EPA
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Lead Risk Assessment Model Training

Disclaimer: The views expressed are those of the author(s) and do not necessarily reflect the views or policies of the U.S. EPA.

Day 1: July 23, 2025

Introductions and Training Overview

- **Training Leaders:**
  - EPA TRW Lead Committee Co-chairs
    - Dr. Michele Burgess (OSRTI), Dr. Charlie Partridge (R8), and Ms. Courtney Carroll (R1)
  - Dr. James Brown, EPA
  - Dr. Mark Follansbee, SRC
- **Training Goals:**
  - Overview of the 3 models used to evaluate risk from lead
    - IEUBK, ALM, and AALM
  - Exercises and demonstrations of these models

For any questions related to lead evaluation, please contact the Lead TRW by email (pbhelp@epa.gov) or visit the TRW website: https://www.epa.gov/superfund/lead-superfund-sites-technical-assistance

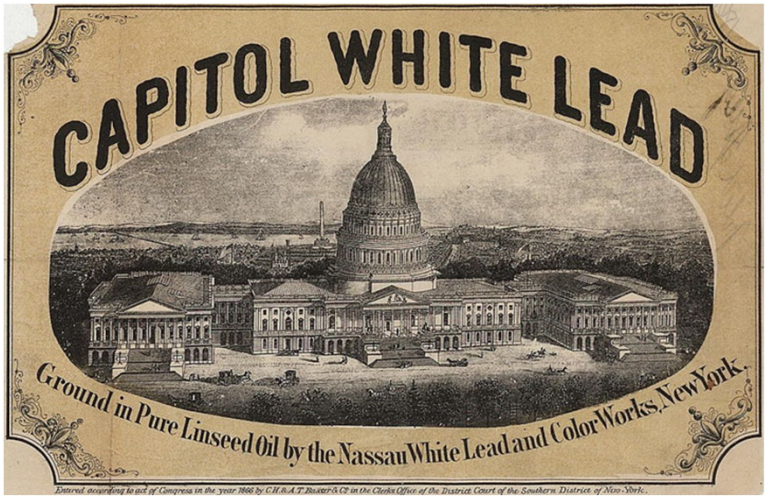
Agenda

Day 1:

- IEUBK and ALM in Lead Risk Assessment
- Overview of the AALM
- Discussion and Q&A
- IEUBK exercises: single runs, finding PRG, use of site-specific bioavailability information
- Discussion and Q&A

Day 2:

- IEUBK exercises: batch mode and intermittent exposure/time-weighted averaging
- Discussion and Q&A
- ALM exercise
- AALM demonstration and intermittent exposure example
- Discussion and Q&A

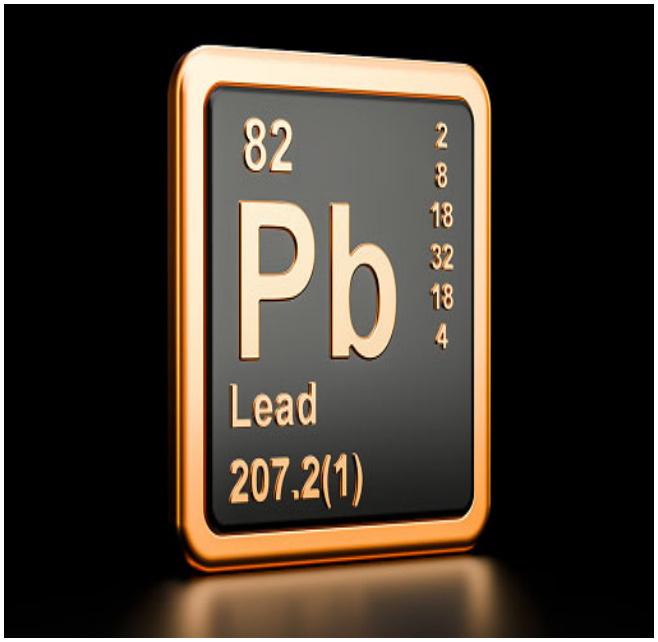


Evaluating Risk from Lead (Pb)

Disclaimer: The views expressed are those of the author(s) and do not necessarily reflect the views or policies of the U.S. EPA.

Why is Lead Risk Evaluated Differently?

- EPA has not found a concentration of lead in blood that does not produce a biological effect
- Therefore, we cannot use traditional risk assessment methods to evaluate risk from lead



Why use Models for Risk Assessment?

1. It is difficult to get representative data and directly link the biomarker (blood lead levels) to a specific source

2. We can evaluate risk management options because models let us estimate changes in blood lead levels from potential changes in exposures

Lead Risk Assessment Models

- EPA uses two models for assessing lead risk at CERCLA sites:
  - Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children – residential exposures
  - Adult Lead Methodology (ALM) – non-residential exposures (commercial/industrial)

https://www.epa.gov/superfund/lead-superfund-sites-software-and-users-manuals

IEUBK Model

Disclaimer: The views expressed are those of the author(s) and do not necessarily reflect the views or policies of the U.S. EPA.

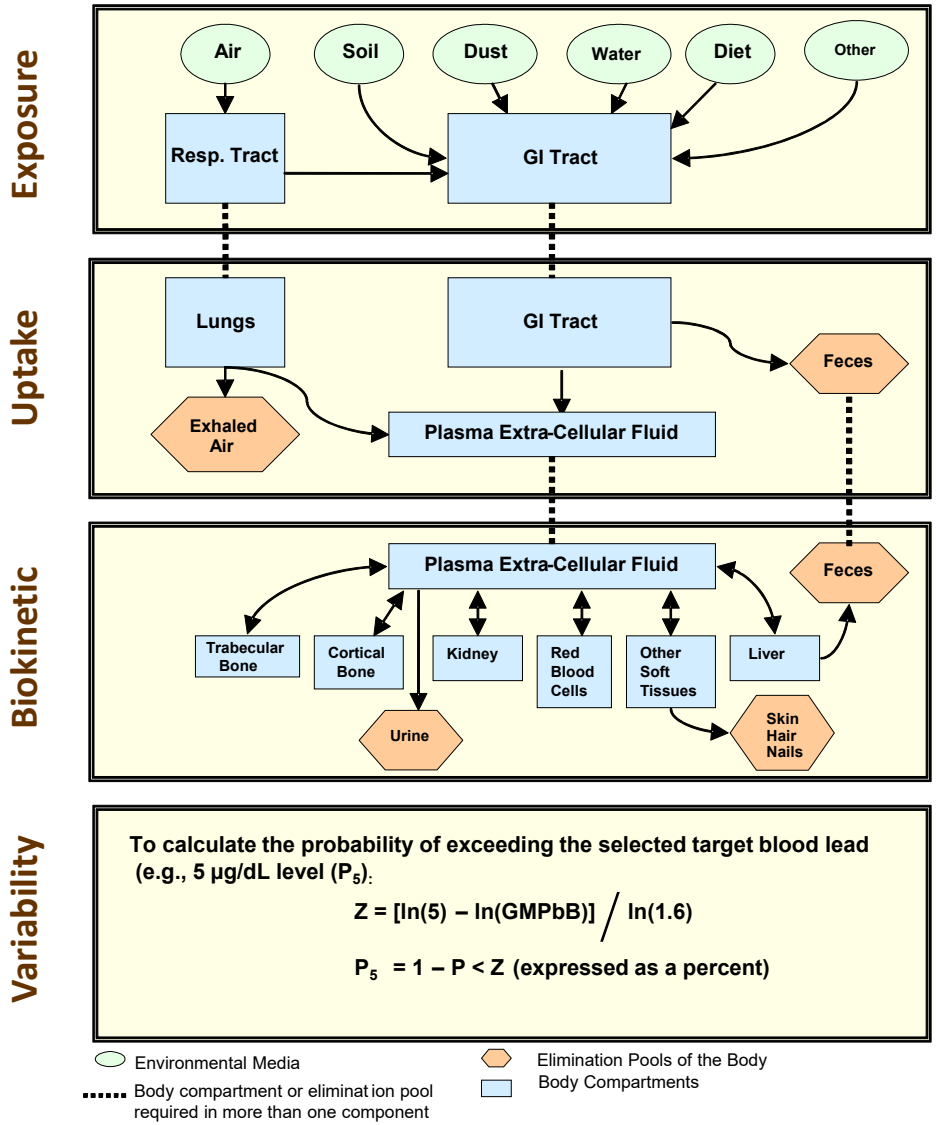
Purpose of the IEUBK Model

Predicts blood lead levels in young (<7 years old) children who are exposed to environmental lead from multiple sources

Predicts risk (percent probability) that a hypothetical child (or group of similarly exposed children) will have a blood lead level exceeding the selected target (e.g., 5 µg/dL) due to environmental exposure

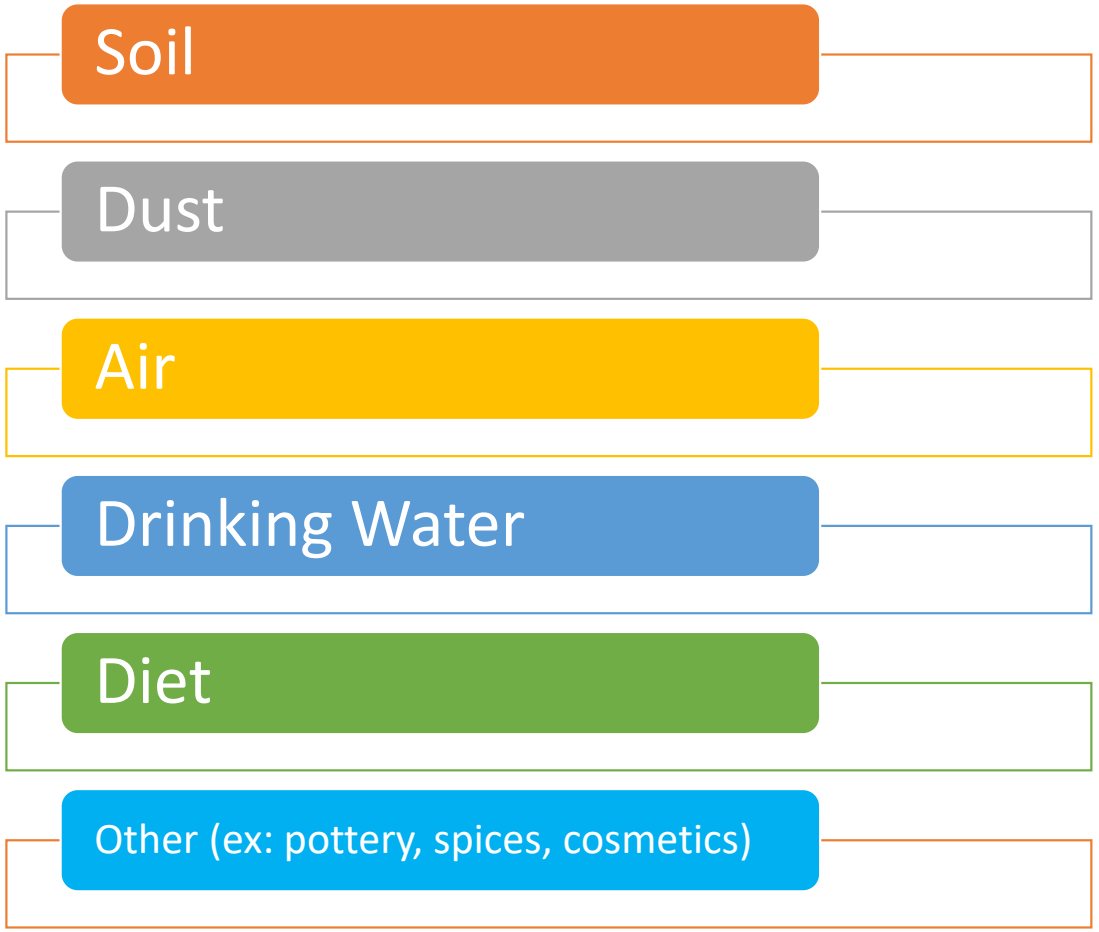
Can be used to calculate a risk-based Preliminary Remediation Goal (PRG) for soil for residential land use

Modules of the IEUBK Model



IEUBK Model Parameters

Multi-media Lead Exposure



Model Parameters – Soil Lead Concentration

- No default value available
- Site-specific surface soil lead concentration should be used as the input
  - Average concentration for the exposure unit
  - From a depth horizon that corresponds to anticipated exposure

Model Parameters – Indoor Dust Lead

- By default, the model will calculate an indoor dust lead concentration based on the outdoor soil concentration and outdoor air concentration

PbD = (PbS * 0.7) + (100*PbA)

- Indoor dust lead = (outdoor soil lead * MSD) + (100 * lead in outdoor air)
- MSD = Mass fraction of soil in indoor dust (currently 0.7)

Model Parameters – Outdoor Air Lead Concentration

- The default air lead concentration in the IEUBK model is 0.1 µg/m³
- Users can input site-specific data if available

Model Parameters – Drinking Water

- The default water concentration in the model is 0.9 µg/L
- Users can input site-specific data if available

Model Parameters – Diet

- Default daily dietary Pb intake estimates in the model are based on FDA food monitoring data and food consumption data from the "What We Eat in America" component of the NHANES survey
- Site-specific dietary information (e.g., from fish ingestion) can be used as well

Fish Ingestion can be Evaluated as an “Alternate Source” in the Model

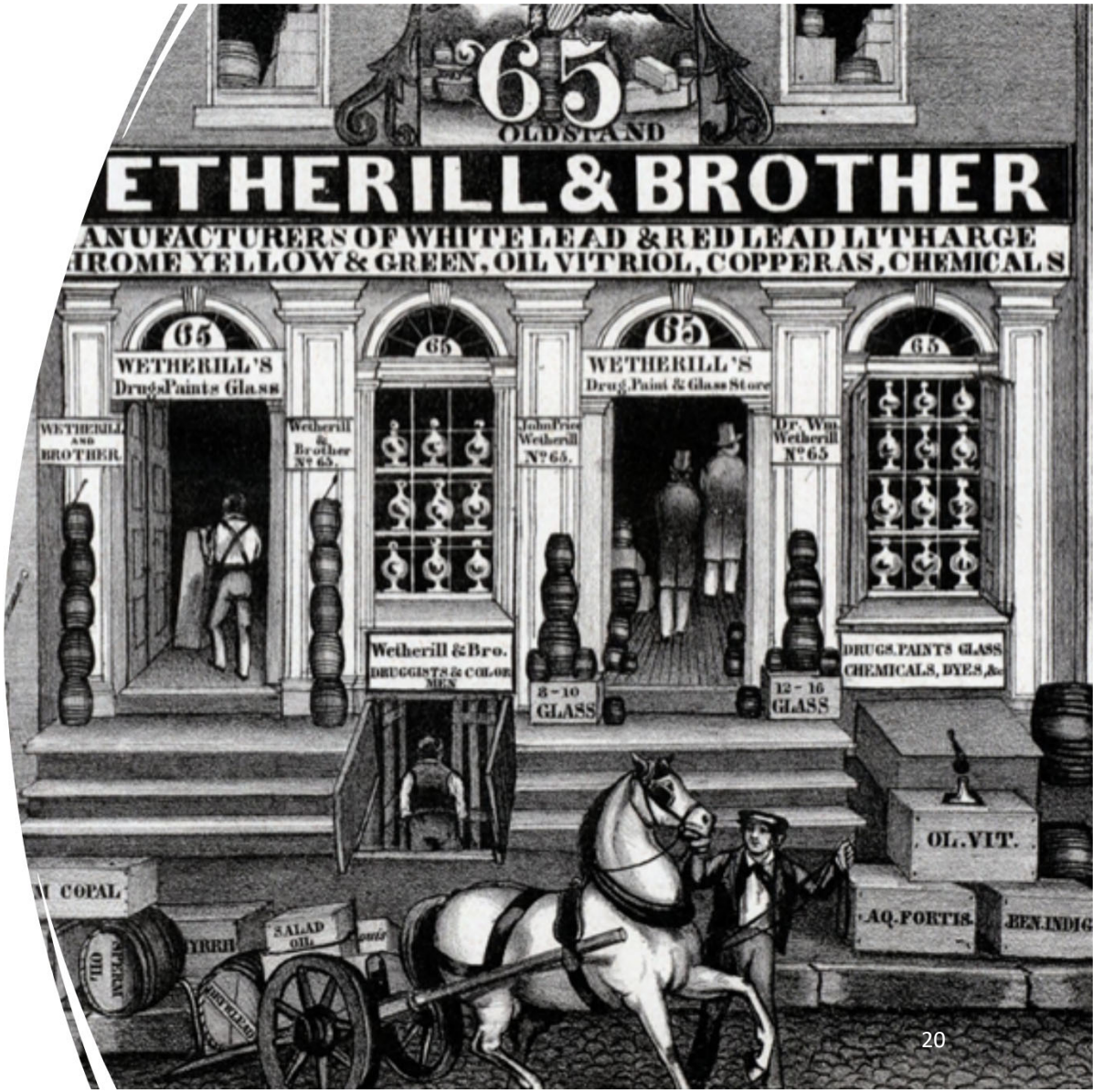
Use when fish ingestion is an exposure pathway in the risk assessment

Requires Pb concentration in fish (µg Pb/g fish) and a fish ingestion rate (g fish/day)

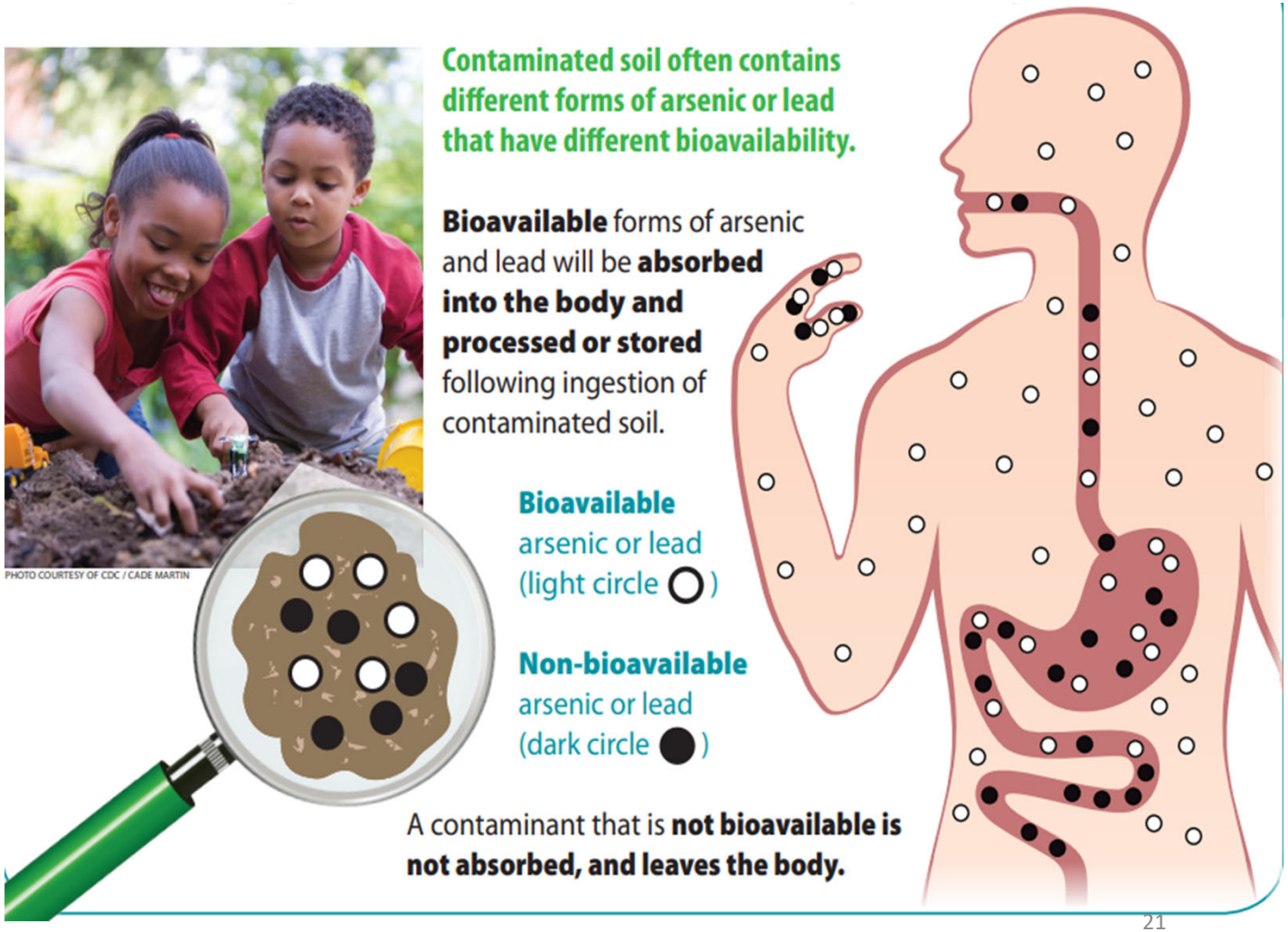
Calculate daily lead intake from fish ingestion and enter data in the model as alternate source

Media	Age-specific Intake Rates (years)							Comments	Citation
	0–1	1–2	2–3	3–4	4–5	5–6	6–7		
Soil/dust ingestion (mg/day)	86	94	67	63	67	52	55	Default values recommended. Intake is apportioned 55% dust & 45% soil	https://semspub.epa.gov/src/document/HQ/400702
Breathing rate (m^3/day)	3.22	4.97	6.09	6.95	7.68	8.32	8.89	Rate not accessible to users, but hours outside and absorption are adjustable	https://semspub.epa.gov/src/document/HQ/400703
Drinking water consumption (L/day)	0.40	0.43	0.51	0.54	0.57	0.60	0.63	Default values recommended	https://semspub.epa.gov/src/document/HQ/400705
Dietary lead intake (µg Pb/day)	2.66	5.03	5.21	5.38	5.64	6.04	5.95	Site-specific data may be used to assess exposure to fish, game, or home-grown produce	https://semspub.epa.gov/src/document/HQ/400706
Alternate source	Site-specific data may be used to account for intake of lead in other sources.							Refer to the IEUBK Model User's Guide for more information	N/A

Please put questions in the Q&A chat



Bioavailability and Risk Assessment



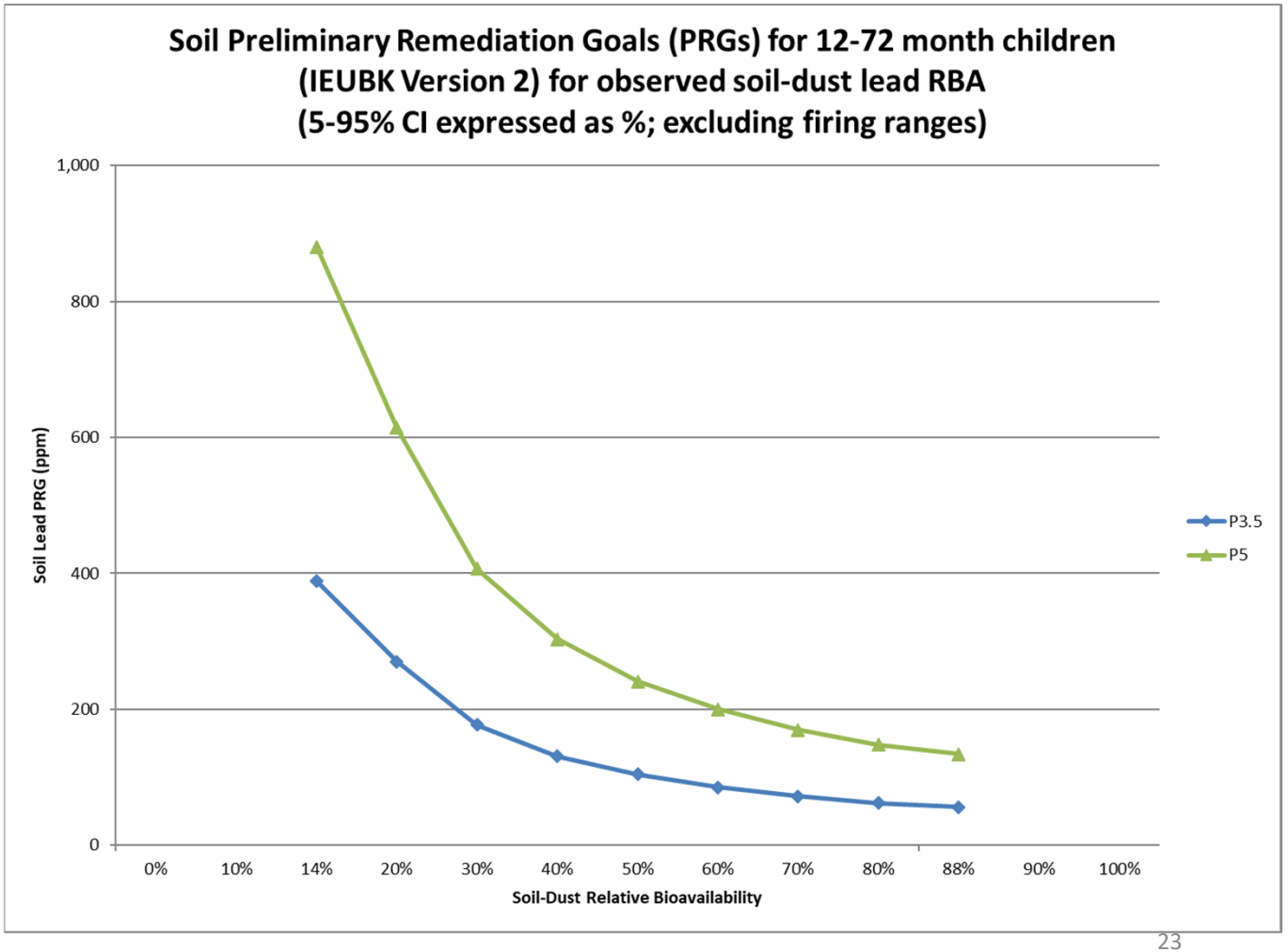
Bioavailability in the IEUBK

The IEUBK has default bioavailability parameters for soil, dust, water and diet

Relative bioavailability is absorption of lead relative to soluble lead (lead acetate) in water

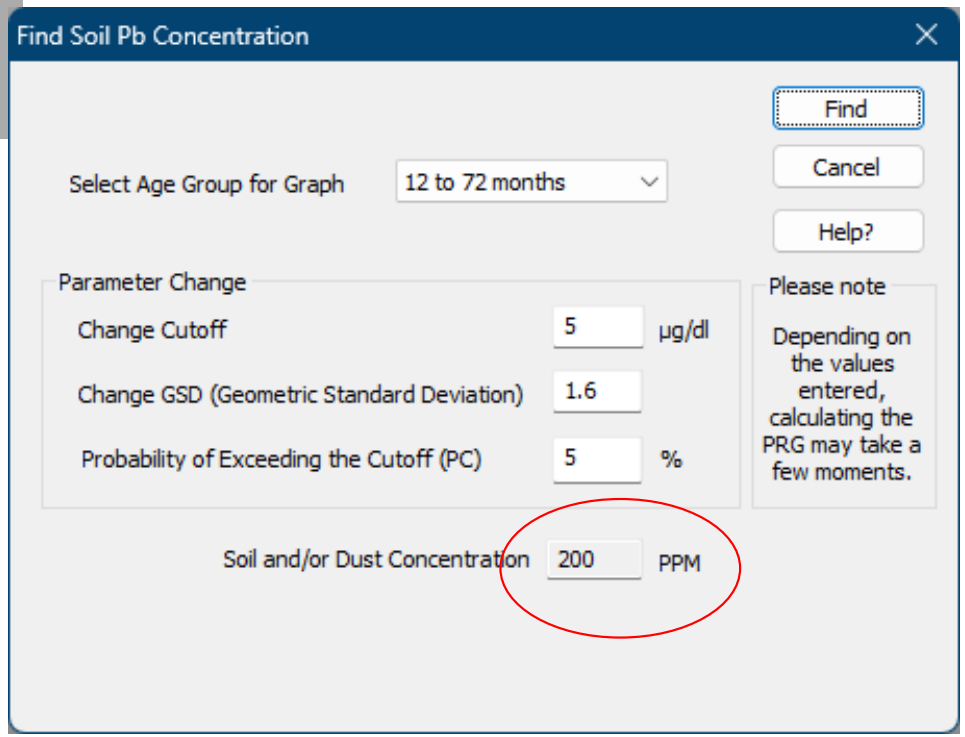
Results of site-specific bioaccessibility studies can be used to adjust the bioavailability parameters for soil and dust. Bioaccessibility results must be converted to enter in the IEUBK as bioavailability (absorption fraction)

How does Bioavailability Impact Site Cleanups?



Calculating PRGs in the IEUBK

Enter site-specific information then use the Find button to calculate the PRG for your exposure scenario.

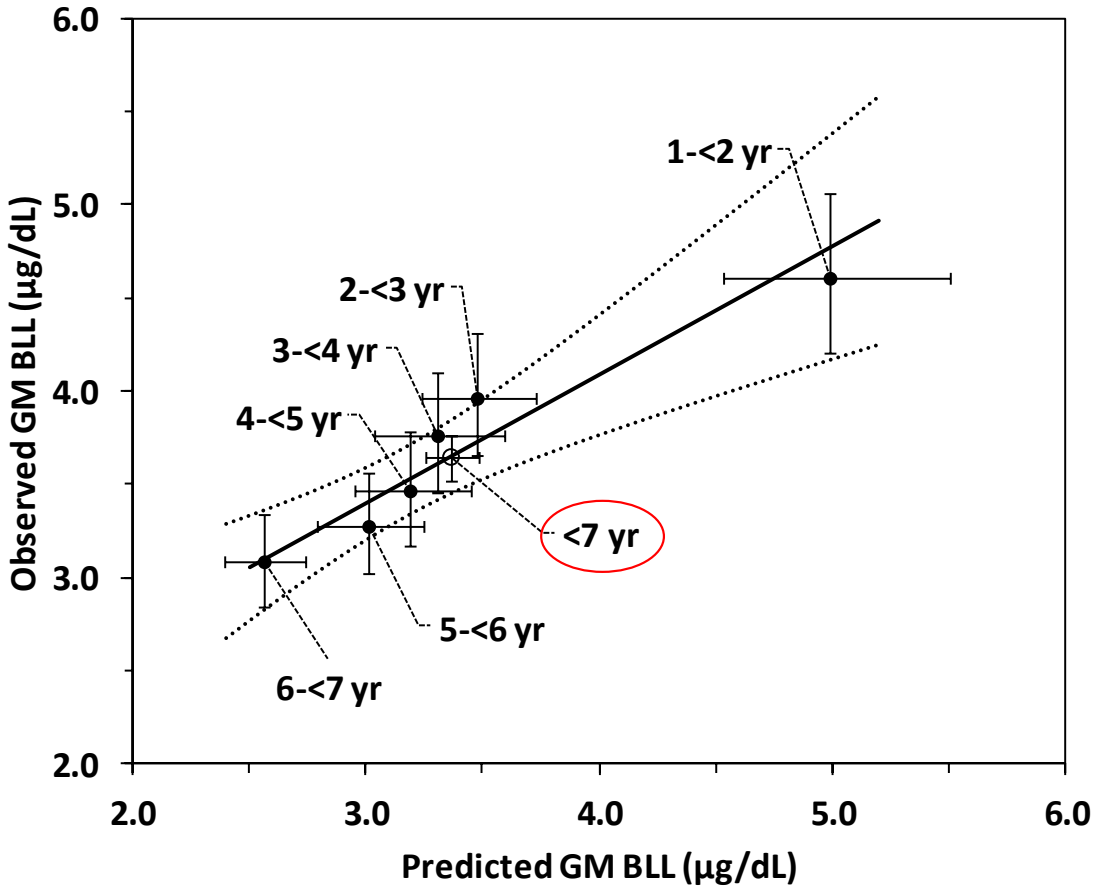


Evaluation of the IEUBK Model

- Evaluation encompasses the following:
  - Scientific underpinnings of the model structure
  - Adequacy of parameter estimates
  - Mathematical relationships (as computer code)
  - Empirical comparisons (predicted vs. observed)
- The process and results of the IEUBK Model evaluation are available on the TRW Lead Committee website
  - 1994 Validation Strategy for the IEUBK
  - 1998 Empirical Comparisons Manuscript (Hogan et al., 1998)
  - 2020 Empirical Comparisons Evaluation: report (ORD, 2021) and manuscript (Brown et al., 2022)

IEUBK Predictive Performance Comparison of PbB

The IEUBK model has a predictive range of approximately ±1 µg/dL



Source: Brown et al. *J Expo Sci Environ Epidemiol. 2022*

Adult Lead Methodology (ALM)

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Purpose of Adult Lead Methodology (ALM)

- Predicts the risk of elevated blood lead levels in non-residential settings (e.g., commercial/industrial sites, deeper soil horizons)
- Used for populations other than young children (i.e., >84 months old or >7 years)
- Calculates PRG (cleanup level) for soil in non-residential land use

Features of the ALM

- The ALM relates soil-lead intake to blood lead concentrations in women of childbearing age
  - ALM is not a multi-media model
- The goal is to limit exposure to the fetus of the pregnant woman (worker/trespasser) because this is the most sensitive receptor
  - Protecting the fetus will protect other receptors at non-residential sites

Calculations of Blood Lead Concentrations (PbBs) and Risk in Nonresidential Areas

U.S. EPA Technical Review Workgroup for Lead

Version date 06/14/2017

Variable	Description of Variable	Units	GSDi and PbBo from Analysis of NHANES 2009-2014
PbS	Soil lead concentration	µg/g or ppm	1054
$R_{fetal/maternal}$	Fetal/maternal PbB ratio	--	0.9
BKSF	Biokinetic Slope Factor	µg/dL per µg/day	0.4
GSD_i	Geometric standard deviation PbB	--	1.8
PbB_0	Baseline PbB	µg/dL	0.6
IR_S	Soil ingestion rate (including soil-derived indoor dust)	g/day	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
$EF_{S,D}$	Exposure frequency (same for soil and dust)	days/yr	219
$AT_{S,D}$	Averaging time (same for soil and dust)	days/yr	365
PbB_{adult}	PbB of adult worker, geometric mean	µg/dL	2.1
$PbB_{fetal,\ 0.95}$	95th percentile PbB among fetuses of adult workers	µg/dL	5.0
PbB_t	Target PbB level of concern (e.g., 2-8 ug/dL)	µg/dL	**5.0**
$P(PbB_{fetal} > PbB_t)$	**Probability that fetal PbB exceeds target PbB, assuming lognormal distribution**	**%**	**5.0%**

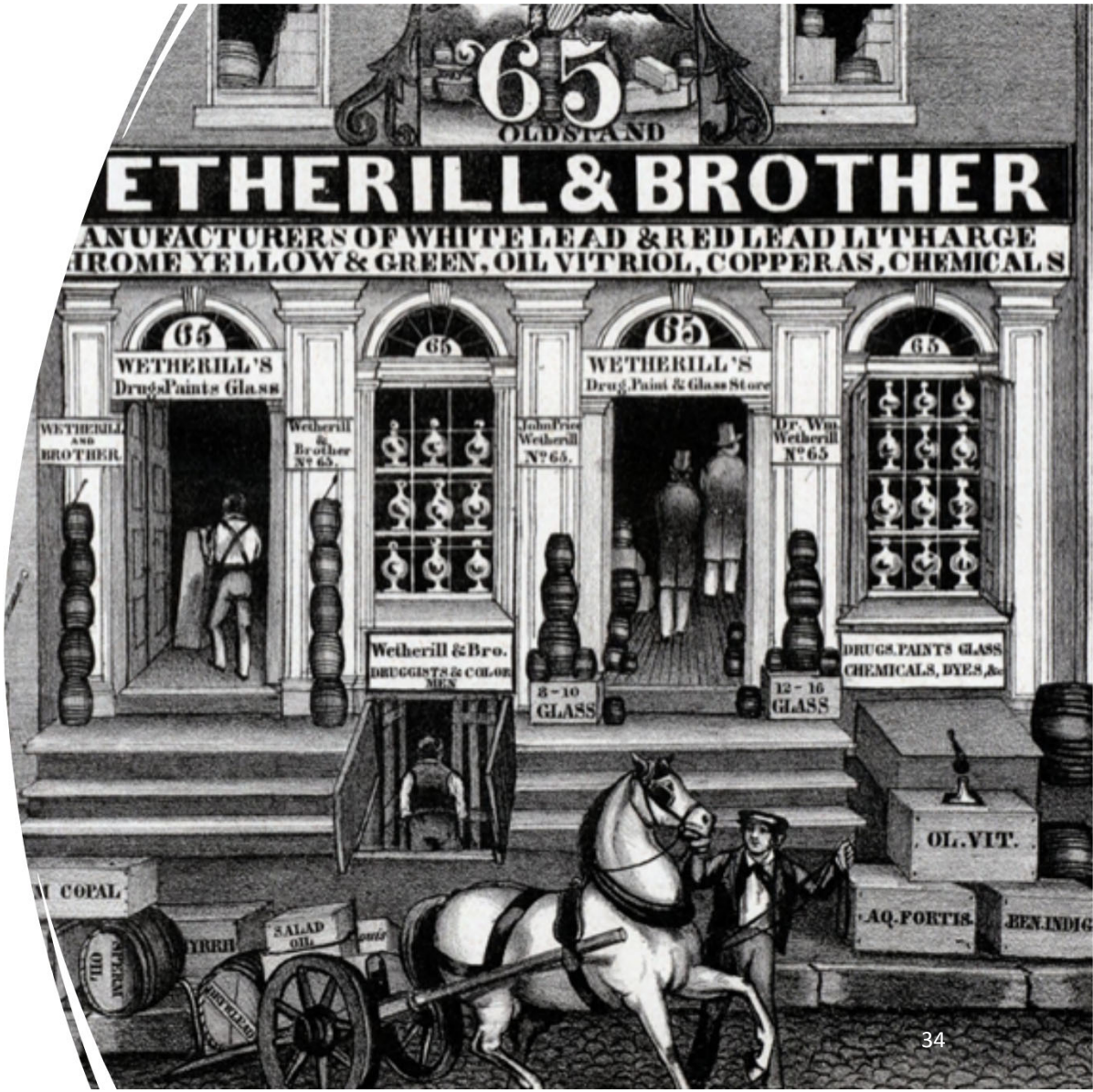
B	C	D	E
Calculations of Preliminary Remediation Goals (PRGs) for Soil in Nonresidential Areas			
U.S. EPA Technical Review Workgroup for Lead, Adult Lead Committee			
Version date 06/14/2017			
Variable	**Description of Variable**	**Units**	**GSDi and PbBo from Analysis of NHANES 2009-2014**
$PbB_{fetal,\ 0.95}$	Target PbB in fetus (e.g., 2-8 µg/dL)	µg/dL	5
$R_{fetal/maternal}$	Fetal/maternal PbB ratio	--	0.9
BKSF	Biokinetic Slope Factor	µg/dL per µg/day	0.4
GSD_i	Geometric standard deviation PbB	--	1.8
PbB_0	Baseline PbB	µg/dL	0.6
IR_S	Soil ingestion rate (including soil-derived indoor dust)	g/day	0.050
$AF_{S,\ D}$	Absorption fraction (same for soil and dust)	--	0.12
$EF_{S,\ D}$	Exposure frequency (same for soil and dust)	days/yr	219
$AT_{S,\ D}$	Averaging time (same for soil and dust)	days/yr	365
PRG in Soil for no more than 5% probability that fetal PbB exceeds target PbB		**ppm**	**1,050**

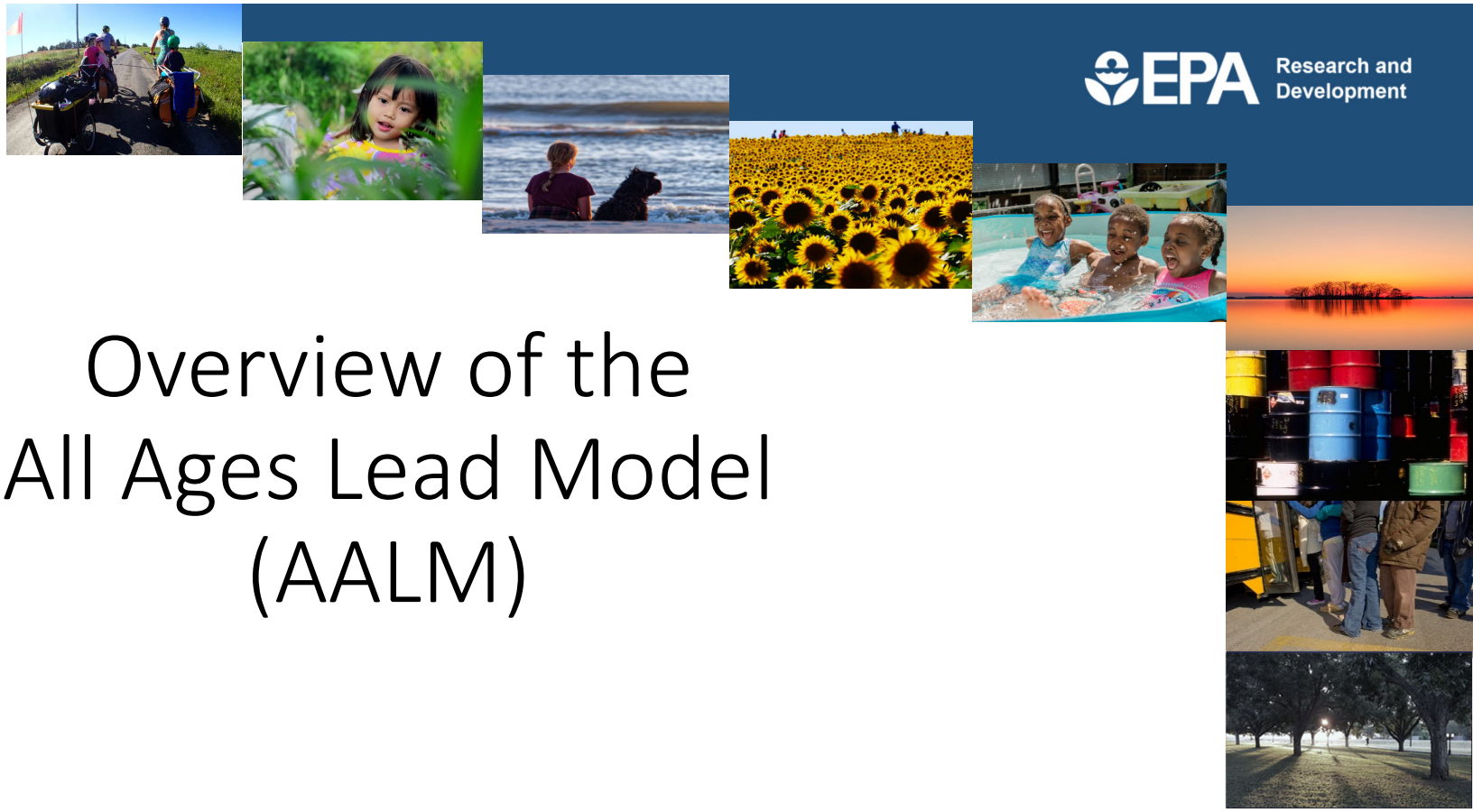
Summary

Key Messages

- Lead models were developed to evaluate risk from lead and to support risk management decisions
- The Integrated Exposure Uptake Biokinetic (IEUBK) model combines exposure across media and is used for young children in a residential setting
- The Adult Lead Methodology (ALM) is used to predict elevated blood lead levels from exposure to lead in soil in a non-residential (e.g., commercial/industrial) setting
- The TRW Lead Committee can be consulted for further guidance in conducting risk assessments for lead or for developing PRGs
- Assistance is available at pbhelp@epa.gov

Please put questions in the Q&A chat





Overview of the All Ages Lead Model (AALM)

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Overview

Purpose:

- Introduce the All Ages Lead Model v3.1 (AALM) and compare to the Integrated Uptake Biokinetic (IEUBK) Model for Lead in Children v2.0

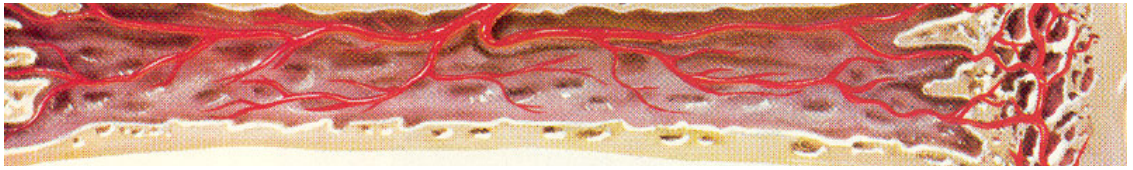
We will review:

- Lead (Pb) exposure & biomarkers
- Its use: *Comparison of IEUBK and AALM*
- AALM
  - *Capabilities*
  - *Evaluation*
    - *SAB peer review of AALM v2.0*
  - *Status and next steps*
- Application
- AALM modeling team

Biomarkers of Pb Exposure

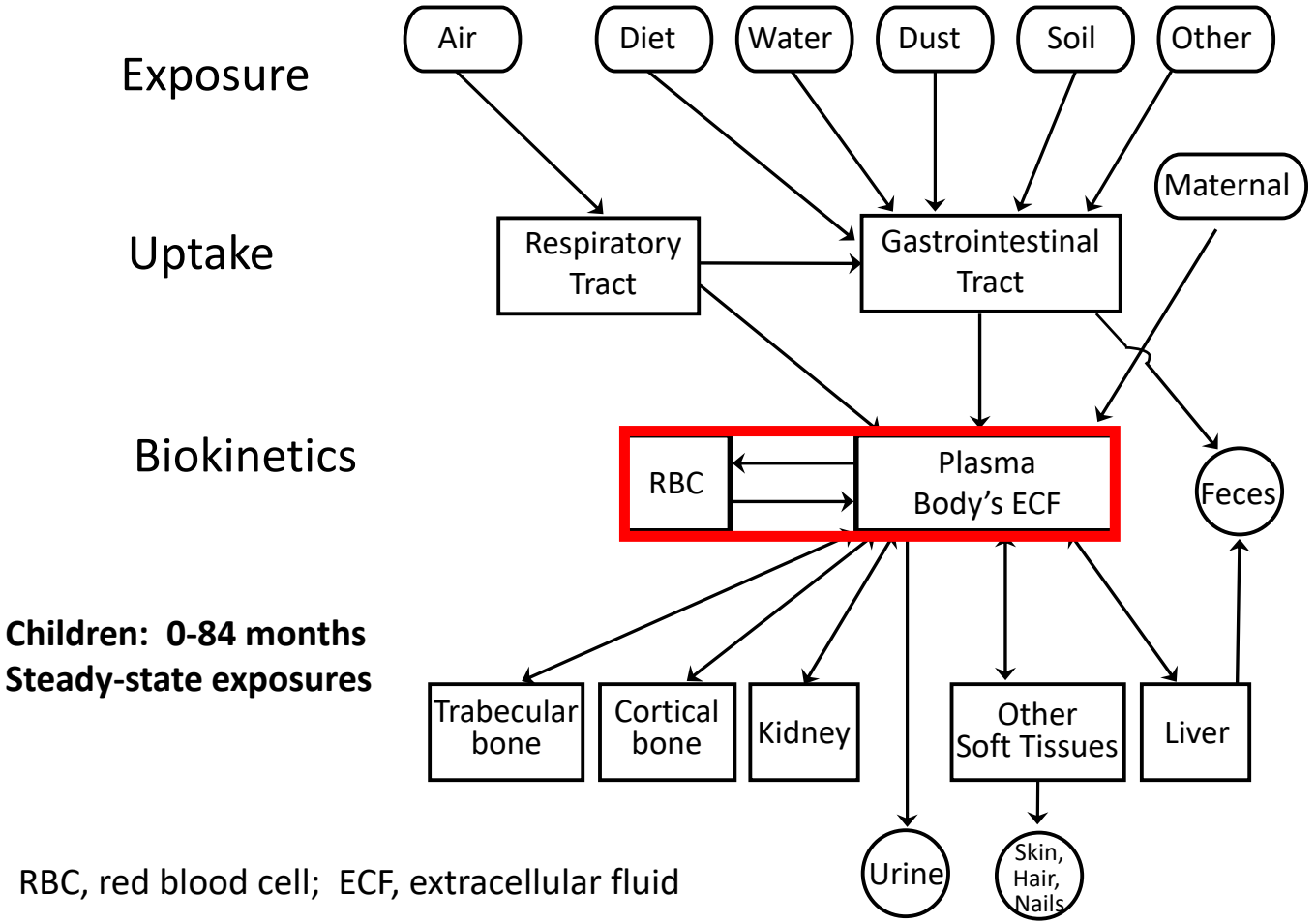
- Blood Pb: most common biomarker; ~1% of Pb body burden; >99% bound to red blood cells (RBC), 1% in plasma and extracellular fluid
  - Generally, indicates recent exposure
  - Children's blood Pb tends to be greatest in the late summer/early fall
  - Pb half-life in blood depends on age and exposure history, can range from days to months
- Bone Pb: accounts for ~70% of Pb body burden in children and more than 90% in adults

Pb is exchanged between blood (via plasma) and compact (Cortical) and spongy (Trabecular) bone



Bone acts as a source of Pb to blood and other tissues for years following exposure

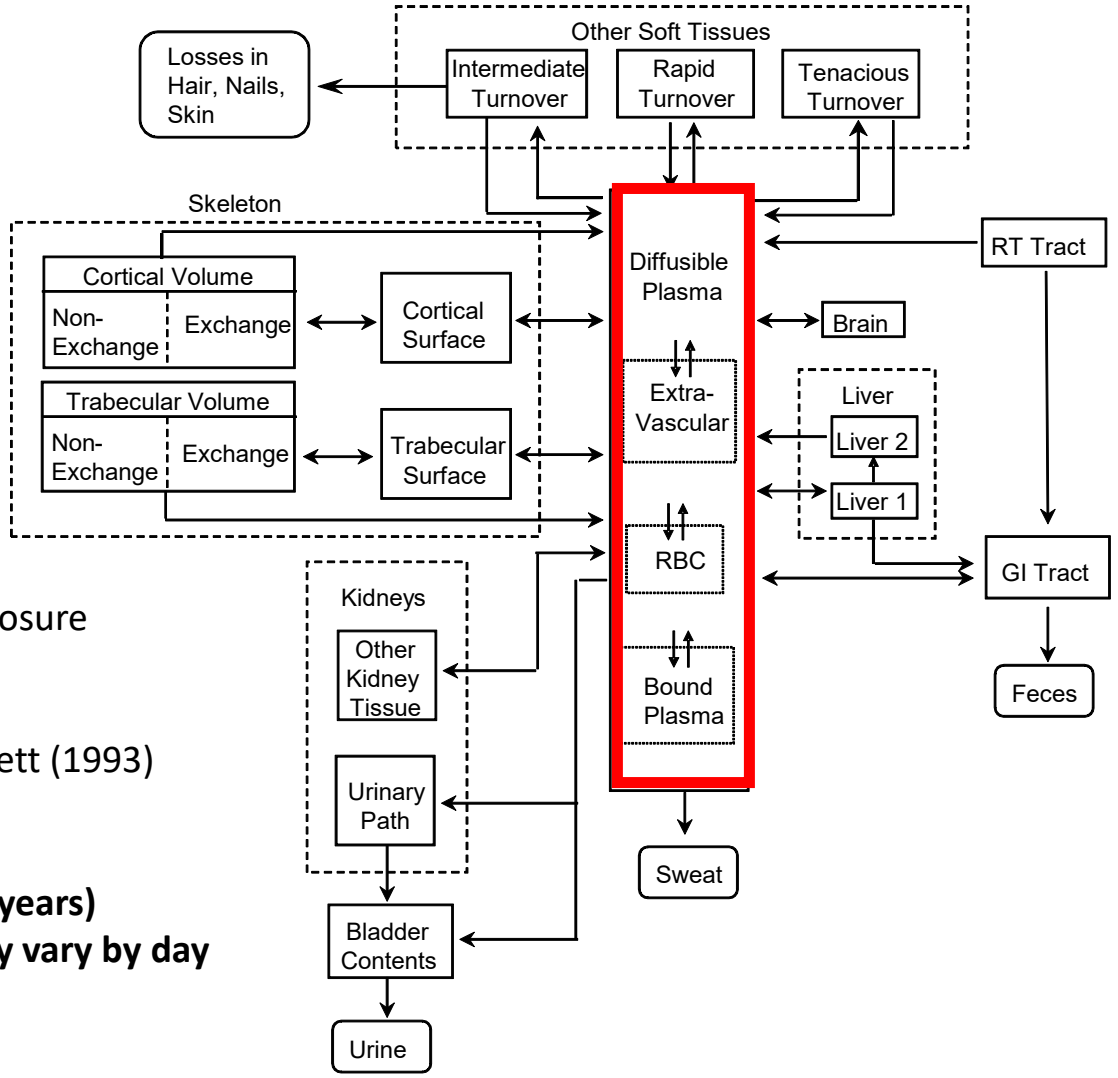
IEUBK Model



Children: 0-84 months
Steady-state exposures

RBC, red blood cell; ECF, extracellular fluid

AALM

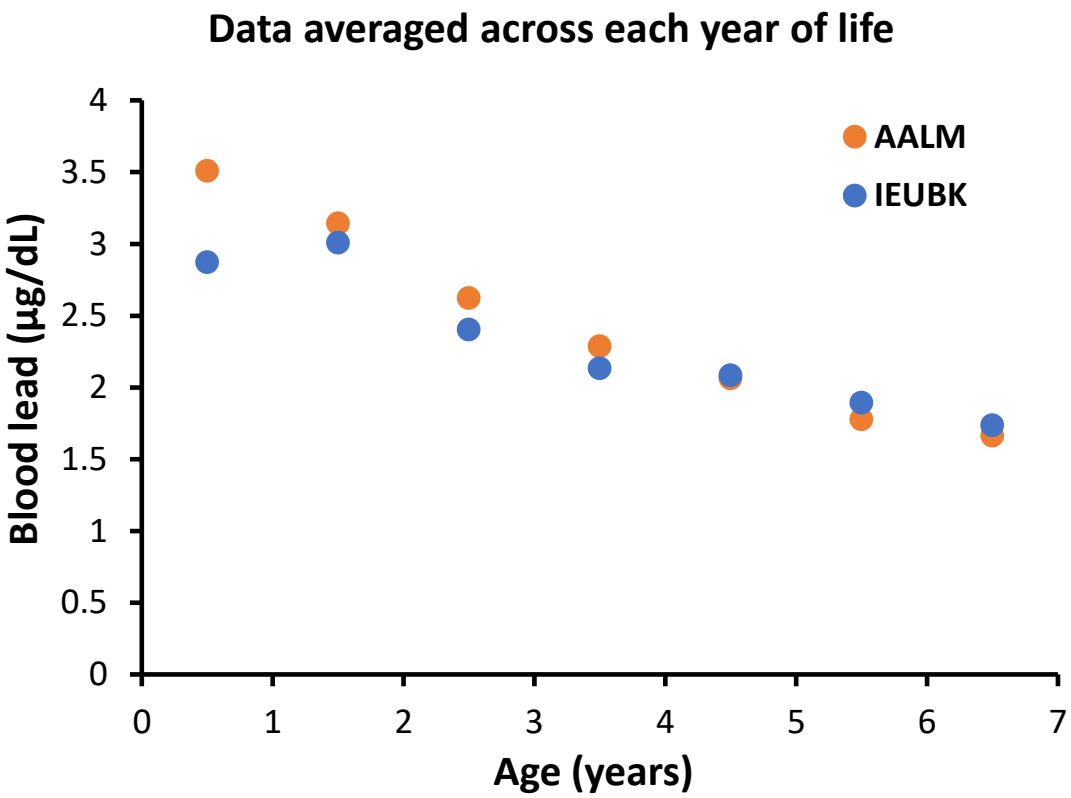


IEUBK-like exposure component

Primarily Leggett (1993) biokinetics

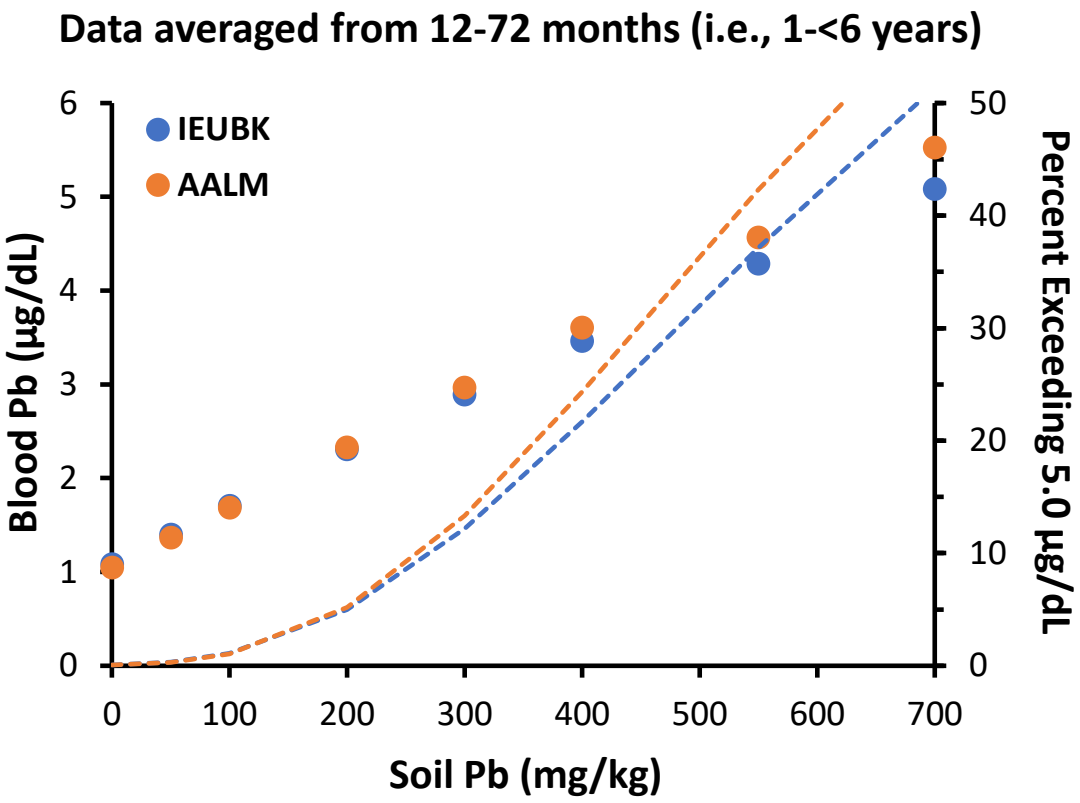
All ages (0-90 years)
Exposures may vary by day

Comparison of IEUBK and AALM



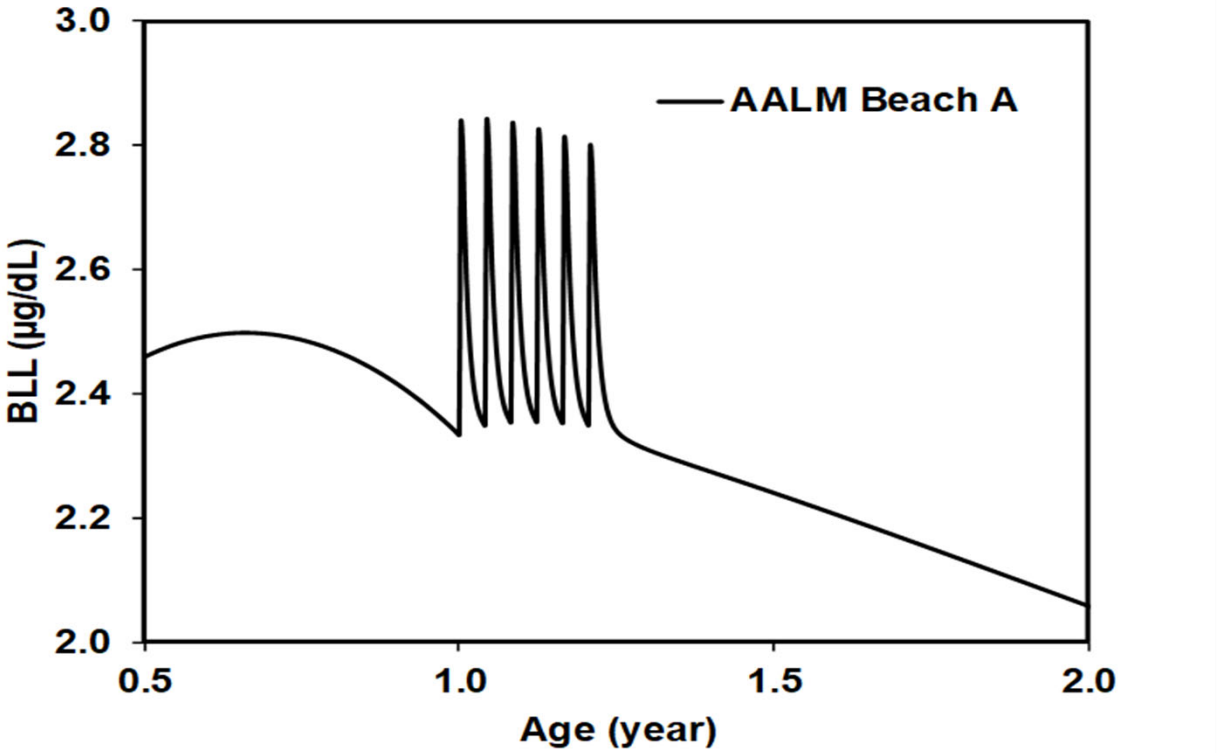
Simulations for an exposure to lead in residential soil at 200 mg/kg using IEUBK v2 exposure defaults in both models

Comparison of IEUBK and AALM



Simulations using IEUBK v2 defaults in both models

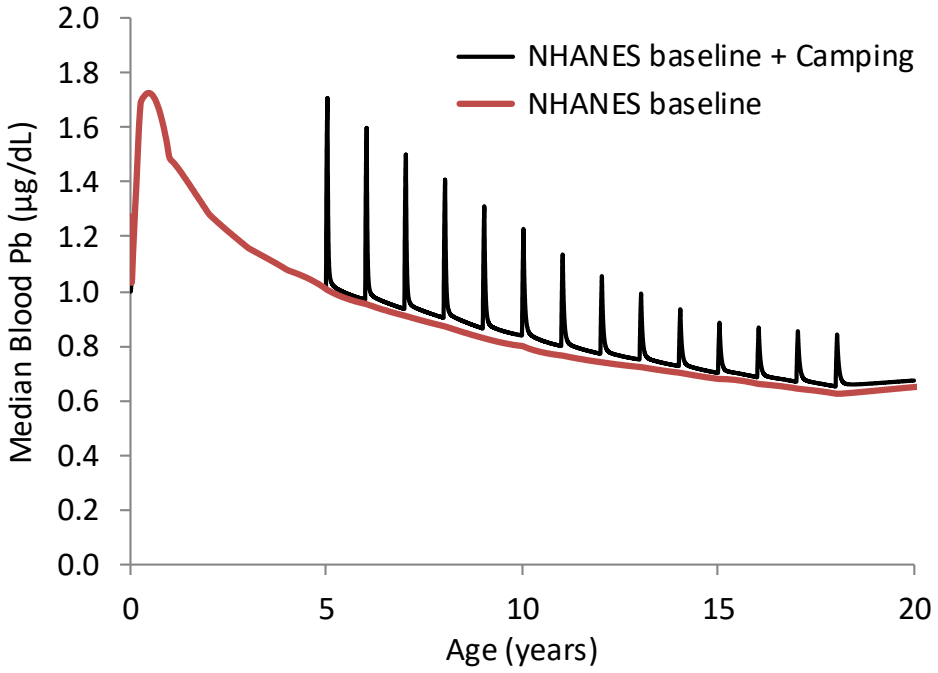
AALM Simulation of Highly Intermittent Exposure



BLLs predicted from the AALM for combined baseline exposures (air, food, drinking water, and residential and indoor dust) and exposures to beach A sediment during a single 3-month season of beach visits.

AALM Evaluation and Capabilities

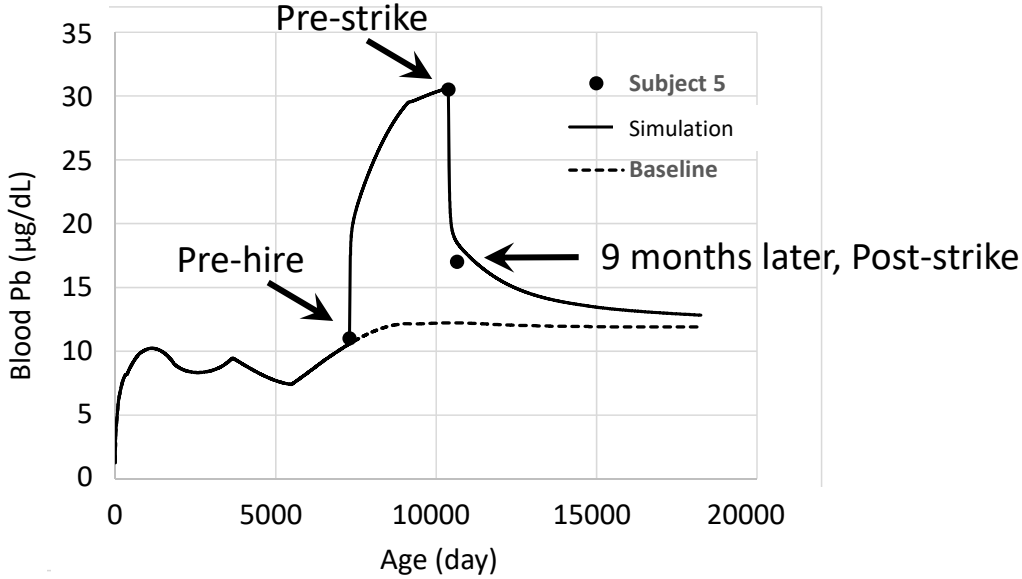
AALM estimated blood Pb changes over NHANES baseline due to intermittent exposures
NHANES = National Health and Nutrition Examination Survey



Exposures are 400 mg-Pb/kg-soil, 2-week camping exposure per year, from age 5 to 18 years

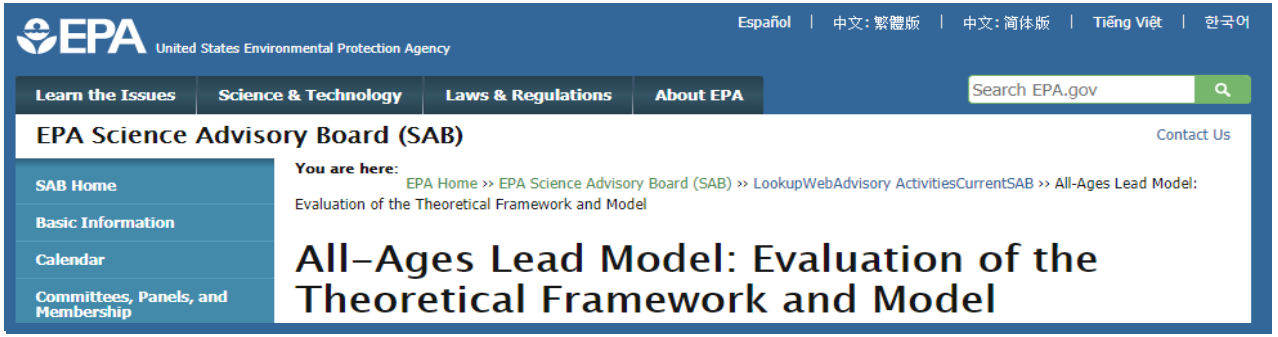
AALM Evaluation and Capabilities

Known change in exposure and measurements of Pb in blood



Subject 5 of 57 from Hattis (1981)

SAB Peer Review of AALM v2.0



- SAB Review Panel Meeting (Oct 17-18, 2019)
  - Panelists praised EPA's work to document the studies and data that underlie the model
  - New version of the AALM is "definitely not black box"
  - Urged clarifying applications and audience, suggesting it may not be well-suited to some uses
- SAB Draft Peer Review Report Teleconference (Apr 23, 2020)
  - "Panel recommends that the Agency's highest priority is to make those changes, clarifications, corrections, and edits to the model and documentation needed to allow use of the AALM 2.0 for research and additional testing."
  - "Panel has described many of these actions in its Tier 1 recommendations" that should be done as soon as possible

Responses to SAB Peer Review of AALM

Development of AALM V3.0 and V3.1 involved:

- Extensive recoding of model
  - Allows for multiple relative bioavailability values by media type
  - Changed mass balance for nonbioavailable Pb
- New user interface
  - Simplified to walk user through simulations
  - Added analysis tab with graphics and calculations
  - Added other functionality for users
- New example runs for users
  - IEUBK example
  - Steady state exposure example
  - Intermittent exposure example

AALM Status and Next Steps

- AALM v3.0 public release (April 2024)
  - https://www.epa.gov/land-research/all-ages-lead-model-aalm
- AALM v3.1 includes a respiratory module (July-August 2025)
  - Particles between 0.001 and 100 µm
  - Variable particle densities and dissolution rates
  - Male or female
  - Children, adolescents, and adults
  - Three activity levels
    - Resting/sitting
    - Light exercise
    - Heavy exercise

AALM Application

The AALM has been used to:

- Support economic analyses related to lead rule making
- Provide weight of evidence support for lead risk assessment for intermittent exposure scenarios
- Assess exposures to spices or alternative homeopathic treatments that contain lead
- Provide regional consultation to health agencies in the event of acute exposure scenarios

AALM Modeling Team

U.S. EPA

- Dr. James S. Brown (EPA)

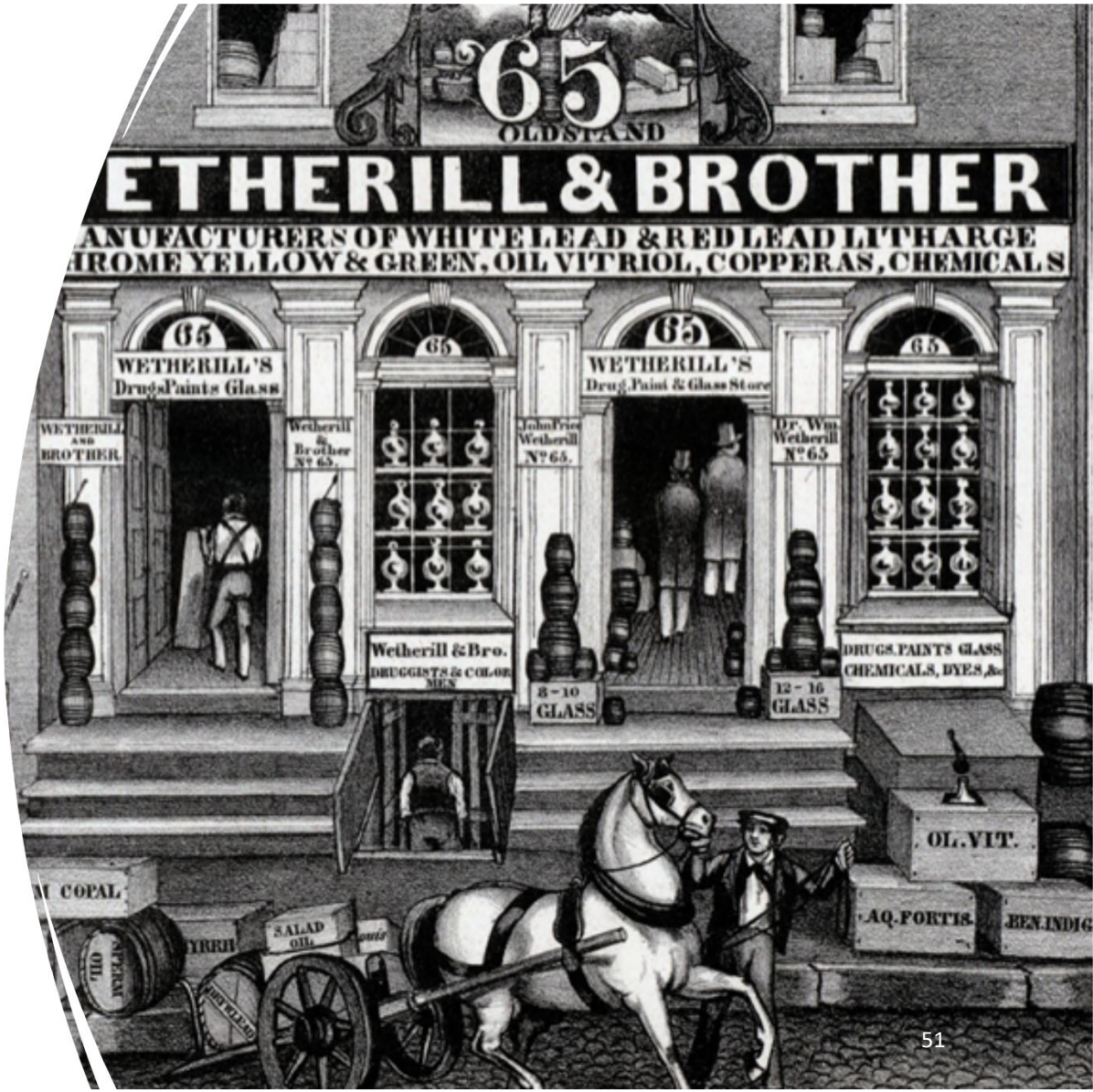
Contract Support

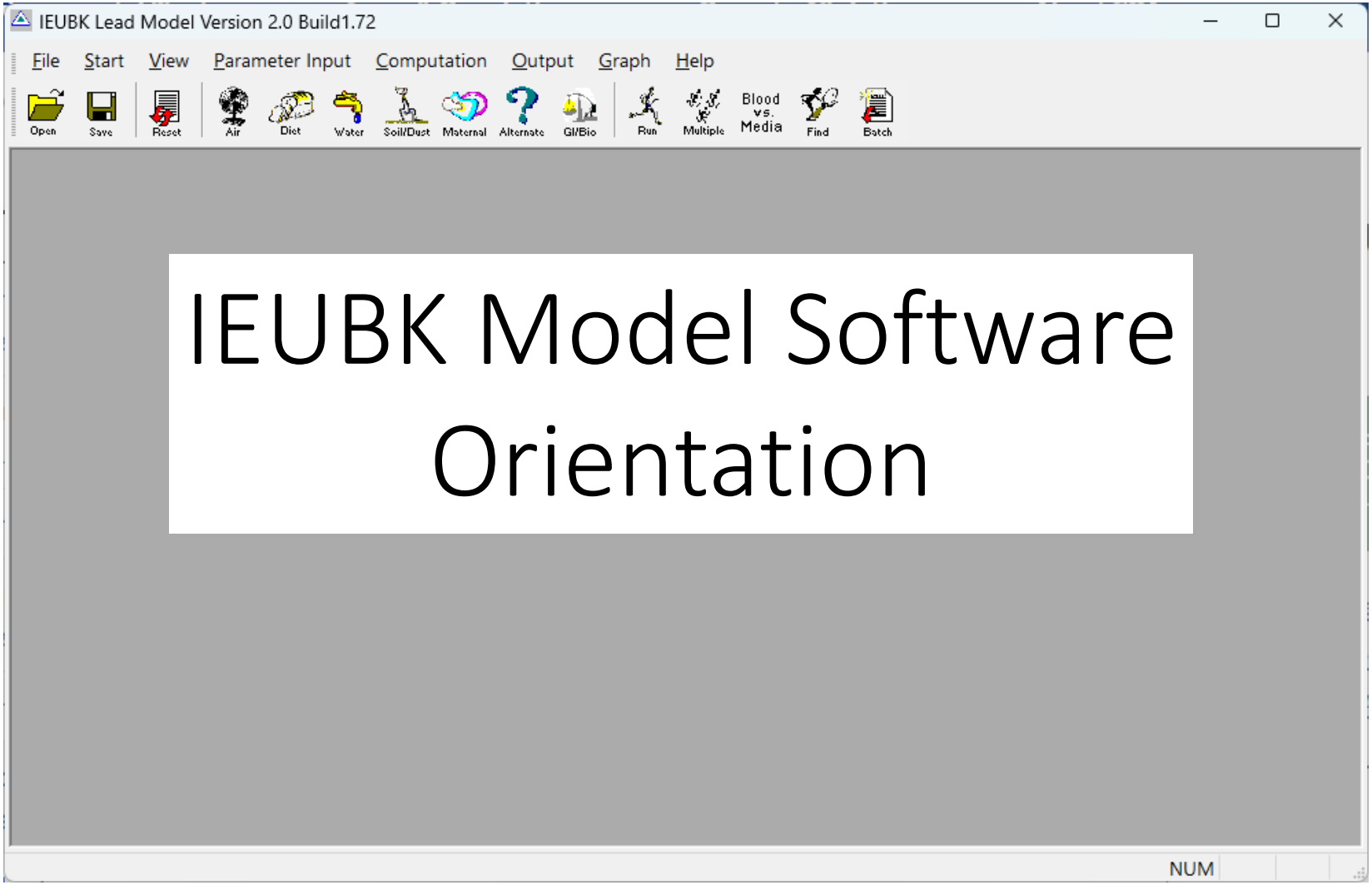
- Dr. Gary L. Diamond (SRC)
- Dr. Mark H. Follansbee (SRC)
- Dr. Graham Glen (ICF)
- Delaney Reilly (ICF)
- Katie Hickok (formerly with ICF)

Summary of Lead Risk Models

	Integrated Exposure Uptake Biokinetic (IEUBK) Model	Adult Lead Methodology (ALM)	All Ages Lead Model (AALM V3.1)
Exposure	Steady state exposures (minimum of 3 months) in young children (0 – 84 months)	Steady state exposures (minimum of 3 months) to adults and children older than 7 years & adolescents	Steady state or highly intermittent, short-term, with a minimum exposure averaging time of 1 day
Receptor Age Range & Sex	Multi-compartmental model for children (0 – 84 months). Both male and female children.	Biokinetic slope factor model for adults and adolescents (with user-specified bioavailability for older children and adolescents). Females.	Multi-compartmental model for children, adolescents, and adults (0 – 90 years). Males or females.
Input Parameters	Only exposure and bioavailability parameters are accessible to user; >100 parameters, 50 are adjustable	All parameters are available to user, but site-specific data are recommended for only 5-6 exposure and bioavailability parameters	All exposure and biokinetics parameters are accessible to user; >300 biokinetic & absorption parameters, as well as ~40 intake rates, # of media concentrations dependent on user-defined exposure scenario
Biological Output	Blood Pb concentration	Blood Pb concentration	Pb concentrations in blood, plasma, bone, soft tissues (kidney and liver); Pb mass in brain and RBC, and excreted Pb mass
Model Usage	Risk assessment tool to support residential lead site risk assessment calculations and cleanup based on children's exposures and predicted blood lead	Risk assessment tool to support nonresidential lead site risk assessment calculations and cleanup based on maternal exposures and protection of fetus	Has the potential to evaluate complex exposure scenarios across all ages

Please put questions in the Q&A chat





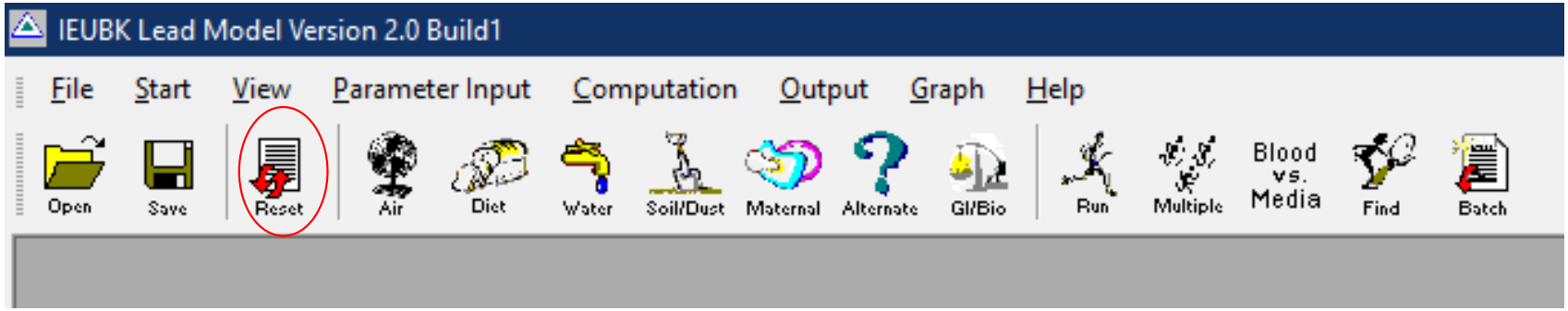
IEUBK Model Software Orientation

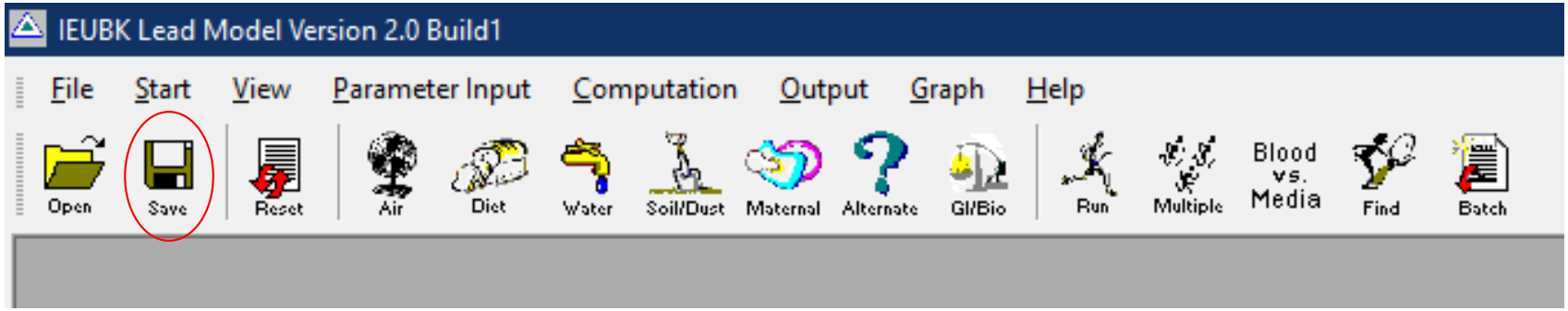
SVD Files: Saving Run Conditions and Loading

SAVE to create SVD file to document run conditions for yourself or another party

OPEN to load run conditions from an SVD file

Resetting the IEUBK to Initial Conditions and Saving



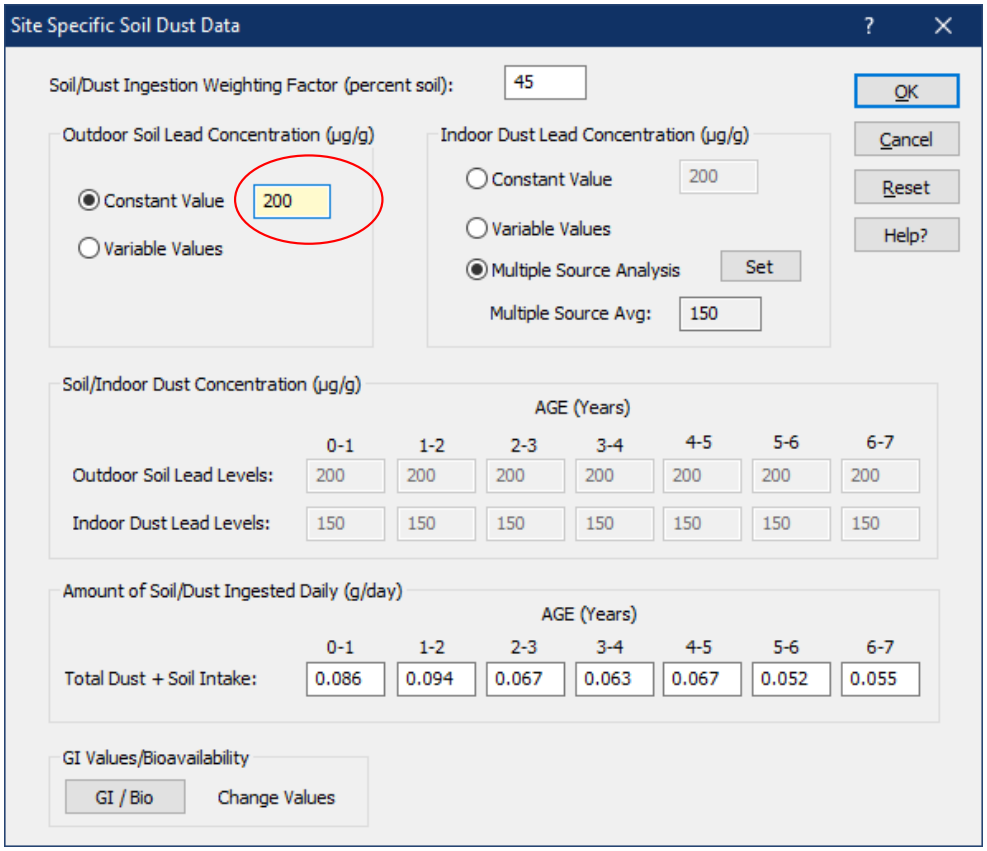


IEUBK- Practice Exercises 1, 2, & 3

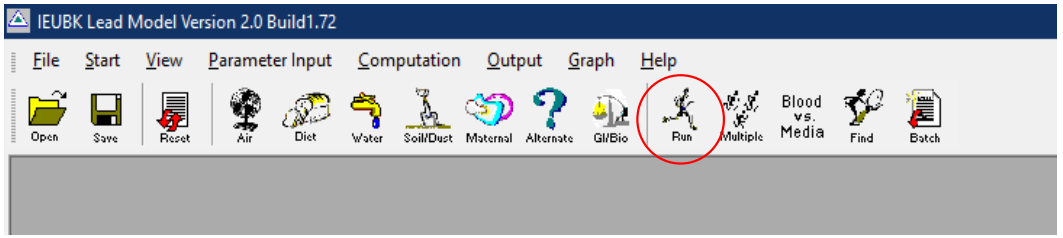
Exercise 1: Single Run

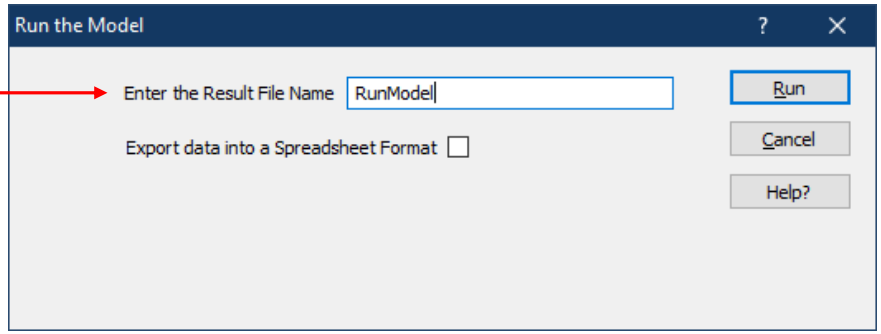
- Average soil concentration is 200 ppm
- All other inputs are default
- **Risk Goal:** no more than 5% probability of exceeding target blood lead level of 5 µg/dL (P5)
- Describe the results in terms of the goal: is the risk goal met or exceeded?

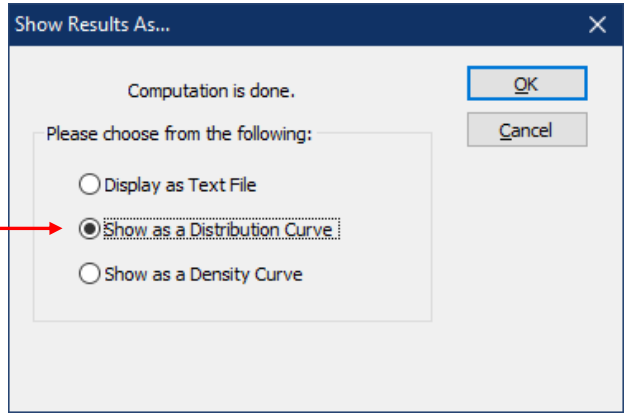
Forward run using site soil lead concentration

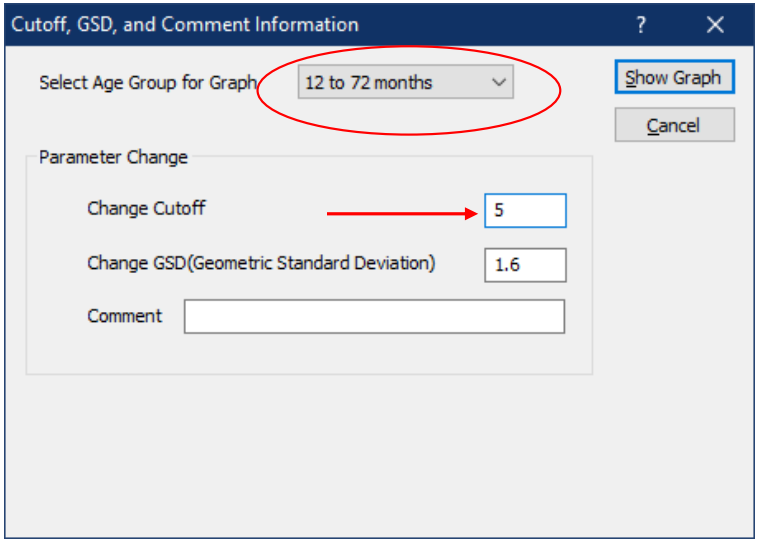


Run the Model

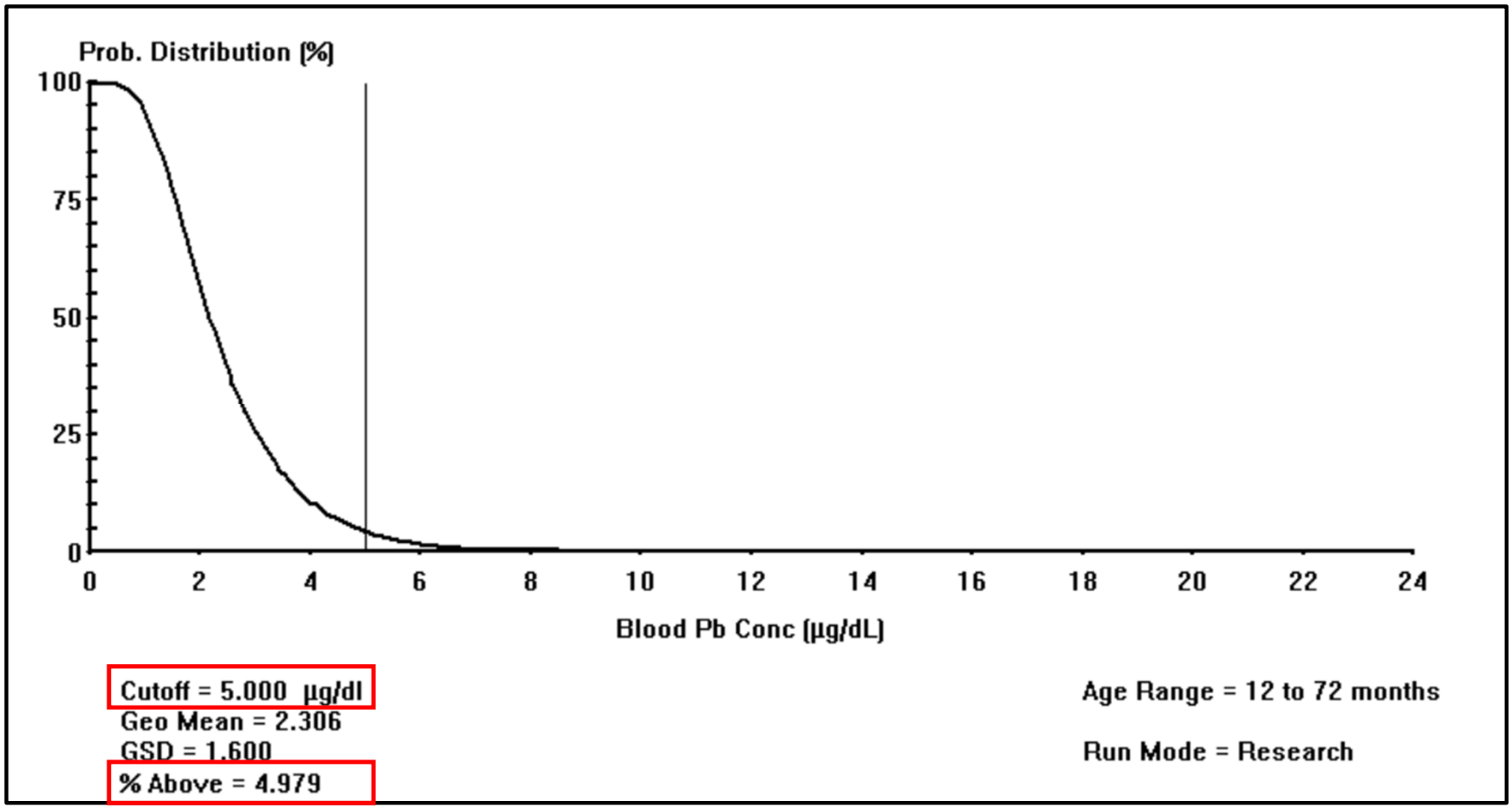








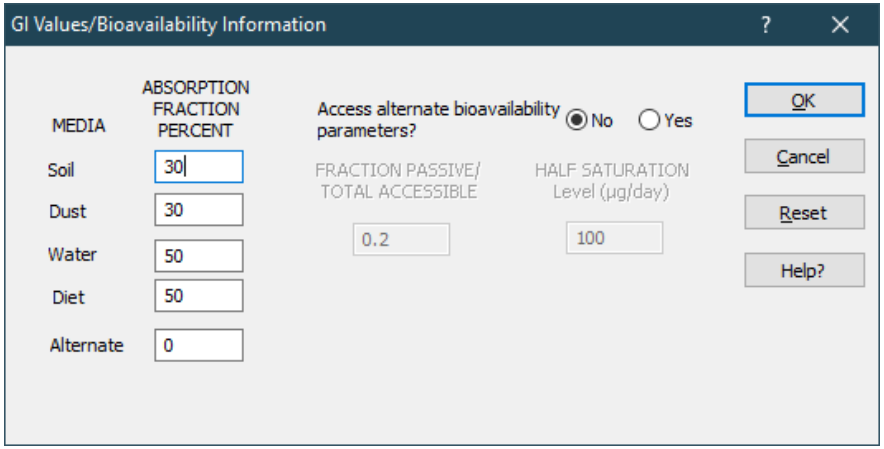
Predicted blood lead in a population of children exposed to 200 ppm lead in soil

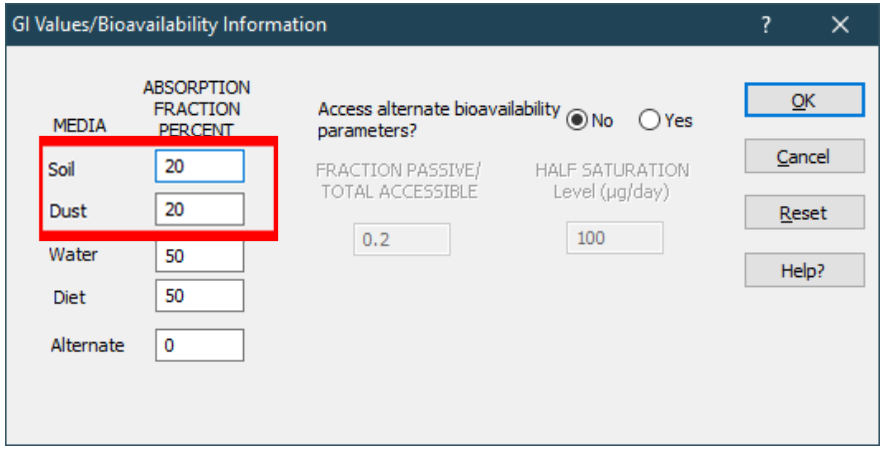


Exercise 2: Single Run with Bioavailability Information

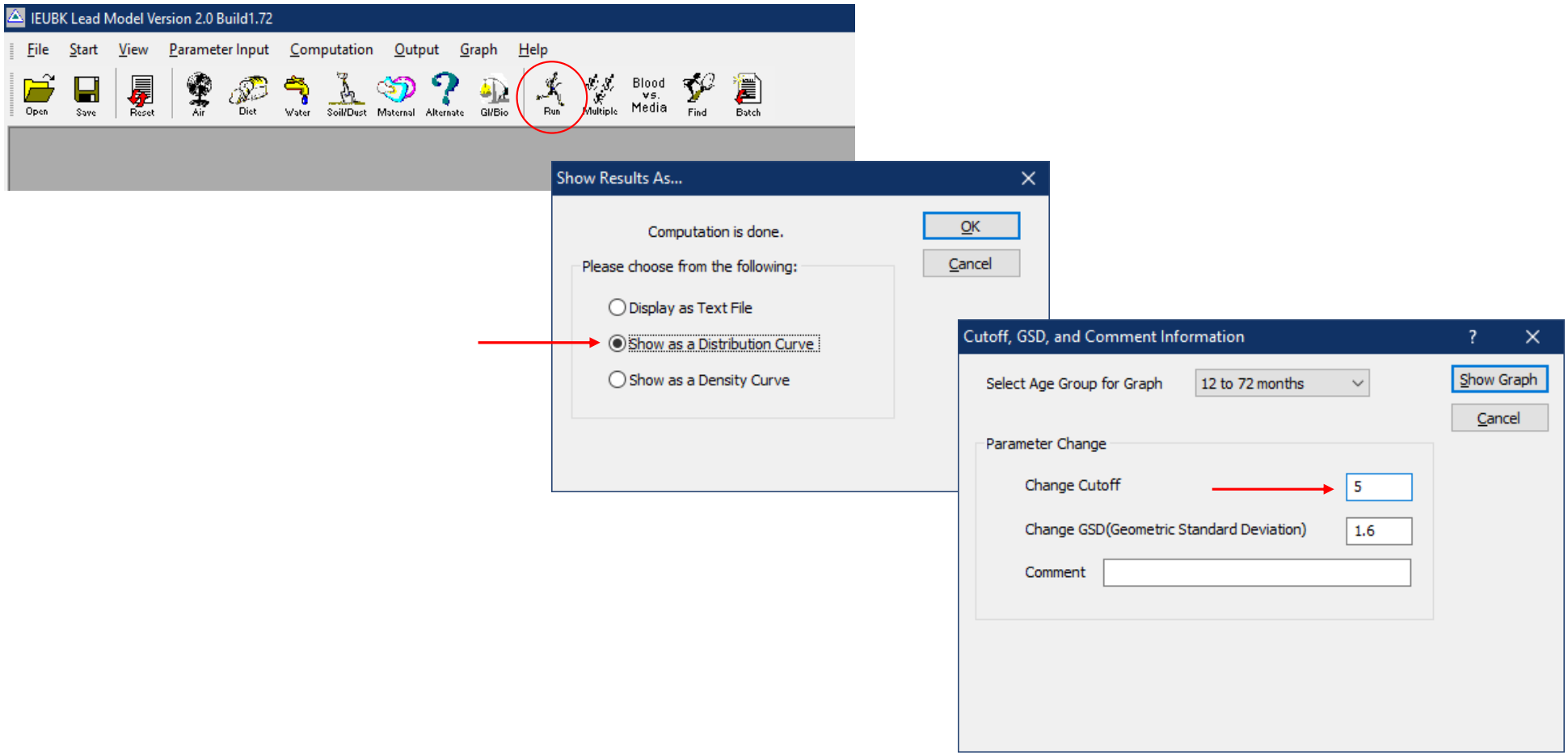
- Soil concentration is still 200 ppm
- However, let's now assume our bioavailability is reduced from a default RBA of 60% to 40%
- **Risk Goal:** no more than 5% probability of exceeding target blood lead level of 5 µg/dL (P5)
- Describe the results in terms of the goal: is the risk goal met or exceeded?

Bioavailability input window data entry when site information supports change from default 60% to 40% relative bioavailability

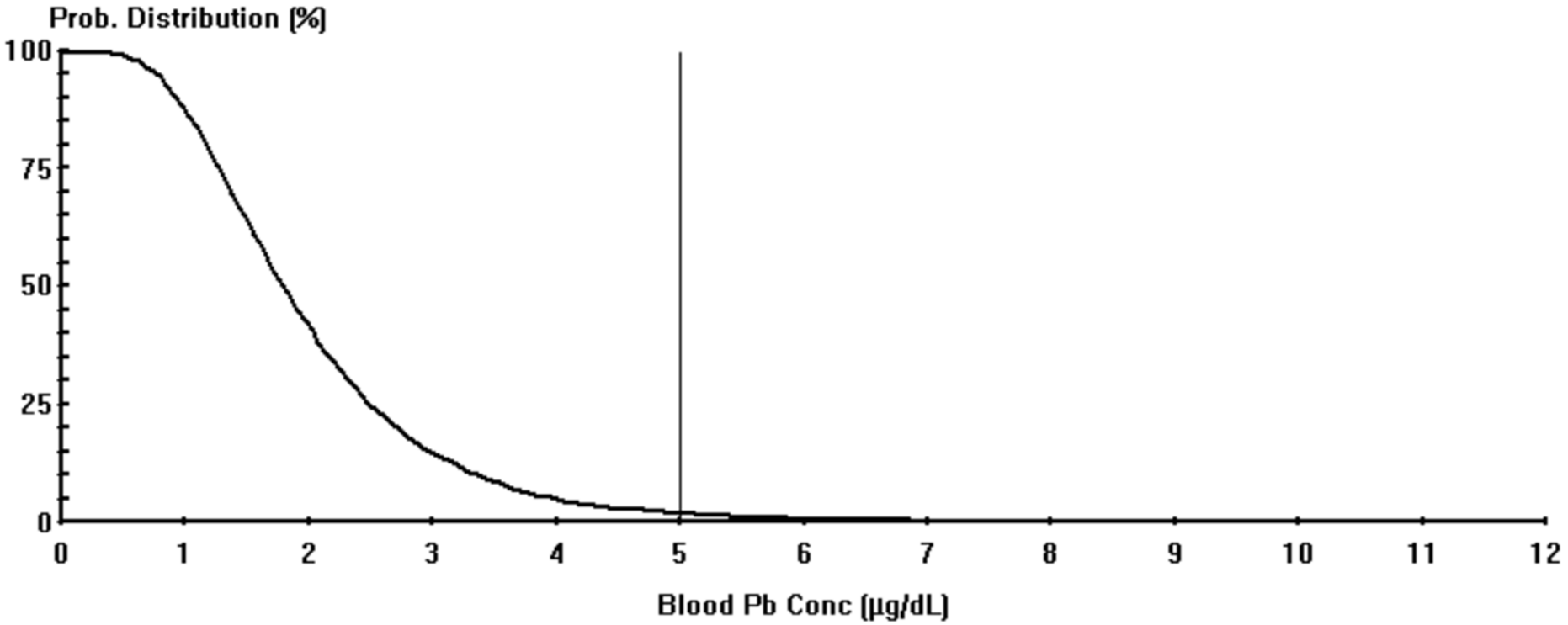




Run the Model



Relative bioavailability decreased from 60% to 40%



Cutoff = 5.000 µg/dl
Geo Mean = 1.893
GSD = 1.600
% Above = 1.938

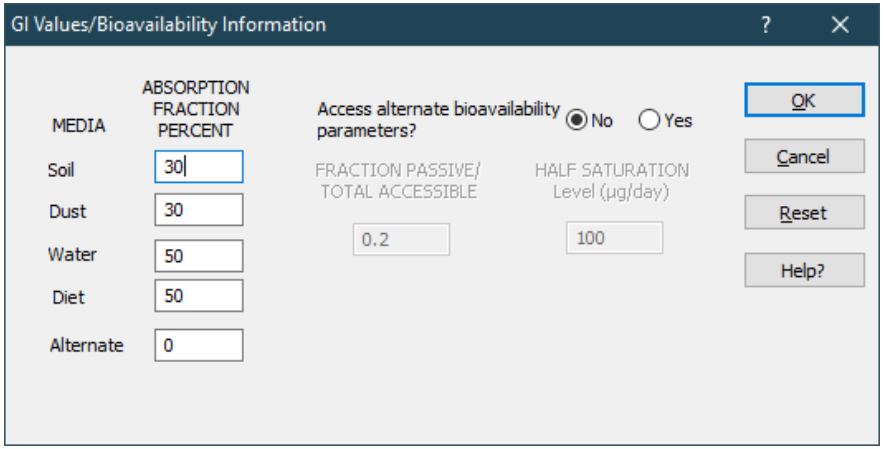
Age Range = 12 to 72 months

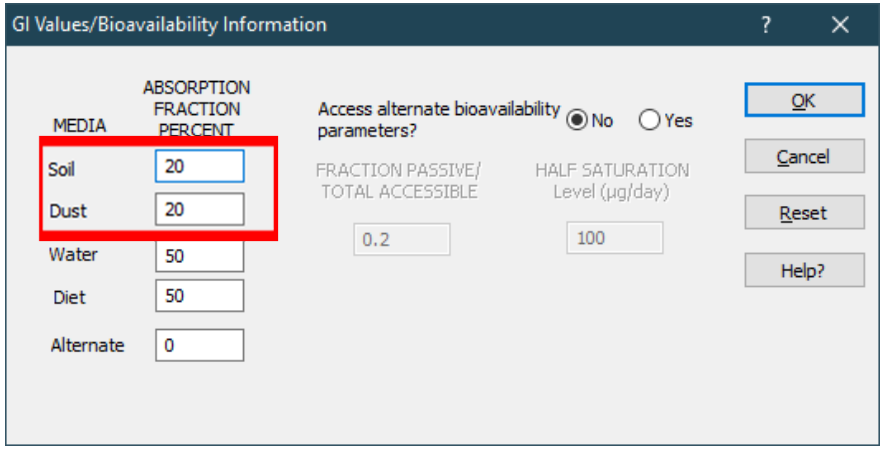
Run Mode = Research

Exercise 3: Find PRG for single run

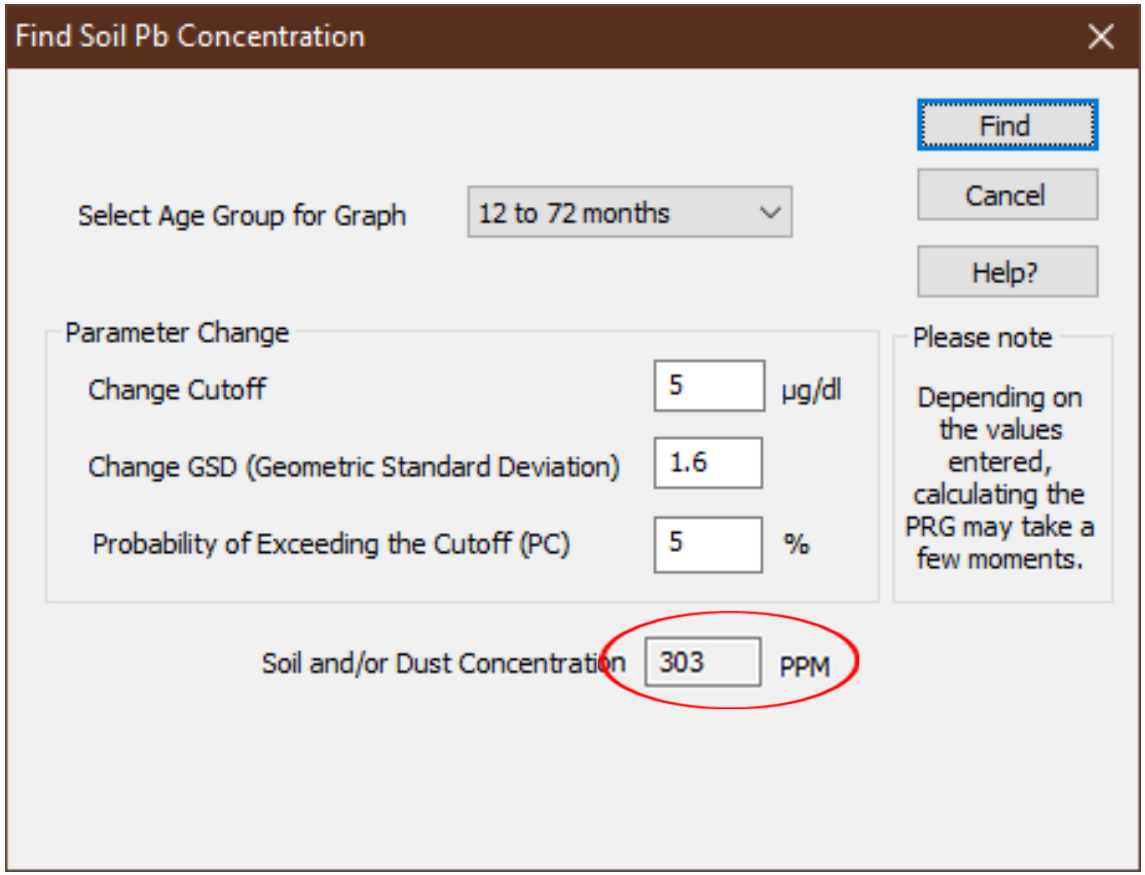
- Find Soil Lead PRG for Risk Goal: no more than 5% probability of exceeding target blood lead level of 5 µg/dL (P5)
- Do this with default values: what is the soil lead PRG?
- Do this with soil lead relative bioavailability of 40%: what is the soil lead PRG?

Bioavailability input window data entry when site information supports change from default 60% to 40% relative bioavailability





Example PRG results with site-specific bioavailability (RBA= 40%)



Discussion and Q&A