Training on Assessment of Relative Bioavailability (RBA) of Soil Arsenic and Lead in Human Health Risk Assessment

Session 2: Applying RBA data to human health risk assessment

OSRTI Technical Review Workgroup

Bioavailability Committee

For More Information

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Session 1 Recap

- What is soil metal bioavailability (RBA)?
- Brief overview of how RBA is measured:
  - Directly: in-vivo animal assays
  - Estimated: measuring IVBA via EPA Method 1340
- 2021 EPA Report: *Guidance for Sample Collection for In Vitro Bioaccessibility Assay for Arsenic & Lead in Soil & Application of RBA Data in Human Health Risk Assessment*

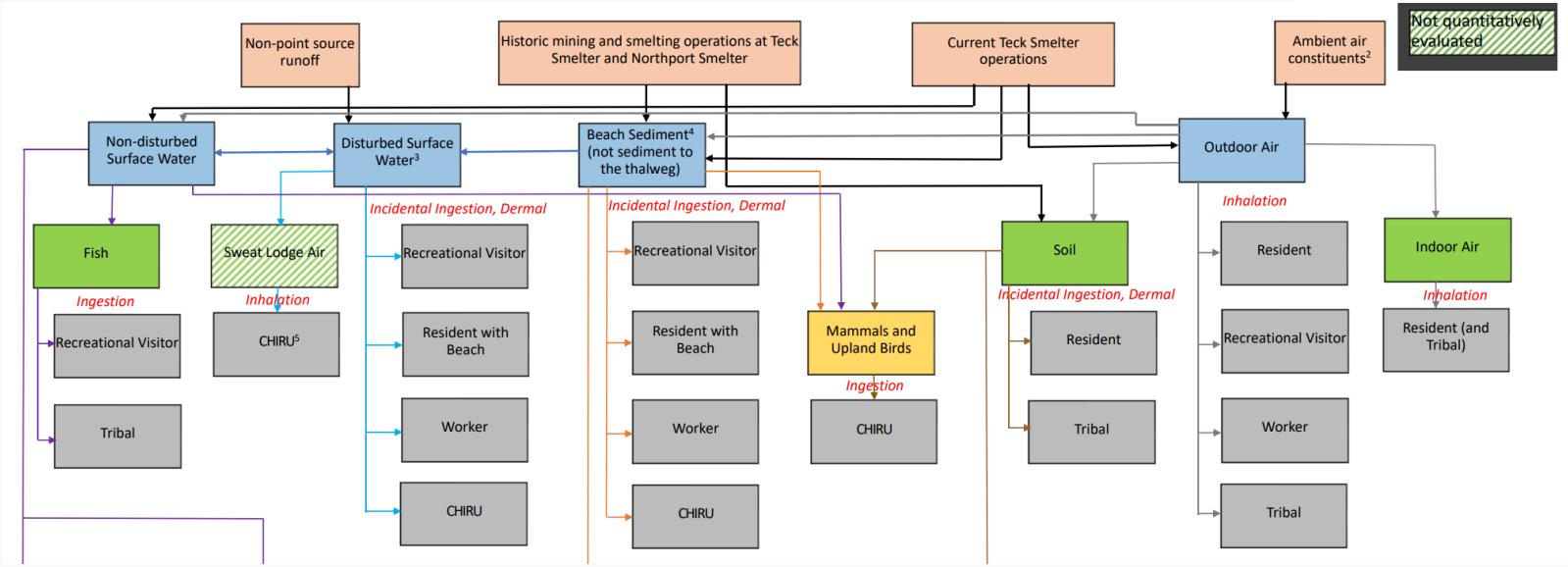
RBA Assessment Training

Session 2: Applying RBA data to human health risk assessment of arsenic and lead contaminated soils

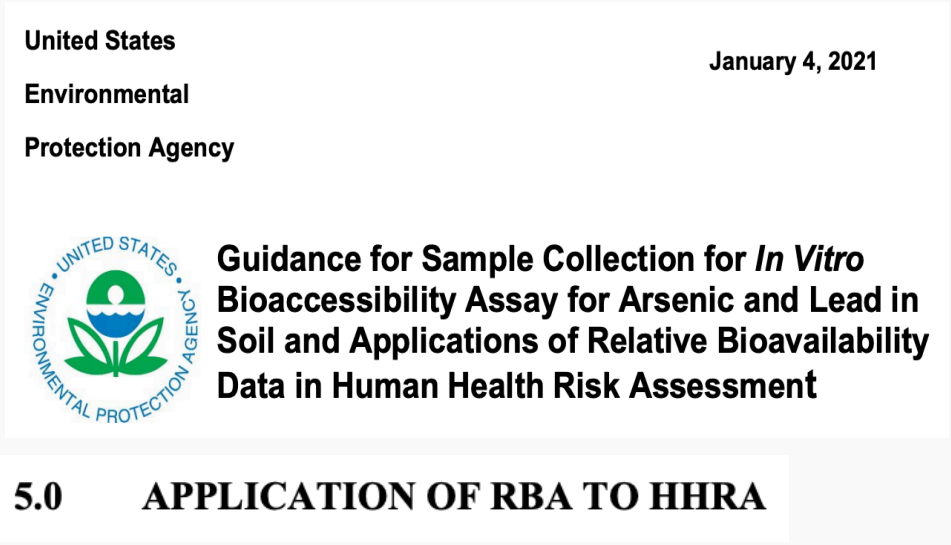
Conceptual Site Model

Can help inform…

- If RBA data would be useful, and if so, how it can be applied
- Reasonable assumptions about RBA behavior -- for example, are there multiple arsenic or lead contaminant sources



RBA Adjustments of HH Risk



United States

Environmental

Protection Agency

January 4, 2021

Guidance for Sample Collection for *In Vitro* Bioaccessibility Assay for Arsenic and Lead in Soil and Applications of Relative Bioavailability Data in Human Health Risk Assessment

5.0 APPLICATION OF RBA TO HHRA

RBA data can be used to adjust:

1. Soil exposure point concentrations
2. For lead, bioavailability parameters in risk models
3. For arsenic, adjustment of a soil contaminant daily oral intake
4. Adjustment of risk-based screening or action levels

RBA Adjustment of EPC

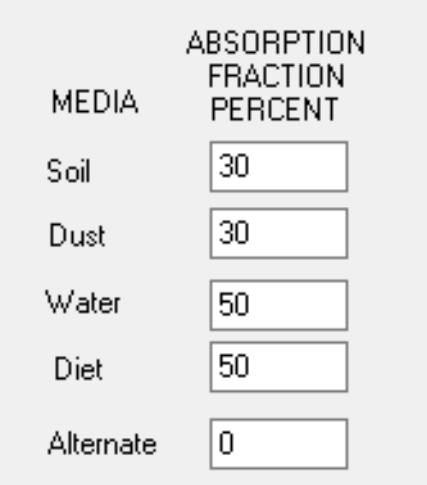
- The exposure point concentration (EPC) represents the average exposure experienced by the receptor within the exposure unit.

  The RBA adjustment is as follows:

Adjusted EPC (mg **bioavailable** Pb/As per kg soil) =
EPC (mg **total** Pb/As per kg soil) x RBA (fraction)

RBA Adjustment of Lead Risk Models

IEUBK Model



adjusted AFPsoil = RBA (fraction) x 50

Where:
50 = AFP assumption of soluble lead in drinking water

ALM

Variable	Description	GSDI & PbBo from NHANES 2009-2014
AF_{S+D}	Absorption Fraction (same for soil & dust)	0.12

adjusted AFS_{+D} = RBA fraction x 0.2

Where:
0.2 = AF assumption of soluble lead in drinking water

RBA Adjustment of Soil Arsenic Daily Intake

Daily Oral Intake (DI)

adjusted DI = DI x RBA

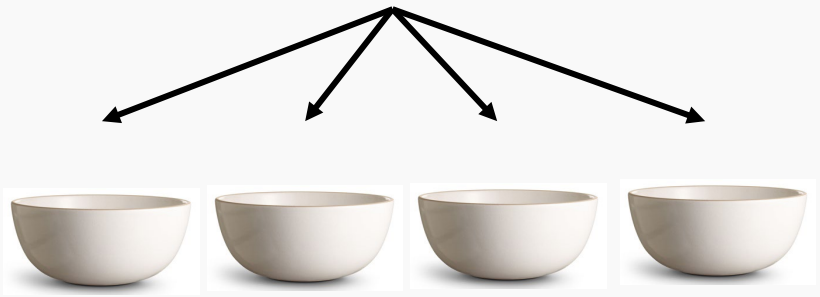
Where:

DI = EPC x HIF

>

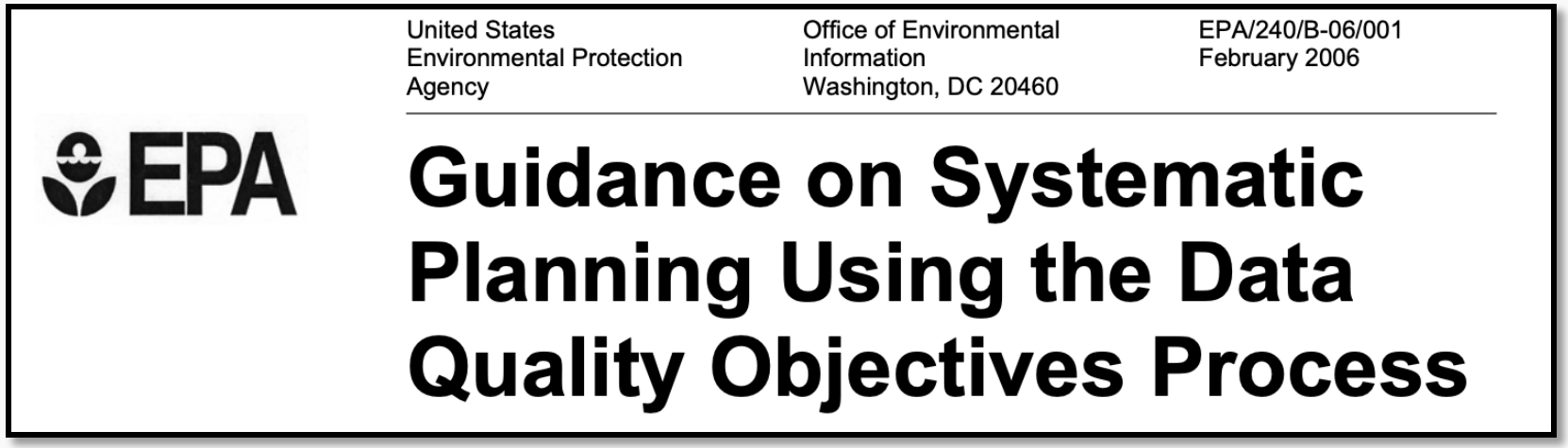
Compare RBA-adjusted DI to RfD or cancer slope factor


no
DOUBLE
DIPPING



Adjust: EPC Abs. Fraction Daily Intake Action Level

Q&A Break



"The DQO Process is a series of logical steps that guides managers or staff to a plan for the resource-effective acquisition of environmental data. **It is both flexible and iterative**, and applies to both decision-making (e.g., compliance/non-compliance with a standard) and estimation (e.g., ascertaining the mean concentration level of a contaminant). The DQO Process is used to establish performance and acceptance criteria, which serve as the basis for designing a plan for collecting data of sufficient quality and quantity to support the goals of the study."

Data Quality Objectives

The development of DQOs is a 7-step process:

1. State the problem
2. ID study goal(s)
3. ID information inputs
4. Define study boundaries
5. Develop the analytical approach
6. Specify performance criteria
7. Develop plan for obtaining data

DQO Process: State the problem

State problem | Goals | Inputs | Boundaries | Analytical approach | Performance criteria | Data/Sampling Plan

- Concern of unacceptable human-health risk from exposure to Pb contaminated soil via the incidental soil ingestion pathway.

DQO Process: Study Goal(s)

State problem | **Goals** | Inputs | Boundaries | Analytical approach | Performance criteria | Data/Sampling Plan

- Does the mean RBA-adjusted soil Pb concentration (EPC) exceed the target risk level?

DQO Process: Information Inputs

State problem | Goals | **Inputs** | Boundaries | Analytical approach | Performance criteria | Data/Sampling Plan

- Site-specific target risk level (or action level)
- Total soil Pb concentration data
- IVBA data (used to estimate RBA)

DQO Process: Study Boundaries

State problem | Goals | Inputs | **Boundaries** | Analytical approach | Performance criteria | Data/Sampling Plan

- **Spatial boundaries** – Identify geographical extent of Site and how it will be divided into decision or exposure units.
- **Temporal boundaries** – Only validated data collected during a certain time period (e.g., 2017 to present), under an EPA-approved QAPP, will be considered.

DQO Process: Analytical Approach

State problem | Goals | Inputs | Boundaries | **Analytical approach** | Performance criteria | Data/Sampling Plan

- Total soil Pb concentration will be measured by hotblock digestion (EPA method 1350) or microwave-assisted digestion (EPA method 3051), with analysis by ICP-OES (EPA method 6010) or ICP-MS (EPA method 6020)
- IVBA data will be measured in accordance with EPA Method 1340

DQO Process: Performance Criteria (cont.)

State problem | Goals | Inputs | Boundaries | Analytical approach | **Performance criteria** | Data/Sampling Plan

- **False compliance** decision error probability goal < 5%
- **False exceedance** decision error probability goal < 20%

DQO Process: Performance Criteria (cont.)

State problem | Goals | Inputs | Boundaries | Analytical approach | **Performance criteria** | Data/Sampling Plan

- **False compliance** decision error probability goal < 5%
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False compliance error

The *measured* EPC < AL, when the *true* EPC > AL

DQO Process: Performance Criteria (cont.)

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- **False compliance** decision error probability goal < 5%
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False compliance error

The *measured* EPC < AL, when the *true* EPC > AL

False exceedance error

The *measured* EPC > AL, when the *true* EPC < AL

DQO Process: Performance Criteria (cont.)

State problem | Goals | Inputs | Boundaries | Analytical approach | **Performance criteria** | Data/Sampling Plan

Action Level = 240 mg/kg bioavailable Pb

DUs TRUE [mean bioavailable Pb] = 270 mg/kg bioavailable Pb

DQO Process: Performance Criteria (cont.)

State problem | Goals | Inputs | Boundaries | Analytical approach | **Performance criteria** | Data/Sampling Plan

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DUs TRUE [mean bioavailable Pb] = 270 mg/kg bioavailable Pb

Sample #	True Values			Measured Values		
	Total [Pb] (mg/kg)	RBA (%)	Bioavailable Pb (mg/kg)	Total [Pb] (mg/kg)	RBA (%)	Bioavailable Pb (mg/kg)
1						
2						
3						
4						
5						
Average						

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	Total [Pb] (mg/kg)	RBA (%)	Bioavailable Pb (mg/kg)	Total [Pb] (mg/kg)	RBA (%)	Bioavailable Pb (mg/kg)
1	375	55	206	360	66	198
2	460	65	299	470	77	306
3	475	58	275	445	69	258
4	340	60	204	350	71	210
5	280	52	145	265	62	137
Average	**386**	**58**	**226**	**378**	**69**	**222**

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Sample representativeness error

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Measurement error

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Total error

Measurement error

DQO Process: Plan for Obtaining Data

State problem | Goals | Inputs | Boundaries | Analytical approach | Performance criteria | **Data/Sampling Plan**

- Develop a soil sampling plan that meets DQO goals and performance criteria, including:
  - Sampling methodology:
    - Estimating RBA for each DU vs. a single, site-wide RBA value
    - Discrete versus composite sampling
  - Statistical methods to estimate minimum sample #'s for totals and IVBA measurement needed to satisfy DQO's.

Estimation of Site-wide RBA

- May be appropriate if % RBA is not expected to vary across the site
- Site-wide RBA may over- or underestimate RBA at any given DU/EU. As a result, there will be lower confidence in the resulting adjusted EPC or adjusted AL.
- In cases where only a subset of decision or exposure units are assessed for RBA, then DQO's should address:
  - A plan for selecting DUs for RBA measurement that ensures resulting data can be used to predict RBAs at DUs not selected for RBA measurement.
  - Statistics to represent RBA at DUs not selected for measurement of RBA.

Mineralogy & Speciation Data

- Information on mineralogy and speciation, if available, may be useful to predict or explain RBA variability at the site.
- If speciation data is not already available, utility of obtaining speciation data should be weighed against that of simply measuring IVBA across more samples
  - Speciation data is technically complex and is often applied to a small subset of samples for the purpose of explaining observed RBA behavior rather than for predicting RBA in lieu of measuring IVBA.

Retrospective RBA Assessments

- Sometimes undertaken at sites based on archived soils collected for some other purpose.
- In these instances, the original sampling design may not have considered DQOs for characterizing RBA.
- Development of RBA-related DQO's is advised so that an appropriate approach to selecting soils for RBA measurement may be developed – whether for archived samples or when collecting new samples.
- In the absence of an appropriate sampling design, archived soils are "convenience samples", rather than a statistical representation of the site, introducing larger uncertainty into the site or DU RBA estimate. **However, including RBA data, even using archived samples, can still increase the accuracy of the overall risk assessment.**

Evaluation of Data Adequacy

- Do the data satisfy quality control limits?
- Was the sampling design followed and, if not, what were the causes, effects and implications of deviations from the plan?
- Do the results satisfy the DQO for RBA at the site?
  - Is the magnitude of the false compliance and false exceedance decision error acceptable, and were assumptions used to estimate decision error still appropriate (these decision errors are addressed further in Training Session 3)

For More Information

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Additional Training Sessions

#	Topic	Date*
1	Intro to RBA assessment	2/12/24
2	**Applying RBA data to human health risk assessment**	**3/1/24**
3	Sample planning to meet site assessment decision confidence objectives	3/18/24
4	Soil sampling best practices & laboratory methods to measure IVBA & RBA	4/1/24

* *Future training session dates are tentative & subject to change*