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

Session 3: Sample Planning to Meet Site Assessment Decision Confidence Goals

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*

Session 2 Recap

- Conceptual site models
- Different ways to apply RBA data
- 7 steps of the DQO development 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

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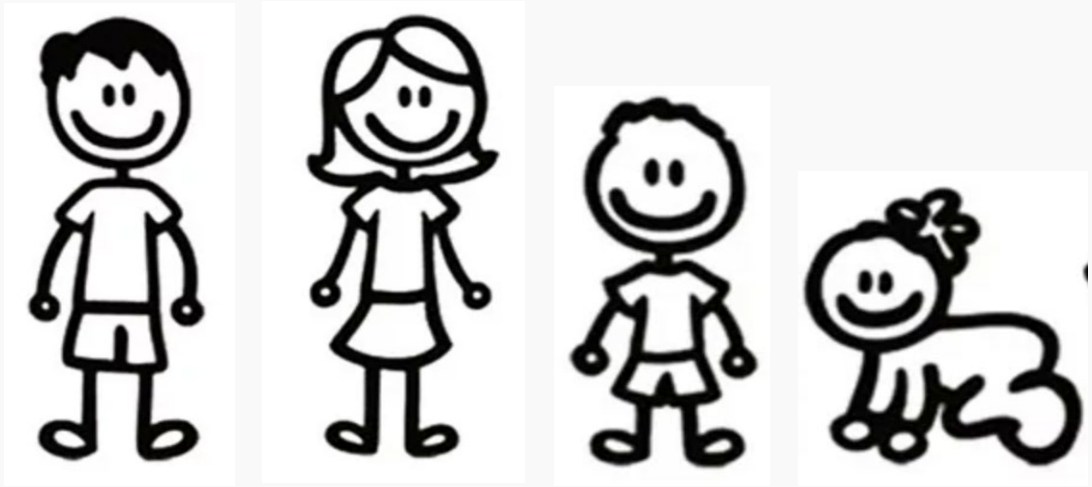
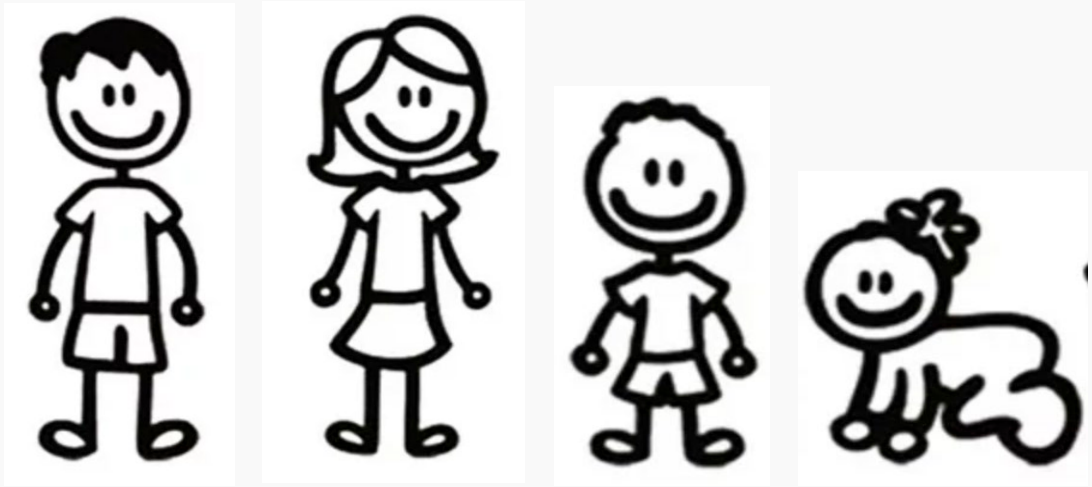
  7. **Develop plan for obtaining data**

RBA Assessment Training

Session 3: Sample planning to meet site assessment decision confidence objectives





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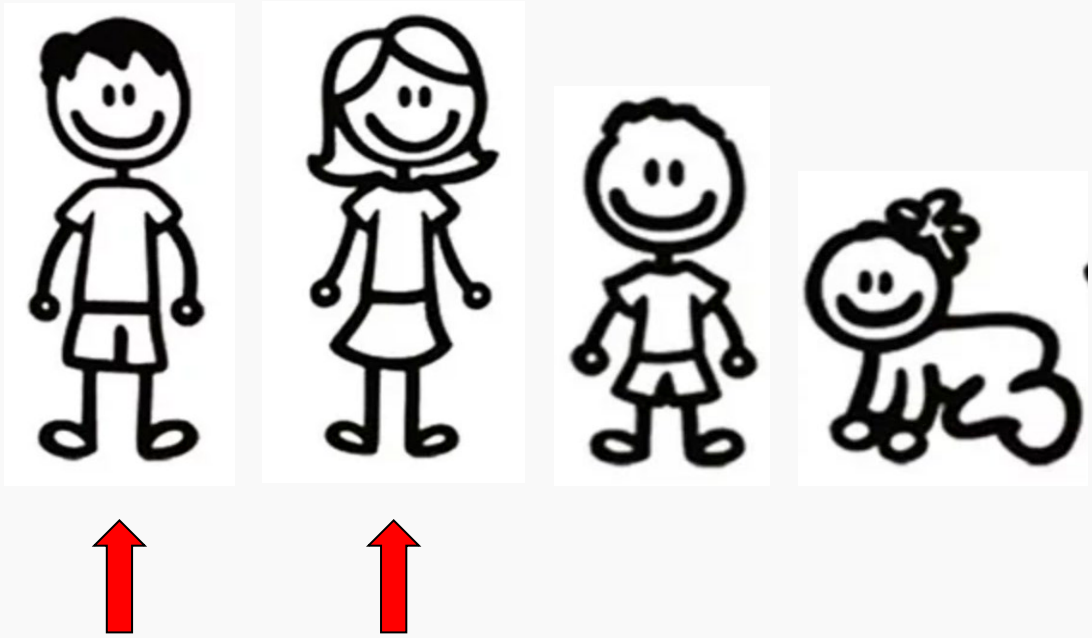
Performance Criteria

- We want to be > 95% confident that if we decide **NOT** to go on a diet, we are making the correct decision (i.e., false compliance decision error < 5%).
- We want to be > 80% confident that if we decide **TO GO** on a diet, we are making the correct decision (i.e., false exceedance decision error < 20%).



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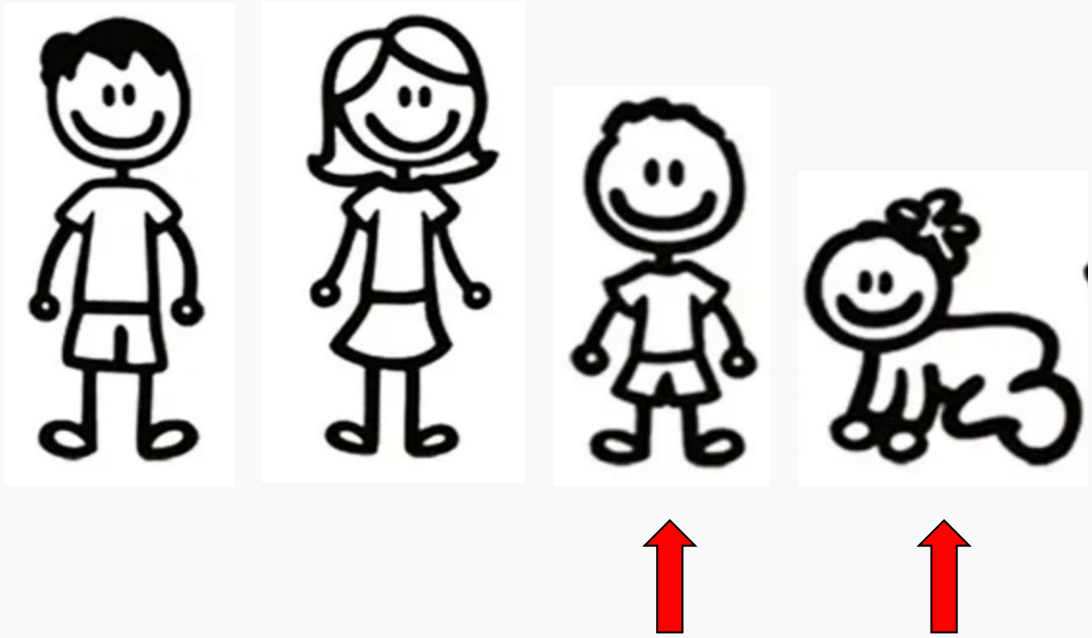

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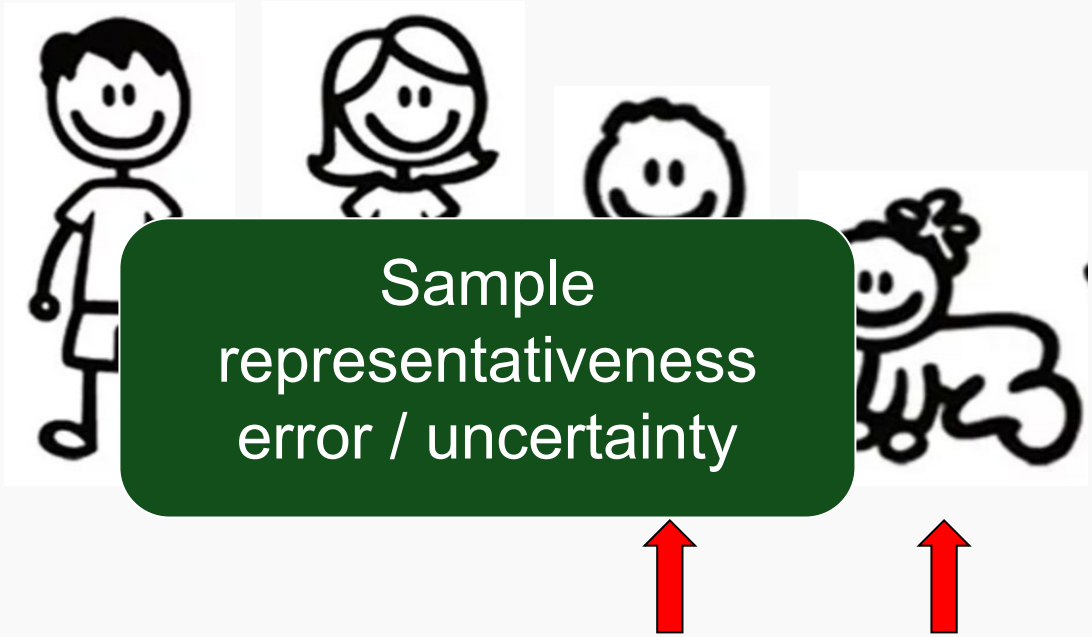

If the <u>average</u> (mean) weight of family members is > 100 lbs, we are going on a family diet.

Does my **Measured** weight = my **True** weight?

Measurement error / uncertainty

Does my **Measured** weight = my **True** weight?

Sample representativeness error + Measurement error

= Total Error

DQO Process: Performance Criteria

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

Sample #	True Values			Measured Values		
	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**

Sample representativeness error

Total error

Measurement error

DQO Process: Performance Criteria

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1	375	55	206	360	66	198
2						
3	475	58	275	445	69	258
4						
5	280	52	145	265	62	137
Average						**250**

Total error

DQO Process: Performance Criteria (cont.)

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

False compliance error

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

False exceedance error

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

- **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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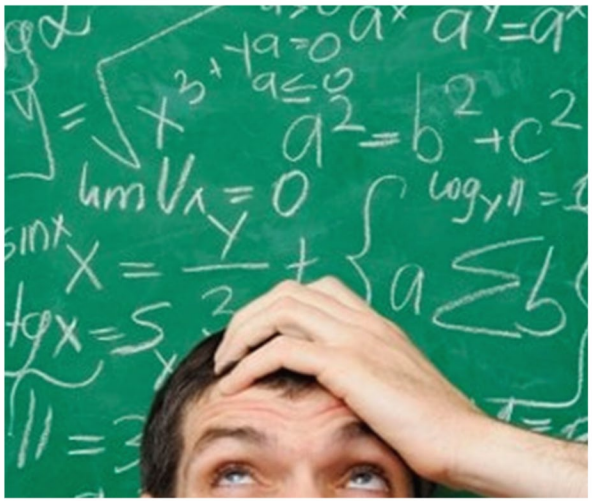
False compliance error

The *measured* EPC

the *true* EPC



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Estimating False Compliance / Exceedance Decision Error Probability

United States

Environmental

Protection Agency

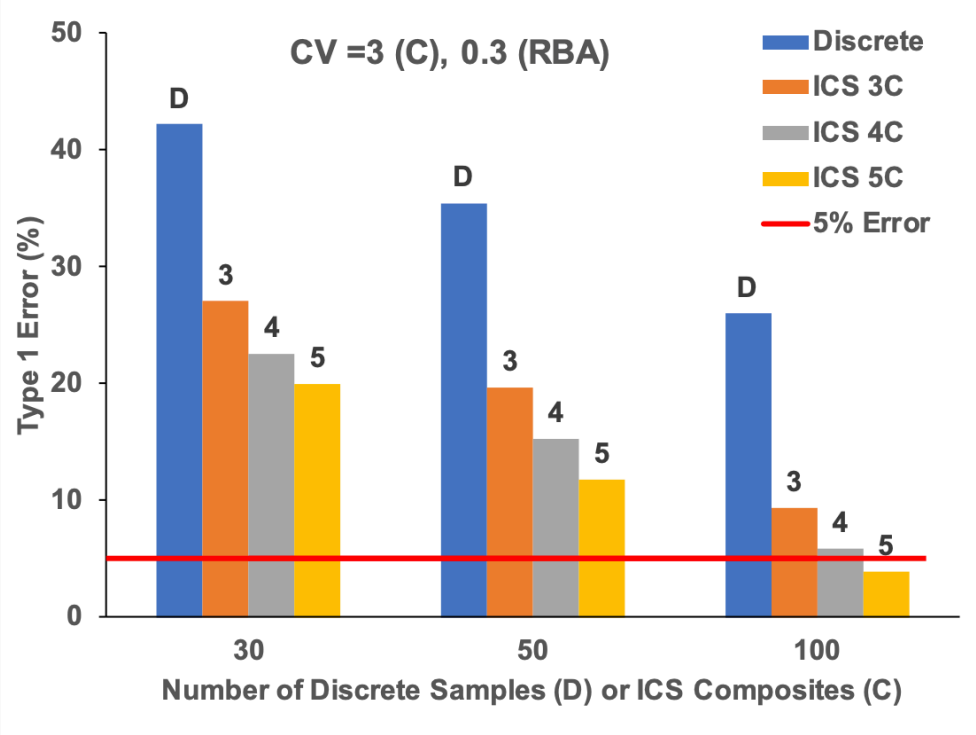
January 4, 2021

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

APPENDIX A: Guidance for Sample Collection for Estimating an RBA-adjusted Exposure Point Concentration for Soil

Estimating False Compliance / Exceedance Decision Error Probability

False Compliance Error →



Q&A Break

Bioavailability Sampling Tool (BAST)

- BAST is a tool developed by the EPA TRW BAC that enables users to generate estimates of false compliance/exceedance decision error for a given sampling plan(s).
- Developed to be applicable both prior to sample collection, to support sample planning, AND after samples have been collected & analyzed, to support evaluation of data adequacy (discussed in Session 2).
- Manuscript describing the conceptual approach of the tool is currently in EPA clearance review.

Important Terms

- **True** - the correct value assuming no measurement or sample representativeness error.

  Note: While samples have 'true' total metal concentration and % RBA values, such values will not be known and must therefore be assumed when estimating false compliance/exceedance decision error.

- **Measured** - a measured value, applied to either an individual sample or mean/quantile value across multiple samples.

Important Terms (cont.)

- **Decision tolerance** - an estimate of the range in the decision/exposure unit's true EPC, relative to the action level, where decision confidence goals are estimated to be met for a given sampling plan.
- **Decision accuracy** - making the correct assessment that the decision/exposure unit's EPC is above or below the action level.
- **Decision precision** - probability that resampling, using the same sampling plan, would lead to the same assessment of the EPC relative to the action level (i.e., that the measured mean EPC is above or below the action level).

Important concepts

1. RBA data can be applied to human health risk assessment of Pb/As contaminated soils in multiple ways. To enable the tool to be universally applicable, it's coded so that RBA data is applied to adjust the mean total soil metal concentration, which is then compared to an action level that has NOT been adjusted for RBA. However, the tool can inform other applications & assumptions, including using RBA to adjust an action level.

Equation

Mean total soil metal concentration *(mg/kg)* x RBA *(fraction)* =

RBA-adjusted soil metal concentration *(mg bioavailable metal/kg soil)*

Important concepts

2. Estimating false compliance / exceedance decision error probability requires certain assumptions be made related to:

   A) expected variability in totals and IVBA across the scale of the decision/exposure unit, and…

   B) the level of soil metal contamination (relative to the action level).

Decision confidence estimates are only as good as the assumptions used to derive them.

1 – decision error probability = decision confidence probability

Important concepts

3. Estimates of decision confidence generated by BAST consider error/uncertainty in …
    A) Sample representativeness
    B) Measurement error

Other sources of error / uncertainty not considered by BAST may contribute to the "true" probability of making a false compliance or false exceedance decision error.

Live Demo of BAST

Additional Info re: BAST

- Process for hosting tool still being finalized
- Has been applied to an actual arsenic-contaminated site as part of beta-testing
- For more information about the tool, please email the BAC Committee @ **bahelp@epa.gov**.

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*