IEUBK Modelling for Establishing HIL A and Conducting Site-Specific Adjustments to the Model

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1.0 General

Previous Health Investigation Levels (HILs) have been established on the basis of both the Integrated Exposure Uptake Biokinetic (IEUBK) model and the use of a threshold provisional tolerable weekly intake (PTWI) available from the WHO. In addition, site-specific assessments of lead exposure were regularly conducted on the basis of the PTWI. The WHO withdrew the PTWI in 2010 and no other peer reviewed toxicity reference values are available. Hence the revision to the HILs in 2011 has relied on the application of the IEUBK model for HILs A, B and C, where children are the most sensitive receptors. HIL D, commercial/industrial, has been derived on the basis of the adult blood lead model.

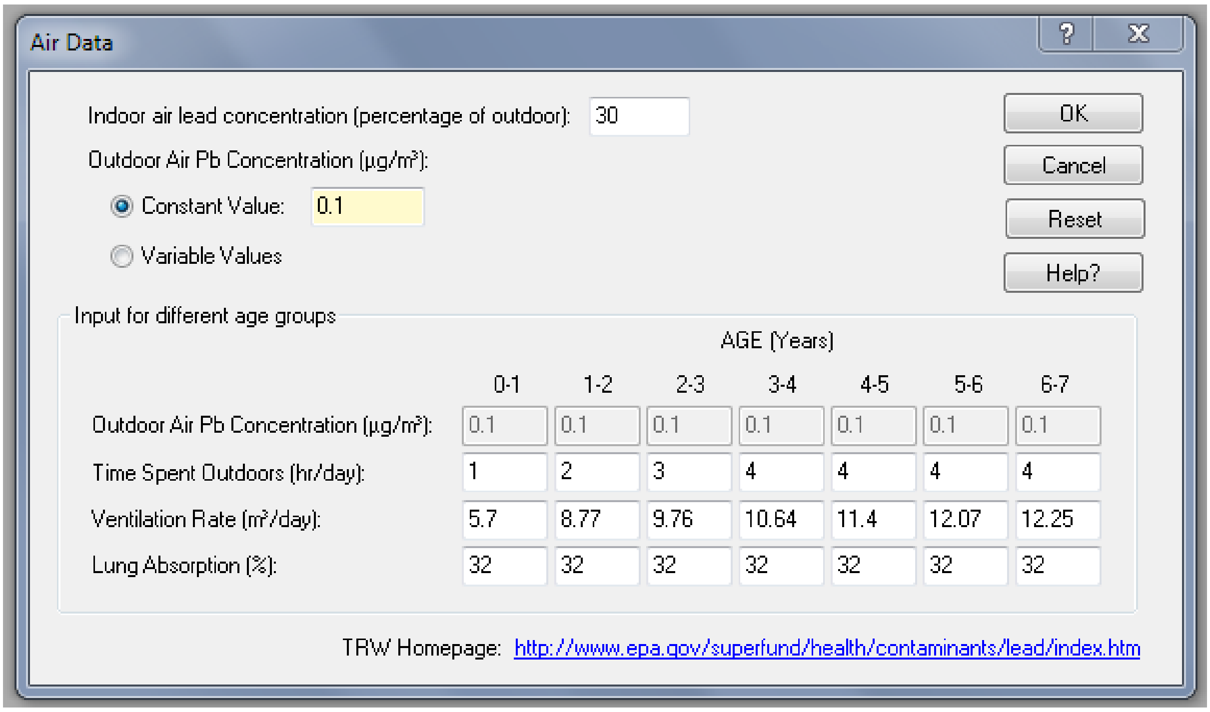
The IEUBK model is a biokinetic model that is used to predict the risk or elevated blood lead concentrations based on a range of environmental exposure sources, and in the context of site contamination, blood lead concentrations based on given soil concentrations. Its use lies in predicting the risk (as a probability) of blood lead concentrations of populations of children of various ages up to 7 years old arising from estimates of soil concentrations along with other sources of lead. The model is "biokinetic" as it models the distribution of lead within body tissue and takes into account factors that alter this distribution. The USA utilises the model as a tool for the generation of clean-up levels of residential soil.

This note presents an overview of how the IEUBK model has been set up for the derivation of the HIL A, low density residential land use. Appendix C of NEPM Schedule B7 (Revision) presents a summary of the parameters adopted in the derivation of the HILs. This note provides specific information on how those values have been entered into the model and identifies those parameters that can be adjusted where appropriate site-specific data is available.

As the model addresses exposures from all sources, intakes from all sources need to be entered into the model, along with parameters that are relevant to potential intakes of contaminated soil and dust.

2.0 Air Data

This entry point enables input of the contribution to total exposure from ambient air lead levels indoors and outdoors, and the age-specific inhalation parameters relevant to the inhalation of lead from ambient air and in dust derived from soil contamination.

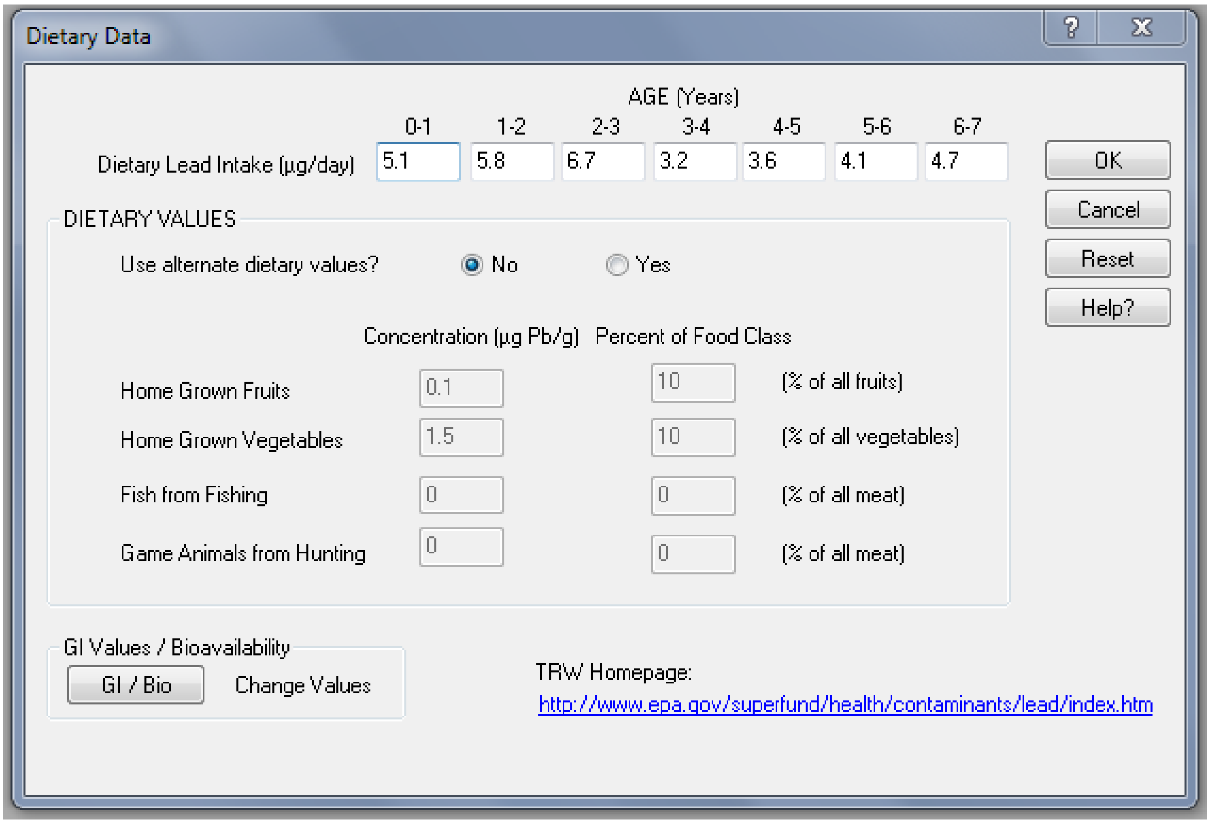


Parameter in IEUBK Model	What it actually is	Value adopted in HIL A	Basis/reference
Indoor air lead concentration (percent of outdoors)	Percentage of the outdoor air Pb concentration that is present indoors	30%	Default value in the IEUBK model. The model is not particularly sensitive to this parameter.
Outdoor Air Pb Concentration (µg/m^3)	This is the concentration of lead in ambient air, derived from all sources.	0.1 µg/m^3	Default value in the IEUBK model, based on a typical 1993 urban air concentration from the US EPA. (Recent monitoring in Australia shows levels at or below 0.05ug/m^3 in 2001)
Time spent outdoors (hours per day)	Age-specific time sent outdoors	As above	Default values in the IEUBK model adopted. The data were also reviewed and found to be consistent with data for infants from Australia (Brinkman et al 1999)
Ventilation rate (m^3/day)	Age-specific inhalation rate for children	As above	The IEUBK default parameters are considered to be too low. The value adopted in the model are mean inhalation rates as per the USEPA Child-specific Exposure Factors Handbook (USEPA, 2008), Table 6-16.
Lung absorption (%)	Percentage of the inhaled intake that is absorbed through the lungs to the blood.	32%	Default value in IEUBK model, note that the US EPA values for children in areas away from point sources range from 25% to 45%.

Unless the assessment being conducted specifically relates to a point source of emissions to air that include lead, there is no need to adjust the parameters adopted in this aspect of the IEUBK model. **Specifically, for the assessment of contaminated land issues it is not appropriate to adjust the parameters adopted in this aspect of the IEUBK model.**

3.0 Dietary Sources

This entry point includes parameters to model intakes of lead from all relevant dietary sources. This includes intakes from purchased produce as well as produce derived from home-grown sources, fishing and game animals (where relevant). The derivation of HIL A has only considered intakes of lead in the diet as summarised by Food Standards Australia New Zealand.



Parameter in IEUBK Model	What it actually is	Value adopted in HIL A	Basis/reference
Dietary lead intake (µg /day)	Intake of lead from all dietary sources. This includes purchased produce.	As above	Values adopted based on data presented in the 20th Australian Total Diet Survey (FSANZ 2003), with conversion to µg/day using mean body weights for each age group from USEPA Child-specific Exposure Factors Handbook (USEPA, 2008), refer to table below.
Use alternate dietary values?	Enables intakes of lead from home-grown produce, fish and game animals (where relevant) to be included where the data is available.	No	In general, for most forms of lead insufficient lead is taken up by plants, however the pathway may need to be considered for soluble forms of lead (refer to discussion below). If there is the potential for intakes to be derived from other site-specific sources such as poultry (including eggs), intakes from site-specific eggs and poultry can be estimated separately and entered into the IEUBK model by adjusting the intake of dietary lead for each age group; or entering the

Parameter in IEUBK Model	What it actually is	Value adopted in HIL A	Basis/reference
			estimated concentration as "game". It is noted that the models available for estimating concentrations of lead in poultry and eggs are highly uncertain and conservative. Hence the management of these exposures using a cover of clean fill in areas where poultry are to be kept may be more appropriate than modelling exposure concentrations and revising the IEUBK model.
GI Values/ Bioavailability	Can be adjusted here or by selecting GI/Bio later as addressed in **Section 7**		

Calculation of Dietary Lead Intakes

	Age (years)							Reference/Notes
	0-1	**1-2**	**2-3**	**3-4**	**4-5**	**5-6**	**6-7**	
Mean Daily Intake - Dietary exposures (µg/kg bw/day)	0.605	0.48	0.48	0.2	0.2	0.2	0.2	Average of lower and upper means reported in the 20th Australian Total Diet Survey for infants (used for 0-1 years), toddlers (used for 1-2 and 2-3 years) and girls and boys (used for 3-7 years), Table A1 (FSANZ 2003)
Body weight (kg)	8.4	12.15	14	16.1	18.25	20.55	23.6	Average (over age group, e.g. average body weight reported for 2 year old and 3 year old used for children aged 2-3 years) of mean body weights from USEPA Child-Specific Exposure Factors Handbook, Table 8-10 (USEPA 2008)
Dietary Intake (µg/day)	5.1	5.8	6.7	3.2	3.6	4.1	4.7	Calculated from parameters above and adopted in the IEUBK Model

The main dietary sources of lead, lead from soldered cans and deposition of lead from atmospheric emissions, are considered (by the USEPA) to be largely managed and are no longer significant. Hence intakes of lead from dietary sources are considered to be relatively constant and unlikely to change significantly. The intakes adopted, from the Australian Total Diet Survey (FSANZ, 2003), are therefore not expected to be adjusted in the assessment of site contamination issues.

Plant uptake from site contamination:

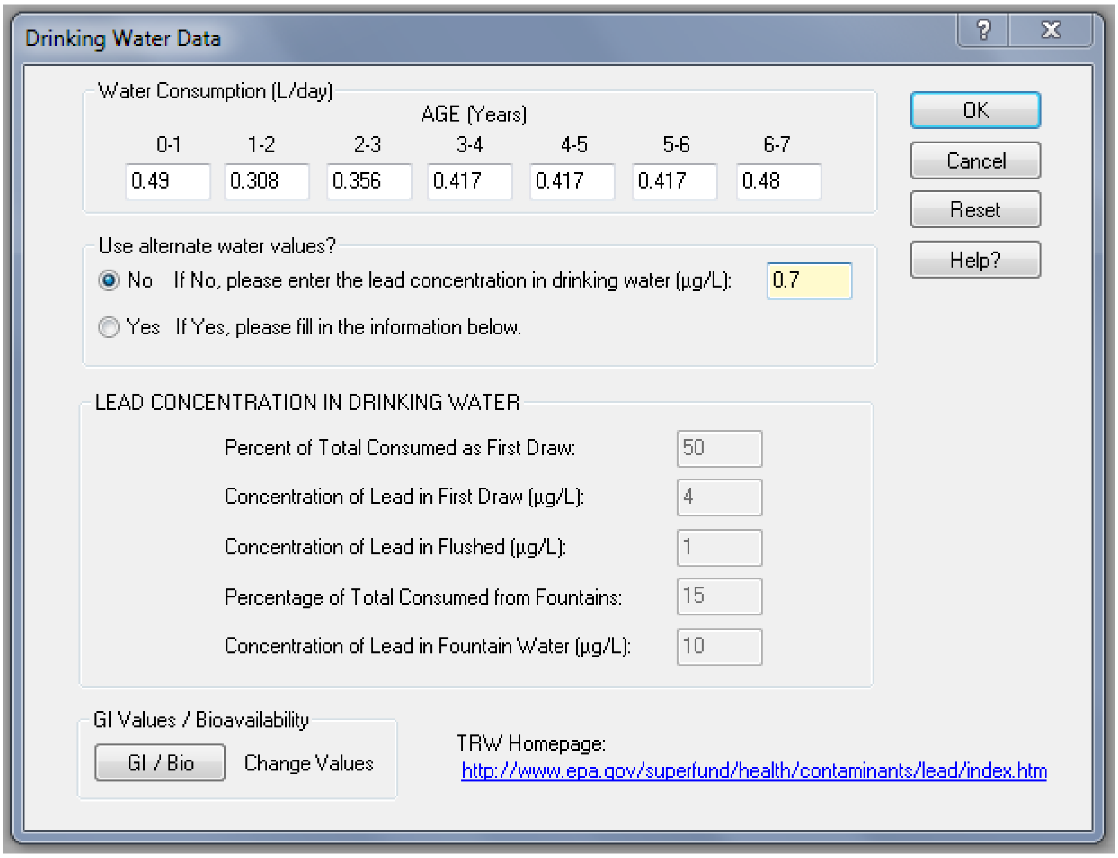
The following is presented in **Appendix A** of the NEPM Revision in relation to the issue of the uptake of lead into home-grown produce:

> IARC (2006) has noted that plant uptake of lead from soil is low due to the low bioavailability of lead in soil and its poor translocation from the root to the shoot. Of all the toxic heavy metals, lead is considered the least phytoavailable. While soil properties affect the potential for uptake and translocation, water soluble and exchangeable lead that is readily available for uptake by plants constitutes only 0.1% of the total lead in most soils. Hence a chelate (such as EDTA) is used to increase lead uptake and translocation where phytoremediation is required.
>
> For the derivation of soil HILs it has been assumed that the small amount of lead that may be taken up into home-grown produce is essentially accounted for in the consideration of intakes from the diet. In areas where the form of lead in soil is more soluble and available for plant uptake a site-specific assessment (including the sampling of home-grown produce) should be considered.

In relation to the assessment of most contaminated sites, there is no need to adjust the parameters adopted in relation to this aspect of the IEUBK model, except where the form of lead present is sufficiently soluble (e.g. sites where the lead source is from lead batteries or other lead salts rather than mineralogical deposits) to require consideration of plant uptake into home-grown produce (fruit and vegetable crops), or there is a significant source of lead emissions to air where deposition onto produce may need to be considered (if not washed well).

4.0 Drinking Water Intakes

This aspect of the IEUBK enables intakes that may be derived from drinking water to be addressed in the model.

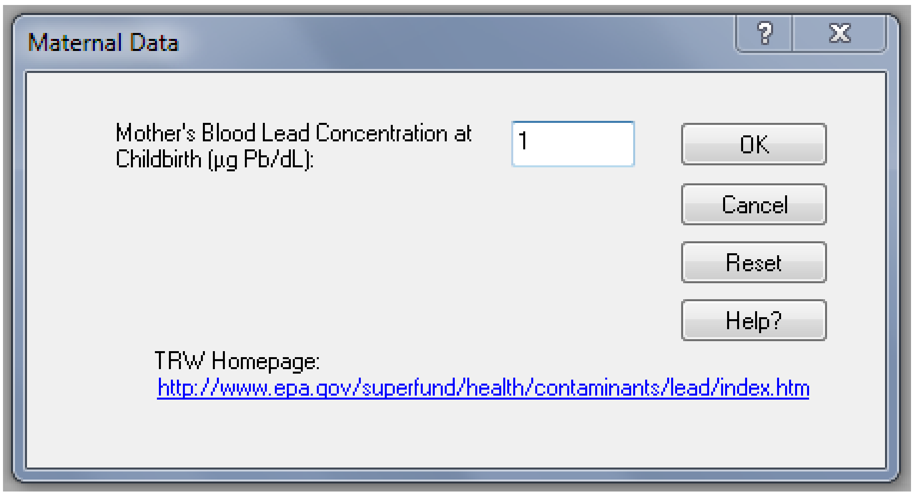


Parameter in IEUBK Model	What it actually is	Value adopted in HIL A	Basis/reference
Water consumption (L/day)	Age-specific water ingestion rates	As above	Mean water intakes from for each age group from USEPA Child-specific Exposure Factors Handbook (USEPA, 2008).
Use alternate water values?	Enables intakes of lead from specific water sources to be incorporated	No	The assessment of contaminated land issues does not include intakes of lead in water from specific water-borne sources (such as lead pipes that are more common in the US than in Australia). Hence these specific sources are not included and are generally not expected to require consideration in the assessment of site contamination. However, the consumption of rainwater in areas where high levels of lead are present may require additional consideration.
Lead concentration in drinking water (µg/L)	Constant concentration of lead in drinking water supply	0.7	Mean concentration reported in South Australian Water supplies over a 5 year monitoring period, considered to be consistent with data from other main Australian water supplies.
GI Values/ Bioavailability	Can be adjusted here or by selecting GI/Bio later as addressed in **Section 7**		

The mean concentration of lead in drinking water supplies in Australia is low. Hence the significance of drinking water as a source of lead intake is low, resulting in little sensitivity in the IEUBK model to the inclusion of different parameters in this aspect of the model. **Hence the parameters adopted should not require adjustment in a site-specific assessment of land contamination.**

5.0 Maternal Data

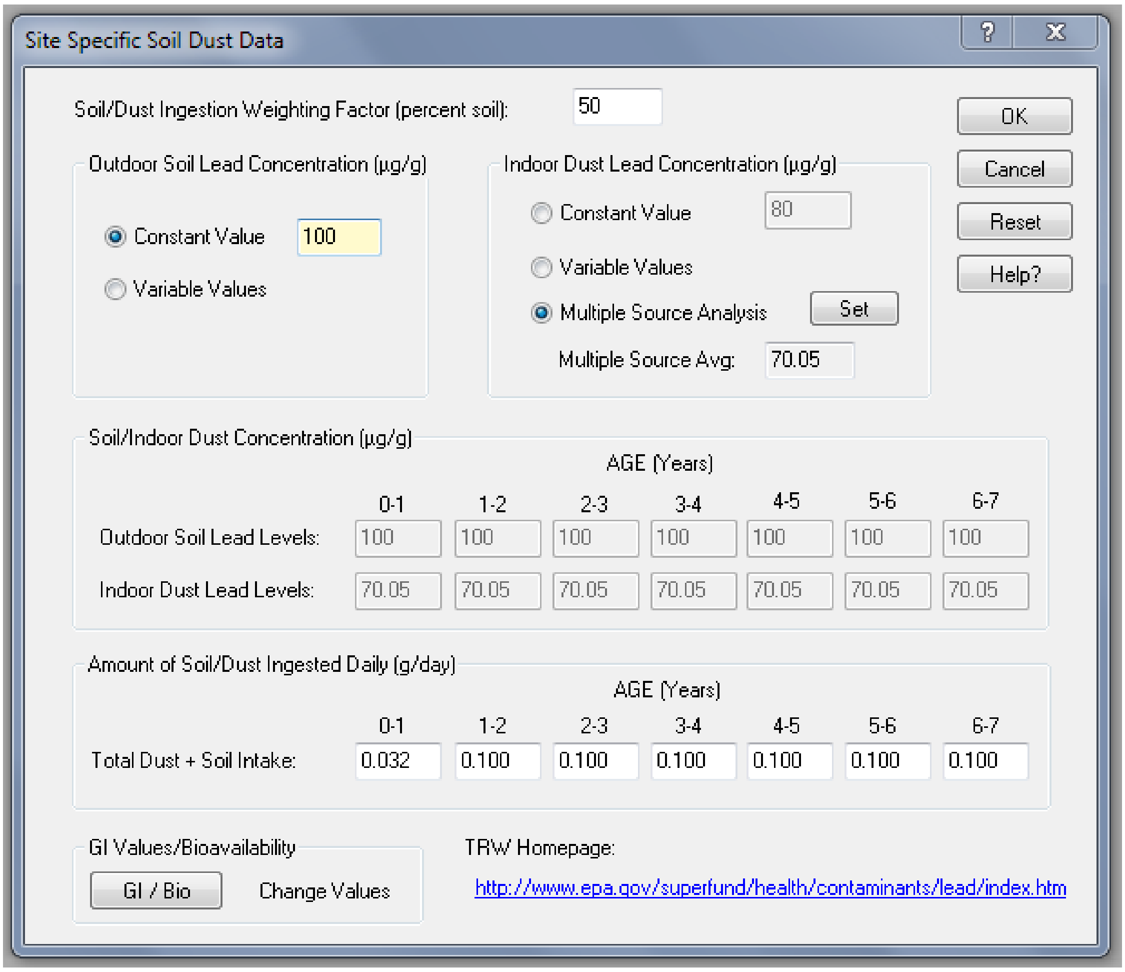
This aspect of the IEUBK model provides the mother's blood level at birth/delivery (i.e. birth of the baby, not the mother's birth). This enables the level of lead that is stored in the tissues of the newborn child to be calculated.



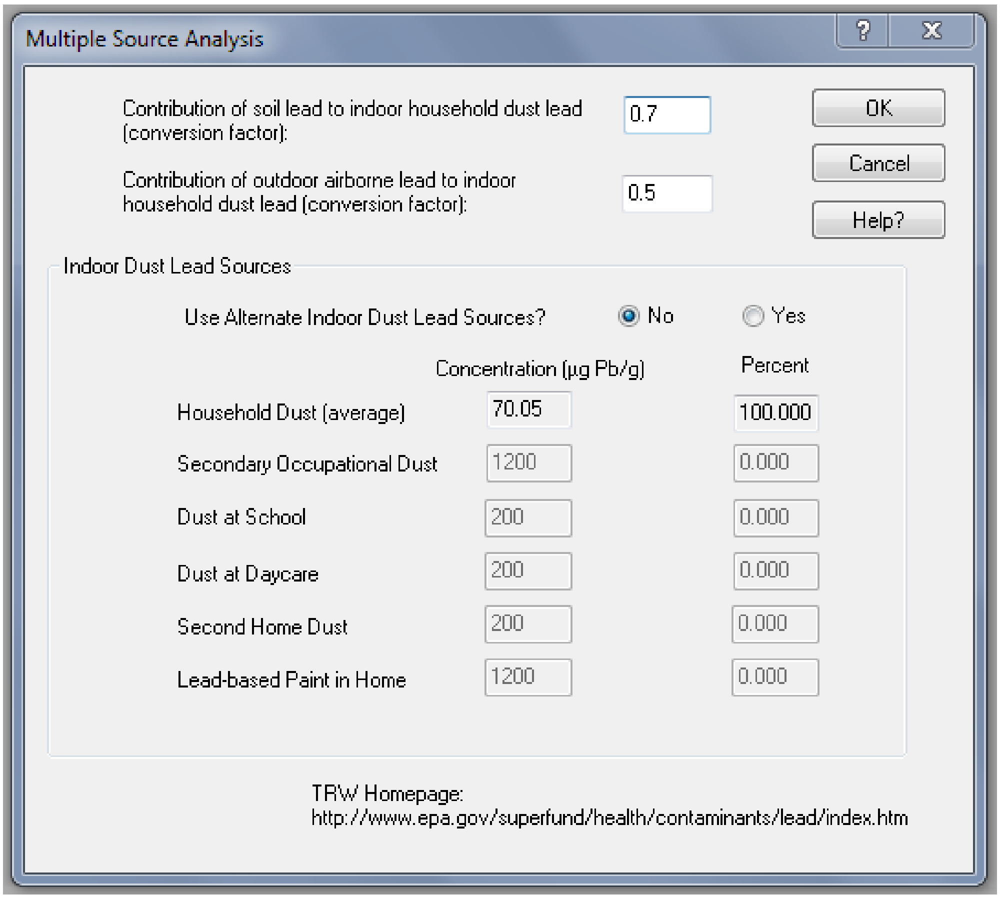
A value of 1 µg/dL has been adopted in the derivation of HIL A. This is the default value presented in the IEUBKwin model, which is lower than the default (2.5 µg/dL) presented in the previous version of the model (USEPA 1994). No discussion is presented as to the reason for the reduced value, however the IEUBK model is not sensitive (<1% difference) to the change of this value from 1 to 2.5 µg/dL for the assessment of children from 0-7 years of age. Note that if assessing exposures by children aged 0-12 months only the selected value may be of importance and should be further evaluated. **For establishing soil risk-based criteria, where intakes from 0-7 years of age are addressed, the parameters adopted for maternal data should not require adjustment in a site-specific assessment of land contamination.**

6.0 Soil and Dust

This aspect of the IEUBK model provides input data more specifically relevant to a contaminated site. The values entered here are related to the intake of lead from contaminated soil and dust.



Parameter in IEUBK Model	What it actually is	Value adopted in HIL A	Basis/reference
Soil/Dust Ingestion Weighting Factor (percent soil)	The percentage of total soil/dust ingestion that is from soil with the remainder derived from dust.	50%	While difficult to measure, review by Paustenbach et al (1997) concluded that approximately 50% of house dust originates from outdoor soil and the Australian Exposure Factor Handbook has suggested it is appropriate for a screening level assessment.
Outdoor Soil Lead Concentration (µg/g)	Concentration of lead in soil, or start value that is revised when deriving criteria	100 µg/g	The IEUBK model has been used to derive soil criteria; hence this value is a start value for the model only.
Indoor Dust Lead Concentration (µg/g)	Concentration of lead in indoor dust, derived from outdoor soil where site contamination is assessed	Multiple source analysis used as detailed below	
Amount of Soil/Dust Ingested Daily (g/day)	Age-specific total intake of soil and dust each day	As above	For ages over 1 year, the NEPM default of 100 mg/day (or 0.1 g/day) has been adopted. For children aged 0 to 1 a value of 32 mg/day, essentially 30 mg/day recommended in the Australian Exposure Factor Handbook has been adopted. These values should not be used in cases where soil-pica or geophagia are suspected. Such scenarios should be considered on a case-by-case basis.
GI Values/ Bioavailability	Can be adjusted here or by selecting GI/Bio later as addressed in **Section 7**		



Parameter in IEUBK Model	What it actually is	Value adopted in HIL A	Basis/reference
Contribution of soil lead to indoor household dust lead (conversion factor)	Mass fraction of soil in indoor dust	0.7 g soil/g dust	IEUBK default considered appropriate to areas in which loose surface soil can be readily transported into the home. The value can be based on site specific information and/or data (refer to USEPA 1998), however note that it is difficult to measure this value as it will depend on the number and movement of children and pets between outdoor and indoor areas, climate (affecting the duration of outdoor to indoor movements throughout the year), vegetative cover, the deposition of soil from neighbouring properties and dust control remediation measures. Where these factors are not known and dust is not managed, then the default value should be used in the risk assessment. A different value can only be adopted where adequately justified for the location (taking into account the above factors)[1] or site-specific data is available.
Contribution of outdoor airborne lead to indoor household dust lead (conversion factor)	Contribution to household dust from the deposition of airborne lead, expressed as a ratio of dust lead to outdoor air lead concentration	0.5 µg/g per $\mu g/m^3$	HIL A has used a low value of 0.5 suggesting that there is a very low contribution to indoor dust derived from ambient air. It is noted that the IEUBK default is 100 and in the derivation of the HIL, the model is not sensitive to this parameter changing from HIL A = 306 mg/kg (where 0.5 is used) to 302 mg/kg (where 100 is used). In a site-specific assessment it is recommended that the default value of 100 be used for this parameter as it may make a difference on some sites where lead concentrations in air are high.
Amount of Soil/Dust Ingested Daily (g/day)	Age-specific total intake of soil and dust each day	As above	For ages over 1 year, the NEPM default of 100 mg/day (or 0.1 g/day) has been adopted. For children aged 0 to 1 a value of 32 mg/day, essentially 30 mg/day recommended in the Australian Exposure Factor Handbook has been adopted. These values should not be used in cases where soil-pica or geophagia are suspected. Such scenarios should be considered on a case-by-case basis.
Use Alternate Indoor Dust Lead Sources?	Enables the assessment of sites where there are other sources of lead exposure in dust from sources other than the onsite soil.	No	Not considered in HIL A as contamination in soil considered most significant source. Unless there are site-specific lead sources that also need to be addressed, this parameter is not expected to change on most contaminated sites.
GI Values/ Bioavailability	Can be adjusted here or by selecting GI/Bio later as addressed in **Section 7**		

[1] It is noted that there is a recent paper (Brattin and Griffin, 2011) where additional data has been collected to support the use of a lower value of 0.35. The paper however does not address issues expected on a wide range of sites, including the movement of pets and children from outdoors to indoors, differences in the climates of the areas evaluated (and relevance to sites in a wider range of climates) or where there are no management measures. As such the lower value is not appropriate for general use on contaminated sites.

7.0 GI Values and Bioavailability

This aspect of the IEUBK model provides inputs in relation to the absolute bioavailability of lead from the various sources assessed. It is important to note that the values presented are absolute bioavailability values, termed as absorption fraction percent in the IEUBK model that incorporates absorption and relative bioavailability/bioaccessibility:

ABA = Abs x RBA

ABA = absolute bioavailability (or absorption fraction percent) entered into the IEUBK model for soil, dust, water and dietary sources

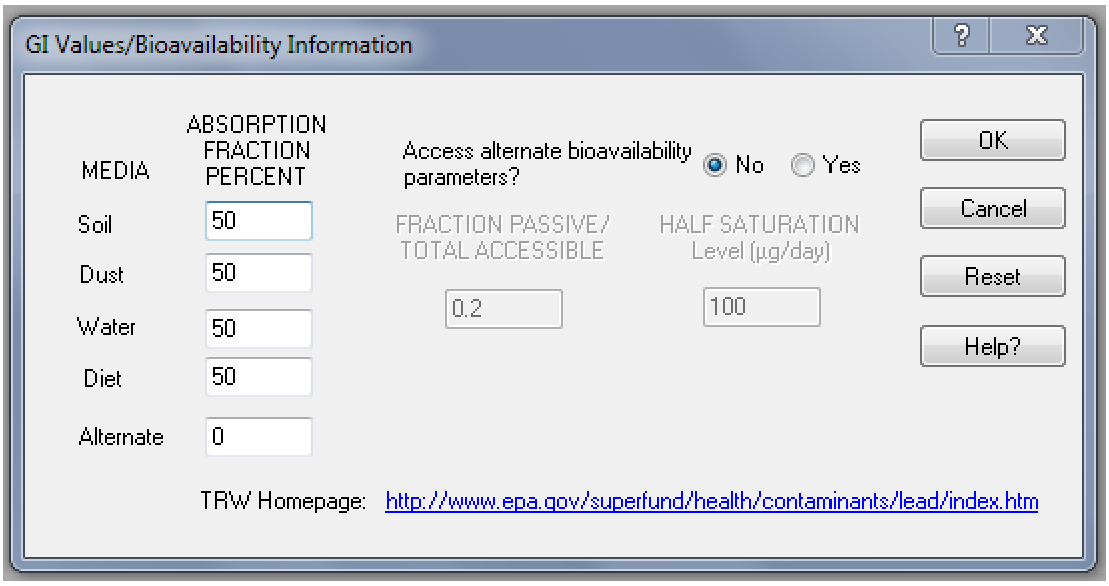
Abs = absorption of soluble lead from GI tract, taken to be 50% for soluble lead acetate as per USEPA (1994) and IARC (2006)

RBA = relative bioavailability (or bioaccessibility) of lead in media assessed. For drinking water and food this is taken to be 100% as the form assessed is assumed to be soluble. For soil and dust, the derivation of HIL A has assumed the presence of soluble lead acetate and has assumed RBA of 100%. However site-specific RBA (relative to soluble lead acetate) data can be collected and used to refine the IEUBK model and derive site-specific soil criteria.

Therefore for soil and dust a site specific absolute bioavailability value can be calculated using the following:

$\mathbf{ABA_{soil/dust} = 50\% \times RBA_{soil/dust}}$

The values used in the derivation of HIL A are presented below.



It is noted that the USEPA (1994) IEUBK model assumes a default of 60% RBA for soil and dust (based on data from mining and smelter sites). When combined with the absorption of 50% this results in a USEPA default absolute bioavailability (ABA) of 30%. The higher value of 100% was adopted in the derivation of HIL A to cover a wide range of lead sources that may be encountered on contaminated land, including those where more soluble forms of lead are present.

<u>Collection and use of Site-specific RBA Data</u>

If site-specific data is to be collected and used in a site-specific IEUBK model, then a sufficient number of representative samples need to be collected and analysed for RBA using correlated methods. It is noted the source of lead contamination and use of the data need to be considered prior to deciding if analysis of RBA will be of benefit to the assessment being conducted. In particular the following should be considered:

- If the source of lead contamination suggests the likelihood of soluble forms of lead (such as lead carbonate) being present, it is considered unlikely that RBA testing will be of benefit. If the data is to be collected the benefit and use of the data should be justified;
- If the concentrations of lead in soil are more than 10 times the relevant investigation criteria, it is considered unlikely that RBA testing will be of benefit as risk management measures are expected to be required regardless of the RBA data. In these situations (where the concentrations are more than 10 times the investigation level) the benefit and use of this data needs to be justified;
- If the lead contamination is to be contained/managed beneath a slab on the site, the collection of RBA data is not expected to be of benefit;

Approved methods:

The *In vivo* juvenile swine model has been determined (for children) to be a reliable method of determining RBA of lead in soil (USEPA 2007). However this method is costly, time consuming and not feasible in many cases. Hence RBA is more commonly estimated measured using *in vitro* tests that are aimed at measuring the extent of lead solubilisation in an extraction solution that resembles gastric fluid. For these *in vitro* tests to be considered accepted methods, they need to have demonstrated good correlation between the results obtained from the *in vivo* and *in vitro* tests. This has been conducted by the USEPA (2007) for a range of soil sampled from mining and smelter sites. The USEPA method/assay, termed IVBA (In Vitro Bioaccessibility) which is also referred to as the Relative Bioavailability Leaching Procedure (RBALP), the Solubility Bioavailability Research Consortium (SBRC) gastric phase (or SBRC-G) or the Simplified Bioaccessibility Extraction Test (SBET) (Ng et al 2009). All of these are considered correlated and approved methods for determining site specific RBA for lead.

When identifying methods that may be used in a site-specific assessment the following should be noted:

- While a good relationship was observed between gastric phase lead dissolution and *in vivo* lead relative bioavailability, the USEPA (2007) cautioned that the majority of samples used were derived from similar sources (mining and milling activities) and that some forms of lead that were absent in these soils may not follow the observed correlation. This has been observed (Smith et al 2011) for peri-urban soils from different sources where lead bioaccessibility in the gastric phase was shown to significantly overestimate lead RBA.

- RBALP may not be appropriate for predicting lead RBA in soils that have been treated with phosphate.

Number of Samples:

No guidance is available in relation to the number of soil samples that need to be collected and analysed for site-specific RBA. Guidance (USEPA 1999) indicates that soil samples should be collected from areas that are reasonable similar (similar geophysical and chemical properties of lead in soil). The <250 µm soil particle size is used in the RBA tests as this more closely represents the size of soil particles that would be expected to adhere to children's hands. In addition it has been found (Jahasz et al 2011) that higher lead concentrations have been associated with the small particle sizes. Hence this preparation is important and is usually conducted by the laboratory undertaking the RBA tests, but should be confirmed.

It is common for the sampling of soil for RBA to only collect a minimum number of representative samples. If the RBA data is to be relied upon for the purposes of providing a sound site-specific soil criterion, then sufficient samples need to be collected to demonstrate that RBA has been adequately characterised. The more samples collected the more reliable and useful the RBA data will be.

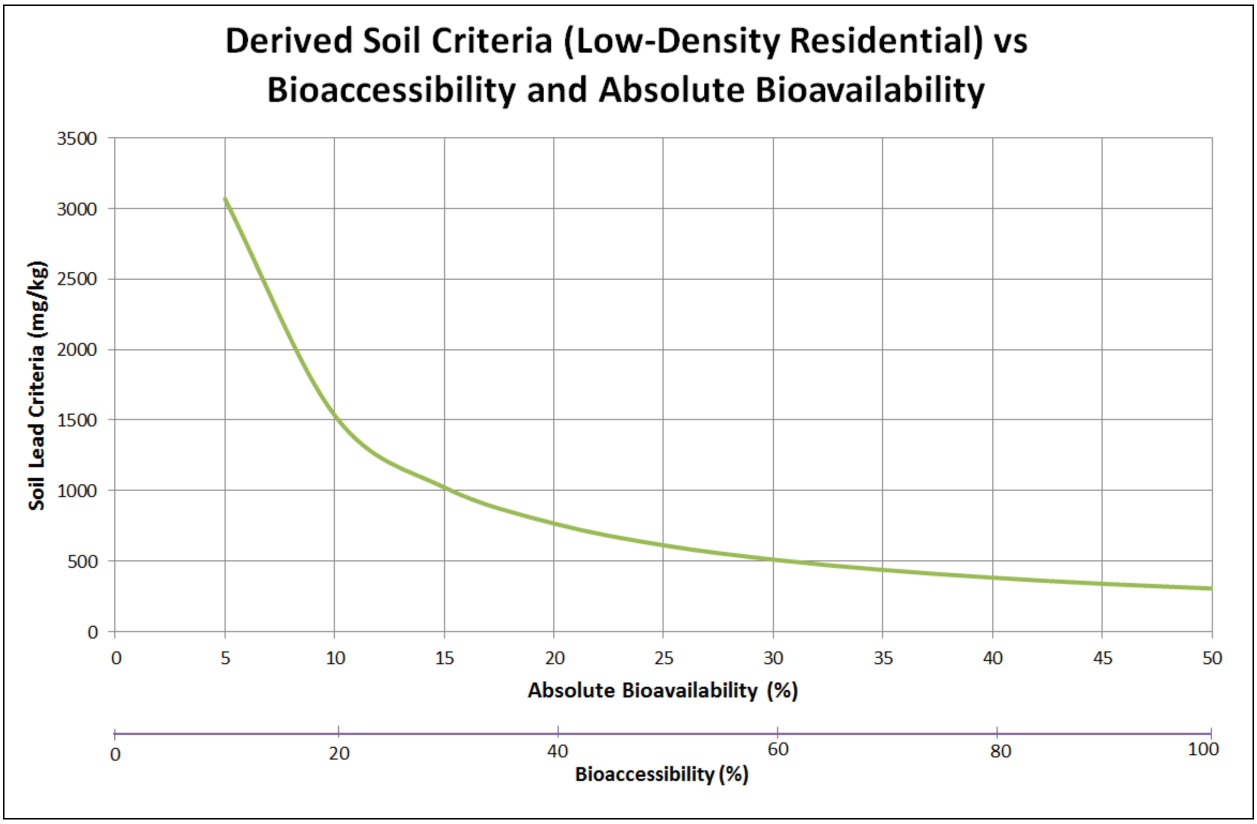
If only a minimal number of RBA samples are collected, and these show a large range of RBA values it is difficult to determine what a representative RBA value would be and typically such assessments default to the use of the maximum RBA value. Such evaluations could be further refined by the collection of additional data from representative soil samples and/or consideration of the geophysical and chemical properties of lead in soil.

Variability in bioaccessibility data:

If the upper value of bioaccessibility is ≥80% then given the heterogeneity of soil contamination, variability in the analysis of lead concentrations in soil and variability in the RBA tests, it is not appropriate to vary the bioaccessibility value from the value of 100% adopted in HIL A.

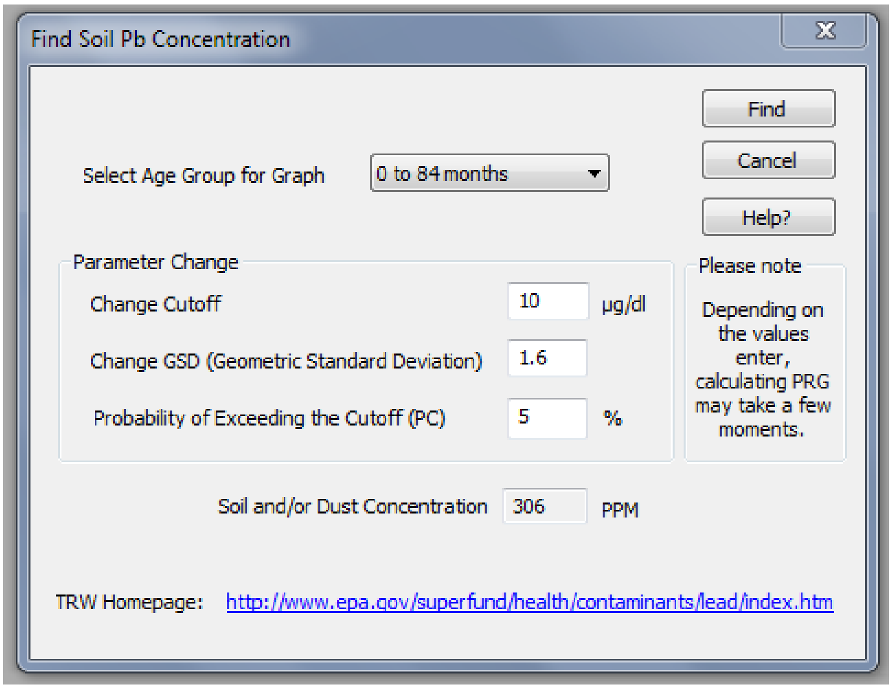
Sensitivity of Soil Criteria

The following graph illustrates the change in soil criteria derived where soil/dust site-specific bioaccessibility varies from 100% to 10%, resulting in absolute bioavailability varying from 50% to 5%.



8.0 Calculation of HIL A

To calculate the HIL A, or a site-specific value, the "Find" section is used in the IEUBK model. This utilises the inputted data to generate a plot of the relationship between blood lead concentration and the exposure to lead in a specific media, soil/dust in this case. The selection enables a soil/dust concentration to be derived that then meets a defined blood lead level.



Parameter in IEUBK Model	What it actually is	Value adopted in HIL A	Basis/reference
Select Age Group for Graph	Ages over which the model generates graph, estimates exposure	0 to 84 months, all ages	For deriving a soil/dust criteria it is appropriate to consider exposures by young children over all ages.
Change Cutoff	Blood lead level of concern	10 µg/dL	Blood lead goal from NHMRC (2009).
Change GSD (Geometric Standard Deviation)	Geometric standard deviation for blood lead	1.6	IEUBK default value for derivation of soil/dust criteria.
Probability of Exceeding the Cutoff (PC)	Probability of exceeding the blood lead goal. A value of 5% results in the calculation of a 95th percentile	5%	IEUBK default value for derivation of soil/dust criteria.

None of the above values need to be changed when deriving site-specific lead criteria.

9.0 References

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