

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

OSRTI Technical Review Workgroup
Bioavailability Committee



Focus of Training

- New guidance on RBA assessment
- Rationale for RBA assessment
- How to incorporate RBA into HHRA
- Methods for RBA measurement
- RBA DQOs and sample planning
- Resources for additional assistance



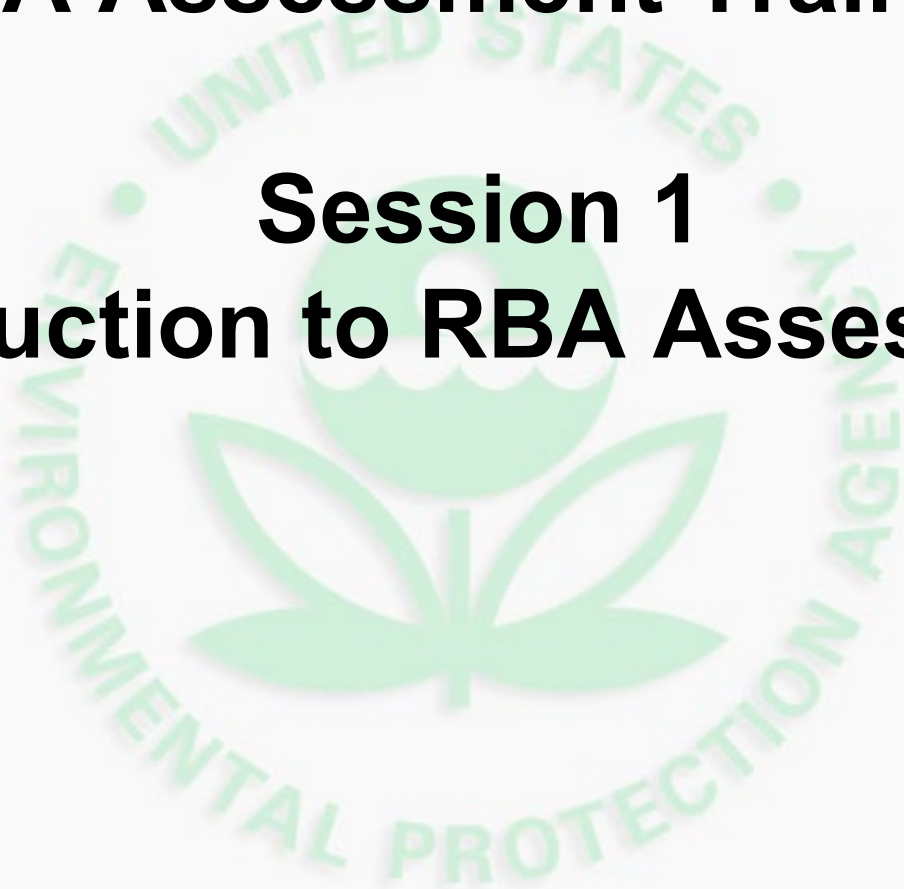
For More Information

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- TRW BAC website (<https://www.epa.gov/superfund/soil-bioavailability-superfund-sites-technical-assistance>)

RBA Assessment Training

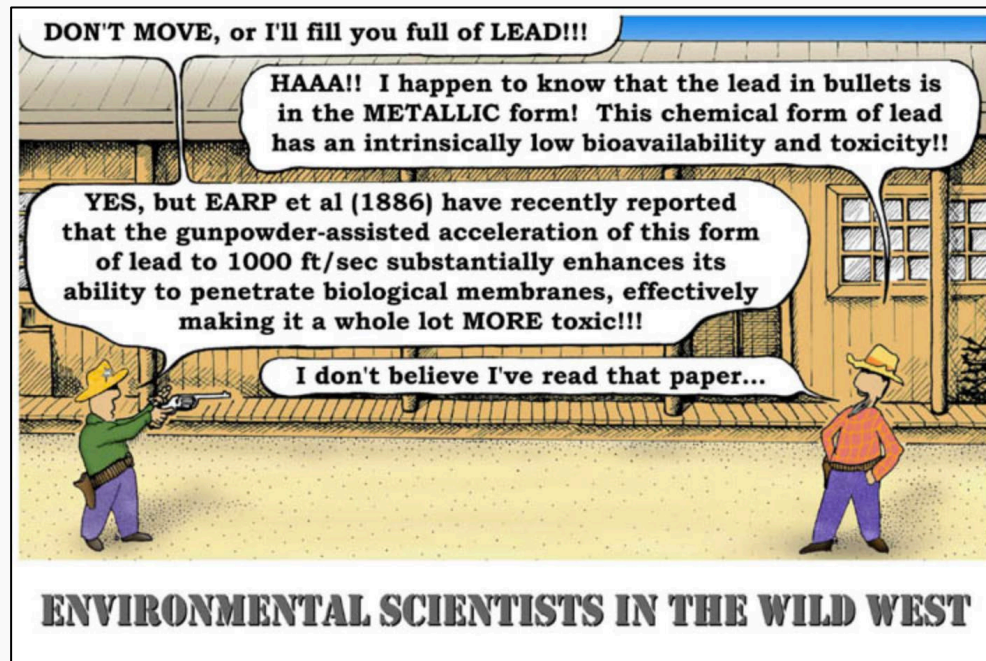
Session 1

Introduction to RBA Assessment

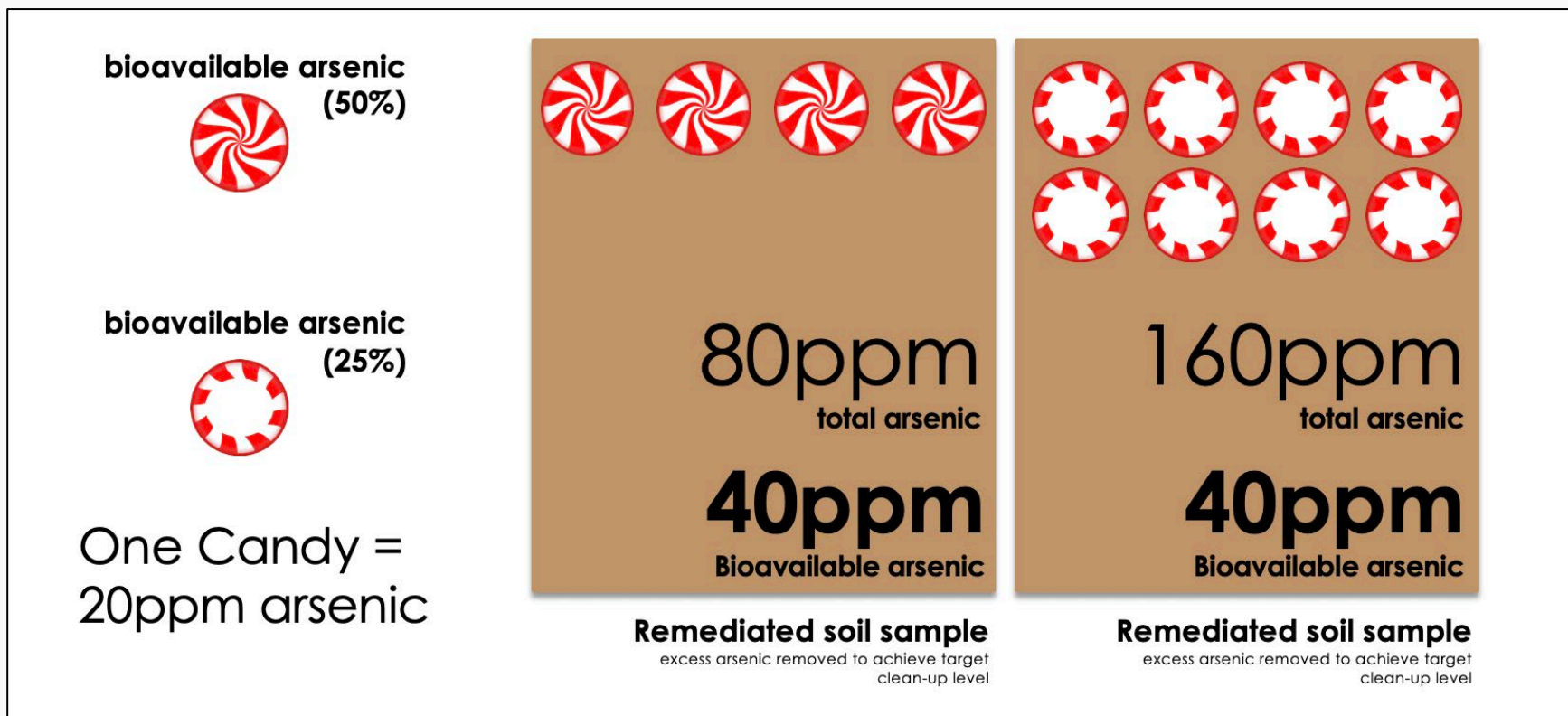


Why is bioavailability important?

The total concentration of arsenic or lead in soil may not provide an accurate measure of risk. Risk will be more accurately assessed after adjusting total soil concentrations for the fraction that is bioavailable.



What is bioavailability?





Bioavailability Definitions

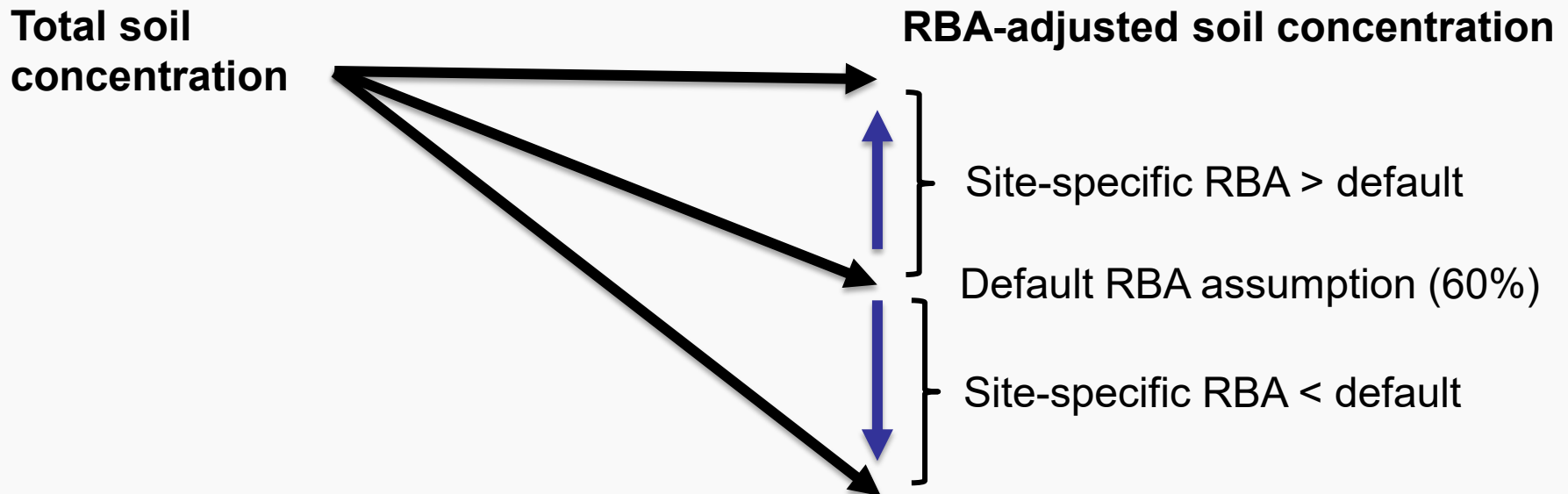
What is bioavailability?

- **Absolute Bioavailability (ABA)** - the fraction of the amount ingested that is absorbed into the human body.
- **Relative Bioavailability (RBA)** - the ratio of the ABA of a contaminant in soil to the ABA of that contaminant in the standard used to develop the toxicity value for that contaminant

$$RBA = \frac{ABA \text{ of arsenic in soil}}{ABA \text{ of arsenic in drinking water}}$$



Effect of RBA on Soil Concentration





How are Risks Adjusted for Bioavailability?

- RBA values may be incorporated into lead risk models (e.g., IEUBK Model, ALM), arsenic toxicity values (e.g., RfD, cancer slope factor), and soil screening levels.
- Site-specific RBA can be measured to replace use of assumed default RBA values





Real-world example of use of bioavailability data in site assessment

- Orchard site contaminated with arsenic
- Initial remedy involved cleanup of 117 acres of contaminated soil
- EPA's ORD conducted bioavailability testing, with results showing that only 30% of soil arsenic was bioavailable
- This enabled a reduction in cleanup from 117 acres to 88 acres, saving **\$9 million in cleanup costs**

- **General rule of thumb:**  **Site-specific RBA**  **Cleanup goal**

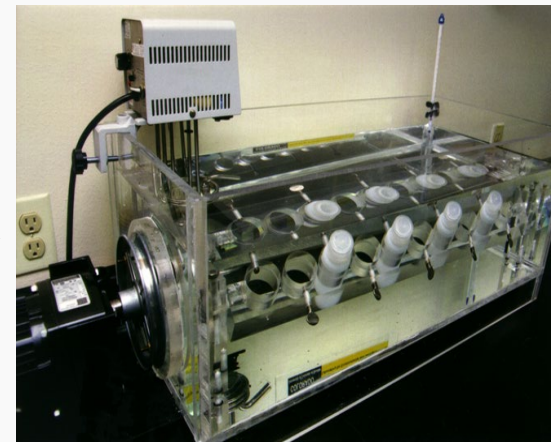


How is RBA directly measured?

- Rats, mice, monkeys and swine have been used to study oral bioavailability of lead and arsenic.
- Animal bioassays rely on measurements of blood, tissue or urine as metrics of absorbed dose for measuring bioavailability
- Previously, a swine model developed by EPA was the most used animal model for measuring arsenic or lead RBA.
- More recently, EPA developed a mouse model for measuring soil arsenic and lead RBA, which is less expensive than the swine model and provides similar results.

IVBA: A high-throughput, cost-effective estimate of RBA

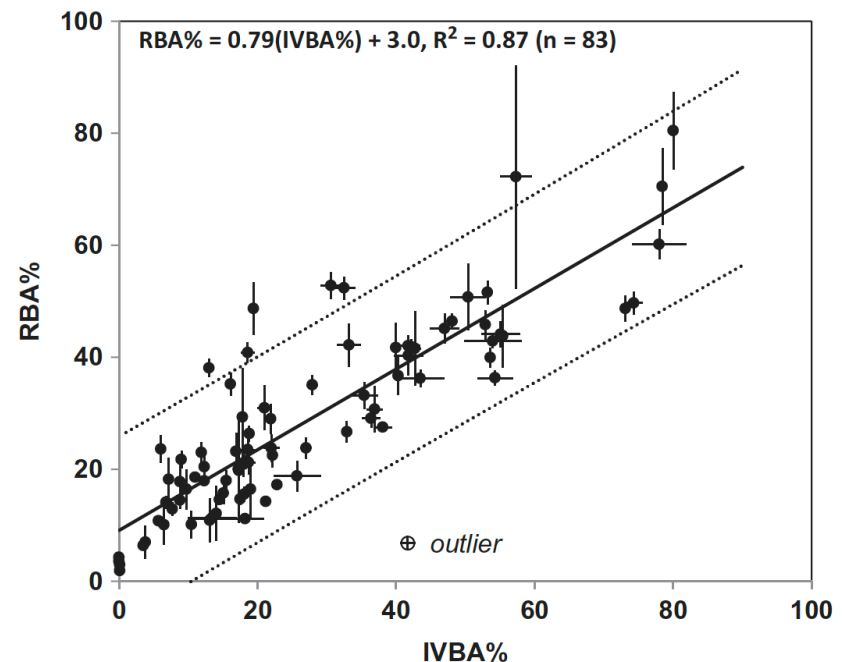
- IVBA (in vitro bioaccessibility) refers to the fraction of total arsenic or lead that is soluble in a gastric-like (i.e., low pH) extraction medium
- EPA has validated **Method 1340** to estimate RBA by measuring arsenic and lead IVBA in soil





Method 1340 IVBA Assay, cont.

- IVBA assays are low-cost and high-throughput and have been shown to correlate with RBA
- Multiple regional EPA and commercial labs are experienced in running this method
- Bioavailability fits in with other soil sampling best practices, including systematic planning, DQO's, incremental soil sampling, and sieving soil to better represent ingestion



From Diamond et al., *Predicting Oral Relative Bioavailability of Arsenic in Soil from in Vitro Biocessibility*, 2016.



Why Assess RBA at your Site?

- Assessment of RBA improves accuracy and increases confidence in risk estimates.
- Improved accuracy may lead to lower cleanup costs, and increased confidence lowers the likelihood of clean-up decision errors.
- EPA OLEM guidance recommends that RBA be measured at all arsenic and lead sites.
- New EPA lead policy is likely to require assessment of lead RBA to support HHRAs.
- New tools and methods provide cost-effective means for assessing RBA at sites.



Q&A Break



Systematic Planning for RBA Data

- Systematic planning is standard for collection of data and must be applied to collection of data used to estimate RBA (typically via measurement of IVBA).
- Incorporate RBA into systematic planning as a modifier to the total concentration of arsenic or lead in soil.
- DQOs for measurement of arsenic and lead concentrations should include measurement of IVBA.
- Soil sampling and analysis plans can include both concentration and RBA.

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

United States

January 4, 2021

Environmental

Protection Agency



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



Purpose of the Sampling Guidance

- Update to the 2015 guidance, to more thoroughly address application for arsenic and lead RBA data to risk assessments.
- Assist risk assessors and risk managers in collecting and effectively utilizing data on RBA of arsenic and lead for use in HHRA.
- Promote consistent application of RBA data across the Regions.
- Improve accuracy of risk estimates for soil arsenic and lead.
- Increase cost-effective risk assessment and risk management.



Emphasis on Systemic Planning

- Systematic planning and DQOs – ensure data collection supports decision needs
- Study design and sample plans created with statistical analyses and the intended data use in mind
- Apply systematic planning to both *future* soil sampling and to sampling archived soils for *retrospective* RBA assessments



Organization of the Guidance

- Purpose, Organization and Terminology (Sections 1-2)
- Rationale for Collecting RBA Data to Support HHRA (Section 3)
- **Laboratory Methods for Measuring RBA (Section 4)**
- **Application of RBA to HHRA (Section 5)**
- **Systematic Planning for Collection of RBA Data (Section 6)**
- Sample Collection, Equipment and Handling, QA/QC, Health and Safety (Sections 7-10)
- **Appendix A. Guidance for Sample Collection for Estimating an RBA-adjusted Exposure Point Concentration for Soil**
- **Attachments: FAQs and examples of applications**

 2015

 REVISED

 NEW



Section 4: Laboratory Methods for RBA

- References to where to find information on animal models.
- Description of validated IVBA assay for arsenic and lead SW-846, Method 1340
- Regression equations for arsenic and lead for converting IVBA to RBA.



Section 5: Application of RBA Data to HHRA

- RBA Adjustments of Bioavailability Parameters in Lead Risk Models
- RBA Adjustment of a Soil Exposure Point Concentration
- RBA adjustment of a Soil Contaminant Daily Oral Intake
- RBA Adjustment of a Soil Risk-based Screening Level or Action Level
- RBA adjustments can be made using any one of these methods. Pick one; not more.



Section 6: Planning for Collection of RBA Data

- Data Quality Objectives for RBA Assessment
- Retrospective RBA Assessments of Archived Soil Samples
- Evaluation of RBA Data Adequacy
- Selection of Appropriate Statistic to Represent RBA at the Site
- Estimation of a Site-wide RBA from RBA Data for Multiple Decision Units
- Use of the Conceptual Site Model to Inform RBA Sampling
- Use of Soil Concentration Data to Select Samples for IVBA Measurement
- Use of Information on Mineralogy (e.g., speciation) to Select RBA Samples and Methods



Appendix A

- How to estimate sample numbers needed for RBA assessment.
- Assumes sample needs are for hypothesis testing; i.e., whether or not the estimated mean RBA-adjusted soil concentration for a contaminant exceeds an action level.
- The approach is applicable to other DQOs (adjustment of IEUBK model or ALM AF parameters, actions levels or daily intakes).
- Includes look-up tables for sample numbers needed to achieve decision confidence objectives (for discrete & ISM sampling).
- Will be supported by web-based tool presented in upcoming training session # 3 (currently scheduled for 3/18/24).



Attached Examples

- A. FAQs on Bioavailability Sampling and Assessments
- B. Calculation of IEUBK Model and Adult Lead Methodology (ALM) Absorption Fraction Parameters from IVBA Results of EPA Method 1340
- C. RBA Adjustment of Decision Unit Exposure Point Concentrations for Arsenic and Lead (case study)
- D. RBA Adjustment of Daily Oral Intake of Arsenic in a Baseline Human Health Risk Assessment (case study)
- E. Retrospective RBA Assessment in Support of a Removal Decision (case study)
- F. RBA Adjustment of a Risk-Based Concentration for Lead (case study)
- G. RBA Adjustment of Absorption Fraction Parameters in the IEUBK Model and ALM (case study)
- H. RBA Adjustment of time-weighted Pb soil exposure concentration



Primary RBA Assessment Guidance

- Guidance for Sample Collection for In Vitro Bioaccessibility Assay (IVBA) for Arsenic (As) and Lead (Pb) in Soil and Applications of Relative Bioavailability (RBA) Data in Human Health Risk Assessment (2021)
- Recommendations for Default Value for Relative Bioavailability of Arsenic in Soil (OSWER 9200.1-113)
- Estimation of Lead Bioavailability in Soil and Dust: Evaluation of the Default Value for the Integrated Exposure Uptake Biokinetics Model for Lead in U.S. Children (OLEM Directive 9200.1-145)



Primary RBA Assessment Guidance, cont.

- Recommendations for Sieving Soil and Dust Samples at Lead Sites for Assessment of Incidental Ingestion (OLEM Directive 9200.1-128)
- Other supporting guidance can be found on the EPA Bioavailability website: <https://www.epa.gov/superfund/soil-bioavailability-superfund-sites-guidance>



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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*