



Training on the IEUBK Model, Adult  
Lead Methodology, and Recent Lead Risk  
Assessment Updates

TRW Lead Committee



# Overview of Lead Model Training

- Introduction (why do we need models?)
- The IEUBK Model -- structure and components
- The U.S. EPA Adult Lead Methodology (ALM)
- Discuss IEUBK & ALM inputs (review data entry windows and input variables, and why some are controversial)
- Risk Assessment Issues and Guidance
- PbB calculation, risk calculation, & PRG



# What is a Biokinetic Model?

- Biokinetic models assess the routes of environmental exposure to a substance and determine the distribution of this substance among the various body tissues in humans.
- Biokinetic models work best when there is a known effect that is associated with a specific tissue concentration in humans.
  - e.g., impaired nerve conduction velocity in children at 10  $\mu\text{g}$  Pb/dL blood.
- Biokinetic models also enable the risk assessor to predict the relative effect of an increase in body tissue that might result from a specific increase in environmental exposure.
  - e.g., the expected blood lead concentration that would result from an increase in soil lead concentration of 500 mg/kg.



# Lead Risk Assessment is Different

- In comparison to most other environmental contaminants, the degree of uncertainty about the health effects of lead is quite low.
- Some of these effects, particularly changes in the levels of certain blood enzymes and in aspects of children's neurobehavioral development, may occur at blood lead levels so low as to be essentially without a threshold.
- EPA decided that it was inappropriate to derive a Reference Dose (RfD) for lead.
- EPA regulates lead exposure by using a biomarker (blood lead concentration).
- Environmental exposures to lead are modeled to predict blood lead levels associated with those exposures.
- CDC established 10  $\mu\text{g}/\text{dL}$  as the Federal level of concern in 1991.



# OSWER Lead Risk Assessment Policy

- The IEUBK Model as the primary tool to generate residential risk-based soil cleanup levels.
- OSWER's risk reduction policy is for no child to have greater than a 5% probability of having a blood lead level  $>10 \mu\text{g/dL}$ .
- Modeling is used to associate environmental exposures with risk and inform cleanup decisions (relative to OSWER's risk reduction goal).
- In general, blood lead survey data should not be used as the only basis for cleanup decisions.



# Purpose of the Lead Models

## **IEUBK (Integrated Exposure Uptake Biokinetic Model)**

- Predicts the blood lead levels in children (under 7 years old) who are exposed to environmental lead from many sources
- Predicts the risk (probability) that a typical or hypothetical child exposed to specified media lead concentrations will have a blood lead level  $\geq 10 \mu\text{g/dL}$  (the blood lead level of concern)
- Predicts PRG (cleanup levels) for various media for residential land use

## **ALM (Adult Lead Methodology)**

- Predicts the risk of elevated blood lead levels in non-residential settings (adult exposure to soil; ultimate receptor is fetus)
- Predicts PRG (cleanup levels) for soil in non-residential land use



# Characteristics of the IEUBK Model

- While IEUBK model risk assessments are more complex than the typical Superfund risk assessment approach, the IEUBK model is not as complex as variance propagation approaches (PRA)
- The IEUBK model employs more site-specific information than other EPA risk assessment models
- The IEUBK model performs well when comparing predicted and observed blood lead levels (*Hogan et al., 1998. Integrated Exposure Uptake Biokinetic Model for Lead in Children: Empirical Comparisons with Epidemiologic Data. Environmental Health Perspectives, Vol. 106 No. S6*)



# Intake – Uptake – Biokinetic Relationship

Daily **Intake** of lead is calculated as follows:

Intake = Media Concentration x Media Intake Rate

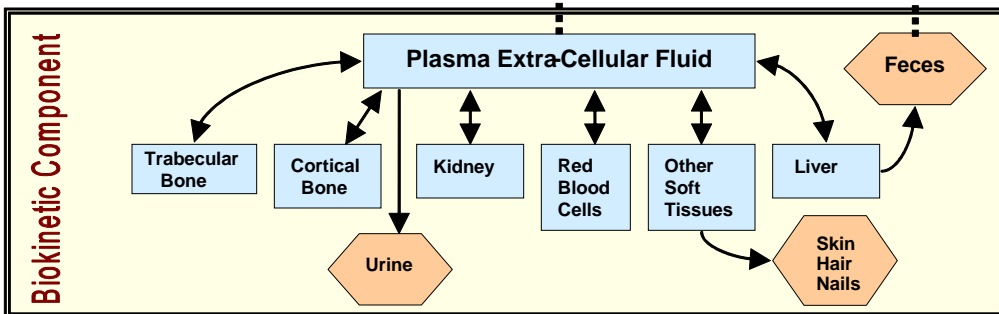
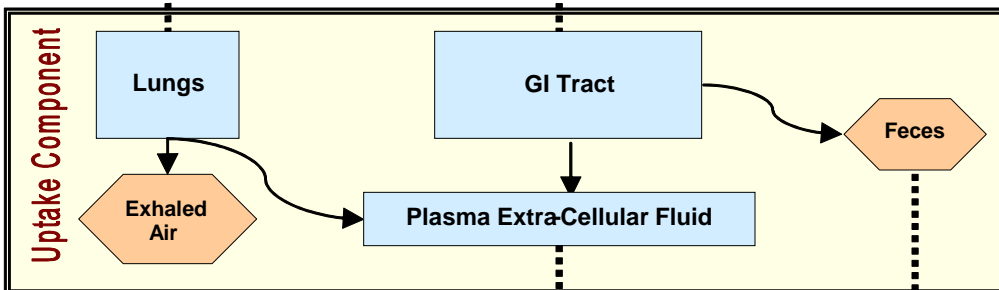
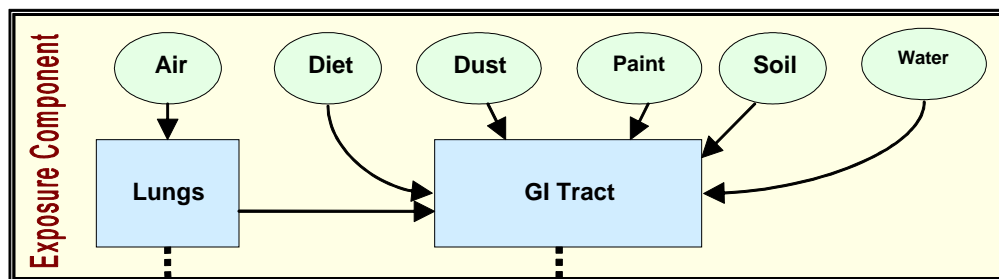
For example:  $\mu\text{g lead/day} = (\mu\text{g lead} / \text{g of media}) \times (\text{g of media} / \text{day})$

**Uptake** is calculated based on media-specific absorption values (defaults are available):  $\text{Uptake} = \text{Intake} \times \text{Absorption Factor}$

**Biokinetic** module estimates transfer rates for Pb moving between compartments and through elimination pathways to derive a predicted long-term steady state geometric mean PbB concentration.

In the final step, the **Probability** module estimates a plausible distribution of PbB concentrations for a given GSD. The distribution is centered on the geometric mean PbB concentration calculated by the Biokinetic Module.





**Variability Component**

To calculate the probability of exceeding the 10 µg/dL level ( $P_{10}$ ):

$$Z = \frac{[\ln(10) - \ln(\text{GMPbB})]}{\ln(1.6)}$$

$$P_{10} = 1 - P < Z \text{ (expressed as a percent)}$$

- Environmental Media
- Elimination Pools of the Body
- Body compartment or elimination pool required in more than one component
- Body Compartments



# History of the IEUBK Model Development

IEUBK is the product of many years of development

1985-89: Initially Office of Air Quality Planning Standards

1989: Development by Superfund following SAB review

1989-2001: DOS version (0.99d) development.

1994-2001: Release of 0.99d version by Superfund with input from EPA, ATSDR, CDC, and SAB.

1998: Independent Validation and Verification (IV&V)

1997-2001: IEUBK (0.99d) was converted to Windows

2001-present: IEUBKwin 1.0 and IEUBKwin 1.1

2005: NAS review



# Independent Reviews of the IEUBK

The reviewers have generally found that the model was scientifically sound and useful for lead risk assessment

1990 SAB review for NAAQS

1992 SAB review and External Peer Review of model

1998 Independent Validation and Verification

1998 SAB review for TSCA Section 403 Regulation

2005 National Academies of Science (NAS) review for Coeur d'Alene site report



# Evaluation and Validation of the IEUBK

IV&V evaluated the following:

1. Scientific underpinnings of the model structure
2. Adequacy of parameter estimates
3. Mathematical relationships (as computer code)
4. Empirical comparisons (predicted vs. observed)

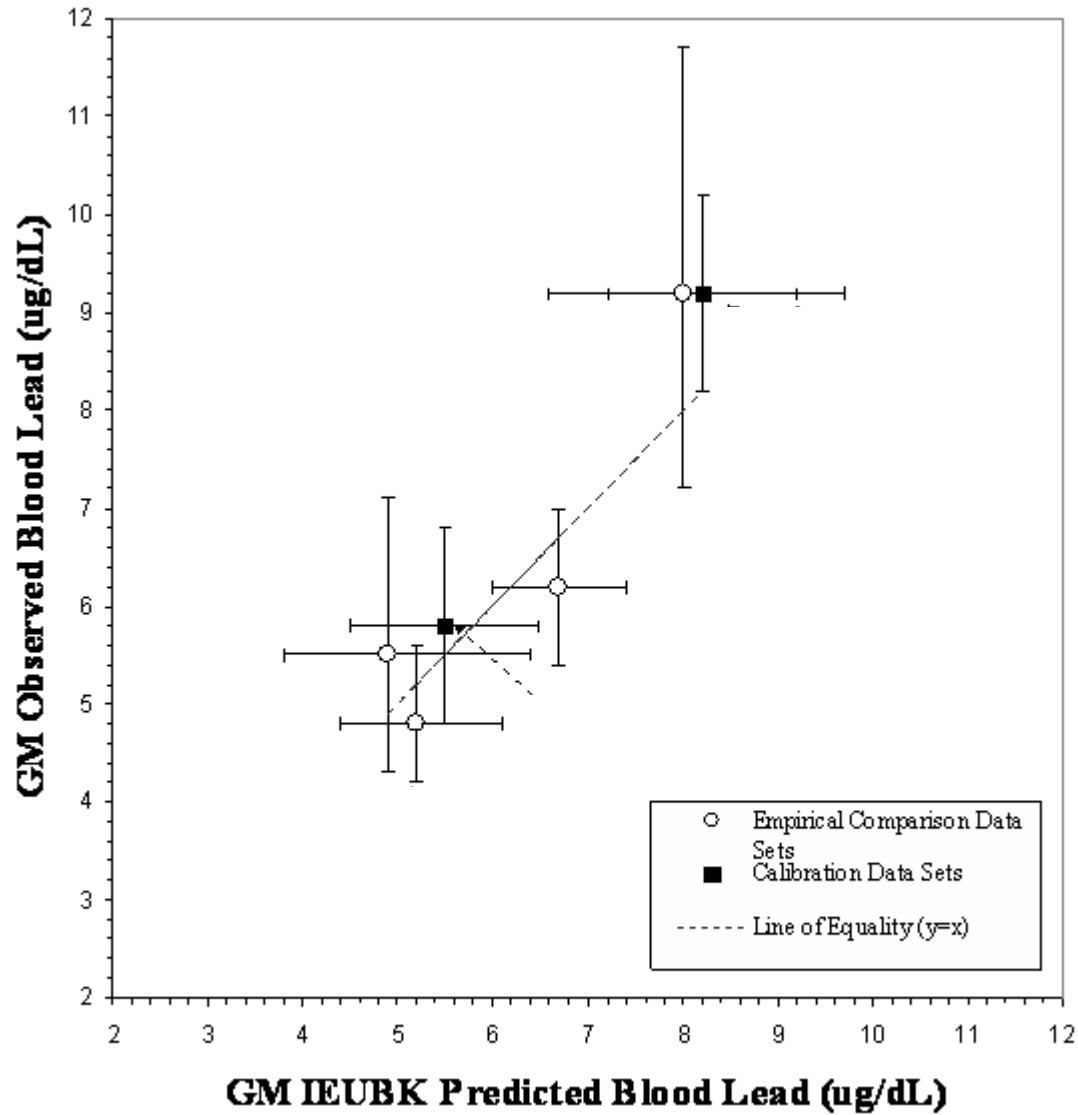
The process and results of the IEUBK validation are available online (TRW web site)

1994 Validation Strategy for the IEUBK

1998 Empirical Comparisons Manuscript (Hogan et al., 1998)



# Comparison of IEUBK Predictions and Observed PbB



Correspondence of observed and IEUBK model-predicted blood lead concentrations by site: Kansas/Missouri, Illinois, Pennsylvania, 1991. The solid points are the GMs, whereas the open points provide 95% CIs for the GMs. Adapted from Hogan et al., 1998

# Comparison of IEUBK Predictions and Observed PbB

**Comparison of Observed and Predicted Geometric Mean Blood Lead and Risk of Exceeding 10 µg/dL for Three Community Blood Lead Studies**

Dataset	N	Observed Blood Lead (µg/dL)		Model Predictions (µg/dL)	
		GM (95% CI)	Percent >10 (95% CI)	GM (95% CI)	Percent >10 (95% CI)
Galena, KA Jasper Co, MI <sup>a</sup>	111	5.2 (4.5-5.9)	20 (13-27)	4.6 (4.0-5.3)	18 (11-25)
Madison Co, IL <sup>a</sup>	333	5.9 (5.5-6.4)	19 (15-23)	5.9 (5.4-6.3)	23 (19-28)
Palmerton, PA <sup>b</sup>	34	6.8 (5.6-8.2)	29 (14-44)	7.5 (6.6-8.6)	31 (16-47)

Excerpts from Air Criteria Document for Lead (October 2006). Original data from Hogan et al. (1998)

CI, confidence interval; GM, geometric means

<sup>a</sup>Children away from home ≤10 hours/week

<sup>b</sup>Children away from home ≤20 hours/week



# IEUBK Exposure Module Components

<b>Media Concentrations for Input</b>		
Soil	Soil must be sampled. Site-specific data required.	Refer to the IEUBK User's Guide and 1994 Guidance Manual for additional information on this input parameter.
Dust	Site-specific data or a value can be derived from soil concentration using multiple source analysis.	Refer to the IEUBK User's Guide and 1994 Guidance Manual for additional information on this input parameter.
Air (default)	0.1 $\mu\text{g}/\text{m}^3$	Ratio of indoor to outdoor air lead concentration is 30%. Site-specific data may be substituted.
Drinking Water (default)	4 $\mu\text{g}/\text{L}$	Site-specific data may be substituted.



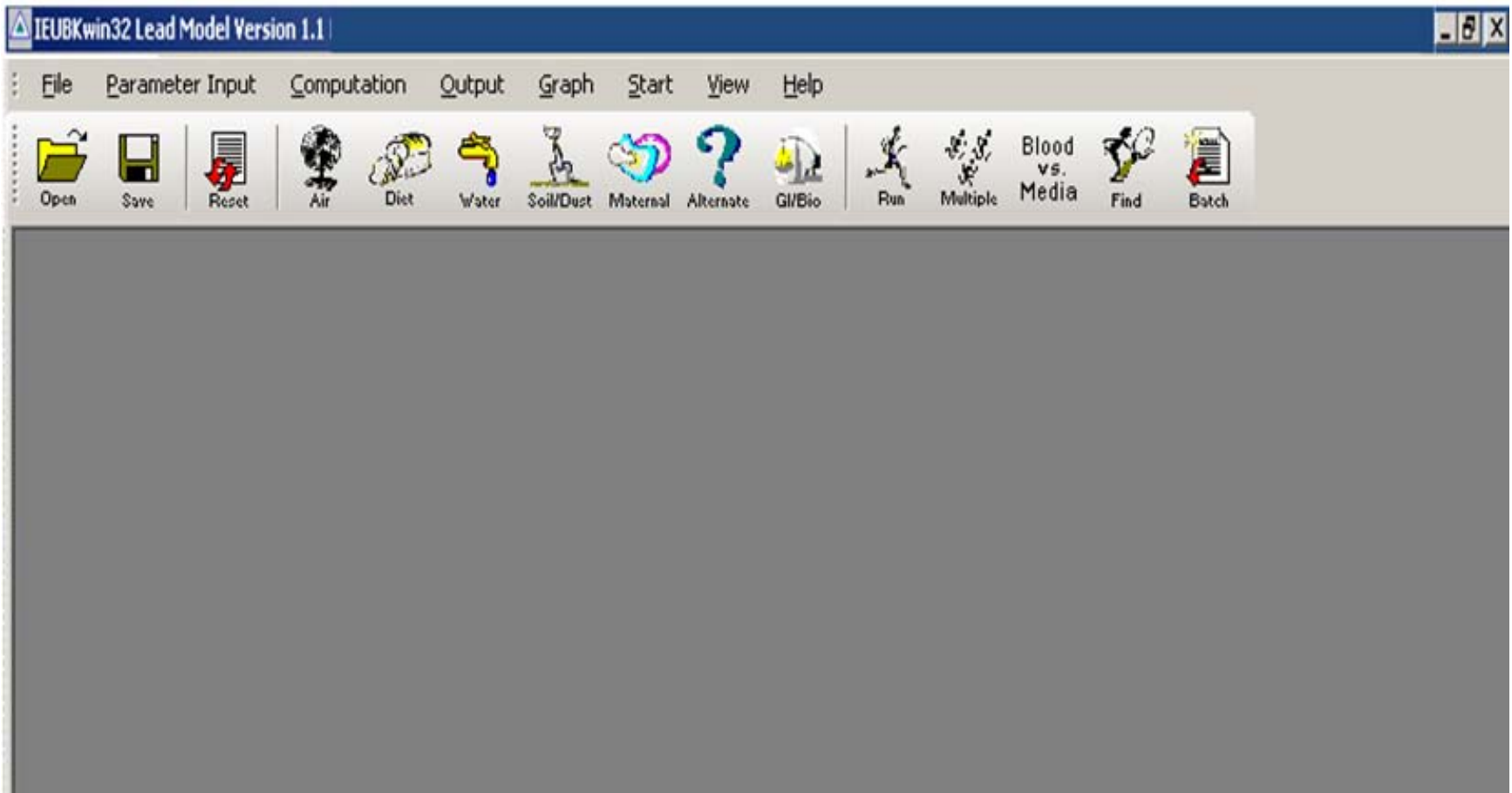
# IEUBK Components (continued)

Media	Age-specific Intake Rates							Comments
	0-1 year	1-2 yrs	2-3 yrs	3-4 yrs	4-5 yrs	5-6 yrs	6-7 yrs	
Soil/dust (mg/day)	85	135	135	135	100	90	85	Default values recommended. Intake is apportioned 55% dust & 45% soil
Air (m <sup>3</sup> /day)	2	3	5	5	5	7	7	Default values recommended
Drinking Water (L/day)	0.2	0.5	0.52	0.53	0.55	0.58	0.59	Default values recommended
Diet (µg Pb/day)	2.26	1.96	2.13	2.04	1.95	2.05	2.22	Site-specific data may be used to assess exposure to fish, game, or home-grown produce.
Alt. Source	Site-specific data may be used to account for intake of lead in other sources							Refer to the IEUBK User's Guide and 1994 Guidance Manual for more information





# IEUBK Model screenshot showing input icons for pathways





# Choosing the User Mode

Choose User Mode

Please choose Beginner or Advanced User Mode?

Beginner

Advanced

Always Start in Advanced User Mode

OK

Help?



# Air Exposure Input

**Air Data** [?] [X]

Indoor air lead concentration (percentage of outdoor):

Outdoor Air Pb Concentration ( $\mu\text{g}/\text{m}^3$ ):

Constant Value:

Variable Values

OK  
Cancel  
Reset  
Help?

Input for different age groups

	AGE (Years)						
	0-1	1-2	2-3	3-4	4-5	5-6	6-7
Outdoor Air Pb Concentration ( $\mu\text{g}/\text{m}^3$ ):	<input type="text" value="0.1"/>	<input type="text" value="0.1"/>	<input type="text" value="0.1"/>	<input type="text" value="0.1"/>	<input type="text" value="0.1"/>	<input type="text" value="0.1"/>	<input type="text" value="0.1"/>
Time Spent Outdoors (hr/day):	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="4"/>	<input type="text" value="4"/>	<input type="text" value="4"/>
Ventilation Rate ( $\text{m}^3/\text{day}$ ):	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="5"/>	<input type="text" value="5"/>	<input type="text" value="5"/>	<input type="text" value="7"/>	<input type="text" value="7"/>
Lung Absorption (%):	<input type="text" value="32"/>	<input type="text" value="32"/>	<input type="text" value="32"/>	<input type="text" value="32"/>	<input type="text" value="32"/>	<input type="text" value="32"/>	<input type="text" value="32"/>

TRW Homepage: <http://www.epa.gov/superfund/health/contaminants/lead/index.htm>



# Dietary Exposure Input

**Dietary Data** [?] [X]

AGE (Years)

	0-1	1-2	2-3	3-4	4-5	5-6	6-7
Dietary Lead Intake (ug/day)	2.26	1.96	2.13	2.04	1.95	2.05	2.22

DIETARY VALUES

Use alternate dietary values?  No  Yes

	Concentration (ug Pb/g)	Percent of Food Class
Home Grown Fruits	0	0 (% of all fruits)
Home Grown Vegetables	0	0 (% of all vegetables)
Fish from Fishing	0	0 (% of all meat)
Game Animals from Hunting	0	0 (% of all meat)
Ethnic Preferences		
Regional Preferences		

GI Values / Bioavailability

GI / Bio Change Values

TRW Homepage:  
<http://www.epa.gov/superfund/programs/lead>

OK  
Cancel  
Help?



# Drinking Water Exposure Input

**Drinking Water Data** [?] [X]

Water Consumption (L/day)

		AGE (Years)						
		0-1	1-2	2-3	3-4	4-5	5-6	6-7
		0.2	0.5	0.52	0.53	0.55	0.58	0.59

Use alternate water values?

No If No, please enter the lead concentration in drinking water ( $\mu\text{g/L}$ ):

Yes If Yes, please fill in the information below.

**LEAD CONCENTRATION IN DRINKING WATER**

Percent of Total Consumed as First Draw:	<input type="text" value="50"/>
Concentration of Lead in First Draw ( $\mu\text{g/L}$ ):	<input type="text" value="4"/>
Concentration of Lead in Flushed ( $\mu\text{g/L}$ ):	<input type="text" value="1"/>
Percentage of Total Consumed from Fountains:	<input type="text" value="15"/>
Concentration of Lead in Fountain Water ( $\mu\text{g/L}$ ):	<input type="text" value="10"/>

GI Values / Bioavailability

TRW Homepage:  
<http://www.epa.gov/superfund/health/contaminants/lead/index.htm>

Buttons: OK, Cancel, Reset, Help?



# Soil and Dust Exposure Input

**Site Specific Soil Dust Data**

Soil/Dust Ingestion Weighting Factor (percent soil):

**Outdoor Soil Lead Concentration ( $\mu\text{g/g}$ )**

Constant Value

Variable Values

**Indoor Dust Lead Concentration ( $\mu\text{g/g}$ )**

Constant Value

Variable Values

Multiple Source Analysis

Multiple Source Avg:

**Soil/Indoor Dust Concentration ( $\mu\text{g/g}$ )**

	AGE (Years)						
	0-1	1-2	2-3	3-4	4-5	5-6	6-7
Outdoor Soil Lead Levels:	<input type="text" value="200"/>	<input type="text" value="200"/>	<input type="text" value="200"/>	<input type="text" value="200"/>	<input type="text" value="200"/>	<input type="text" value="200"/>	<input type="text" value="200"/>
Indoor Dust Lead Levels:	<input type="text" value="150"/>	<input type="text" value="150"/>	<input type="text" value="150"/>	<input type="text" value="150"/>	<input type="text" value="150"/>	<input type="text" value="150"/>	<input type="text" value="150"/>

**Amount of Soil/Dust Ingested Daily (g/day)**

	AGE (Years)						
	0-1	1-2	2-3	3-4	4-5	5-6	6-7
Total Dust + Soil Intake:	<input type="text" value="0.085"/>	<input type="text" value="0.135"/>	<input type="text" value="0.135"/>	<input type="text" value="0.135"/>	<input type="text" value="0.100"/>	<input type="text" value="0.090"/>	<input type="text" value="0.085"/>

**GI Values/Bioavailability**

TRW Homepage: <http://www.epa.gov/superfund/health/contaminants/lead/index.htm>



# Multiple Source Analysis Detail

**Multiple Source Analysis** [?] [X]

Contribution of soil lead to indoor household dust lead (conversion factor):

Contribution of outdoor airborne lead to indoor household dust lead (conversion factor):

[OK] [Cancel] [Help?]

**Indoor Dust Lead Sources**

Use Alternate Indoor Dust Lead Sources?  No  Yes

	Concentration (ug Pb/g)	Percent
Household Dust (average)	<input type="text" value="150"/>	<input type="text" value="100.000"/>
Secondary Occupational Dust	<input type="text" value="1200"/>	<input type="text" value="0.000"/>
Dust at School	<input type="text" value="200"/>	<input type="text" value="0.000"/>
Dust at Daycare	<input type="text" value="200"/>	<input type="text" value="0.000"/>
Second Home Dust	<input type="text" value="200"/>	<input type="text" value="0.000"/>
Lead-based Paint in Home	<input type="text" value="1200"/>	<input type="text" value="0.000"/>

TRW Homepage:  
<http://www.epa.gov/superfund/programs/lead>



# Bioavailability Information Input

**GI Values/Bioavailability Information** [?] [X]

MEDIA	ABSORPTION FRACTION PERCENT	Access alternate bioavailability parameters?	FRACTION PASSIVE/TOTAL ACCESSIBLE	HALF SATURATION Level ( $\mu\text{g}/\text{day}$ )
Soil	<input type="text" value="30"/>	<input checked="" type="radio"/> No <input type="radio"/> Yes	<input type="text" value="0.2"/>	<input type="text" value="100"/>
Dust	<input type="text" value="30"/>			
Water	<input type="text" value="50"/>			
Diet	<input type="text" value="50"/>			
Alternate	<input type="text" value="0"/>			

TRW Homepage: <http://www.epa.gov/superfund/health/contaminants/lead/index.htm>

Buttons: OK, Cancel, Reset, Help?

**Drinking Water Data**

Water Consumption (L/day):  
0-1:  1-2:

Use alternate water values?  
 No If No, please enter  
 Yes If Yes, please fill in

LEAD CONCENTRATION IN

Percent of Total Consumed from Fountains:

Concentration of Lead in Flushed ( $\mu\text{g}/\text{L}$ ):

Percentage of Total Consumed from Fountains:

Concentration of Lead in Fountain Water ( $\mu\text{g}/\text{L}$ ):

GI Values / Bioavailability

TRW Homepage: <http://www.epa.gov/superfund/health/contaminants/lead/index.htm>





# Alternate Exposure Input

## Alternate Source Intake

If you change the alternate source intake, remember to change the Alternate Source Absorption Percent on the GI/Bioavailability data entry screen.

Its default value is 0.0% which must be changed if intakes are not 0.0.

OK

## Alternate Source Data

Alternate Lead Intake ( $\mu\text{g}/\text{day}$ )

AGE (Years)

0-1    1-2    2-3    3-4    4-5    5-6    6-7

OK

Cancel

Reset

Help?

GI Values / Bioavailability

GI / Bio

Change Values

TRW Homepage: <http://www.epa.gov/superfund/health/contaminants/lead/index.htm>



# Maternal Exposure Input

**Maternal Data** [?] [X]

Mother's Blood Lead Concentration at  
Childbirth ( $\mu\text{g Pb/dL}$ ):

OK

Cancel

Reset

Help?

TRW/ Homepage:  
<http://www.epa.gov/superfund/health/contaminants/lead/index.htm>



# Run Risk Calculation (forward equation)

**Run the Model** [?] [X]

Enter the Result File Name

Export data into a Spreadsheet Format

TRW Homepage:  
<http://www.epa.gov/superfund/health/contaminants/lead/index.htm>



**Show Results As...** [X]

Computation is done.

Please choose from the following:

- Display as Text File
- Show as a Distribution Curve
- Show as a Density Curve

TRW Homepage:  
<http://www.epa.gov/superfund/programs/lead>



**Cutoff, GSD, and Comment Information** [?] [X]

Select Age Group for Graph

Parameter Change

Change Cutoff

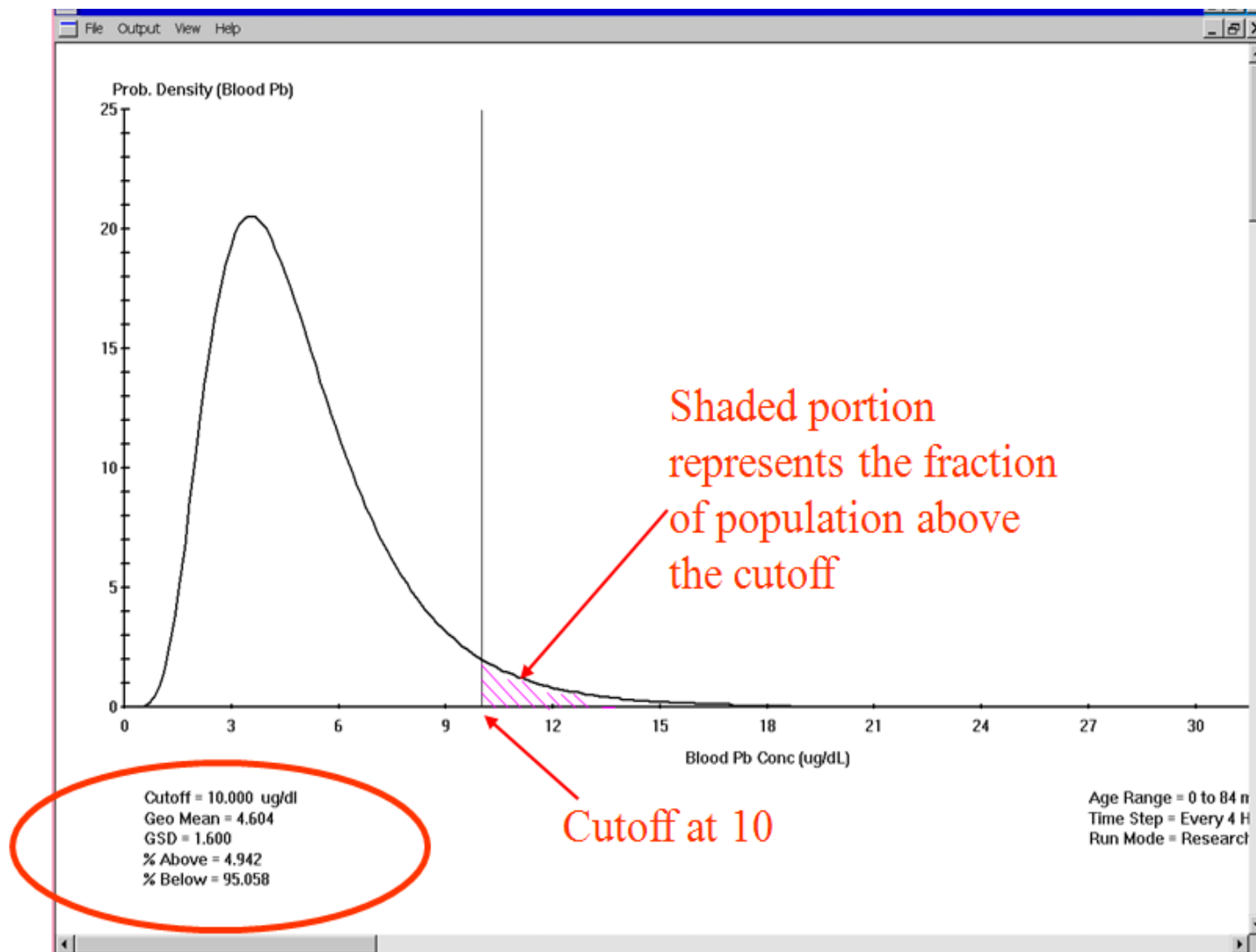
Change GSD(Geometric Standard Deviation)

Comment

TRW Homepage:<http://www.epa.gov/superfund/programs/lead>



# Output from the IEUBK Model





# Run PRG Calculation (backward equation)

**Find Soil Pb Concentration**

Select Age Group for Graph: 0 to 84 months

Find  
Cancel  
Help?

Parameter Change

Change Cutoff: 10 µg/dl

Change GSD (Geometric Standard Deviation): 1.6

Probability of Exceeding the Cutoff (PC): 5 %

Please note  
Depending on the values enter, ca m.

Soil and/or Dust Concentration: 0 PPM

TRW Homepage: <http://www.epa.gov/superfund/health/contaminants/le>

**Find Soil Pb Concentration**

Select Age Group for Graph: 0 to 84 months

Find  
Cancel  
Help?

Parameter Change

Change Cutoff: 10 µg/dl

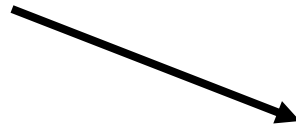
Change GSD (Geometric Standard Deviation): 1.6

Probability of Exceeding the Cutoff (PC): 5 %

Please note  
Depending on the values enter, calculating PRG may take a few moments.

Soil and/or Dust Concentration: 418 PPM

TRW Homepage: <http://www.epa.gov/superfund/health/contaminants/lead/index.htm>





# Sensitivity Analysis

- Predicted PbB and total lead uptake were most sensitive to the amount of soil/dust ingested per day.
- Predicted PbB and total lead uptake were moderately sensitive to the following (listed in decreasing relative sensitivity):
  - absorption fraction for soil dust and diet,
  - soil lead concentration,
  - indoor dust lead concentration,
  - dietary lead concentration,
  - contribution of soil lead to indoor dust lead, and
  - half-saturation absorbable intake (based on output-input ratio).
- The predicted probability of exceeding a specified level of concerns is very sensitive to changes in the GSD.



# IEUBK Strengths and Limitations

- Strengths:
  - Integrates multimedia exposure and relates it to a well characterized biomarker of effect
  - Risk predictions and PRG over a range of exposure scenarios
  - Inputs tailored to support Superfund site risk assessment
  - Risk information complementary to a public health (PbB) study or when no public health (PbB) study is available
- Limitations:
  - Cannot assess short-term, periodic or acute exposures (exposures must be for at least 1 day per week for 90 consecutive days)
  - Cannot assess pica exposures
  - Cannot assess dust exposures using loading data
  - Cannot assess age groups >7 years



# EPA Adult Methodology (ALM)

- Adopted and modified from Bowers et al. (1994)
- Uses a simplified biokinetic slope factor (BKSF)
- Slope relates change in PbB ( $\mu\text{g/dL}$ ) per  $\mu\text{g/day}$  Pb absorbed
- Exposure and other variables differ from IEUBK (IR, bioavailability, etc.)





# ALM Spreadsheet (Risk Calculation)

## Calculations of Blood Lead Concentrations (PbBs)

U.S. EPA Technical Review Workgroup for Lead, Adult Lead Committee

Version date 6/21/09

Variable	Description of Variable	Units	GSDi and PbBo from Analysis of NHANES 1999-2004	GSDi and PbBo from Analysis of NHANES III (Phases 1&2)
PbS	Soil lead concentration	ug/g or ppm	2240	1235
$R_{\text{fetal/maternal}}$	Fetal/maternal PbB ratio	--	0.9	0.9
BKSF	Biokinetic Slope Factor	ug/dL per ug/day	0.4	0.4
$GSD_i$	Geometric standard deviation PbB	--	1.8	2.1
$PbB_0$	Baseline PbB	ug/dL	1.0	1.5
$IR_S$	Soil ingestion rate (including soil-derived indoor dust)	g/day	0.050	0.050
$IR_{S+D}$	Total ingestion rate of outdoor soil and indoor dust	g/day	--	--
$W_S$	Weighting factor; fraction of $IR_{S+D}$ ingested as outdoor soil	--	--	--
$K_{SD}$	Mass fraction of soil in dust	--	--	--
$AF_{S,D}$	Absorption fraction (same for soil and dust)	--	0.12	0.12
$EF_{S,D}$	Exposure frequency (same for soil and dust)	days/yr	219	219
$AT_{S,D}$	Averaging time (same for soil and dust)	days/yr	365	365
<b><math>PbB_{\text{adult}}</math></b>	<b>PbB of adult worker, geometric mean</b>	<b>ug/dL</b>	<b>4.2</b>	<b>3.3</b>
$PbB_{\text{fetal}, 0.95}$	95th percentile PbB among fetuses of adult workers	ug/dL	10.0	10.0
$PbB_t$	Target PbB level of concern (e.g., 10 ug/dL)	ug/dL	10.0	10.0
<b><math>P(PbB_{\text{fetal}} &gt; PbB_t)</math></b>	<b>Probability that fetal PbB &gt; <math>PbB_t</math>, assuming lognormal distribution</b>	<b>%</b>	<b>5.0%</b>	<b>5.0%</b>



# Recommended PbB<sub>0</sub> and GDS<sub>i</sub> Input

Calculations of Preliminary Remediation Goals (PRGs)  
 U.S. EPA Technical Review Workgroup for Lead, Adult Lead Committee  
 Version date 6/21/09 EDIT RED CELLS

Variable	Description of Variable	Units	GSD <sub>i</sub> and PbB <sub>0</sub> from Analysis of NHANES 1999-2004	GSD <sub>i</sub> and PbB <sub>0</sub> from Analysis of NHANES III (Phases 1&2)
PbB <sub>Fetus, 95%</sub>	95 <sup>th</sup> percentile PbB in fetus	ug/dL	10	10 ←
R <sub>Fetus/Maternal</sub>	Fetal/maternal PbB ratio	--	0.9	0.9
BKSF	Biokinetic Slope Factor	ug/dL per ug/day	0.4	0.4
GSD <sub>i</sub>	Geometric standard deviation PbB	--	1.8	2.1 ←
PbB <sub>0</sub>	Baseline PbB	ug/dL	1.0	1.5 ←
IR <sub>s</sub>	Soil ingestion rate (including soil-derived indoor dust)	g/day	0.050	0.050
AF <sub>s, D</sub>	Absorption fraction (same for soil and dust)	--	0.12	0.12
EF <sub>s, D</sub>	Exposure frequency (same for soil and dust)	days/yr	219	219
AT <sub>s, D</sub>	Averaging time (same for soil and dust)	days/yr	365	365
<b>PRG</b>		<b>ppm</b>	<b>2,240</b>	<b>1,235</b>



# Guidance for the IEUBK and ALM

- Model documentation (user's guides and validation information)
- Short Sheets
  - MSD
  - Ingestion Rate
  - Sieving
  - Sampling Guidance
  - Small Arms Firing Range
  - Exposure Point Concentration
  - Residential Dust Guidance
- Residential Sites Handbook
- TRW Bioavailability Guidance
- Frequently Asked Questions (FAQs)

**TRW Lead Committee Web Site: [www.epa.gov/superfund/lead](http://www.epa.gov/superfund/lead)**



# Soil Lead Bioavailability Guidance

Guidance for Evaluating the Oral Bioavailability of Metals in Soils  
for Use in Human Health Risk Assessment

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United States  
Environmental  
Protection Agency

OSWER 9285.7-80



**Guidance for Evaluating the Oral Bioavailability of  
Metals in Soils for Use in Human Health Risk  
Assessment**

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OSWER 9285.7-77

May 2007

## **ESTIMATION OF RELATIVE BIOAVAILABILITY OF LEAD IN SOIL AND SOIL-LIKE MATERIALS USING *IN VIVO* AND *IN VITRO* METHODS**



# Assessing Risk Example Exposure Scenarios

1. Site exposure to lead for a residential community where single (arithmetic mean) media concentrations is available
  - Risk: IEUBK single run mode
  - PRG: IEUBK find media concentration
  
2. Residential exposure to lead in soil with individual residence media concentrations
  - Risk: IEUBK batch mode run
  - PRG: IEUBK find media concentration
  
3. Exposure to lead contaminated soil on an industrial property
  - Risk: ALM
  - PRG: ALM
  
4. Adolescent recreational exposure to contaminated soil
  - Risk: ALM
  - PRG: ALM



# Case Studies

1. IEUBK: Single run with 500 ppm soil and default (old) dietary data. Risk calculation.
2. IEUBK: Single run with 500 ppm soil and new dietary data (attached). Risk calculation.
3. IEUBK: PRG calculation using new dietary data and modified drinking water value. Also saving and reloading a data file and reset all parameters.
4. IEUBK: Multiple runs for soil range using new dietary data and modified drinking water value. Plot of risk calculations.
5. IEUBK: Find media concentration for soil without and with new dietary data and interpretation of GM PbB output.
6. IEUBK: Creating a batch mode input file from a spreadsheet file (attached).
7. IEUBK: Running a batch mode to calculate risk.
8. ALM: Example data entry for non-residential scenario. Calculation of risk and PRG.



# Case Studies

ALM example scenario: non residential exposure scenario for a soil-intensive contact scenario.

What is PRG?

Use  $PbB_0$  &  $GSD_i$  from recent NHANES and IRs  
of 100 mg/day

PRG = Approx 620 ppm



# Case Studies

Is the following health protective?

Residential soil PRG is 600 ppm for future use. PbA =  $0.05 \mu\text{g}/\text{m}^3$ ,  
PbW = 1 ppb, Soil bioavailability = 21%.

Enter media data and use new dietary values

Use find media concentration

Yes, PRG is <5% NTE  $10 \mu\text{g}/\text{dL}$





## Case Studies

Is the following health protective?

PRG of 2500 ppm for a fire monitoring station occupied by adults  
7 days per week for 4 months (16 weeks) of the year.

Use ALM with EF = 112 days/year

IRs=50 mg/day

No, PRG is >5% NTE 10  $\mu$ g/dL



# Case Studies

Assuming that 2500 ppm is the selected soil lead concentration for those fire monitoring stations (occupied by adults), what is the maximum duration that they can be occupied (assuming continuous exposure)?

$$\text{IRs} = 50 \text{ mg/day}$$

Reduce EF to achieve is <5% NTE 10  $\mu\text{g/dL}$

Approximately 15 weeks



# Wrap up

EPA provides risk tools and guidance to assess lead exposure at hazardous waste sites. The TRW Lead Committee is available to support users when questions or when novel applications arise

- Evaluate & develop models and other risk tools
- Provide technical support for the development and implementation of EPA guidance on lead
- Review application of risk assessment tools
- Provide technical assistance to end users for use of non-standard (site-specific) values

TRW Lead Committee Members are EPA staff from  
Regions, Headquarters, and Labs



# TRW Lead Committee

## Co-Chairs

- Mary Ballew (Region 1)
- Mike Beringer (Region 7)
- Jim Konz (OSRTI HQ)

## TRW Web page:

[www.epa.gov/superfund/lead](http://www.epa.gov/superfund/lead)

## Contact the TRW hotline

- Send an e-mail to [pbhelp@epa.gov](mailto:pbhelp@epa.gov)
- Call the toll-free TRW hotline at 1-866-282-8622