) (U.S. EPA, 2007a).

In the IEUBK model, bioavailability, which is referred to as the *Absorption Fraction*, represents a central tendency estimate for lead that is absorbed in a child's gastrointestinal tract into the systemic circulation of blood. Soluble lead in water and food is estimated to have an ABA of 0.5 (50%) based on the bioavailability of soluble lead acetate (*i.e.*, the standard reference material). Lead in soil and dust, however, are estimated to have an ABA of 0.3 (30%). This value corresponds to an RBA of 0.6 (60%; *i.e.*, $RBA=ABA_{\text{soil or dust}}/ABA_{\text{soluble lead acetate}} = 0.3/0.5$). These values were designed to provide representative estimates of lead absorption in children in the

[5] As the amount of lead ingested increases the actual amount of lead absorbed in the gastrointestinal tract may be lower due to saturable absorption (see Figure 3).

U.S. but are not intended to replace representative site-specific data. U.S. EPA (2007a) provides examples of the variability of soil lead RBA for a variety of sites in the United States. The TRW Lead Committee recognizes that bioavailability of lead in soil is influenced by a variety of factors and that there are limitations in both the *in vivo* and *in vitro* assays (U.S. EPA, 2007b). Nevertheless, utilization of *in vivo* (juvenile swine) assays (*i.e.*, bioavailability) and more cost-effective *in vitro* assays (*i.e.*, bioaccessibility; IVBA) to provide site-specific estimates of RBA reduces uncertainty in estimates of potential human health risk at a site[6].

***IN VIVO* METHOD (SWINE ASSAY) - Literature Review**

The TRW Lead Committee identified nineteen reports with information on bioavailability of lead in soil and "soil-like" materials in juvenile swine (Bannon et al., 2009; Casteel et al., 1996a–d; 1997a,b; 1998a–d; 2001; 2004; 2006a–c; Juhasz et al., 2009; Marschner et al., 2006; Smith et al., 2009). Collectively, these studies conducted in swine include 47 estimates of lead RBA for 46 different soil or "soil-like" test materials (Table 2, two RBA estimates are available for the material identified as *Palmerton 2*).

Bannon et al. (2009) measured RBA of lead in eight soil samples from small arms firing ranges in the U.S. The soil samples were sieved to ≤250 μm, and soil lead concentration ranged from 4,549 mg/kg to 24,484 mg/kg. As described by Bannon et al. (2009), the lead values used for dosing animals ranged from 4,503 mg/kg to 23,409 mg/kg (Table 2). The soil samples were thoroughly characterized with regard to lead mineral phase, particle size distribution, and lead matrix association using electron microprobe analysis.

Casteel et al. (1996a–d; 1997a,b; 1998a–d; 2001; 2004; 2006a–c) measured RBA of lead in 27 soil and soil-like materials from the U.S. The soil samples included discrete and composite samples from a number of Superfund sites, as well as two soil samples spiked with galena or National Institute for Standards and Technology (NIST) Standard Reference Material (SRM) lead paint. Test materials were sieved to ≤250 μm, and the lead concentrations ranged from 723 mg/kg to 14,200 mg/kg (Table 2). The soil samples were thoroughly characterized with regard to lead mineral phase, particle size distribution, and lead matrix association using electron microprobe analysis. Because the intent of this analysis was to focus on materials that would be representative of soil at Superfund sites, the galena-enriched soil and NIST SRM paint samples were excluded from the analysis.

Juhasz et al. (2009) measured RBA of lead in five soil samples from two sites: an urban residential site and a former domestic incinerator in Australia. Samples were sieved to ≤250 μm, and soil lead concentrations ranged from 646 mg/kg to 3,905 mg/kg (Table 2). Soil samples were characterized for pH, organic carbon, and concentrations of phosphorous, iron, aluminum, and lead. Although the soil samples in this study are from outside the U.S., the samples are included in the analysis because they represent various sources of urban soil lead contamination not represented in other data sets (*e.g.,* domestic incinerator). In addition, there is no reason to believe these sources of lead would be appreciably different from similar sources in the U.S.

[6]Each system is based on the concept of rate and/or extent of lead solubility in gastrointestinal (*in vivo*) or similar gastric fluid (IVBA) (U.S. EPA, 2007a).

Marschner et al. (2006) measured RBA of lead in five soil samples from Germany. Soil samples were sieved to ≤1 mm, and lead concentrations ranged from 200 mg/kg to 6,330 mg/kg. Soil samples were characterized for clay (%), pH, organic carbon, and concentrations of arsenic, cadmium, lead, chromium, and nickel. Lead doses ranged from 13.9 mg/animal to 445.3 mg/animal (99 to 3,181 µg/kg-bw, respectively; Table 2). However, this study was excluded from the analysis of soil RBA due to the sieving size of this study differing from the other juvenile swine studies. The particle size (i.e., using ≤1 mm rather than ≤250 µm) is known to affect bioavailability of soil.

Smith et al. (2009) measured RBA of lead in two soil samples from Tacoma, Washington. The lead in the soil samples was presumed to come from smelter emissions. Soil samples were sieved to ≤250 µm, and the lead concentration of each sample was 1,000 mg/kg (Table 2). Soil samples were characterized for clay (%), pH, organic carbon, CO_2, and lead concentration.

***IN VIVO* METHOD (SWINE ASSAY) - Analysis**

Table 2 presents the RBA estimate and descriptive information for each test material, and summary statistics for RBA estimates are provided in Tables 3 and 4. Distributions of RBAs are shown in Figure 1. The dataset includes a total of 47 different test materials, collected from 29 different sites. Because the intent of this analysis was to focus on materials that would be representative of *in situ* contaminated soils at Superfund sites, eight of the 47 test materials were excluded. These materials included a soil sample spiked in the laboratory with galena, a soil sample spiked in the laboratory with NIST SRM lead paint, and 5 soils that were sieved to exclude particles >1 mm (soils used to support Superfund risk assessments are sieved to exclude particles >250 µm or >150 µm). Analysis of the resulting subset of 39 (24 sites) soils resulted in a median RBA estimate of 75% and the 5^{th}–95^{th} percentile range is 11–>100% (Table 3). The 39 soils included 8 soils collected from firing ranges, each of which had an RBA of approximately 100% (mean =108%, SD 18; Bannon et al., 2009). When firing range soils were excluded, the median for 31 soils (16 sites) was 60% and the 5^{th}–95^{th} percentile range was 11–97% (Table 3). The mean RBA for the 31 soils (excluding firing ranges) was 54% (SD 32; Table 4). The relatively high RBA for the firing range soils may reflect the high abundance of relatively un-encapsulated lead carbonate (30–90% abundance) and lead oxide (1–60%) in these soils. Similarly, a soil sample (low lead concentration) mixed with a NIST paint standard (55% lead carbonate, 44% lead oxide) also had a relatively high bioavailability (72%, Casteel et al., 2006a). Samples of smelter slag, or soils contaminated with slag, had relatively low RBA (14–40%, n=3) as did a sample from a mine tailings pile (RBA=6%), and a sample of finely ground galena mixed with soil (1%; Casteel et al., 2006a). A single estimate for RBA of interior dust was 51% for one sample collected at the Herculaneum site (Casteel et al., 2006c).

***IN VITRO* METHOD (IVBA) - Literature Review**

A review of soil lead RBA estimates predicted from the IVBA assay identified 270 estimates of lead RBA in soils obtained from 11 hazardous waste sites in U.S. EPA Regions 7 and 8 (U.S. EPA, 2007a). In addition, a review of interior dust lead RBA estimates made using the IVBA assay identified 100 estimates of lead RBA in dusts obtained from the Herculaneum Lead Smelter and Omaha Lead Superfund sites. Small arms firing ranges that utilized the IVBA method to assess bioaccessibility of lead in the firing range soil was also reviewed (Bannon et al., 2009).

***IN VITRO* METHOD (IVBA) - Analysis**

Summary statistics for estimated RBAs based on the IVBA assay are presented in Tables 5 to 8.

- Table 5 presents the summary statistics of RBA estimates of soil and interior dust for 270 test materials collected at 11 different sites. The distribution of soil and dust RBA values is shown in Figure 2.
- In Table 6, the individual test material estimates have been aggregated by site, and summary statistics for the site mean RBAs are presented.
    - The median (50th percentile) for the site-wide RBA estimates based on IVBA assays was 63%, and the 5^{th}–95^{th} percentile range was 34–71% (n=270 soil samples, 11 sites; Table 6). The mean RBA was 57% (SD 15; Table 6).
- Table 7 presents the statistics for the RBA estimates at each site. The 5^{th} - 95^{th} percentile range of RBA estimates based on IVBA was less than the corresponding range of *in vivo* RBA values reported in Tables 3 and 4. A possible contributor to the narrower range of the RBAs that were based on IVBAs may be that the IVBA dataset was limited to soil samples from mining and smelter sites at U.S. EPA Regions 7 and 8.
- Excluded from the IVBA data were 8 soils collected at firing ranges that had a mean RBA based on IVBA of 81% (SD 5%; Bannon et al., 2009). The corresponding mean *in vivo* RBA was 108% (SD 18; Bannon et al., 2009). As noted previously, the relatively high RBA for the firing range soils may reflect the high abundance of relatively un-encapsulated lead carbonate (30–90% abundance) and lead oxide (1–60%) in these soils.
- Table 8 presents a comparison of estimated RBAs for soil and interior dust from two sites is presented in. Mean lead RBA estimates for the Herculaneum site were 47% (SD 7, n=10 samples) for interior dust and 69% (SD 3, n=12 samples) for soil. At the Omaha Superfund site, mean lead RBA estimates were 73% (SD 10, n=90 samples) for interior dust and 70% (SD 10, n=45 samples) for soil.

RESULTS FROM ANALYSES OF DATA FROM *IN VIVO* AND *IN VITRO* METHODS

Of the 27 sites (excluding firing ranges), the estimates include 12 based on swine bioassays and 11 based on IVBA assays. Distributions of RBAs for various relevant strata of the data set described in this memorandum are shown in Table 3. The sample of estimates for soils based on the combined data from IVBA assays (site means) and swine assays (excluding firing ranges and soils sieved to exclude particle sizes >250 μm) has a median RBA of 61% and a 5^{th}–95^{th} percentile range of 14–88% (n=301 soil samples, 27 sites; Table 3). Excluding firing ranges where lead may have RBA values of 100%, soil lead RBA can be expected to have values that fall within the 5^{th}–95^{th} percentile range.

UNCERTAINTY

Limitations in these data preclude making statistical inference about lead RBA in U.S. soils or predicting lead RBA at any specific site. The RBA estimates evaluated were derived from an opportunistic sample of soils and dusts collected at sites where there was a regulatory interest (*e.g.,* remedial investigation or risk assessment) and sufficient resources for analysis (for sites where *in vivo* data are available). Although the data set includes samples from sites impacted by various sources of lead contamination (*e.g.*, mining/smelting, incinerator, shooting ranges), the predominant lead sources in the data set are mining and smelting. As a consequence, the soil

and dust samples are not a statistical sample of soils in any geographic region in the U.S. or for a given source of lead contamination, and extrapolation of these parameters to U.S. soils in general or to a soil at a specific site would be highly uncertain. Nevertheless, the data set has unique value for describing the distribution of lead RBA values that have been encountered in soils from various sites of regulatory interest.

The sample of RBAs shows large variability, both across sites and within sites. The 5^{th}–95^{th} percentile range of RBAs for all soils (excluding firing ranges) is 14–88% for combined IVBA and juvenile swine assays. A wide range of variability within sites is also evident. Within sites coefficients of variation (SD/mean) range from 1 to 87% of the mean based on IVBA results. This range suggests that, at some sites, adequate assessment of a representative value for site-wide soil lead RBA would require sampling at many different locations to ascertain variability. Sources contributing to the variability in these data have not been fully explained, although the relatively strong relationship between IVBA and *in vivo* RBA (*i.e.*, $R^2 > 0.9$) suggests that factors that govern bioaccessibility (*e.g.*, solubility at stomach pH) are important determinants of RBA (Casteel et al., 2006a; U.S. EPA, 2007a). Therefore, some of the variability observed may reflect variability in factors that determine lead solubility (*e.g.*, lead mineralogy, soil characteristics, physical characteristics of lead particles), which may be dependent on the source of lead as well as the fate of lead contamination in the soil.

The swine assay has not been evaluated against data in children, and the primary rationale for using the assay is based on similar physiology (U.S. EPA, 2007a). This data set includes RBA estimates derived from several different swine bioassay protocols (*e.g.*, single dose, multiple dose) and comparisons of results from each protocol when applied to the same test materials are not available. Some soil materials assayed were sieved to include relatively large particle sizes (*i.e.*, <1 mm, Marschner et al., 2006) that may not represent particles that would be expected to adhere to skin (which is predominately particles <250 μm) and, therefore, be irrelevant to risk assessment (Kissel et al., 1996; Choate et al., 2006). For this reason, summary statistics are presented in this memorandum with and without the Marschner et al. (2006) data.

The regression equation relating RBA (swine study data) and IVBA (EPA Method 1340) used in this analysis (Drexler and Brattin, 2007) is not applicable to other *in vitro* assays that have been developed for estimating lead IVBA. Because the regression equation is based on those data, it should not be used to estimate RBA from these *in vitro* assays without validation against *in vivo* RBA measurements made on the same test materials.

Comparisons of *in vitro* assays applied to the same soil test materials have also found considerable variability in IVBA estimates (Saikat et al., 2007; Van de Wiele et al., 2007). This variability has been attributed to differences in assay conditions, including pH, liquid:soil ratios, inclusion or absence of food material, and differences in methods used to separate dissolved and particulate lead (*e.g.*, centrifugation vs. filtration). Given the dependence of IVBA results on assay conditions, *in vitro* assays used to predict *in vivo* RBA should be further evaluated against *in vivo* RBA estimates to quantify uncertainty in RBA predictions for sites that differ from those in the validation (U.S. EPA, 2007a). Furthermore, the IVBA assay used in studies of interior dust has not been evaluated against *in vivo* RBA estimates for dust samples. Although, it is expected that a validated IVBA methodology for soil would perform well for predicting RBA of interior dust, this expectation has not been experimentally confirmed. Factors that may affect *in*

vitro predictions of RBA of interior dust lead could include particle size distribution of interior dust lead and the composition of the dust matrix, which may be quite different from that of soil.

The use of the IVBA assay for predicting *in vivo* RBA of soils that have been treated with high levels of phosphate (*e.g.*, 1% phosphoric acid w/w) is **not recommended**. A comparison of *in vitro* bioaccessibility and *in vivo* RBA of lead in soils that were treated or not treated with phosphate (0.75 or 1% phosphoric acid w/w) showed that while phosphate treatment decreased *in vitro* bioaccessibility, it had no significant effect on *in vivo* RBA measured in swine (U.S. EPA, 2004). X-ray diffraction (XRD) studies of lead mineralogy of soils indicate that treatment of soil with phosphate will promote the formation of insoluble pyromorphite which, in theory, would be expected to decrease lead bioavailability (Scheckel and Ryan, 2004). However, *in vitro* extraction assays also perturb the *in situ* equilibrium between lead pyromorphite and more soluble lead species, and some *in vitro* assays actually promote the formation of insoluble pyromorphite (Scheckel at al., 2005). The *in vitro* formation of pyromorphite could result in an underestimate of *in situ* bioaccessibility and *in vivo* RBA. The TRW will provide recommendations related to phosphate amendments in the future and are available for consultation in the interim.

RECOMMENDATIONS FOR THE IEUBK MODEL

Based on this analysis, the TRW recommends maintaining 0.3 (30%) the value for the *Absorption Fraction* for soil and dust variable (See Figure 3). This value corresponds to an RBA of 0.6 (60%) and is a central tendency value of the reported measured IVBAs from soils that are not firing ranges. Unless site-specific RBA information is available from a validated assay, the TRW recommends a default RBA of 1.0 (100%) be used in cases where site history indicates that the site was a firing range. However, for all other sites the TRW does not recommend changing this value unless site-specific information is available that meet the Data Quality Objectives (U.S. EPA, 2006) of the site.

The TRW recommends that all lead-contaminated Superfund Sites include representative site-specific bioavailability using the validated SW-846 Method 1340 IVBA test for estimating soil lead RBA at the site (U.S. EPA, 2017)[7]. The TRW also recommends that a central tendency estimate from representative site-specific IVBA analyses be used as the input to the IEUBK model for all decision units within a site. Using a central tendency estimate for calculation of risk or a soil cleanup goal is consistent with using central tendency values as inputs to the IEUBK model (White et al., 1998).

IMPACT ON IEUBK MODEL PREDICTIONS

[7] The Office of Superfund Remediation and Technology Innovation has determined that a specific *in vitro* bioaccessibility (IVBA) assay for lead is a validated method for predicting RBA of lead in soils for use in site-specific human health risk assessment (U.S. EPA, 2007a,b, 2008, 2009, 2017). This IVBA assay is less expensive than and less time consuming than *in vivo* bioavailability bioassays that have been used to estimate soil lead RBA. As a result, this IVBA assay can be used to systematically characterize soil lead RBA at sites (*i.e.*, multiple samples per site) to reduce uncertainty in site-specific risk assessments and cleanup goals. https://www.epa.gov/hw-sw846/sw-846-update-vi-announcements#UpdateVI-PhaseI

This memo supports the existing default absorption fraction of 0.3 (30%) in the IEUBK model. Hence there is no change (see Figure 3). Unless site-specific RBA information is available from a validated assay, the TRW recommends a default RBA of 1.0 (100%) be used in cases where site history indicates that the site was a firing range.

REFERENCES

Bannon, D.I.; Drexler, J.W.; Fent, G.M.; Casteel, S.W.; Hunter, P.J.; Brattin, W.J.; Major, M.A. 2009. Evaluation of small arms range soils for metal contamination and lead bioavailability. Environ Sci Technol. Dec 15; 43(24):9071-6.

Casteel, S.W.; Weis, C.P.; Henningsen, G.M.; Hoffman, E.; Brattin, W.J.; Hammon, T.L. 1996a. Bioavailability of lead in soil samples from the Smuggler Mountain NPL Site: Aspen, Colorado. Available in the public docket for the site.

Casteel, S.W.; Weis, C.P.; Henningsen, G.M.; Hoffman, E.; Brattin, W.J.; Hammon, T.L. 1996b. Bioavailability of lead in soil samples from the Jasper County, Missouri Superfund Site. ‡

Casteel, S.W.; Brown, L.D; Dunsmore, M.E.; Weis, C.P.; Henningsen, G.M.; Hoffman, E.; Brattin, W.J.; Hammon, T.L. 1996c. Bioavailability of lead in slag and soil samples from the Murray Smelter Superfund Site. ‡

Casteel, S.W.; Brown, L.D; Dunsmore, M.E.; Weis, C.P.; Henningsen, G.M.; Hoffman, E.; Brattin, W.J.; Hammon, T.L. 1996d. Bioavailability of lead in soil samples from the New Jersey Zinc NPL Site: Palmerton, Pennsylvania. ‡

Casteel, S.W.; Cowart, R.; Weis, C.P.; Henningsen, G.M.; Hoffman, E.; Brattin, W.J.; Guzamn, R.J.; Starost, M.F.; Payne, J.T.; Stockham, S.L.; Becker, S.V.; Drexler, J.W.; Turk, J.R. 1997a. Bioavailability of lead to juvenile swine dosed with soil from the Smuggler Mountain NPL site, Colorado. Fund. Appl. Toxicol. 36:177-187.

Casteel, S.W.; Guzman, R.; Starost, M.F.; Weis, C.P.; Henningsen, G.M.; Hoffman, E.; Brattin, W.J.; Hammon, T.L. 1997b. Bioavailability of lead in soil samples from the Kennecott NPL Site: Salt Lake City, Utah. ‡

Casteel, S.W.; Weis, C.P.; Henningsen, G.M.; Hoffman, E.; Brattin, W.J.; Hammon, T.L. 1998a. Bioavailability of lead in a soil sample from the Butte NPL Site: Butte, Montana. ‡

Casteel, S.W.; Brown, L.D; Dunsmore, M.E.; Weis, C.P.; Henningsen, G.M.; Hoffman, E.; Brattin, W.J.; Hammon, T.L. 1998b. Bioavailability of lead in soil and mine waste from the California Gulch NPL Site: Leadville, Colorado. ‡

Casteel, S.W.; Weis, C.P.; Henningsen, G.M.; Hoffman, E.; Brattin, W.J.; Hammon, T.L. 1998c. Bioavailability of lead in a slag sample from the Midvale Slag NPL Site: Midvale, UT. ‡

Casteel, S.W.; Brown, L.D; Dunsmore, M.E.; Weis, C.P.; Henningsen, G.M.; Hoffman, E.; Brattin, W.J.; Hammon, T.L. 1998d. Bioavailability of lead in unweathered Galena-enriched soil. ‡

Casteel, S.W.; Brattin, W.J.; Hammon, T.L. 2001. Bioavailability of lead in test materials from the VB-I70 Site: Denver, Colorado. ‡

Casteel, S.W.; Evans, T.J.; Brattin, W.J.; Wahlquist, A.M. 2004. Relative bioavailability of lead in test materials from a Superfund Site in Omaha, Nebraska. ǂ

Casteel, S.W.; Weis, C.P.; Henningsen, G.M.; Brattin, W.J. 2006a. Estimation of relative bioavailability of lead in soil and soil-like materials using young swine. Environ Health Perspect. 114 (8): 1162-1171.

Casteel, S.W.; Fent, G.; Tessman, R.; Brattin, W.J.; Wahlquist, A.M. 2006b. Relative bioavailability of lead in soils from the Big River Mine Tailings Site and the surrounding residential areas. ǂ

Casteel, S.W.; Fent, G.; Tessman, R.; Brattin, W.J.; Wahlquist, A.M. 2006c. Relative bioavailability of lead in soil from the Herculaneum Lead Smelter Site in Herculaneum, Missouri: Study 2. ǂ

Choate, L.M.; Ranville, J.F.; Bunge, A.L.; Macalady, D.L. 2006. Dermally adhered soil: 1. Amount and particle-size distribution. Integr Environ Assess Manag 2(4): 375-384. Available online at: http://www.ncbi.nlm.nih.gov

Drexler, J.W. and Brattin, W.J. 2007. An *in vitro* procedure for estimation of lead relative bioavailability with validation. Hum Ecol Risk Assess. 13(2): 383-401.

Hogan, K.; Marcus, A.; Smith, R.; White, P. 1998. Integrated exposure, uptake, biokinetic model for lead in children: Empirical comparison with epidemiologic data. Environ. Health Perspect. 106(Suppl 6): 1557–1567. Available online at: http://www.ncbi.nlm.nih.gov.

Juhasz, A.L.; Weber, J.; Smith, E.; Naidu, R.; Marschner, B.; Rees, M.; Rofe, A.; Kuchel, T.; Sansom, L. 2009. Evaluation of SBRC-Gastric and SBRC-Intestinal Methods for the Prediction of *In Vivo* Relative Lead Bioavailability in Contaminated Soils. Environmental Science and Technology 43: 4503–4509.

Kissel, J.C.; Richter, K.Y.; Fenske, R.A. 1996. Factors affecting soil adherence to skin in hand-press trials. Bull Environ Contam Toxicol 56(5): 722-728.

Marschner, B.; Welge, P.; Hack, A.; Wittsiepe, J.; Wilhelm, M. 2006. Comparison of soil Pb *in vitro* bioaccessibility and *in vivo* bioavailability with Pb pools from a sequential soil extraction. Environmental Science and Technology 40(8): 2812-2818.

Saikat, S.; Barnes, B.; Westwood, D. 2007. A review of laboratory results for bioaccessibility values of arsenic, lead and nickel in contaminated UK soils. J Environ Sci Health A Tox Hazard Subst Environ Eng, 42: 1213–1221.

Scheckel, K.G. and Ryan, J.A. 2004. Spectroscopic speciation and quantification of lead in phosphate-amended soils. J Environ. Qual 33: 1288-1295.

Scheckel, K.G.; Ryan, J.A.; Allen, D.; Lescano, N.V. 2005. Determining speciation of Pb in phosphate-amended soils: Method limitations. Sci Total Environ 350(1-3): 261-272.

Smith, D.M., Jr.; Mielke, H.W.; Heneghan, J. B. 2009. Subchronic lead feeding study in male rats and micropigs. Environ Toxicol. 24(5): 453-461. October.

U.S. Environmental Protection Agency (U.S. EPA). 1989. Review of the National Ambient Air Quality Standard for Lead: Exposure Analysis Methodology and Validation. EPA 450/2-89-011. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. June 1989.

U.S. Environmental Protection Agency (U.S. EPA). 1994a. Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children. United States Environmental Protection Agency, Office of Emergency and Remedial Response. Publication Number 9285.7-15-1. EPA/540/R-93/081.

U.S. Environmental Protection Agency (U.S. EPA). 1994b. Validation Strategy for the Integrated Exposure Uptake Biokinetic Model for Lead in Children [EPA 9285.7-21]

U.S. Environmental Protection Agency (U.S. EPA). 1998. Short Sheet: IEUBK Model Mass Fraction of Soil in Indoor Dust (M_{SD}) Variable. U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response: Washington, DC. EPA #540-F-00-008, OSWER #9285.7-34. June. Available online at: http://www.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). 2004. Mine Waste Technology Program. Phosphate Stabilization of Heavy Metals Contaminated Mine Waste Yard Soils, Joplin, Missouri NPL Site. Cincinnati, OH, U.S. Environmental Protection Agency. EPA 600/R-04/090 April, 2004. Available online at: http://www.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). 2006. Guidance on Systematic Planning Using the Data Quality Objectives Process. EPA/240/B-06/001. Available online at: http://www.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). 2007a. Estimation of Relative Bioavailability of Lead in Soil and Soil-like Materials Using *In Vivo* and *In Vitro* methods. OSWER 9285.7-77. May 2007. Available online at: http://www.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). 2007b. Guidance for Evaluating the Oral Bioavailability of Metals in Soils for Use in Human Health Risk Assessment. Transmittal Memo from James E. Woolford to the Regions, dated July 3, 2007. Available online at: http://www.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). 2008. Standard Operating Procedure for an *In Vitro* Bioaccessibility Assay for Lead in Soil. OSWER 9200.1-86. November 2008. Available online at: http://www.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). 2009. Validation assessment of *in vitro* lead bioaccessibility assay for predicting relative biovailability of lead in soils and soil-like materials at superfund sites. OSWER 9200.3-51. Washington D.C. Available online at: http://www.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). 2017. Release of Standard Operating Procedure for an *In Vitro* Bioaccessibility assay for Lead and Arsenic in Soil and Validation Assessment of *In Vitro* Arsenic Bioaccessibility Assay for Predicting Relative Bioavailability of

Arsenic in Soils and Soil-like Materials at Superfund Sites. OLEM 9355.4-29 April 20, 2017. Available online at: http://www.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). 2020. Memorandum from John Vandenberg, Director Health and Environmental Effects Assessment Division OSRTI, OLEM To Brigit Lowery, Director Assessment and Remediation Division, OSRTI, OLEM. Subject: Evaluation of IEUBK version 2.0 model performance. September 23.

Van de Wiele, T.R.; Oomen, A.G.; Wragg, J.; Cave, M.; Minekus, M.; Hack, A.; Cornelis, C.; Rompelberg, C.J.M.; De Zwart, L.L.; Klinck, B.; Van Wijnen, J.; Verstraete, W.; Sips, A. 2007. Comparison of five *in vitro* digestion models to *in vivo* experimental results: Lead bioaccessibility in the human gastrointestinal tract. J Environ Sci Health A Tox Hazard Subst Environ Eng, 42: 1203–1211. Available online at: http://dx.doi.org

White, P.D.; Van Leeuwen, P.; Davis, B.D.; Maddaloni, M.; Hogan, K.A.; Marcus, A.H.; Elias, R.W. 1998. The conceptual structure of the integrated exposure uptake biokinetic model for lead in children. Environ Health Perspect 106 Suppl 6: 1513-1530. Available online at: http://ehpnet1.niehs.nih.gov

Table 2. Summary of Results of Swine RBA Studies

Source	Test Material	Lead (mg/kg soil)	Dose (µg/kg bw)	RBA[a]	Preferred Range[b]	LCL 95	UCL 95	Study Protocol	Study
Australia	Domestic incinerator	2885	1154	10		NA	NA	Single gavage dose, RBA estimated from blood AUC	Juhasz et al. 2009
		2980	1192	11		NA	NA	Single gavage dose, RBA estimated from blood AUC	Juhasz et al. 2009
		3905	1562	15		NA	NA	Single gavage dose, RBA estimated from blood AUC	Juhasz et al. 2009
Australia	Urban residential	646	258.4	18		NA	NA	Single gavage dose, RBA estimated from blood AUC	Juhasz et al. 2009
		765	306	19		NA	NA	Single gavage dose, RBA estimated from blood AUC	Juhasz et al. 2009
Big River Mine Tailings Site, Desloge, MO	Mine tailings (TM1)	2628	50–300	40	30–51			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 2006b; Results presented in Section 4.4.2 of RA
	Residential yard (TM2)	2510	50–300	80	54–1.09			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 2006b; Results presented in Section 4.4.2 of RA
California Gulch NPL Site, Leadville, CO	AV slag	10600	25–225	20		9	31	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		10600	25–225	18	16–20			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1998b
California Gulch NPL Site, Leadville, CO	FeMn PbO	4320	25–225	105		57	156	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		4320	25–225	90	87–94			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1998b
California Gulch NPL Site, Leadville, CO	Oregon Gulch tailings	1270	225	6		-1	15	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		1270	225	6	5–6			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1998b
California Gulch NPL Site, Leadville, CO	Phase I, residential	7510	25–225	72		38	107	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		7510	25–225	74	71–76			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1998b
Germany, Bruchsal	Home garden	237	214	40		NA	NA	28-day repeated dosing, RBA estimated from tissue Pb	Marschner et al. 2006
Germany, Carl-1	Coal mine	786	277	63		NA	NA	28-day repeated dosing, RBA estimated from tissue Pb	Marschner et al. 2006
Germany, Hamburg	River deposit	578	279	36		NA	NA	28-day repeated dosing, RBA estimated from tissue Pb	Marschner et al. 2006

Table 2. Summary of Results of Swine RBA Studies

Source	Test Material	Lead (mg/kg soil)	Dose (µg/kg bw)	RBA[a]	Preferred Range[b]	LCL 95	UCL 95	Study Protocol	Study
Germany, Lothringen-1	Coal mine	200	99	17		NA	NA	28-day repeated dosing, RBA estimated from tissue Pb	Marschner et al. 2006
Germany, Oker-11	Floodplain, playground	6330	3181	55		NA	NA	28-day repeated dosing, RBA estimated from tissue Pb	Marschner et al. 2006
Herculaneum Lead Smelter, Herculaneum, MO	HER-3201 soil	2131	75–675	82	65–102			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 2006c
	Soil			97 (soil) 52 (dust)					Section 3.5.2 of RA
Jasper County, MO Superfund Site	High level Pb mill	6940	75–675	82		51	114	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		6940	75–675	79	82–76			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996d
Jasper County, MO Superfund Site	High level Pb smelter	10800	75–625	61		43	79	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		10800	75–675	58	56–61			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996b
Jasper County, MO Superfund Site	Low level Pb yard	4050	75–625	90		63	120	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		4050	75–675	80	78–82			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996b
Kennecott Site, Salt Lake City, UT	Bingham Creek, channel soil	6330	75–675	27		19	36	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		6330	75–675	28	27–28.9			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1997b
Kennecott Site, Salt Lake City, UT	Bingham Creek, residential	1590	75–450	27		17	40	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		1590	75–450	30.7	28.8–32.5			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1997b; Bioavailability study documented in separate report: US EPA 1997.
Midvale Slag NPL Site, Midvale, UT	OU 2 (water quenched slag)	8170	75–675	14		7	24	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		7900	75–675	17	14–20			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1998c; Bioavailability study documented in separate report: US EPA 1998.

Table 2. Summary of Results of Swine RBA Studies

Source	Test Material	Lead (mg/kg soil)	Dose (µg/kg bw)	RBA[a]	Preferred Range[b]	LCL 95	UCL 95	Study Protocol	Study
Murray Smelter Superfund Site, Murray City, UT	Slag	11700	75–625	40		23	64	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		11500	75–675	53	55–51			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996c
Murray Smelter Superfund Site, Murray City, UT	Soil	3200	75–675	51		29	79	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		3200	75–675	71	67–75			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996c; Bioavailability study documented in separate report: US EPA, 1996.
NA[c]	Galena-Enriched Soil	11200	75–675	1		0	3	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		11200	75–675	≤1				15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1998d
NA[d]	NIST Paint	8350	75–675	72		44	98	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
New Jersey Zinc NPL, Palmerton, PA	Location 2	3230	25–225	60		34	93	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		3230	25–225	67	74-60			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996d
		3230	25–225	86		43	152	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
New Jersey Zinc NPL, Palmerton, PA	Location 4	2150	25–225	49		29	72	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		2150	25–225	54	58–50			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996d
Omaha Superfund Site, Omaha, NE	(TM2)	1630	75–400	74	72–76			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 2004
				83				15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Results presented in Appendix B and Table 4-3 of RA. RBA values based on re-analysis, original analysis resulted in RBA values of 1.01 and 0.74
Omaha Superfund Site, Omaha, NE	TM1	1650	75–400	101	101–102			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 2004
				96				15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Results presented in Appendix B and Table 4-3 of RA. RBA values based on

Table 2. Summary of Results of Swine RBA Studies

Source	Test Material	Lead (mg/kg soil)	Dose (µg/kg bw)	RBA[a]	Preferred Range[b]	LCL 95	UCL 95	Study Protocol	Study
									re-analysis, original analysis resulted in RBA values of 1.01 and 0.74
Silver Bow Creek/Butte Area NPL Site, Butte, MT	Soil	8530	75–675	14		6	23	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		8600	75–675	19	17–22			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1998a
Small arms range, AK	Soil	13992	~75–500[e]	116		86	160	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Bannon et al. 2009
Small arms range, LA	Soil	15705	~75–500[e]	112		79	155	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Bannon et al. 2009
Small arms range, MD	Soil	15667	~75–500[e]	140		80	218	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Bannon et al. 2009
Small arms range, MD	Soil	23333	~75–500[e]	103		69	142	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Bannon et al. 2009
Small arms range, NE	Soil	14372	~75–675[e]	93		59	153	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Bannon et al. 2009
Small arms range, OR	soil	19464	~75–675[e]	112		81	151	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Bannon et al. 2009
Small arms range, SD	Soil	4503	~75–675[e]	77		55	108	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Bannon et al. 2009
Small arms range, WA	Soil	23409	~75–675[e]	107		67	155	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Bannon et al. 2009
Smuggler Mountain NPL Site, Aspen, CO	Aspen berm	14200	75–675	74		48	108	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		14200	75–675	60	56–65			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996a
Smuggler Mountain NPL Site, Aspen, CO	Residential composite	3870	75–675	75		50	104	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		3870	75–675	61	58–72			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996a
Tacoma, WA	Soil	1000	153	40		NA	NA	30-day in diet, RBA estimated from tissue Pb	Smith et al. 2009
Vasquez Boulevard/I-70 Site (VB-I70), Denver, CO	Eastern sample (TM1)	723	75–500	87	87–88			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 2001; Bioavailability study documented in separate report: EPA. 2001.

Table 2. Summary of Results of Swine RBA Studies

Source	Test Material	Lead (mg/kg soil)	Dose (µg/kg bw)	RBA[a]	Preferred Range[b]	LCL 95	UCL 95	Study Protocol	Study
	Western sample (TM2)	987	75–500	81	76–85			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 2001; Bioavailability study documented in separate report: EPA. 2001

AK: Arkansas; CO: Colorado; LA: Louisiana; MD: Maryland; MO: Missouri; MT: Montana; NE: Nebraska; OR: Oregon; PA: Pennsylvania; SD: South Dakota; UT: Utah; WA: Washington; OU-2: Operable Unit-2; NA: not available; TM: test material; NPL: National Priorities List; LCL: 5% lower confidence limit; UCL: 95% upper confidence limit.

[a]Values reported herein are as reported by the cited report, and may differ from other reports.
[b] Preferred Range refers to the interval from the RBA based on blood to the mean of the blood RBA and tissue mean RBA. The suggested point estimate (RBA) is the mid-point of the preferred range.
[c]A mixture of approximately 5.8% NIST SRM 2589b and 94.2% low-Pb soil (<50 mg/kg) collected in Leadville, Colorado (Casteel et al., 2006a).
[d]A mixture of approximately 1.2% galena and 98.8% low-Pb soil (<50 mg/kg) collected in Leadville, Colorado (Casteel et al., 2006a).
[e]Doses were estimated from plots in Figure A of Bannon et al. (2009).

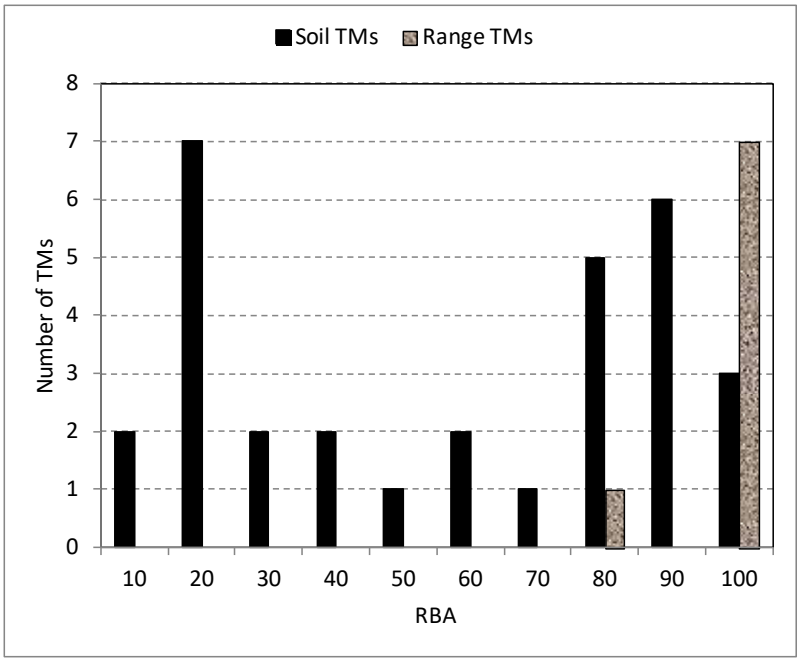

Figure 1. Distribution of test material (TM) RBAs based on swine assays. Shown are soil TMs (n=31) excluding galena-enriched soil (n=1; Casteel et al., 2006a), the NIST SRM paint sample (n=1; Casteel et al., 2006a), soil from firing range (n=8; Bannon et al., 2009), soils sieved at ≤1 mm (n=5; Marschner et al., 2006), and one interior dust sample from the Herculaneum site.

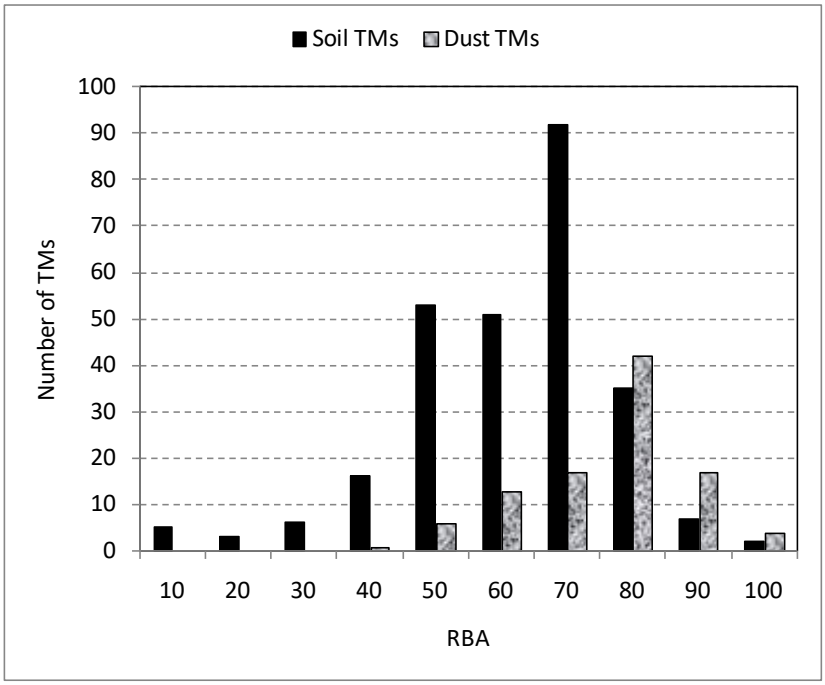

Figure 2. Distribution of soil and dust test material (TM) RBAs based on IVBA from soil (n=270 from 11 sites) and dust (n=100 from 2 sites) data in shown in Table 4.

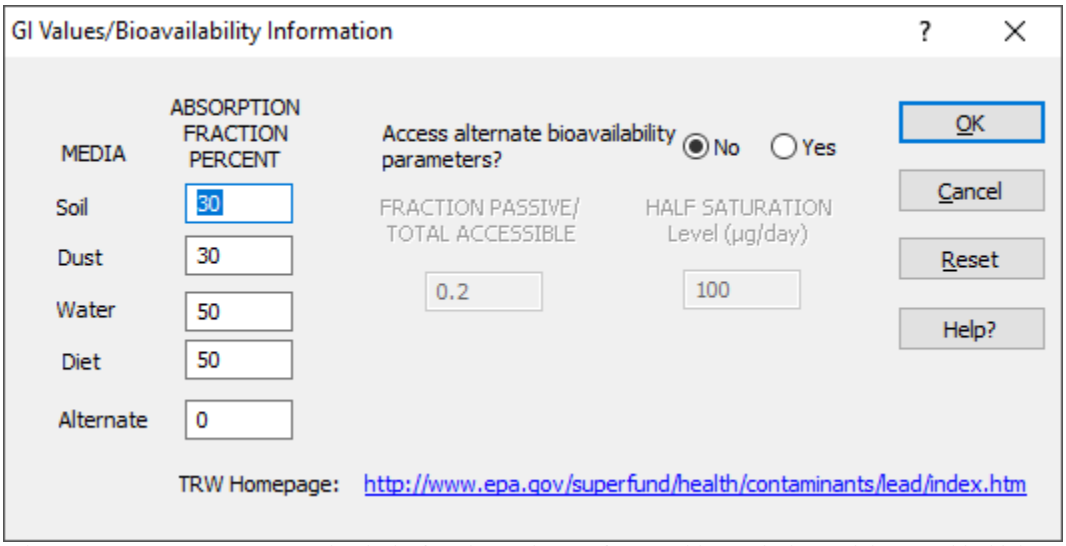

Figure 3. Recommended default values for soil and dust bioavailaibity shown in the IEUBK model GI Values/Bioavailability Information Data Entry Window.

Table 3. Summary statistics of RBA estimates based on swine assays. The median value was used instead of the mean, because it is a more relevant statistic for this data set

Sample	Median RBA	5–95% Range	N (Samples/Sites)
Swine Assays			
All test materials (TMs)	63	10–>100	47/29
All soil TMs[a]	75	11–>100	39/24
All soil TMs[b]	60	11–97	31/16
IVBA Assays			
All soil[c]	60	30–76	270/11
All soil sites[d]	63	34–71	270/11
Dust[c]	74	48–88	100/2
Combined Swine and IVBA Assays			
All soil sites (excluding firing ranges)[b]	61	14–88	301/27

[a]Excludes galena (n=1), NIST paint (n=1), Herculaneum dust (n=1), and 1 mm sieved samples (n=5).
[b]Excludes small arms firing ranges (n=8), galena (n=1), NIST paint (n=1), 1 mm sieved samples (n=5) and an interior dust sample from the Herculaneum site (n=1).
[c]See Table 5
[d]See Tables 6 - 8

Table 4. Summary statistics for test material (TM) RBAs based on swine assays

	RBA	Soil RBA	Soil RBA
Parameter	**All TMs**	**All Soil TMs[a]**	**Firing Ranges Excluded[b]**
N	47	39	31
Number of sites	29	24	16
Mean	61	65	54
SD	36	37	32
5%	10	11	11
25%	27	27	20
50%	63	75	60
75%	87	92	82
95%	112	112	97

Mean, arithmetic mean; N, number of TMs; SD, standard deviation; %, percentile
[a]Excludes galena (n=1), NIST paint (n=1), Herculaneum dust (n=1), and 1 mm sieved samples (n=5).
[b]Excludes small arms firing ranges (n=8), galena (n=1), NIST paint (n=1), 1 mm sieved samples (n=5) and an interior dust sample from the Herculaneum site (n=1). Mean RBA for small arms firing ranges was 108% (±18% SD).

Table 5. Summary statistics for soil and interior dust RBAs based on IVBA

Parameter	All Soil RBA	All Interior Dust RBA
N	270	100
Mean	57	71
SD	16	12
5%	30	48
25%	47	62
50%	60	74
75%	67	78
95%	76	88

Mean: arithmetic mean; N: number of TMs; SD: standard deviation; %: percentile

Table 6. Summary statistics of site soil mean RBAs based on IVBA

Parameter	Soil RBA (All Sites) [a]
N	11
Mean	57
SD	15
SE	5
5%	34
25%	48
50%	63
75%	68
95%	71

Mean: arithmetic mean; N: number of test materials (TMs); SD: standard deviation; SE: standard error; %: percentile

[a]Each site represented by the mean RBA for all soil TMs at the site.

Table 7. Summary statistics of individual site soil RBAs based on IVBA[a]

Site	N	Mean	SD	CV	5%	25%	50%	75%	95%
Barker-Hughesville	17	23	20	0.87	1	8	21	31	60
Big River Mine Tailings	32	68	3	0.05	63	67	68	69	72
East Helena	20	63	7	0.11	53	58	63	69	72
Eureka Mills	17	64	10	0.15	52	57	62	69	82
Herculanuem	12	69	3	0.05	64	66	69	71	73
VBI70	2	72	1	0.01	72	72	72	73	73
Madison County	25	61	9	0.14	48	54	63	67	68
Omaha	45	70	10	0.14	57	64	67	75	88
Pittsburg Zinc	18	44	10	0.22	24	40	46	48	58
St. Joe State Park	46	46	7	0.15	36	41	45	50	58
Washington County	15	51	10	0.19	41	44	48	57	67

CV: coefficient of variation; Mean: arithmetic mean; N: number of test materials (TMs); SD: standard deviation; %: percentile
[a]Values presented were rounded in Microsoft Excel after the calculations were performed.

Table 8. Comparison of summary statistics for site soil and dust RBAs, based on IVBA

	Herculaneum Lead Smelter		Omaha Lead	
Parameter	**Soil RBA**	**Dust RBA**	**Soil RBA**	**Dust RBA**
N	12	10	45	90
Mean	69	47	70	73
SD	3	7	10	10
5%	64	37	57	57
25%	66	44	64	67
50%	69	48	67	74
75%	71	53	75	80
95%	73	56	88	88

Mean: arithmetic mean; N: number to TMs; SD: standard deviation; %: percentiles