1 ***Starting Soon*: Bioavailability of Contaminants in Soil: Considerations for Human Health Risk Assessment**

Poll Question

- Access online document: http://bcs-1.itrcweb.org/
- Download PowerPoint file
  - CLU-IN training page at http://www.clu-in.org/conf/itrc/bcs/
  - Under “Download Training Materials”
- Download Decision Process Flowchart, BCS-1 Definition of Terms, and Review Checklist, for reference during the training class
  - https://clu-in.org/conf/itrc/bcs/ITRC-BCS-TrainingHandouts.pdf
- Using Adobe Connect
  - Related Links (on right)
    - Select name of link
    - Click “Browse To”
  - Full Screen button near top of page
- Follow ITRC

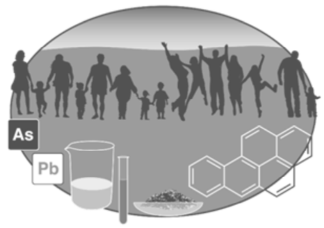
Poll Question: What is Your Experience Level with Soil Contaminant Bioavailability?

- little or no experience
- some knowledge and experience
- expert

2

Welcome – Thanks for joining this ITRC Training Class

Bioavailability of Contaminants in Soil: Considerations for Human Health Risk Assessment



Bioavailability of Contaminants in Soil: Considerations for Human Health Risk Assessment (BCS-1)

ITRC Technical and Regulatory Guidance document

Sponsored by: Interstate Technology and Regulatory Council (www.itrcweb.org)
Hosted by: US EPA Clean Up Information Network (www.cluin.org)

Training Course Overview:

ITRC Guidance: Bioavailability of Contaminants in Soil: Considerations for Human Health Risk Assessment (BCS-1) http://bcs-1.itrcweb.org/

Risk-based cleanup goals are often calculated assuming that chemicals present in soil are absorbed by humans as efficiently as the chemicals dosed during the toxicity tests used to determine regulatory toxicity values (such as the Reference Dose or Cancer Slope Factor). This assumption can result in inaccurate exposure estimates and associated risks for some contaminated sites because the amount of a chemical absorbed (the chemical's bioavailability) from contaminated soil can be a fraction of the total amount present. Properly accounting for soil-chemical interactions on the bioavailability of chemicals from soil can lead to more accurate estimates of exposures to soil contaminants and improve risk assessments by decreasing uncertainty.

The basis for this training course is the ITRC guidance: Bioavailability of Contaminants in Soil: Considerations for Human Health Risk Assessment (BCS-1). This guidance describes the general concepts of the bioavailability of contaminants in soil, reviews the state of the science, and discusses how to incorporate bioavailability into the human health risk assessment process. This guidance addresses lead, arsenic, and polycyclic aromatic hydrocarbons (PAHs) because evaluating bioavailability is better understood for these chemicals than for others, particularly for the incidental ingestion of soil.

The target audience for this guidance and training course are:

- Project managers interested in decreasing uncertainty in the risk assessment which may lead to reduced remedial action costs.
- Risk assessors new to bioavailability or those who want additional confidence and training in the current methods and common practices for using bioavailability assessment to more accurately determine human health risk at a contaminated site.

As a participant in this training you should learn to:

- Value the ITRC document as a "go-to" resource for soil bioavailability
- Apply the decision process to determine when a site-specific bioavailability assessment may be appropriate
- Use the ITRC Review Checklist to develop or review a risk assessment that includes soil bioavailability
- Consider factors that affect arsenic, lead and PAH bioavailability
- Select appropriate methods to evaluate soil bioavailability
- Use tools to develop site-specific soil bioavailability estimates and incorporate them into human health risk assessment

Learners can envision themselves implementing the ITRC guidance through case study applications. Training participants are encouraged to view the associated ITRC guidance, Bioavailability of Contaminants in Soil: Considerations for Human Health Risk Assessment (BCS-1) prior to attending the class.

ITRC (Interstate Technology and Regulatory Council) www.itrcweb.org
Training Co-Sponsored by: US EPA Technology Innovation and Field Services Division (TIFSD) (www.clu-in.org)
ITRC Training Program: training@itrcweb.org; Phone: 402-201-2419

3

Housekeeping

- Course time is 2¼ hours
- This event is being recorded
- Trainers control slides
  - **Want to control your own slides?** You can download presentation file on Clu-in training page
- Questions and feedback
  - **Throughout training:** type in the “Q & A” box
  - **At Q&A breaks:** unmute your phone with #6 to ask out loud
  - **At end of class:** Feedback form available from last slide
    - **Need confirmation of your participation today?** Fill out the feedback form and check box for confirmation email and certificate

Copyright 2019 Interstate Technology & Regulatory Council, 50 F Street, NW, Suite 350, Washington, DC 20001

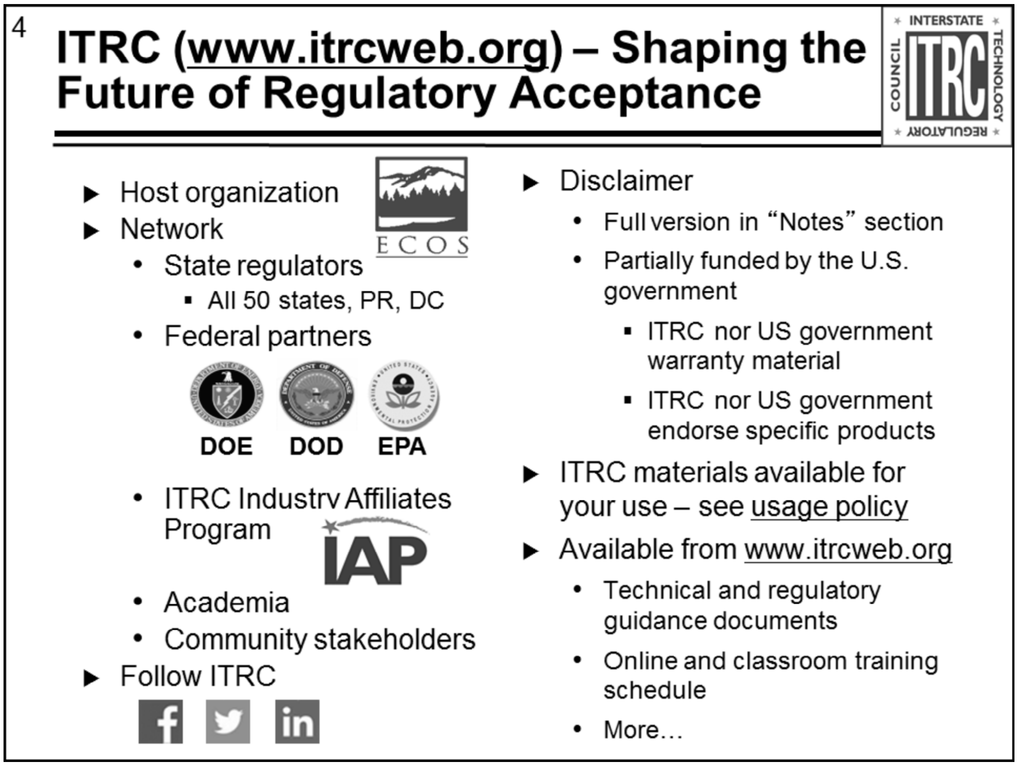
Notes:

I’m sure that some of you are familiar with these rules from previous CLU-IN events, let’s run through them quickly for our new participants.

We have started the seminar with all phone lines muted to prevent background noise. Please keep your phone lines muted during the seminar to minimize disruption and background noise. During the question and answer break, press #6 to unmute your lines to ask a question (note: *6 to mute again). Also, please do NOT put this call on hold as this may bring unwanted background music over the lines and interrupt the seminar.

Use the “Q&A” box to ask questions, make comments, or report technical problems any time. For questions and comments provided out loud, please hold until the designated Q&A breaks.

Everyone – please complete the feedback form before you leave the training website. Link to feedback form is available on last slide.



The Interstate Technology and Regulatory Council (ITRC) is a state-led coalition of regulators, industry experts, citizen stakeholders, academia and federal partners that work to achieve regulatory acceptance of environmental technologies and innovative approaches. ITRC consists of all 50 states (and Puerto Rico and the District of Columbia) that work to break down barriers and reduce compliance costs, making it easier to use new technologies and helping states maximize resources. ITRC brings together a diverse mix of environmental experts and stakeholders from both the public and private sectors to broaden and deepen technical knowledge and advance the regulatory acceptance of environmental technologies. Together, we're building the environmental community's ability to expedite quality decision making while protecting human health and the environment. With our network of organizations and individuals throughout the environmental community, ITRC is a unique catalyst for dialogue between regulators and the regulated community.

For a state to be a member of ITRC their environmental agency must designate a State Point of Contact. To find out who your State POC is check out the "contacts" section at www.itrcweb.org. Also, click on "membership" to learn how you can become a member of an ITRC Technical Team.

Disclaimer: This material was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency thereof, nor any of their employees, makes any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government or any agency thereof. The views and opinions of authors expressed herein do not necessarily state or reflect those of the United States Government or any agency thereof and no official endorsement should be inferred.

The information provided in documents, training curricula, and other print or electronic materials created by the Interstate Technology and Regulatory Council ("ITRC" and such materials are referred to as "ITRC Materials") is intended as a general reference to help regulators and others develop a consistent approach to their evaluation, regulatory approval, and deployment of environmental technologies. The information in ITRC Materials was formulated to be reliable and accurate. However, the information is provided "as is" and use of this information is at the users' own risk.

ITRC Materials do not necessarily address all applicable health and safety risks and precautions with respect to particular materials, conditions, or procedures in specific applications of any technology. Consequently, ITRC recommends consulting applicable standards, laws, regulations, suppliers of materials, and material safety data sheets for information concerning safety and health risks and precautions and compliance with then-applicable laws and regulations. ITRC, ERIS and ECOS shall not be liable in the event of any conflict between information in ITRC Materials and such laws, regulations, and/or other ordinances. The content in ITRC Materials may be revised or withdrawn at any time without prior notice.

ITRC, ERIS, and ECOS make no representations or warranties, express or implied, with respect to information in ITRC Materials and specifically disclaim all warranties to the fullest extent permitted by law (including, but not limited to, merchantability or fitness for a particular purpose). ITRC, ERIS, and ECOS will not accept liability for damages of any kind that result from acting upon or using this information.

ITRC, ERIS, and ECOS do not endorse or recommend the use of specific technology or technology provider through ITRC Materials. Reference to technologies, products, or services offered by other parties does not constitute a guarantee by ITRC, ERIS, and ECOS of the quality or value of those technologies, products, or services. Information in ITRC Materials is for general reference only; it should not be construed as definitive guidance for any specific site and is not a substitute for consultation with qualified professional advisors.

Bryn Thoms is a hydrogeologist with Oregon Department of Environmental Quality's (ODEQ's) Cleanup Program in Eugene, Oregon. Since 1998, Bryn has worked in ODEQ's Cleanup Program with prior experience in environmental consulting. Bryn oversees a variety of cleanup projects including solvent groundwater plumes, legacy pesticide sites, former wood products mill sites, petroleum releases, and abandoned mine lands. His work on abandoned mine lands has led him to assisting on cleanup of mercury mines and artisanal gold mines internationally. In 2015, he became active with ITRC in the Bioavailability of Contaminants in Soil Team as a result of overseeing one of the first ODEQ projects that utilized bioavailability adjustments in human health risk assessment. Bryn helped develop the Decision Section of the Bioavailability Guidance document, where his regulatory experience provided valuable perspective on incorporating bioavailability into the regulatory cleanup process. He has led presentations on assessment and cleanup of mercury and arsenic-contaminated sites to several university geochemistry classes, NGOs, and the Peru Ministry of Environment. Bryn earned a bachelor's degree in geology from Oregon State University in Corvallis, Oregon in 1992. He has been an Oregon registered professional geologist since 1997.

Geoffrey Siemering is a researcher with the Department of Soil Science at University of Wisconsin in Madison. Beginning his work with UW-Madison in 2014, Geoff conducts research and develops outreach programming on soil contaminant issues at the interface of public health and environmental regulation. Recent projects include bioavailability of lead in urban soils, reuse of lead and zinc mine-scarred agricultural land, quantification of cheesemaking and vegetable processing facility wastewater soil denitrification, and determination of anthropogenic polycyclic aromatic hydrocarbon baseline values for urban Wisconsin. He also has experience with triad-approach monitoring of aquatic herbicide impacts, and radionuclide waste disposal. Prior to UW-Madison, Geoff worked for the San Francisco Estuary Institute and Lawrence Livermore National Laboratory. Since 2015, Geoff has contributed to ITRC's Bioavailability of Contaminants in Soil. Geoff earned a bachelor's degree in geochemistry from Pomona College, Claremont, California in 1994 and a master's degree in soil science from the University of California, Berkeley in 1999.

Kevin Long is a Principal Consultant in Terraphase's Princeton, NJ office. Since 2000, he has applied risk assessment and risk management strategies to support site characterization, risk management, and redevelopment at hazardous waste and brownfield sites under Superfund, RCRA, and various state and provincial cleanup programs. Working on such projects, he has helped to control unacceptable human exposures at dozens of sites, including those that may pose an imminent and substantial danger to human health. Such projects have involved addressing contamination in all sorts of environmental media and, in many cases, have required complex exposure assessment, fate and transport modeling, statistical analysis, risk management design, and risk communication. He has been a member of the ITRC Risk Assessment team since 2012. Kevin earned a bachelor's degree in 2000 and master's degree in 2006, both in Civil and Environmental Engineering, from Princeton University in Princeton, NJ.

Dr. Valerie Hanley is a Staff Toxicologist in the Human and Ecological Risk Office at the California Department of Toxic Substances Control (DTSC) in Sacramento, CA. Valerie has been with DTSC since 2008. She recently authored a Human Health Risk Assessment Note on how to evaluate Arsenic contaminated sites with a specific emphasis on how and when to use bioavailability in those site evaluations. Valerie has been involved in the study of arsenic bioavailability since 2009 when DTSC was awarded funding from US EPA to evaluate and develop new methods to determine arsenic bioavailability in mining soils. Through this work Valerie helped develop the California Arsenic Bioaccessibility (CAB) Method, which is now recommended for use in sites throughout California. Valerie joined the ITRC Bioavailability in Contaminated Soils Team in 2015 and is one of the lead authors on the arsenic chapter of the document. In addition to her work on arsenic, Valerie evaluates Human Health Risk Assessments for a variety of sites and is involved in DTSC's Safer Consumer Products program. Valerie earned a Bachelor's degree in Molecular, Cellular, and Developmental Biology from The University of California (UC) Santa Cruz in 2001 and her PhD in Comparative Pathology from UC Davis in 2007. She completed a postdoctoral fellowship at UC Davis in Respiratory Toxicology in 2008.

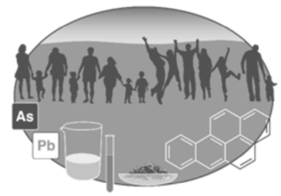
Barrie Selcoe is a Principal Technologist with Jacobs in Houston, Texas. Barrie has worked at Jacobs since 2018, specializing in human health risk assessment. She is responsible for planning and overseeing human health risk-based activities at hazardous waste sites across the U.S. and internationally. She utilizes numerous federal (USEPA and Department of Defense) and state guidance documents in risk assessment projects, and is involved in all stages of site planning, investigation and reporting, cleanup level identification, and remedial action planning. She has been involved in risk assessments in 40 states and about 20 countries. She has worked on risk assessments incorporating incremental sampling and site-specific bioaccessibility studies. She has provided risk assessment services for numerous Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)/Superfund sites, Resource Conservation and Recovery Act (RCRA) facilities, state-program sites, voluntary actions, and international projects. She has prepared risk assessments for various types of sites, including industrial and commercial facilities, industrial and municipal landfills, bulk fuel terminals, rivers, U.S. Department of Defense facilities, and residential areas. Prior to Jacobs (which purchased CH2M in 2018), she worked as a human health risk assessor for 19 years with CH2M, 7 years with Philip Environmental, and 3 years with O'Brien & Gere Engineers. Since 2012, Barrie has contributed as a team member on ITRC's Risk Assessment team, Bioavailability in Contaminated Soil team, TPH Risk Evaluation at Petroleum-Contaminated Sites team, and PFAS team. She earned a bachelor's degree in microbiology from San Diego State University in San Diego, California in 1986, and a Master's of Public Health from the University of Pittsburgh Graduate School of Public Health in Pittsburgh, Pennsylvania in 1999.

Anita Meyer is a risk assessor and toxicologist with the Army Corps of Engineers Environmental and Munitions Center of Expertise. She works for the Huntsville Center and is located in Omaha, Nebraska. Since 1997 Anita has gained experience with CERCLA and RCRA risk assessments on formerly used defense sites, military munitions response program sites, former Manhattan Project sites, Army and Air Force active sites and on EPA Superfund projects. Beginning in 2009, Anita has supported the Department of Defense (DoD) Chemical and Material Risk Management Program Directorate, leading DoD interagency reviews of EPA toxicological assessments, as well as regulatory risk assessments for TSCA. Anita represents the Army and the Corps of Engineers on interagency committees and workgroups related to environmental investigation and cleanup. She has been a member of four ITRC technical teams, Bioavailability in Contaminated Soils, Incremental Sampling Methodology, Risk Assessment, and Risk Assessment Resources. She provides risk assessment expertise on Corps of Engineers projects and has utilized bioavailability assessments on former skeet target ranges. Anita also consults on DoD and Army policy, writes Corps of Engineers guidance, and teaches Corps of Engineers courses on risk assessment and in systematic planning. Prior to joining the Corps of Engineers Anita performed cancer and drug development research. Anita earned a bachelor's degree in biological sciences in 1984 and a master's degree in cell biology and genetics in1987 from the University of Nebraska in Lincoln, Nebraska. She is certified by the American Board of Toxicology (DABT).

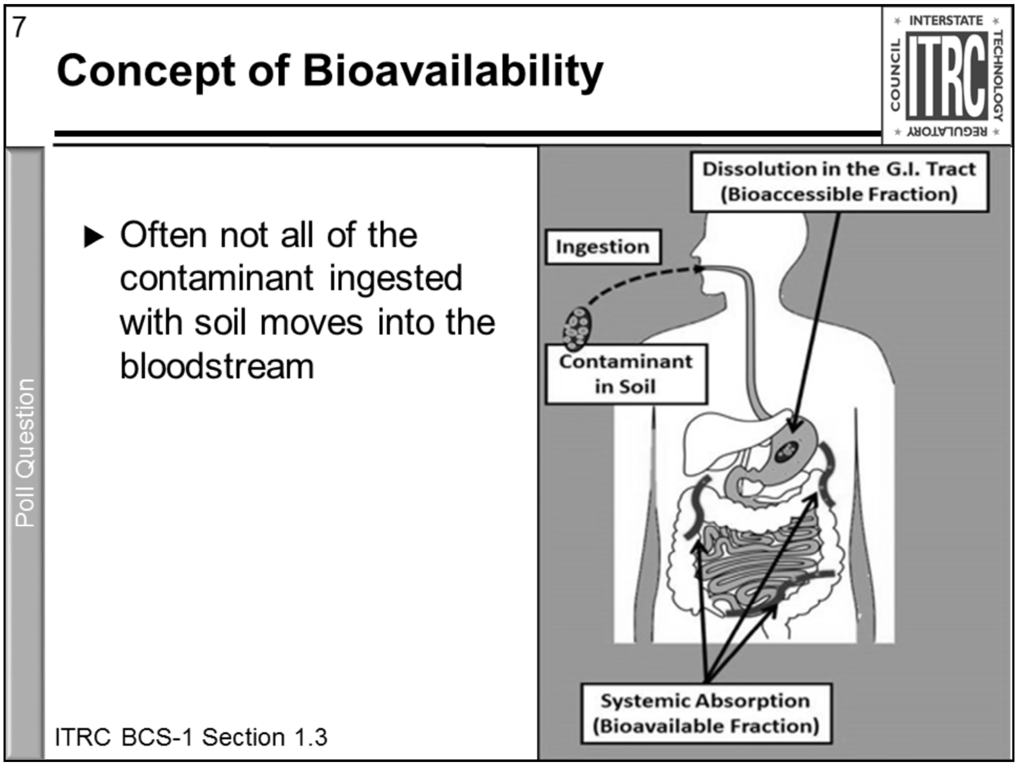
6

Today's Training Road Map

- Importance of Evaluating Bioavailability in Soils
- Bioavailability Basics
- Case Study 1 (Arsenic Site)
- Questions and Answers
- Case Study 2 (Lead Site)
- Discussion: Polycyclic Aromatic Hydrocarbons (PAHs)
- Taking Action
- Questions and Answers



No associated notes.



Poll: If a contaminant is ingested and passes through (is not absorbed FROM) the human gastrointestinal tract (G.I. Tract), DOES IT CONTRIBUTE TO SYSTEMIC RISK?

Yes

No

I don't know

Answer is NO because our risk assessment process for ingestion of contaminated soil focuses on risks from systemic exposure to contaminants in soil. The next sections of this training and the ITRC document address *exactly* this issue.

8

You Should Learn to…

- Value the ITRC document as a "go-to" resource for soil bioavailability
- Apply decision process to determine when a site-specific bioavailability assessment may be appropriate
- Use the ITRC Review Checklist to develop or review a risk assessment that includes soil bioavailability
- Consider factors that affect arsenic, lead and polycyclic aromatic hydrocarbons (PAH) bioavailability
- Select appropriate methods to evaluate soil bioavailability
- Be able to incorporate soil bioavailability into human health risk assessments

No associated notes.

9

Why You Should Consider Evaluating Bioavailability in Soils

- Reduces uncertainty, provides a more accurate understanding of chemical exposures and associated risk
- Leads to a more effective use of resources without compromising health protection
- May reduce remedial action costs and increase flexibility of remedial options
- Risk assessment allows for modifying exposure factors to better represent site conditions

Photo courtesy of Geoff Siemering, University of Wisconsin, 2017

No associated notes.

10

Your Resource for Bioavailability in Soils – ITRC Guidance

ITRC BCS-1

http://bcs-1.itrcweb.org/

No associated notes.

11

Focus of ITRC Training and Guidance

- Bioavailability of contaminants in soil to humans
  - Bioavailability in sediment or in reference to ecological receptors (see ITRC Guidance: http://www.itrcweb.org/contseds-bioavailability/)
- Specifically covers As (arsenic), Pb (lead), and polycyclic aromatic hydrocarbons (PAHs)
  - Although guidance can be used for assessing bioavailability of other contaminants
- Focuses on the soil ingestion pathway
- Limited dermal bioavailability information as it relates to PAHs

No associated notes.

12

Bioavailability Tools

- Web-based Guidance Document ITRC BCS-1
  - The go-to guide for bioavailability assessments

(Provided in the Webinar Handouts)

- Decision Process Flow Chart - Section 4.1
  - Will be presented in both case studies
- Definition of Terms
- Review Checklist
  - Can be used as a tool to review a bioavailability assessment
  - Can be used to prepare a bioavailability study

ITRC BCS-1 http://bcs-1.itrcweb.org/

No associated notes.

13

A Regulator's Experience with Bioavailability – Learning Opportunities

Poll Question

- Regulator with limited experience in bioavailability overseeing arsenic cleanup project
- Consultant recommends assessing bioavailability of arsenic at site
- Project manager and team toxicologist agree to using bioavailability in risk assessment
- Risk assessment presented much lower risk than previous estimates
- Significantly reduced remedial action costs
- Increased the accuracy of the risk estimate

Photo source: Red Rock Road ECSI #1855, OEQ, 2009

Poll Question: (was originally shown as participants log on slide 1) and brought back here to show results and discuss

- little or no experience
- some knowledge and experience
- expert

14

Today's Training Road Map

Importance of Evaluating Bioavailability in Soils

↓

➡ Bioavailability Basics

↓

Case Study 1 (Arsenic Site)

↓

Questions and Answers

↓

Case Study 2 (Lead Site)

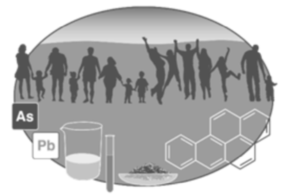
↓

Discussion: Polycyclic Aromatic Hydrocarbons (PAHs)

↓

Taking Action

Questions and Answers



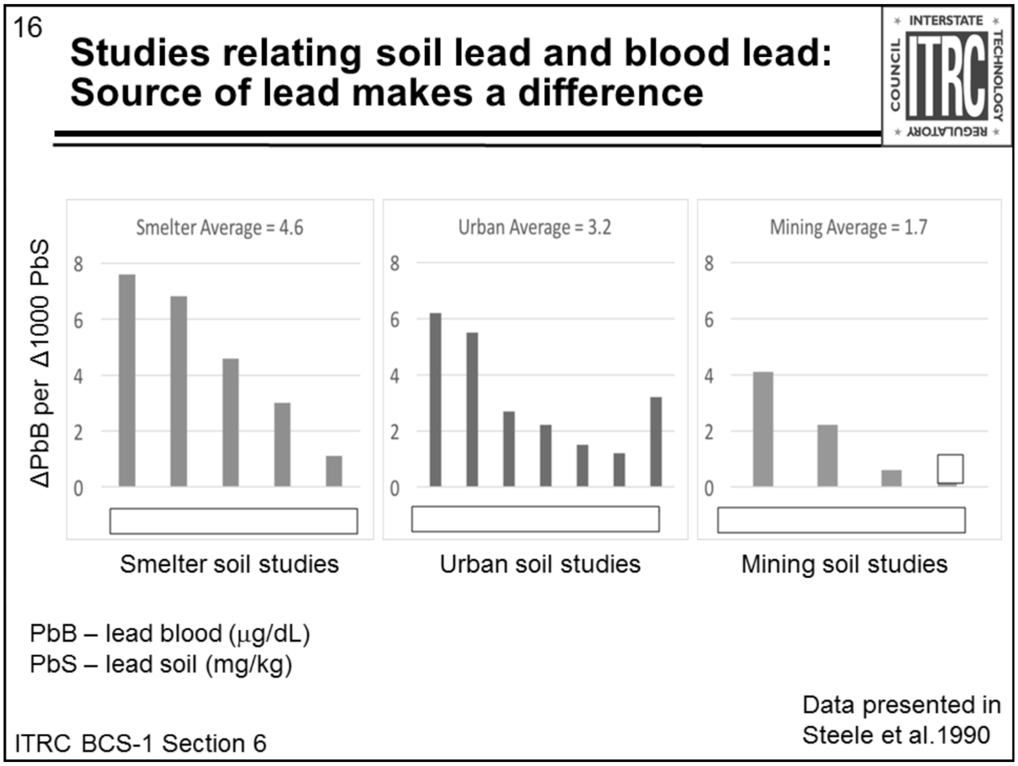
No associated notes.

15

Bioavailability of Contaminants in Soil Basics

- History: how we recognized the issue
- Relevance to Human Health Risk Assessment
- Concepts with applicability to all chemicals
- Key definitions
- In vivo - in vitro correlation (IVIVC)
- Soil properties that influence bioavailability

No associated notes

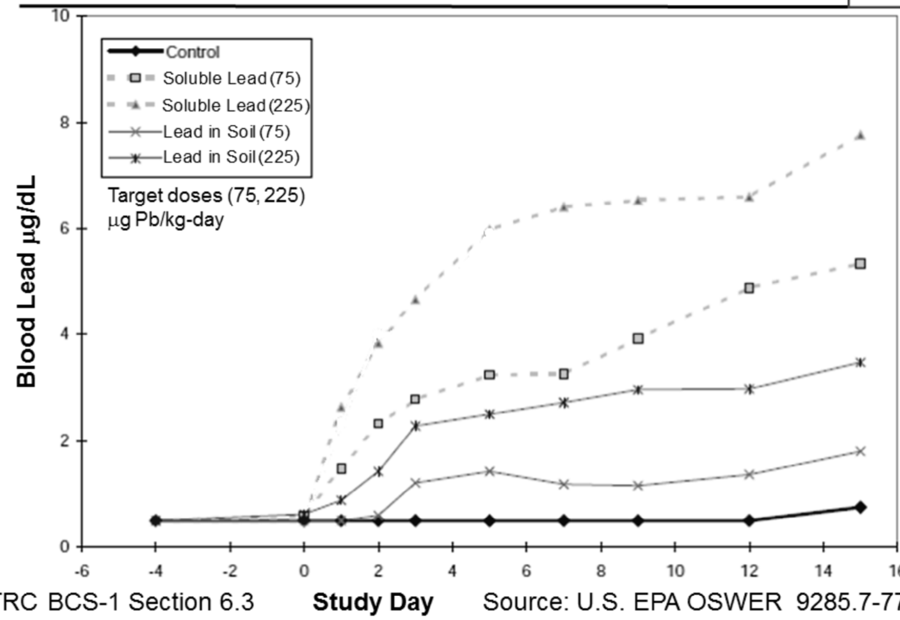


Steele, M. J., B. D. Beck, B. L. Murphy, and H. S. Strauss. 1990. "Assessing the Contribution from Lead in Mining Wastes to Blood Lead." Regulatory Toxicology and Pharmacology, 11: 158-190.

17

Demonstrating RBA of Lead in Soil with Animal Models

RBA – Relative Oral Bioavailability



ITRC BCS-1 Section 6.3 Source: U.S. EPA OSWER 9285.7-77 2007

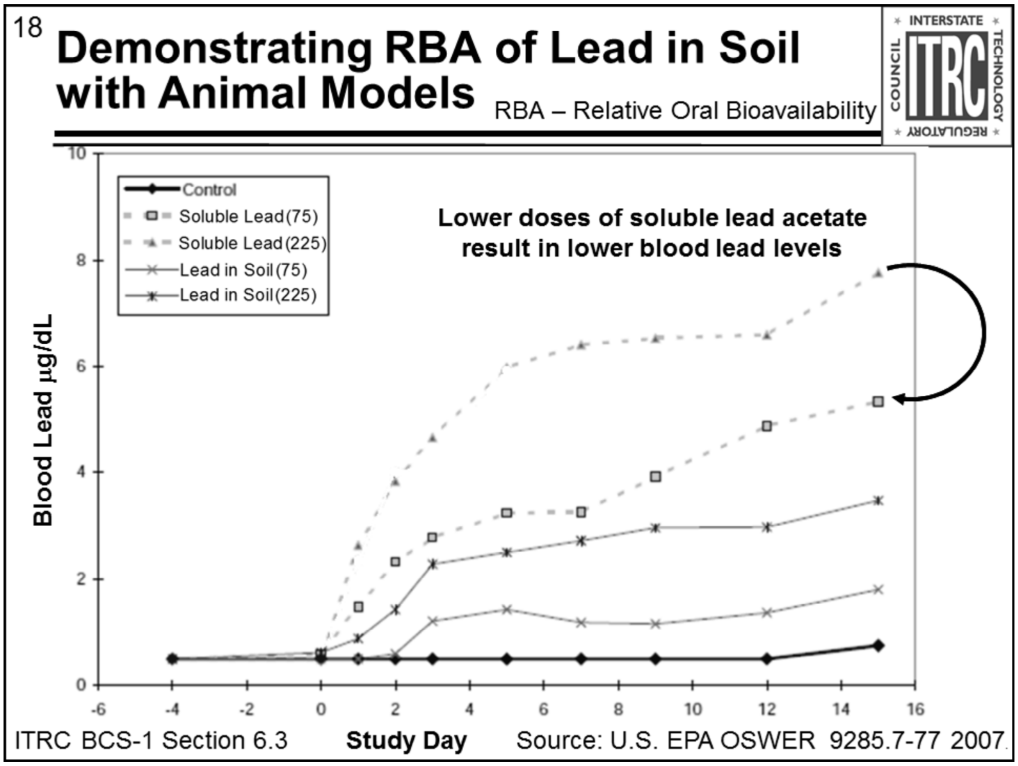
Range: 1% (Galena-enriched soil) to 105%

Lowest site soil was 6%, for Tailings sample from California Gulch

Highest value California Gulch Fe/Mn PbO

Target lead dose (75, 225) – expressed in units of <u>micrograms</u> of lead per kg of body weight per day.

USEPA. 2007b. “Estimation of relative bioavailability of lead in soil and soil-like materials using in vivo and in vitro methods.” OSWER 9285.7-77. Washington, D.C.: Office of Solid Waste and Emergency Response. https://semspub.epa.gov/work/HQ/175416.pdf

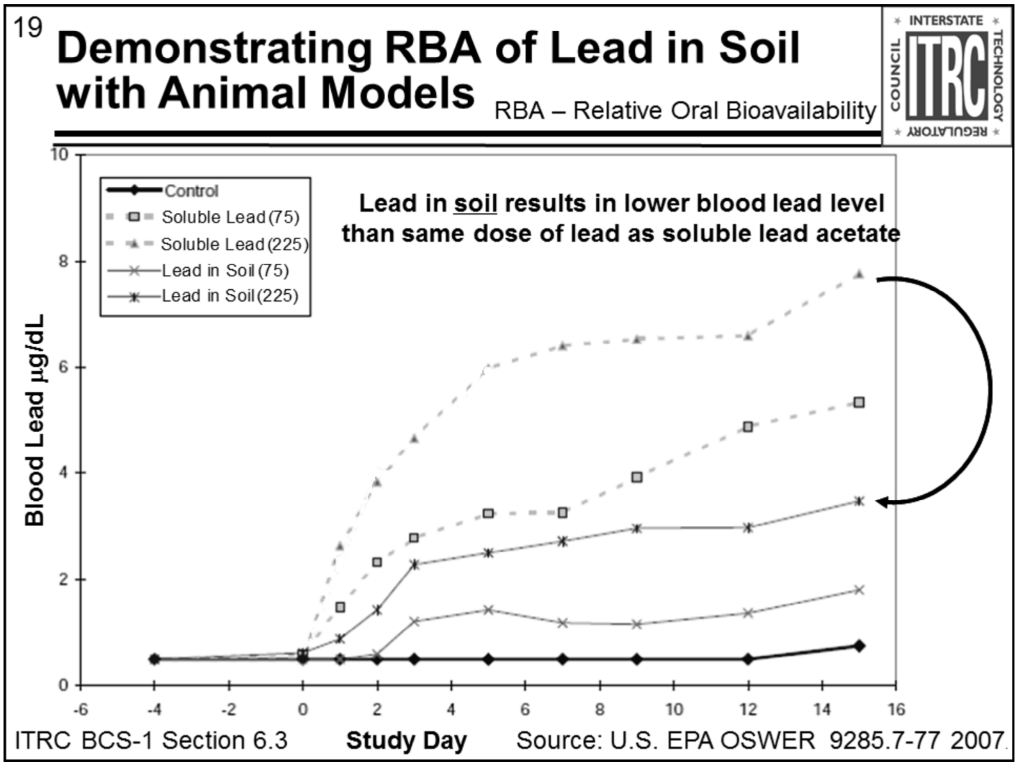


Range: 1% (Galena-enriched soil) to 105%

Lowest site soil was 6%, for Tailings sample from California Gulch

Highest value California Gulch Fe/Mn PbO

USEPA. 2007b. “Estimation of relative bioavailability of lead in soil and soil-like materials using in vivo and in vitro methods.” OSWER 9285.7-77. Washington, D.C.: Office of Solid Waste and Emergency Response. https://semspub.epa.gov/work/HQ/175416.pdf

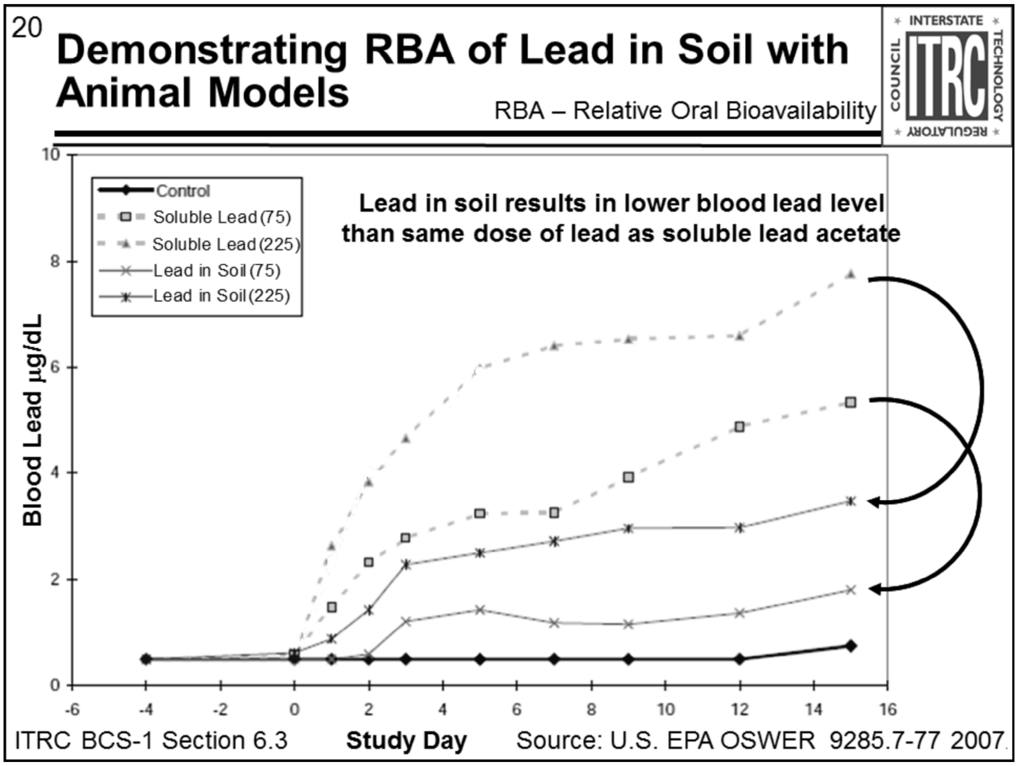


Range: 1% (Galena-enriched soil) to 105%

Lowest site soil was 6%, for Tailings sample from California Gulch

Highest value California Gulch Fe/Mn PbO

USEPA. 2007b. "Estimation of relative bioavailability of lead in soil and soil-like materials using in vivo and in vitro methods." OSWER 9285.7-77. Washington, D.C.: Office of Solid Waste and Emergency Response. https://semspub.epa.gov/work/HQ/175416.pdf



Graph of concentration of lead in blood over time.

USEPA. 2007b. “Estimation of relative bioavailability of lead in soil and soil-like materials using in vivo and in vitro methods.” OSWER 9285.7-77. Washington, D.C.: Office of Solid Waste and Emergency Response. https://semspub.epa.gov/work/HQ/175416.pdf

21

Regulatory Recognition of Using Bioavailability for Risk Assessment

"*If the medium of exposure [at] the site… differs from the medium of exposure assumed by the toxicity value… an absorption adjustment may… be appropriate.*"

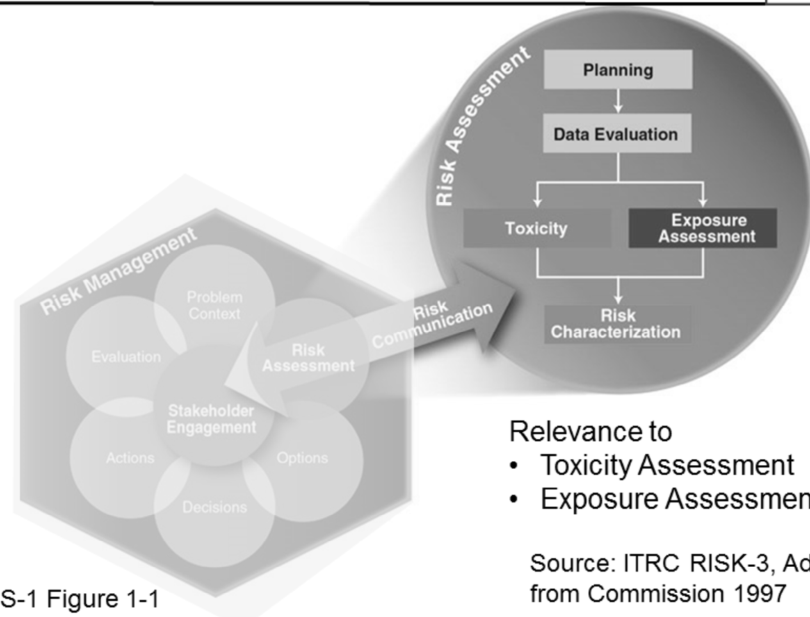
"*[to] adjust a food or soil ingestion exposure estimate to match a RfD or slope factor based on… drinking water…*"

USEPA 1989 "Risk Assessment Guidance for Superfund (RAGS)" EPA/540/1-89/002

USEPA. 1989. "Risk Assessment Guidance for Superfund. Volume I: Human Health Evaluation Manual (Part A). Interim Final." *EPA/540/1-89/002*. Washington, D.C.: Office of Emergency and Remedial Response. U.S. Environmental Protection Agency.

22

Bioavailability: Relevance to Human Health Risk Assessment



Relevance to
- Toxicity Assessment
- Exposure Assessment

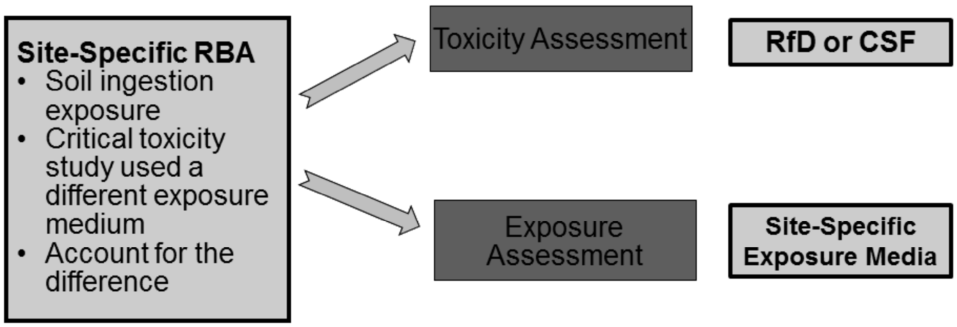
ITRC BCS-1 Figure 1-1

Source: ITRC RISK-3, Adapted from Commission 1997

Commission, Presidential/Congressional. 1997. “Framework for Environmental Health Risk Management.” Final Report, Volume 1. Washington, D. C.: The Presidential/Congressional Commission on Risk Assessment and Risk Management.

23

Bioavailability: Relevance to Toxicity Assessment and Exposure Assessment



RBA – Relative Oral Bioavailability
RfD – Reference Dose
CSF – Cancer Slope Factor

ITRC BCS-1 Section 9

No associated notes

24

Definition: Relative Oral Bioavailability (RBA)

- Comparison of bioavailability of a chemical in different dosing media

- $$\text{RBA} = \frac{\text{Absolute Bioavailability from Soil}}{\text{Absolute Bioavailability from form dosed in critical toxicity study}}$$

ITRC BCS-1 Section 1.3

No associated notes

25

Incorporation of RBA Results into Human Health Risk Assessment (HHRA)

$$\text{Exposure} = \frac{C_s \times RBA \times IR \times EF \times ED}{BW \times AT}$$

C_s	(Concentration in soil)	=	site-specific, mg/kg
RBA	(Relative bioavailability)	=	site-specific, unitless
IR	(Ingestion rate)	=	mg soil / day
EF	(Exposure Frequency)	=	days / year
ED	(Exposure Duration)	=	years
AT	(Averaging time)	=	days
BW	(Body weight)	=	kg

ITRC BCS-1 Section 9.1.3.2

26

Bioavailability Evaluation Can Apply to All Chemicals

- Including priority listed chemicals

The ATSDR 2017 Substance Priority List

2017 Rank	Substance Name
1	ARSENIC
2	LEAD
3	MERCURY
4	VINYL CHLORIDE
5	POLYCHLORINATED BIPHENYLS
6	BENZENE
7	CADMIUM
8	BENZO(A)PYRENE
9	POLYCYCLIC AROMATIC HYDROCARBONS
10	BENZO(B)FLUORANTHENE

https://www.atsdr.cdc.gov/SPL/index.html#content-main

- Although current default assumes RBA of 100% for all chemicals in soil except arsenic and lead (default 60%)

ATSDR 2017. "Substance Priority List." Agency for Toxic Substances and Disease Registry. https://www.atsdr.cdc.gov/SPL/index.html#content-main

27

Definition: Bioaccessibility

$$\text{Bioaccessible Fraction (\%)} = \frac{\text{Mass of chemical soluble from soil}}{\text{Total mass of chemical present in soil}} \times 100$$

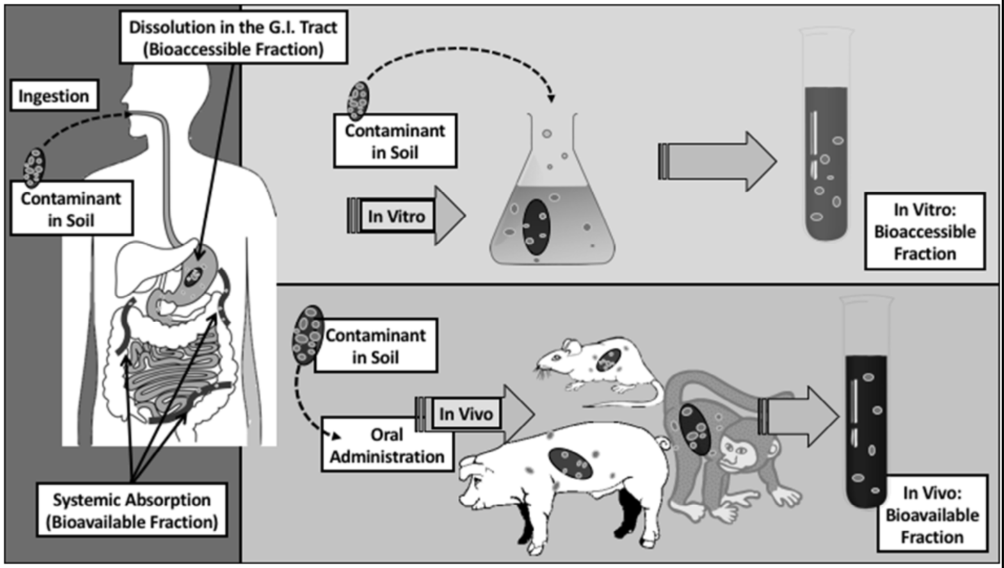
- Fraction of total amount of chemical present that is soluble / available for uptake
- In vitro methods attempt to characterize this parameter
  - In vitro bioaccessibility (IVBA)

ITRC BCS-1 Section 5.2

No associated notes

28

Schematic of Bioavailability and Bioaccessibility

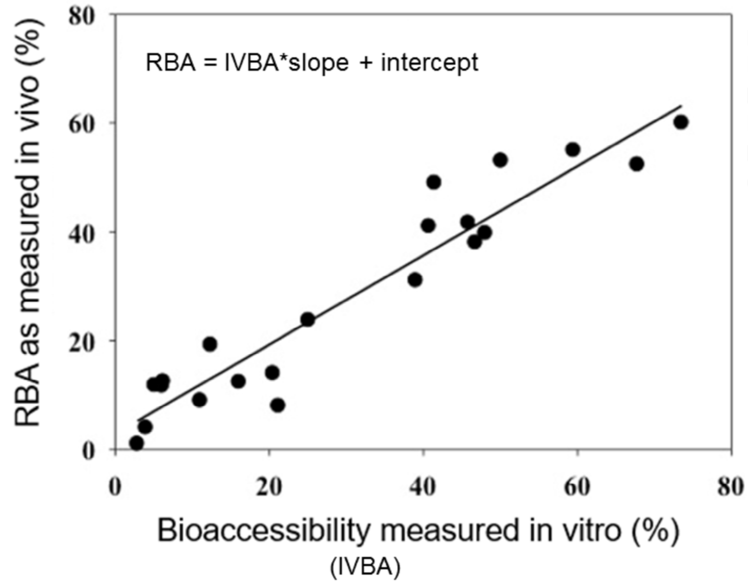


ITRC BCS-1 Figure 1-2

No associated notes

29

Developing an IVIVC to Predict RBA



RBA: Relative Oral Bioavailability

IVBA: In Vitro Bioaccessibility

IVIVC: In Vivo - In Vitro correlation

ITRC BCS-1 Figure 7-2 and Section 5.2.3

Source: DTSC 2016

“The goal of IVIVC is to promote an in vitro IVBA test method to replace in vivo RBA feeding studies. Successful IVIVC has been established when the RBA of a test soil can be determined using a predictive model (for example, simple linear regression), and meet the USEPA requirement (2007b) that “the in vitro result (entered as input) will yield an estimate of the in vivo value (as output).” If a good IVIVC has been established, then the in vitro data for soils can be used as the sole basis for adjusting RBA in a human health risk assessment” (BCS-1 document, Section 5.2.3).

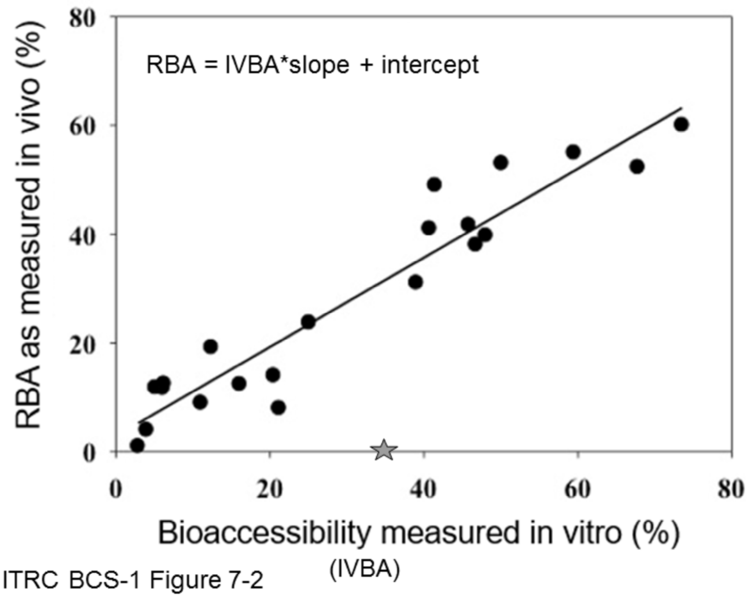
The IVIVCs for lead and arsenic that currently have approval from regulatory agencies were developed either by aggregating information about several (or many) soils that were investigated over several different studies, or were part of a large-scale study that included many soils.

Generally, IVIVC development requires significant research. So IVIVCs for use in risk assessment are generally either developed and published in the peer-reviewed literature, or developed with the involvement of regulatory agencies – and frequently both!

USEPA. 2007b. “Estimation of relative bioavailability of lead in soil and soil-like materials using in vivo and in vitro methods.” OSWER 9285.7-77. Washington, D.C.: Office of Solid Waste and Emergency Response. https://semspub.epa.gov/work/HQ/175416.pdf

30

Using an IVIVC to Predict RBA



RBA: Relative Oral Bioavailability

IVBA: In Vitro Bioaccessibility

IVIVC: In Vivo - In Vitro correlation

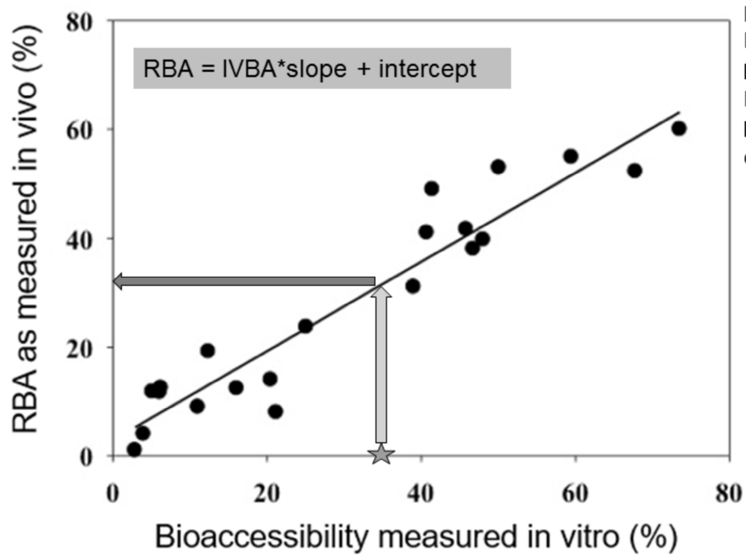
ITRC BCS-1 Figure 7-2

Source: DTSC 2016

See notes on Slide 29

31

Using an IVIVC to Predict RBA



(IVBA)

RBA: Relative Oral Bioavailability

IVBA: In Vitro Bioaccessibility

IVIVC: In Vivo - In Vitro correlation

ITRC BCS-1 Figure 7-2

Source: DTSC 2016

See notes on Slide 29.

32

Definition: In Vivo - In Vitro correlation (IVIVC)

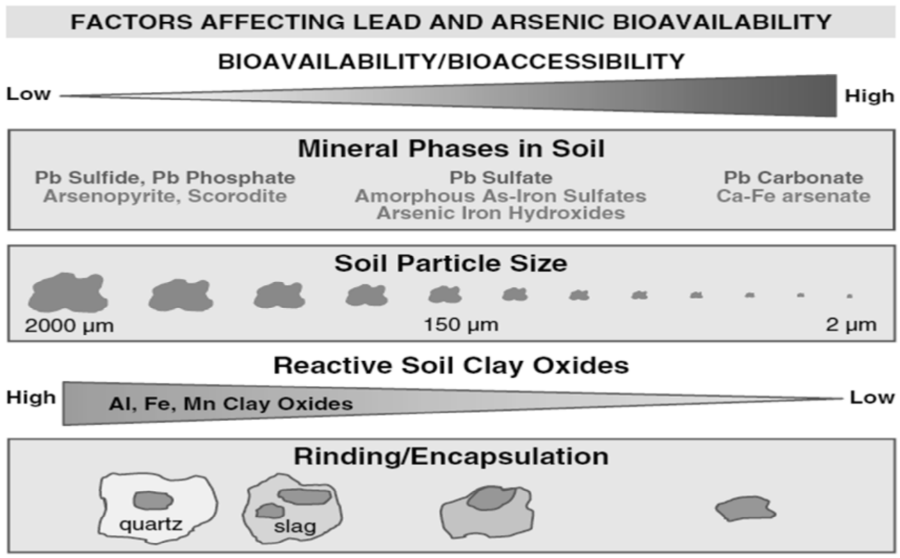
- Refers to a correlation between in vitro bioaccessibility results and in vivo bioavailability results
  - Good correlation indicates that the in vitro method provides a good prediction of bioavailability
  - Poor correlation indicates that the in vitro method is not a good predictor of bioavailability, and likely not a valid surrogate for estimating bioavailability

ITRC BCS-1 Section 5.2.3

No associated notes

33

Bioavailability Impacted by Mineralogy, Particle Size, Encapsulation, Soil Properties



ITRC BCS-1 Figure 3-1

No associated notes.

34

Regulatory Recognition of Using Bioavailability for Risk Assessment

Poll Question

- Lead: specific guidance on using bioavailability in the risk assessment of lead-contaminated sites (USEPA 2007)
- Arsenic: Significant efforts to summarize and evaluate the bioavailability of arsenic from soil (USEPA 2012, USEPA 2017a,b,c)
- Completed a review of the available information on dioxins (USEPA 2015)
- Guidance to evaluate arsenic from California and Hawaii (DTSC 2016, Hawaii DOH, 2010, 2012)
- Several site-specific precedents
  - Pb, As, Cd, dioxins, PAHs.

ITRC BCS-1 Section 2

Poll Question: Does the state you work in use bioavailability when assessing risk?

- Yes

- No

-Don’t Know

35

Today's Training Road Map

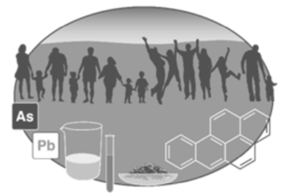
Importance of Evaluating Bioavailability in Soils

↓

Bioavailability Basics

↓

➡ Case Study 1 (Arsenic Site)



↓

Questions and Answers

↓

Case Study 2 (Lead Site)

↓

Discussion: Polycyclic Aromatic Hydrocarbons (PAHs)

↓

Taking Action

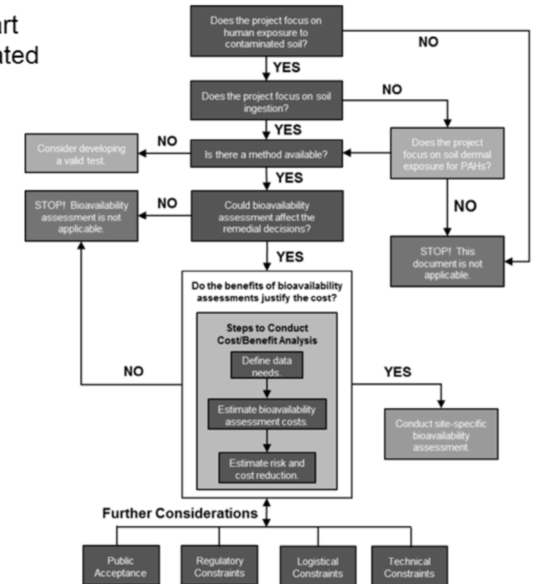
Questions and Answers

No associated notes.

36

Considerations for Bioavailability Decision Process Flowchart

Full size flow chart available in "Related Links"

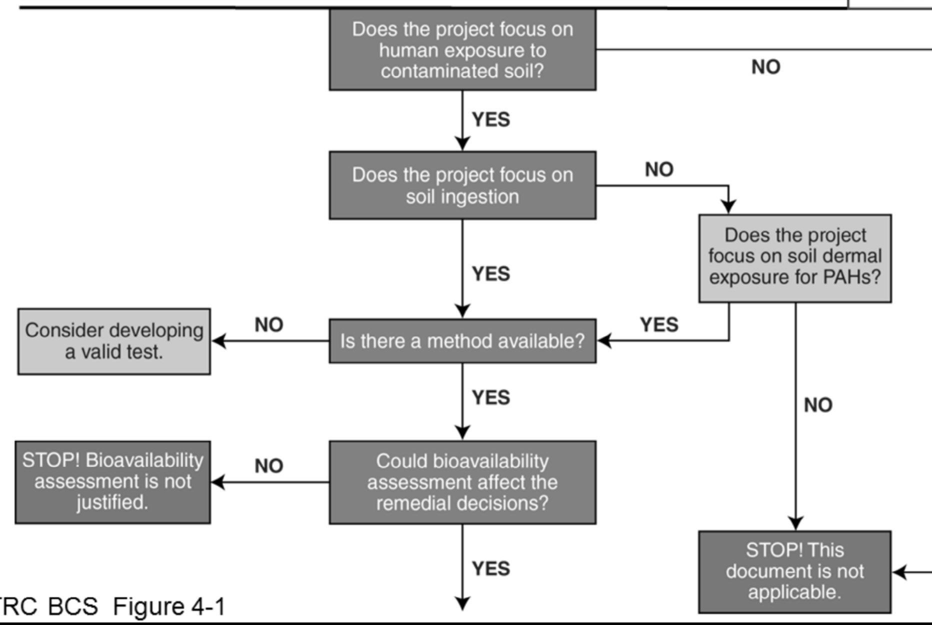


ITRC BCS-1 Figure 4-1

No associated notes

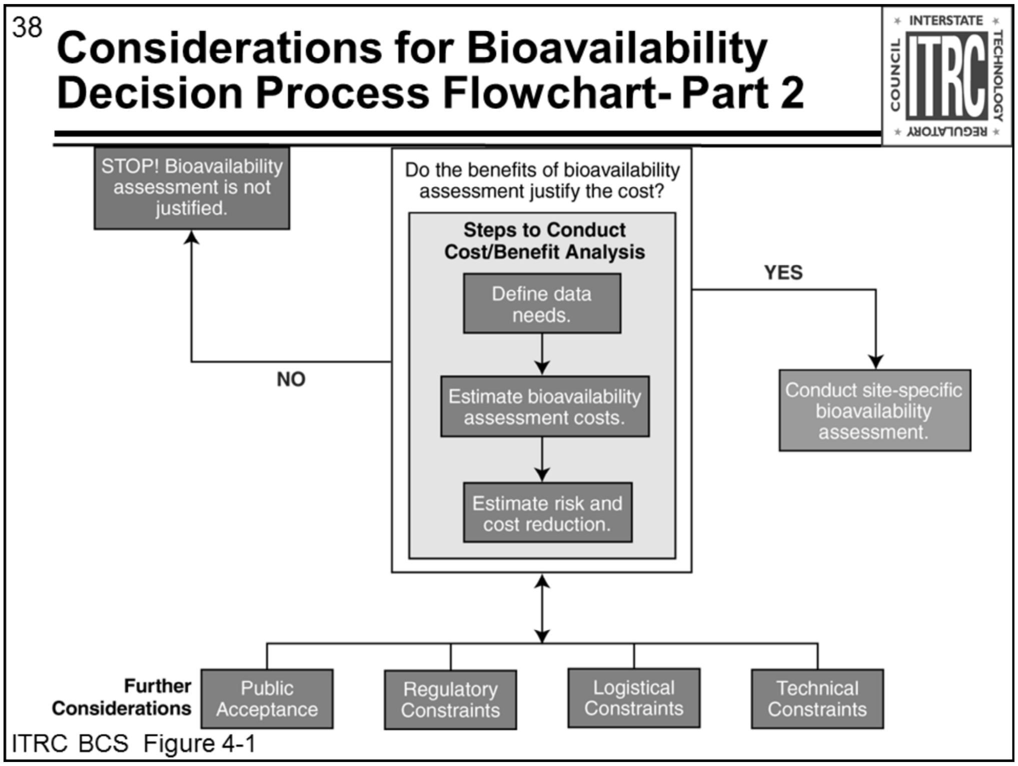
37

Considerations for Bioavailability Decision Process Flowchart- Part 1



ITRC BCS Figure 4-1

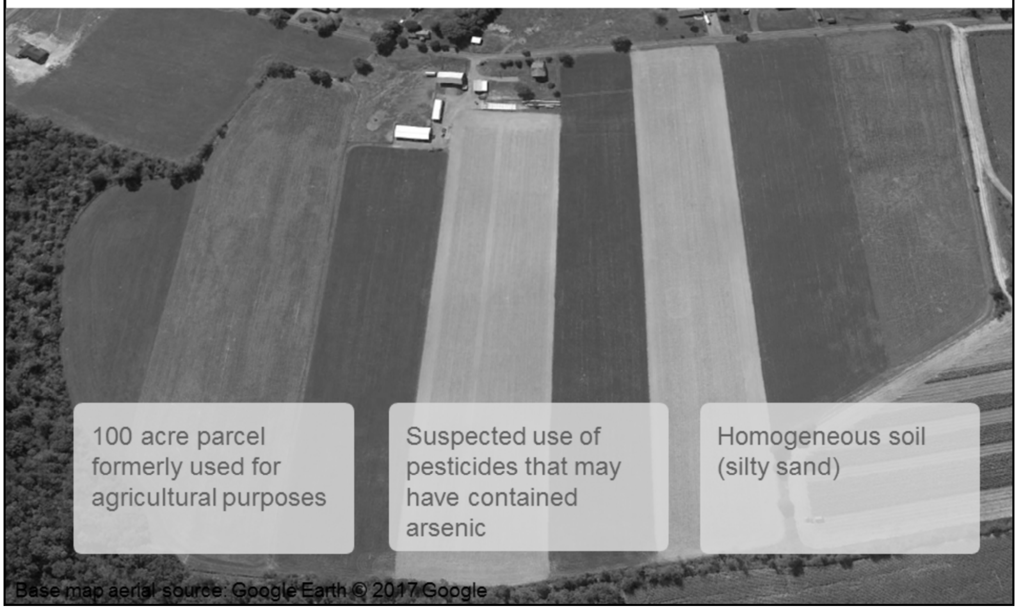
No associated notes



No associated notes

39

Arsenic Case Study: Former Agricultural Parcel



No associated notes.

40

Arsenic Case Study: Usage and Activity Boundaries

No associated notes

41

Considerations for Bioavailability Decision Process Flowchart

Does the project focus on human exposure to contaminated soil?

ITRC BCS Figure 4-1

No associated notes.

Arsenic Case Study: Planned Mixed Use Redevelopment

No associated notes.

Arsenic Case Study: Residential Land Use

Photo courtesy of K. Long

No associated notes.

44

Arsenic Case Study: Residential Land Use

Photo courtesy of K. Long

No associated notes.

45

Arsenic Case Study: Residential Land Use

Photo courtesy of V. Hanley

No associated notes.

46

Arsenic Case Study: Recreational Land Use

Photo courtesy of K. Long

No associated notes.

47

Considerations for Bioavailability Decision Process Flowchart

Does the project focus on soil ingestion

ITRC BCS Figure 4-1

No associated notes.

48

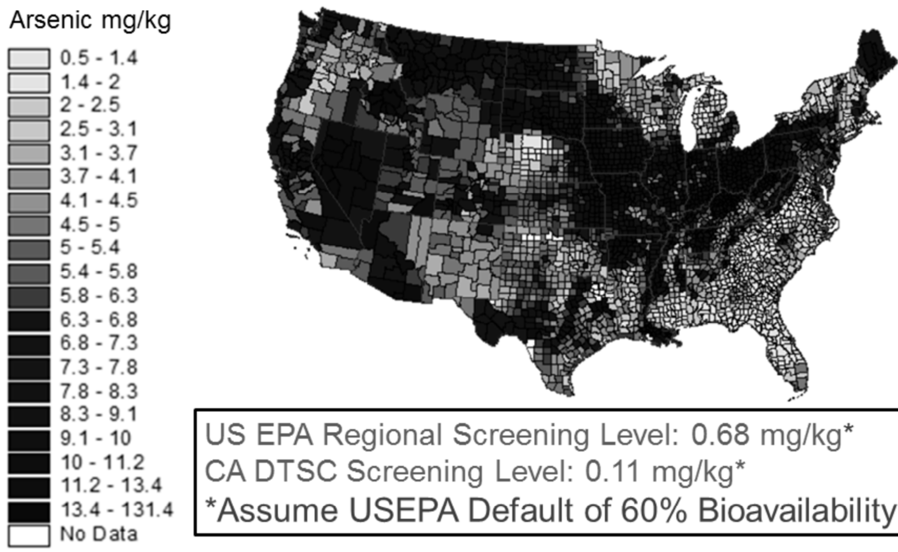
Incorporation of RBA Results into Human Health Risk Assessment (HHRA)

$$\text{Exposure} = \frac{C_s \times RBA \times IR \times EF \times ED}{BW \times AT}$$

C_s	(Concentration in soil)	=	site-specific, mg/kg
RBA	(Relative bioavailability)	=	site-specific, unitless
IR	(Ingestion rate)	=	mg soil / day
EF	(Exposure Frequency)	=	days / year
ED	(Exposure Duration)	=	years
AT	(Averaging time)	=	days
BW	(Body weight)	=	kg

ITRC BCS-1 Section 9.1.3.2

Background Arsenic in Soils > Residential Risk-based Concentrations



US EPA Regional Screening Level: 0.68 mg/kg*

CA DTSC Screening Level: 0.11 mg/kg*

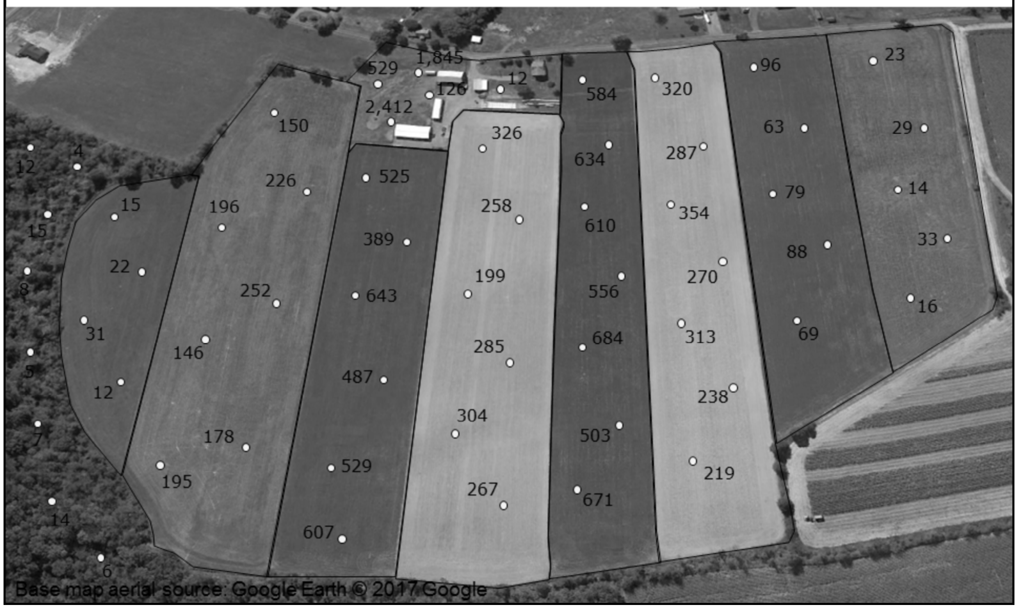
*Assume USEPA Default of 60% Bioavailability

Source USGS 2008:
https://mrdata.usgs.gov/geochem/doc/averages/as/usa.html

ITRC BCS-1 Figure 7-1

USGS (United States Geological Survey). 2008. “National Geochemical Survey, Geochemistry by County.” https://mrdata.usgs.gov/geochem/doc/averages/countydata.htm.

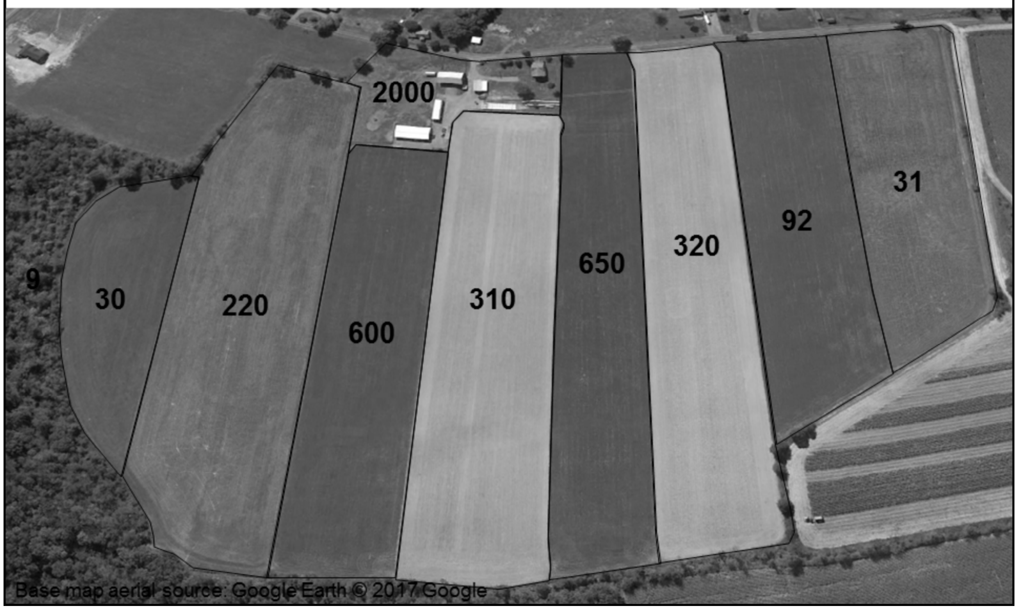
Arsenic Case Study: Measured Concentrations (mg/kg)



No associated notes.

51

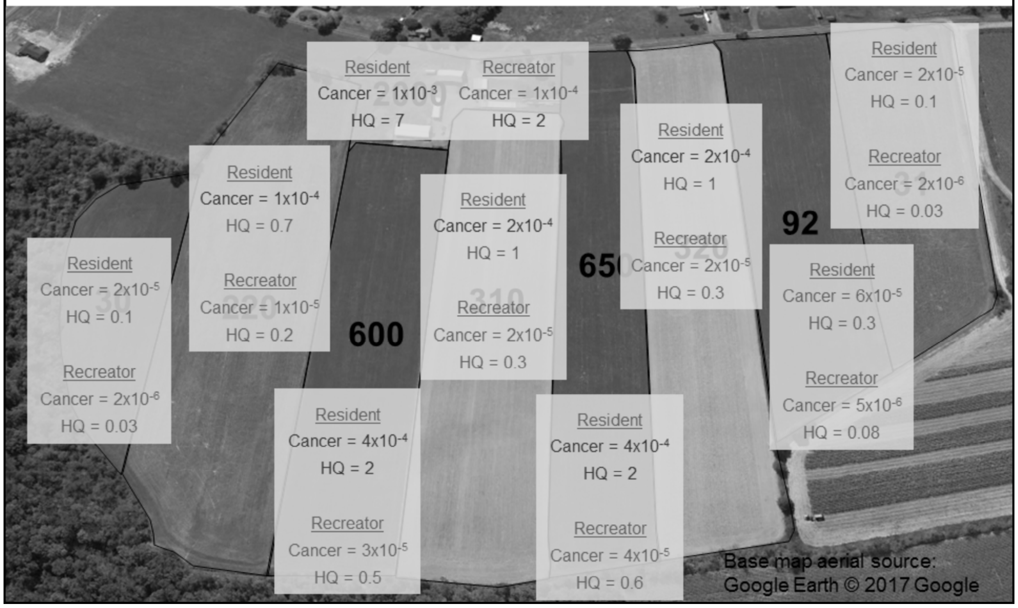
Arsenic Case Study: Average Concentrations (mg/kg)



No associated notes

52

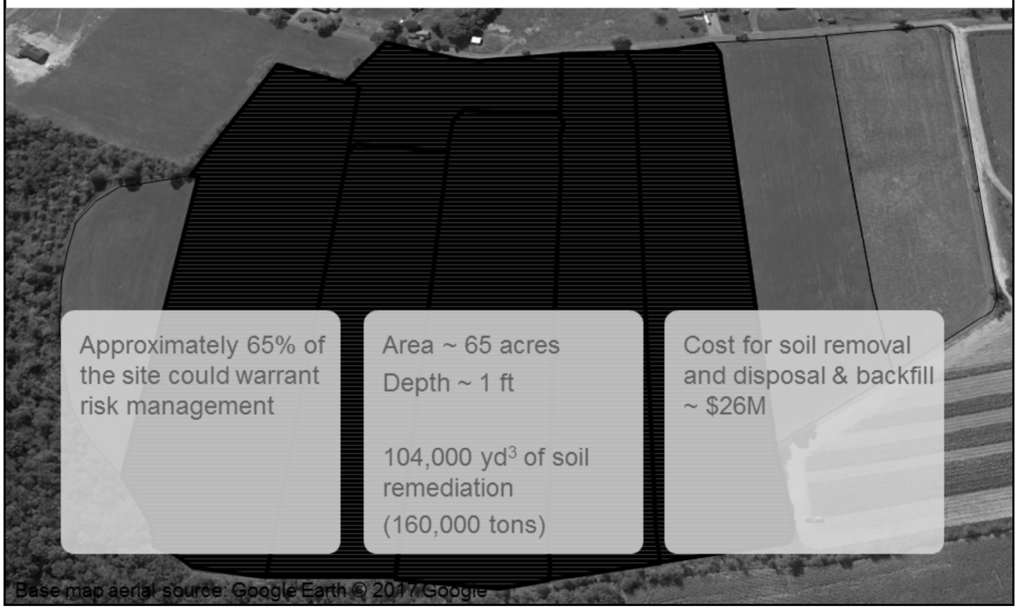
Arsenic Case Study: Risk Characterization (60% RBA)



No associated notes

53

Arsenic Case Study: Areas Warranting Remediation (60% RBA)



No associated notes

54

Considerations for Bioavailability Decision Process Flowchart

Is there a method available?

ITRC BCS Figure 4-1

No associated notes.

55

Available Methods for Determining Arsenic Bioavailability In Vivo

Animal model	Biomarkers of arsenic exposure	Reference
Juvenile Swine	Steady state urinary excretion	Rodriguez et al. 1999; Casteel et al. 2006; Weis and LaVelle, 1991; Basta et al. 2007; Denys et al. 2012; Brattin and Casteel 2013
	Single dose blood AUC	USEPA 1996; Juhasz et al. 2007, 2008
Mice (C57BL/6)	Steady state urinary excretion	Bradham et al. 2011
Monkeys (*Cebus*, *Cynomolgus*)	Single dose urinary excretion	Freeman et al. 1995; Roberts et al. 2002, 2007; USEPA 2009

ITRC BCS-1 Table 7-1

No associated notes.

56

Available Methods for Determining Arsenic Bioavailability In Vitro

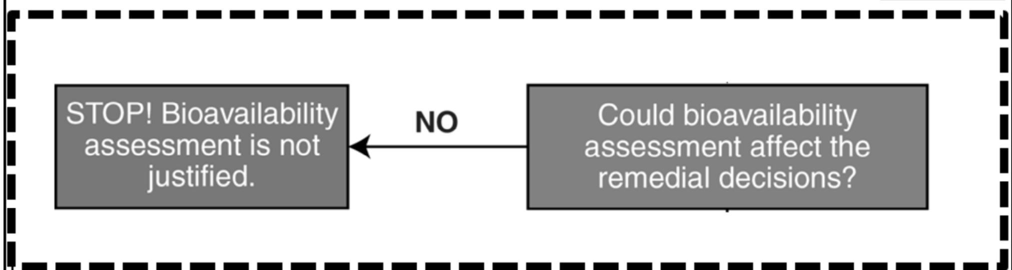
Method	Key Reference	Notes
USEPA Method 1340 **Also known as RBALP, SBRC, and USEPA 9200**	Diamond et al. 2016	Method adopted by USEPA. Guidance issued May 2017 https://semspub.epa.gov/work/HQ/196750.pdf
California Arsenic Bioaccessibility Method (CAB)	Whitacre et al. 2017	Method adopted by California DTSC Guidance issued Aug. 2016 http://www.dtsc.ca.gov/AssessingRisk/upload/HHRA-Note-6-CAB-Method-082216.pdf
Unified BARGE Method (UBM)	Wragg et al.2011 Denys et al. 2012	ISO certification (17924) – widely used throughout Europe. https://www.bgs.ac.uk/barge/home.html
In Vitro Gastrointestinal Method (IVG)	Basta et al. 2007 Rodriguez et al., 1999	No regulatory guidance exists to support this method. First published method to report strong IVIVC, but did not include interlaboratory round robin study necessary for regulatory guidance and approval by USEPA.
Physiological Based Extraction Test (PBET)	Ruby et al. 1996	No regulatory guidance exists to support this method.

ITRC BCS-1 Table 7-3

No associated notes.

57

Considerations for Bioavailability Decision Process Flowchart



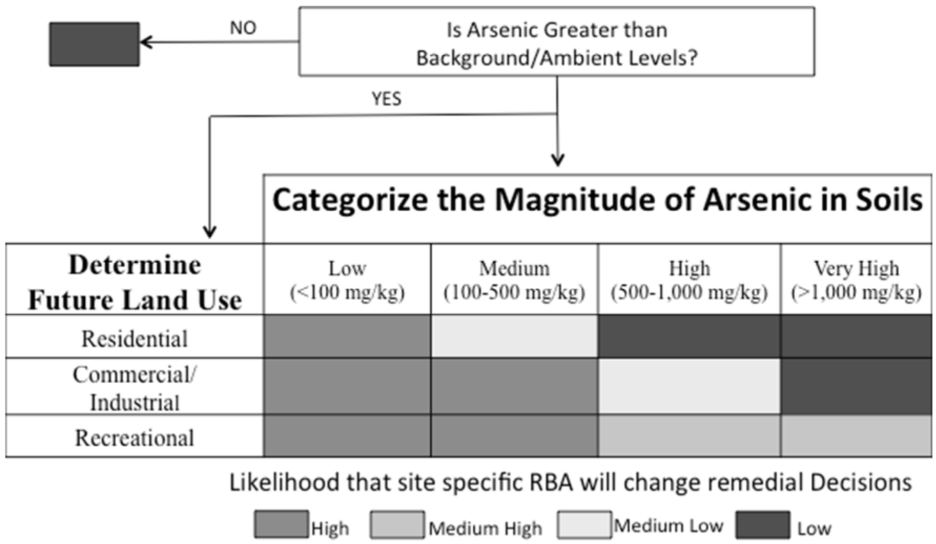
ITRC BCS Figure 4-1

No associated notes.

58

Likelihood of RBA Affecting Remediation Decisions for Arsenic-contaminated Sites

RBA – Relative Oral Bioavailability



ITRC BCS Figure 7-3

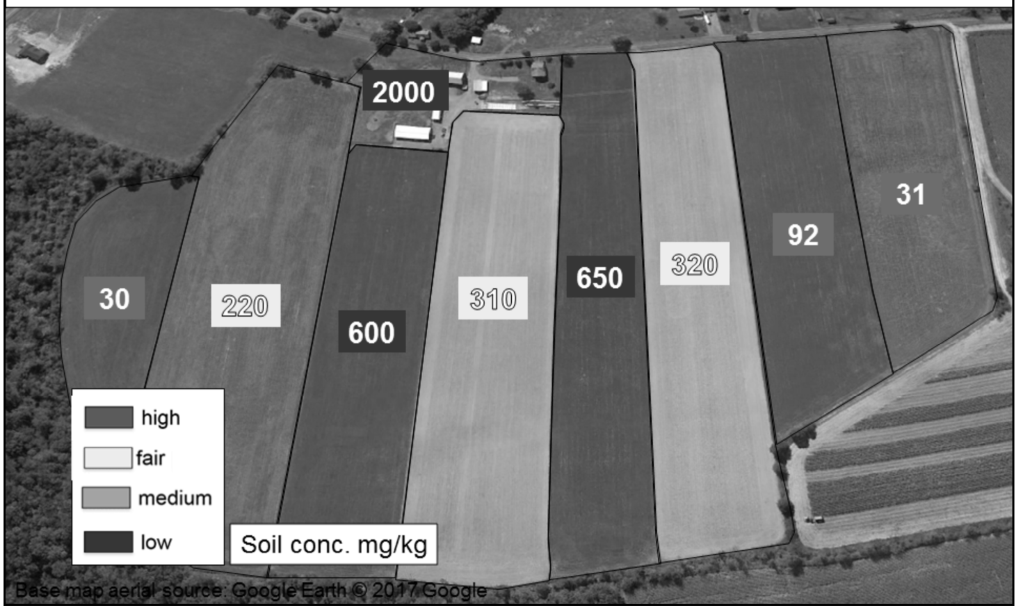
Source: Adapted from California DTSC 2016

DTSC. 2016. "Human Health Risk Assessment Note 6: Recommended Methodology for Evaluating Site-Specific Arsenic Bioavailability in California Soils." Sacramento, CA: California Environmental Protection Agency. https://www.dtsc.ca.gov/AssessingRisk/upload/HHRA-Note-6-CAB-Method.pdf

59

Will RBA Affect Remediation Decisions? Residential Exposure

RBA – Relative Oral Bioavailability

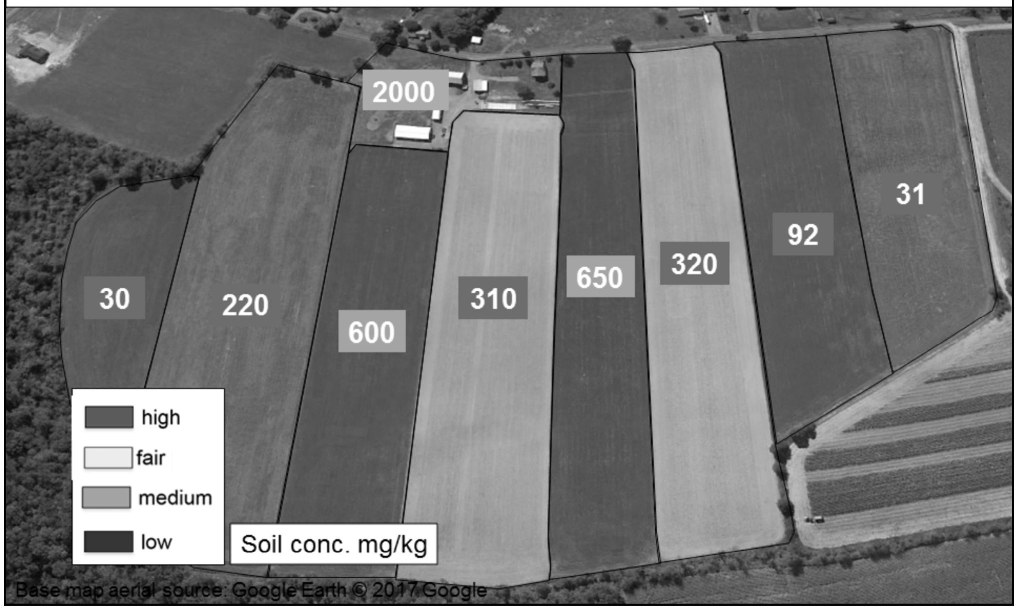


No associated notes

60

Will RBA Affect Remediation Decisions? Recreational Exposure

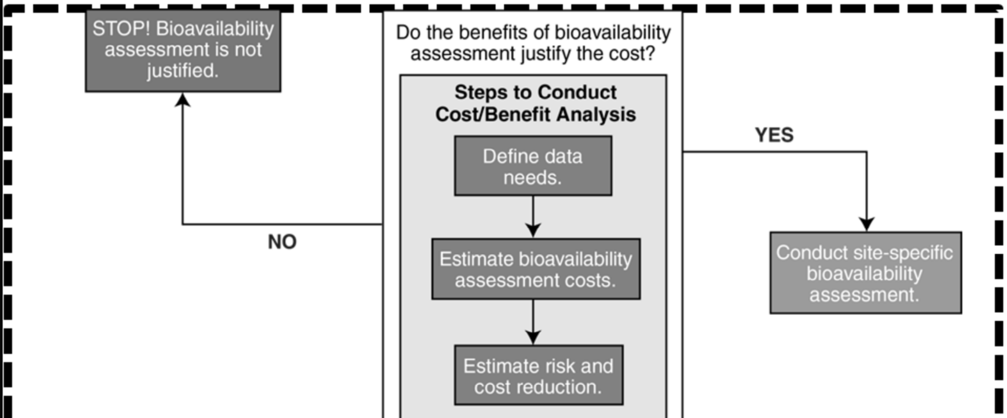
RBA – Relative Oral Bioavailability



No associated notes

61

Considerations for Bioavailability Decision Process Flowchart



ITRC BCS Figure 4-1

No associated notes.

62

Poll Question

Poll Question

- How much do you think the in vitro bioavailability study would cost for this site?
  - $1,000
  - $20,000
  - $100,000

Poll Question: How much do you think the in vitro bioavailability study would cost for this site?

$1,000

$20,000

$100,000

63

Approximate Costs for Bioavailability Analysis

Analysis	Approximate Unit Cost Per Sample (USD)	Provider
Soil properties	$500-$1,000 (per sample)	Commercial labs
Soil mineralogy	$200-$1,000 (per sample)	Academic and commercial labs
IVBA for Pb or As	$150–$1,000 (per sample)	Academic and commercial labs
IVBA for PAHs	$350 - $1000 (per sample)	Academic and commercial labs
In vivo (mouse, rat)	$25,000-$30,000 (per study)	Academic or government labs
In vivo (swine)	$75,000 (for 3 soils, metals only)	Academic labs
In vivo (primate)	$90,000 (for three soils, metals only)	Academic labs

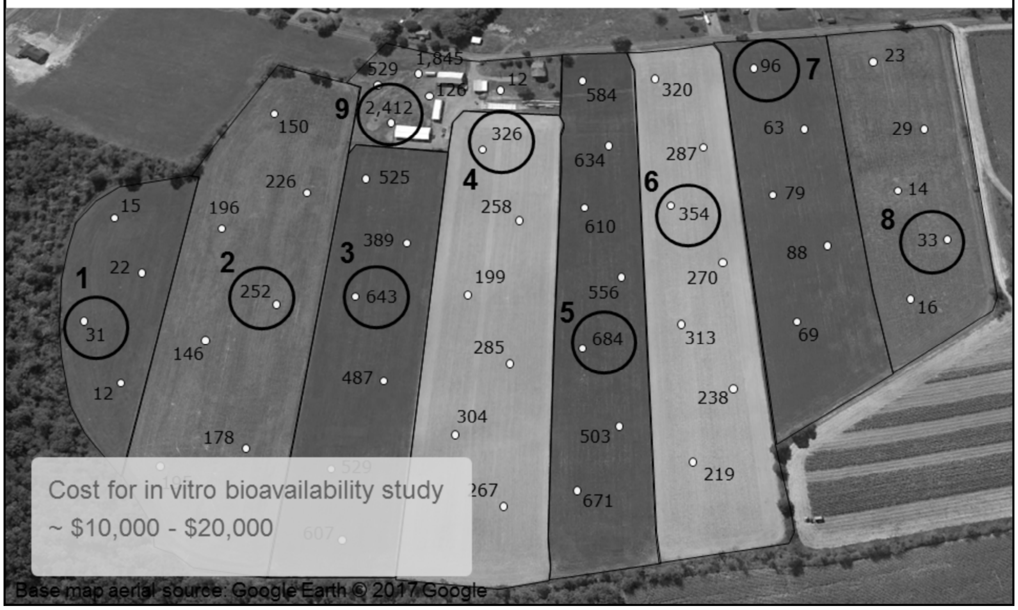
ITRC BCS-1 Table 4-1

Cost data collected in 2015-16

No associated notes.

64

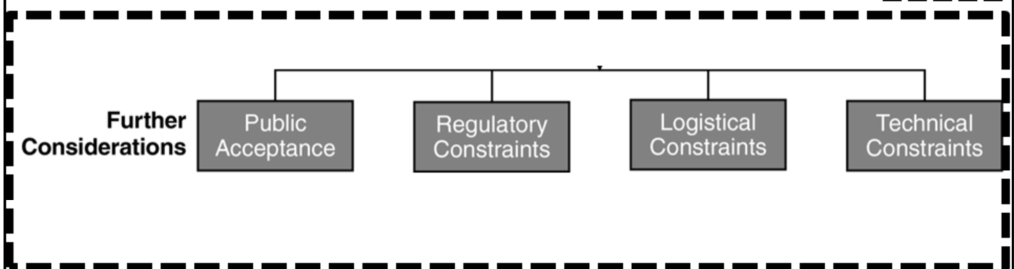
Arsenic Case Study: Conducting Bioavailability Study



No associated notes

65

Considerations for Bioavailability Decision Process Flowchart

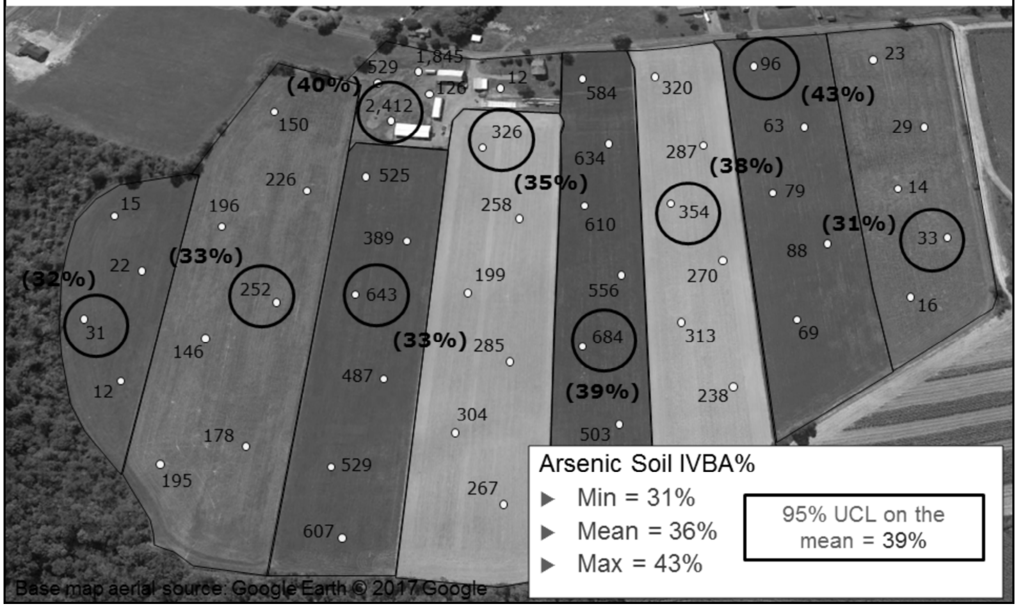


ITRC BCS Figure 4-1

No associated notes

66

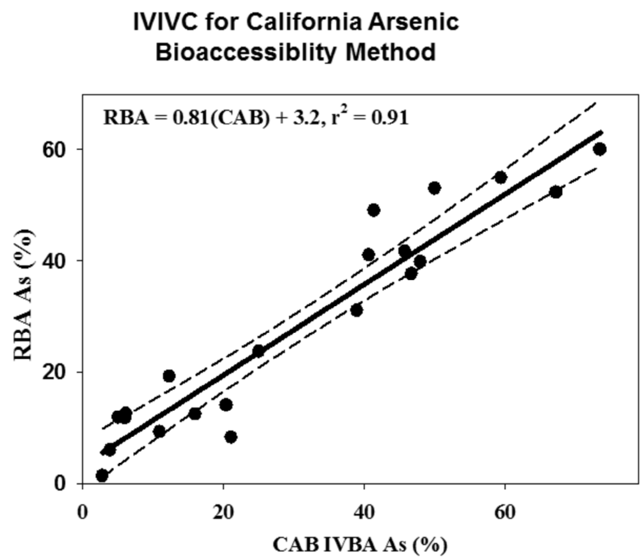
Arsenic Case Study: Conducting Bioavailability Study



No associated notes

67

In Vivo-In Vitro Correlation (IVIVC) Using IVBA (%) to Predict RBA (%)



IVBA = 39%
RBA = 35%

ITRC BCS-1 Figure 7-2

Source: DTSC 2016

In vitro analysis gives IVBA %, which can be used to determine RBA using a validated IVIVC. This is an example from the CAB method

DTSC. 2016. "Human Health Risk Assessment Note 6: Recommended Methodology for Evaluating Site-Specific Arsenic Bioavailability in California Soils." Sacramento, CA: California Environmental Protection Agency. https://www.dtsc.ca.gov/AssessingRisk/upload/HHRA-Note-6-CAB-Method.pdf

68 **Arsenic Case Study: Incorporation of Results into Human Health Risk Assessment (HHRA)**

- Cancer Risk

$$ELCR = \frac{C_s \times \boxed{RBA} \times IR \times EF \times ED}{(1/CSF) \times BW \times AT \times CF}$$

- Non-Cancer Hazard

$$HQ = \frac{C_s \times \boxed{RBA} \times IR \times EF \times ED}{RfD \times BW \times AT \times CF}$$

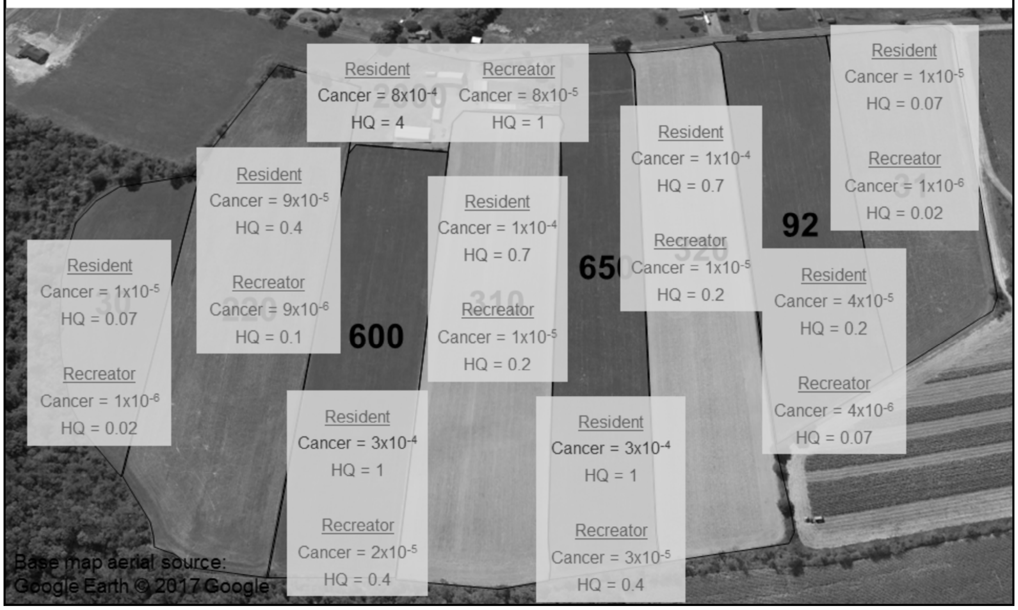
AT	(Averaging time)	=	days (for cancer – 70 years x 365 days/year; for noncancer - ED x 365 days/year)
BW	(Body weight)	=	kg
C_s	(Concentration in soil)	=	site-specific, mg/kg
CF	(Conversion factor)	=	1.0E+6 mg/kg
CSF	(Cancer slope factor)	=	chemical-specific, $(mg/kg\text{-}day)^{-1}$
ED	(Exposure duration)	=	years
EF	(Exposure frequency)	=	days/year
ELCR	(Excess Lifetime Cancer risk)	=	unitless
HQ	(Hazard quotient)	=	unitless
IR	(Ingestion rate)	=	mg/day
RBA	(Relative bioavailability)	=	site-specific, unitless
RfD	(Oral reference dose)	=	chemical-specific, mg/kg-day

ITRC BCS-1 Section 9.1.3.2

No associated notes

69 Arsenic Case Study: Risk Characterization (35% RBA)

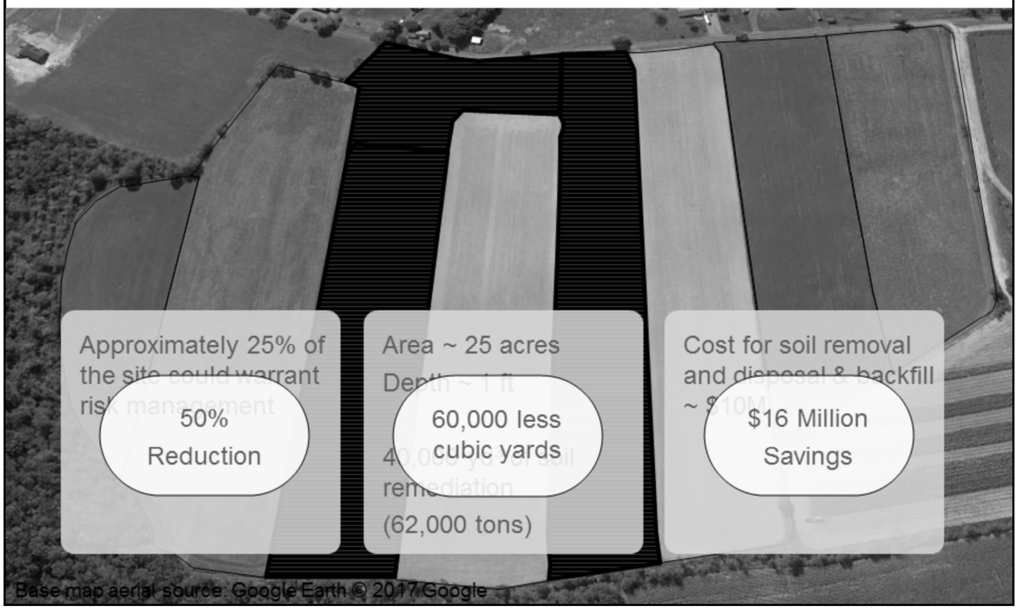
RBA – Relative Oral Bioavailability



No associated notes

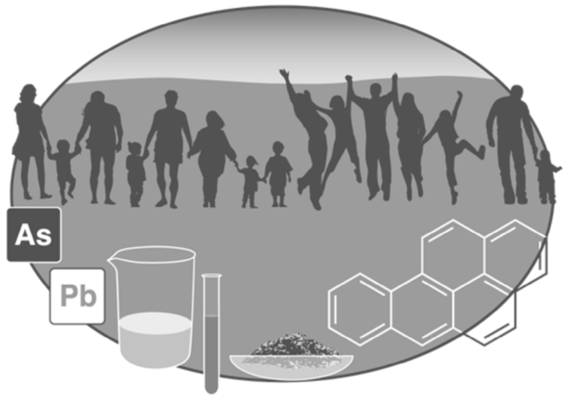
70 **Arsenic Case Study: Areas Warranting Remediation (35% RBA)**

RBA – Relative Oral Bioavailability



No associated notes

Question and Answer Break



No associated notes

72

Today's Training Road Map

Importance of Evaluating Bioavailability in Soils

↓

Bioavailability Basics

↓

Case Study 1 (Arsenic Site)

↓

Questions and Answers

↓

➡ Case Study 2 (Lead Site)

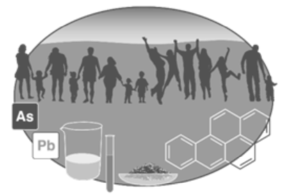
↓

Discussion: Polycyclic Aromatic Hydrocarbons (PAHs)

↓

Taking Action

Questions and Answers



No associated notes.

73

Lead Case Study

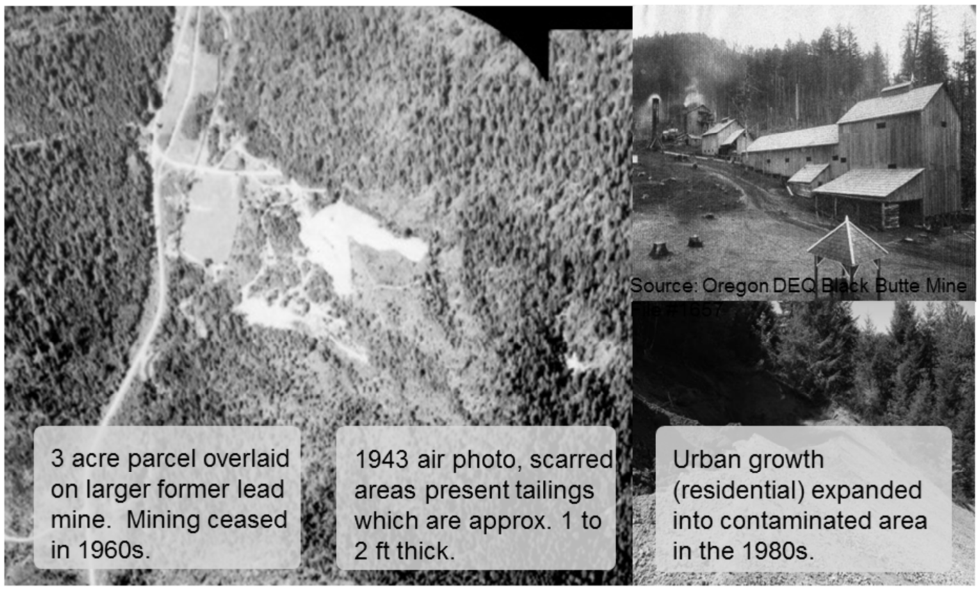
- Case study is presented as a series of meetings between regulator and consultant
- Historic lead mining area
- Contaminant source – lead tailings
- Residential area
- Future land uses are residential and commercial

Source: Pixnio.com

No associated notes

74

Lead Case Study: Former Lead Mining Area



No associated notes

75

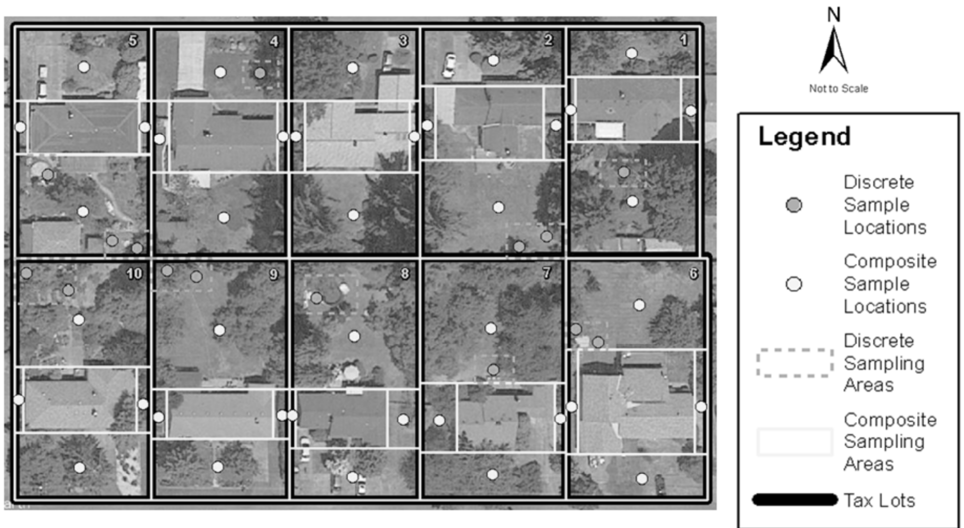
Lead Case Study: Site is Now a Residential Area

Base map aerial source: Google Earth © 2017 Google Map Data © Google 2017

No associated notes.

76

Lead Case Study: Soil Samples Collected on All Properties for Total Lead



Source: Google Earth

Lead-Contaminated Residential Sites handbook
https://semspub.epa.gov/work/HQ/175343.pdf

Base map aerial source: Google Earth © 2017 Google

USEPA. 2003. “Superfund lead-contaminated residential sites handbook.” *OSWER 9285.7-50*. Washington, D.C.: Office of Emergency and Remedial Response.

77

Lead Case Study: Total Lead Sampling Complete

- Available samples for nature & extent
  - 10 properties; 4 yards each (1 composite sample/yard) = 40 samples
  - 5 properties with gardens (2 discrete samples/garden) = 10 samples
  - 5 properties with play areas (1 discrete sample/play area) = 5 samples
- Total lead concentrations
  - 380 to 1,321 mg/kg, arithmetic mean = 850 mg/kg, low standard deviation
- Background - 30 mg/kg
- Soil type – Well graded gravel with fines and thin organic silt at surface


Source: Pixnio.com

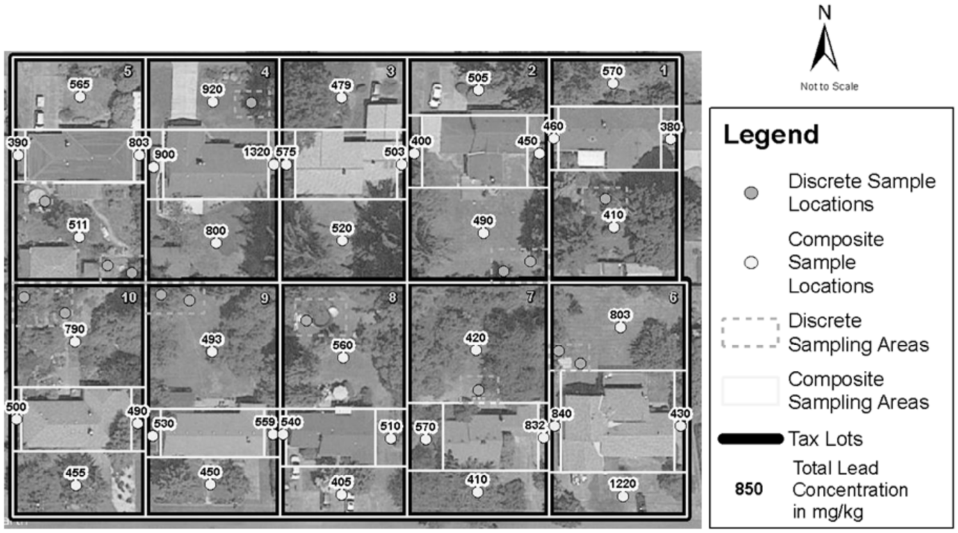

Source: User:Srl/Wikimedia Commons/CC-BY-SA-3.0


Source: Pixnio.com

No associated notes

78

Lead Case Study: All Properties Exceed Default Cleanup Level



Base map aerial source: Google Earth © 2017 Google

Current state residential screening level = 400 mg/kg

No associated notes

79

Lead Case Study: Estimated Costs Could Justify a Site-Specific Bioavailability Study

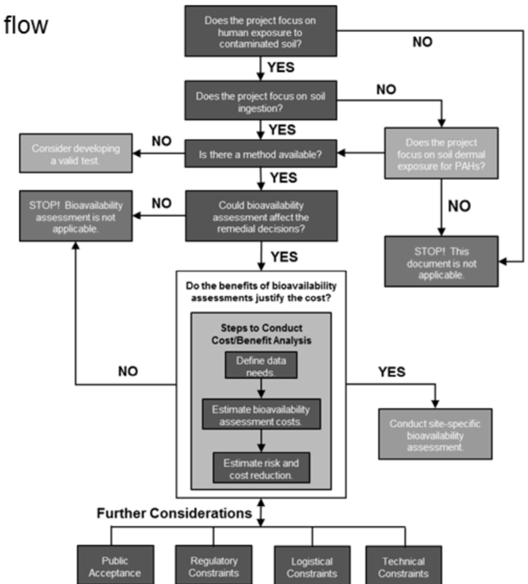
- Excavation volume based on nature & extent sampling
  - 3 acres
  - 1 to 2 ft depth
  - ~5,000 cy
- Estimated excavation cost = $700,000
- ~250 truck trips @ 20 yards each during remediation
- Disposal is large portion of $
- ~2 weeks for excavation and yard restoration

No associated notes

80

Lead Case Study: Need to Determine if Bioavailability Study is Worthwhile

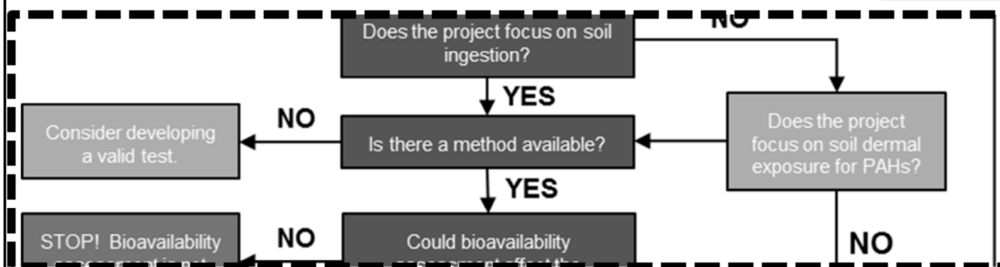
Full size decision flow chart available in "Related Links"



ITRC BCS-1 Figure 4-1

No associated notes

Lead Case Study: Methodology?



ITRC BCS-1 Section 6.3.3

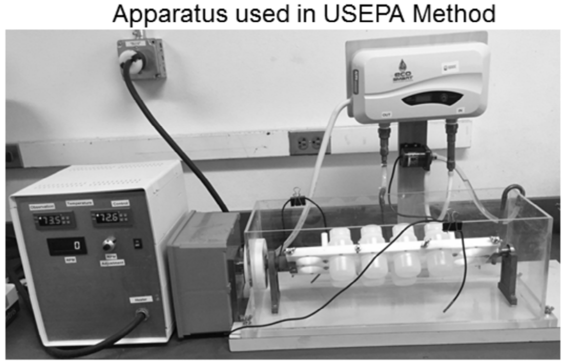
No associated notes

82

Lead Case Study: USEPA Recent Guidance on Lead IVBA Testing

- USEPA "Standard Operating Procedure for an In Vitro Bioaccessibility Assay for Lead and Arsenic in Soil" (2017) – Method 1340
- Soil Bioavailability at Superfund Sites Web Page
  https://www.epa.gov/superfund/soil-bioavailability-superfund-sites-guidance

Apparatus used in USEPA Method



ITRC BCS-1 Section 6.3.3

Photo courtesy of Geoff Siemering, University of Wisconsin, 2017

USEPA. 2017c. "Method 1340 In Vitro Bioaccessibility Assay for Lead in Soil." *SW-846 Update VI*. Washington, D. C.

https://www.epa.gov/superfund/soil-bioavailability-superfund-sites-guidance

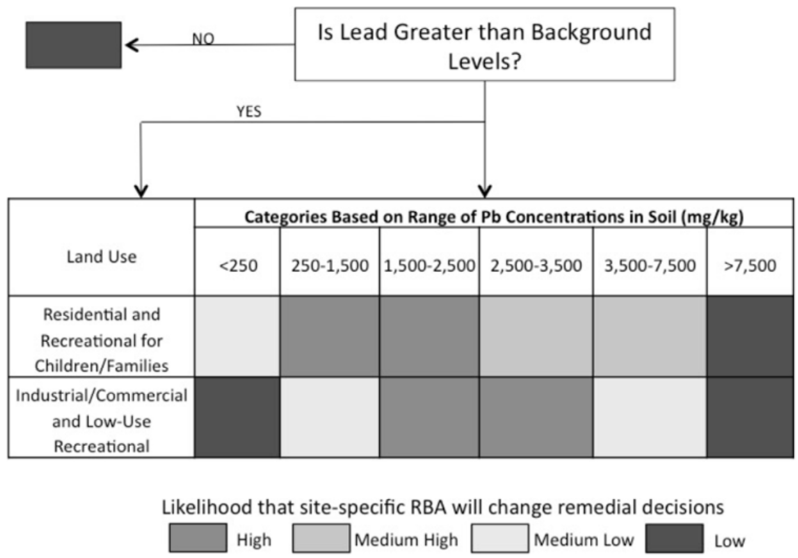
83

Lead Case Study: Should Studies be In Vitro or In Vivo?

- Reasons we don't need in vivo
  - Lead has been well studied with a variety of soils with good in vivo - in vitro correlation
  - Site soil is well-characterized
  - Site soil type & waste type are similar to those tested by USEPA
  - Site soil type has an established in vivo – in vitro correlation

No associated notes

Lead Case Study: Bioavailability Study Could Affect Remediation Decisions

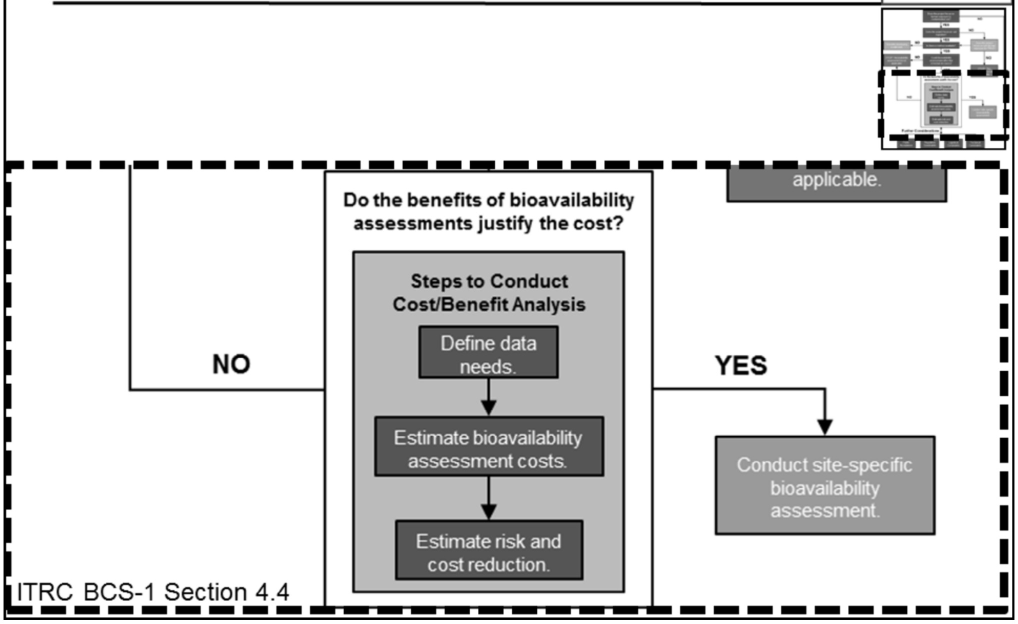


ITRC BCS-1 Figure 6-3

No associated notes

85

Lead Case Study: Cost Benefit Analysis

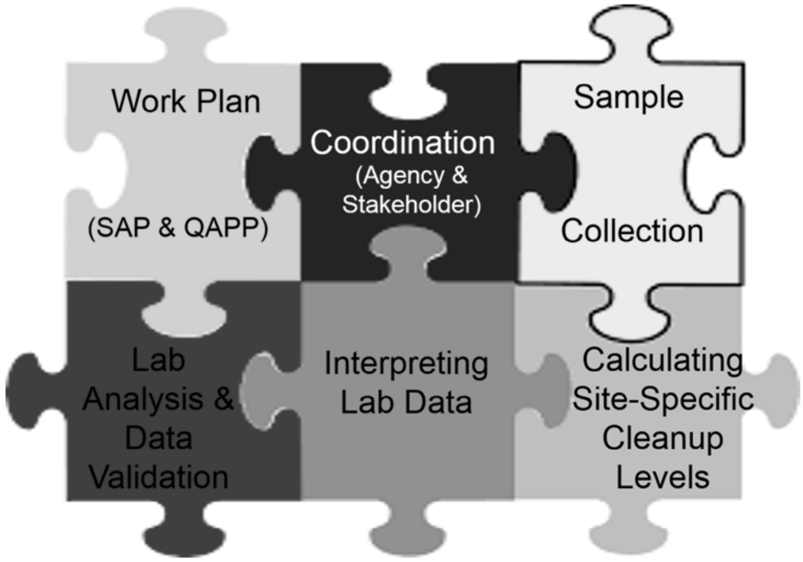


ITRC BCS-1 Section 4.4

No associated notes

86

Lead Case Study: Bioavailability Study has Various Components



ITRC BCS-1 Section 4.4

No associated notes

Poll Question

Poll Question

- How many samples should be collected for bioavailability testing (not including duplicate samples) at this 3-acre site? (Note: nature & extent sampling is complete)
  - 1 incremental sample across 3 acres
  - 2 incremental samples across 3 acres
  - 10 incremental samples across 3 acres
  - 1 discrete sample per property
  - 2 discrete samples per property

Source: pixabay.com

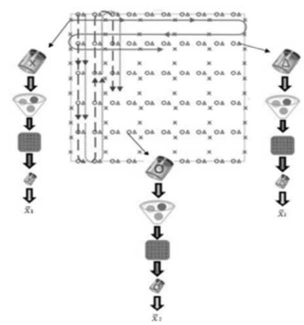
No associated notes.

88

Lead Case Study: Guidance on Lead Sampling for IVBA Testing

- USEPA "Guidance for Sample Collection for In Vitro Bioaccessibility Assay for Lead (Pb) in Soil" (2015)
  - "2 composites made up of 30 increments"
  - "In general, for most risk assessment applications, acceptable Type I error rate can be expected if ITRC (2012) recommendations are followed (30 increments per composite"
- Equal representation (volume, depth) from all increments
- Collected in triplicate
- ITRC ISM guidance at www.itrcweb.org/ism-1

INCREMENTAL SAMPLING DESIGN



ITRC BCS-1 Section 9.1.6

ITRC ISM-1 Figure 1-2

USEPA. 2015a. "Guidance for Sample Collection for Bioaccessibility Assay for Lead (Pb) in Soil." *OSWER 9200.3-100*.

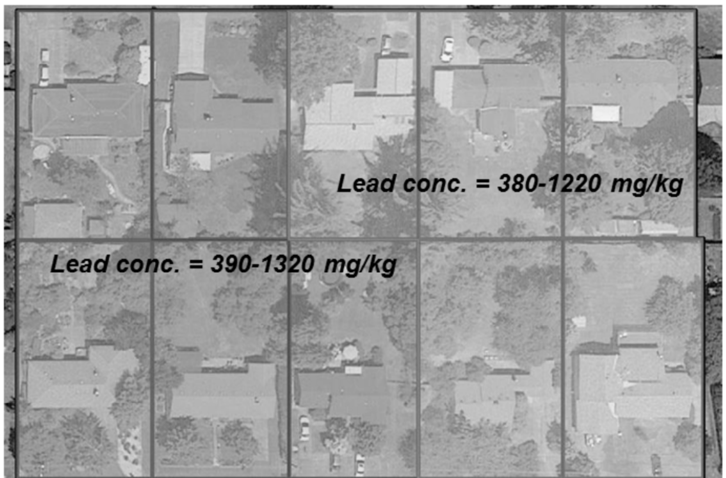
https://www.epa.gov/superfund/soil-bioavailability-superfund-sites-guidance#lead

ITRC. 2012. "Incremental Sampling Methodology." *ISM-1*. Washington, D.C.: Interstate Technology & Regulatory Council, Incremental Sampling Methodology

https://www.epa.gov/superfund/soil-bioavailability-superfund-sites-guidance Team. www.itrcweb.org/ism-1.

89

Lead Case Study: Where Should IVBA Samples be Collected?



Source: Google Earth
Base map aerial source: Google Earth © 2017 Google

DU could be the entire area or property boundary

Single source of lead - agreed on 2 DUs with a similar concentration range

Sample across entire DU because fill is present in whole DU and exposures occur anywhere

1 triplicate incremental sample in each DU

DU = decision unit

ITRC BCS-1 Section 9.1.6

No associated notes

90

Lead Case Study: Use USEPA Guidance on Soil Sieving

- USEPA "Recommendations for Sieving Soil and Dust Samples at Lead Sites for Assessment of Incidental Ingestion" (2016)
- Sieve soil to <150 µm
- Reasonable upper-bound estimate of the soil/dust fraction that is most likely to stick to hands/ objects and be ingested
- Potential for lead enrichment in <150 µm particles at some sites
- Size fraction recommended for IVBA studies

Photo courtesy of Geoff Siemering, University of Wisconsin, 2017

USEPA. 2016e. "Recommendations for sieving soil and dust samples at lead sites for assessment of incidental ingestion. ." *OLEM Directive 9200.1-128*. Washington, D.C.: USEPA.

https://www.epa.gov/superfund/lead-superfund-sites-guidance#sampling

91

Lead Case Study: Potential Cost Impacts on the Project

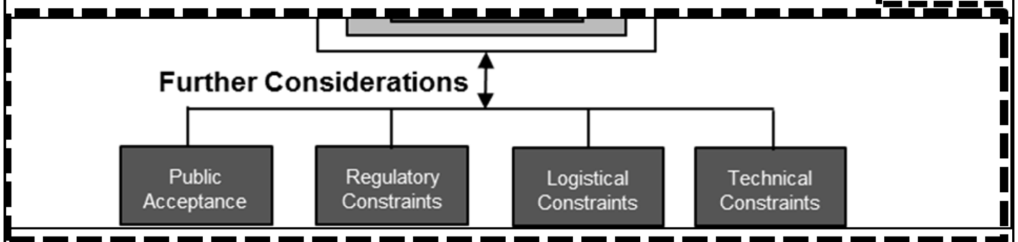
- Without bioavailability study (based on existing nature & extent sampling only)
  - excavation volume = 5000 cy (1-2 ft. depth, 3 acres)
  - ~$700,000
- After bioavailability study (potentially)
  - Possible RBA = 20 to 30%
  - Excavation volume = 0 cy
  - ~$30,000 (cost of study)
    - Work planning
    - Sampling & analysis
    - Reporting
  - Remedy will be protective

Photo Source: Oregon DEQ Black Butte Mine File #1657

No associated notes

92

Lead Case Study: Further Considerations



- Not addressed in previous public meetings
- Prepare Fact Sheet with overview of bioavailability concepts and study details
- Further discussed in ITRC document

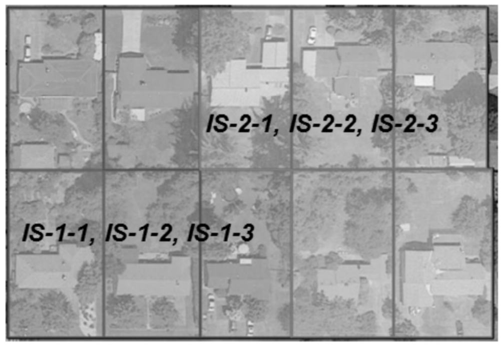
ITRC BCS-1 Section 4.5

No associated notes

93

Lead Case Study: Planning Meeting Resolved Path Forward

- Use USEPA Method 1340
- Divide site into 2 decision units
- Collect an incremental sample in triplicate from each decision unit
- Calculate site-specific soil cleanup levels using results



Base map aerial source: Google Earth © 2017 Google

No associated notes

94

Lead Case Study: Follow-up Meeting Held to Discuss Study Results

- Work Plan was submitted and approved
- Bioavailability study samples were collected
- Laboratory provided results for the samples
- Meeting between agency and consultant

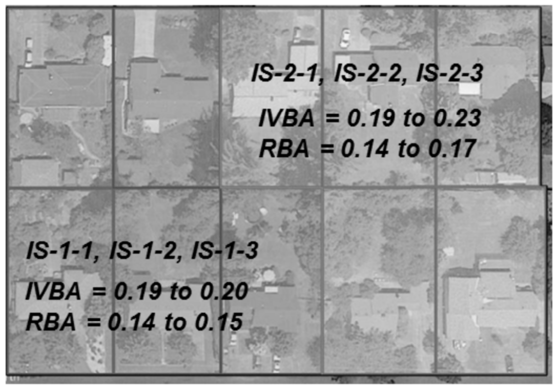
Source: Pixnio.com

No associated notes

95

Lead Case Study: RBA Predicted from IVBA

- Laboratory measured in vitro bioaccessibility (IVBA)
- Used data to predict relative bioavailability (RBA)
- Linear regression model established by USEPA (2007): $RBA = 0.88 \times IVBA - 0.028$



ITRC BCS-1 Section 9.1.9.2

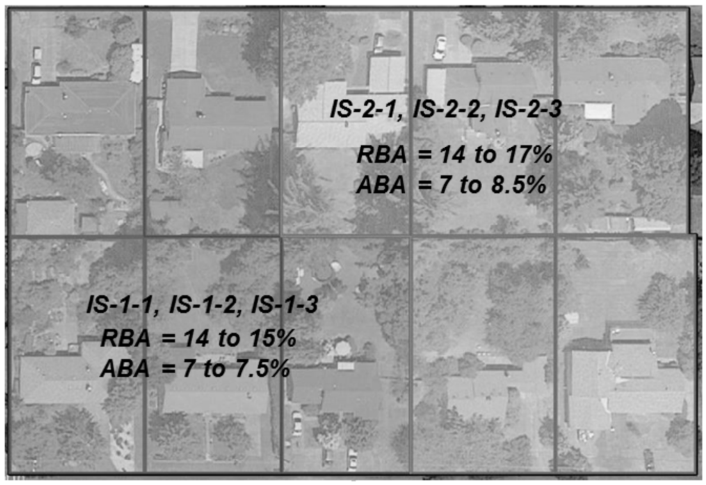
Base map aerial source: Google Earth © 2017 Google

No associated notes

96

Lead Case Study: Absolute Bioavailability (ABA) Results Similar Between Samples

$ABA_{soil} = 50\% \times RBA_{soil}$



Source: Google Earth

ABA:
The fraction of an ingested dose that is absorbed and reaches systemic circulation

ITRC BCS-1 Section 9.1.9.2

Base map aerial source: Google Earth © 2017 Google

No associated notes

97

Poll Question

Poll Question

- What RBA % would you use in a site-specific risk-based cleanup level calculation?
  - Maximum of 6 values (17%)
  - Average of 6 values (15%)
  - Higher 95% UCL on the mean of the 2 triplicate samples (16.5%)

No associated notes.

98 **Lead Case Study: Site-specific Bioavailability Data Incorporated into Lead Models**

- Pharmacokinetic models are used to evaluate lead exposures
- Residential land use – Integrated Exposure Uptake Biokinetic (IEUBK) Model
- Commercial land use – Adult Lead Methodology
- Default RBA in models is 60%
- Guidance document discusses methodology to incorporate site-specific RBA
- Site-specific RBA data reduces uncertainty

ITRC BCS-1 Section 9.1.9.2

No associated notes

99

USEPA Recently Published Guidance on Target Blood Lead Levels

- USEPA "Update of the Adult Lead Methodology's Default Baseline Blood Lead Concentration and Geometric Standard Deviation Parameters and the Integrated Exposure Uptake Biokinetic Model's Default Maternal Blood Lead Concentration at Birth Variable" (2017)

  "OLEM recognizes adverse health effects as blood lead concentrations below 10 ug/dL. Accordingly, OLEM is updating the soil lead strategy to incorporate this new information."

  (OLEM = USEPA Office of Land and Emergency Management)

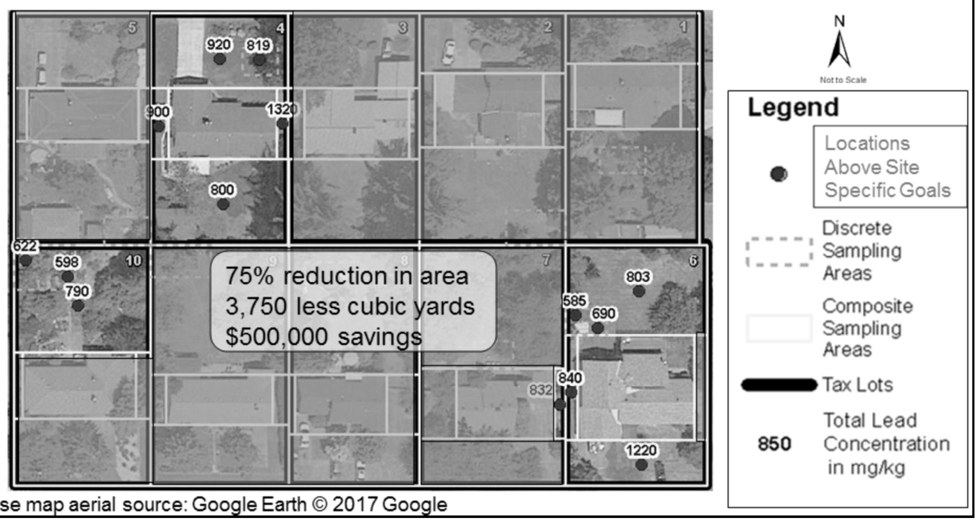
- ITRC RISK-3 (2015) – Section 5.1.5 addresses lead toxicity and blood lead levels

https://www.epa.gov/superfund/lead-superfund-sites-guidance#adultlead

100

Lead Case Study: Area Warranting Remediation (16.5% RBA) – Residential

- Lower site-specific RBA than default (lower site risk)
- Site-specific cleanup level = 580 mg/kg (5 µg/dL blood lead target, 16.5% RBA)
- State default cleanup level = 400 mg/kg (10 µg/dL blood lead target, 60% RBA)



Base map aerial source: Google Earth © 2017 Google

No associated notes.

101

Lead Case Study: No Area Warranting Remediation (16.5% RBA) - Commercial

- Potential for future commercial zoning
- Lower site-specific RBA than default (lower site risk)
- Site-specific cleanup level = 3,800 mg/kg (5 µg/dL blood lead target, 16.5% RBA)
- State default cleanup level = 800 mg/kg (10 µg/dL blood lead target, 60% RBA)
- No excavation needed for commercial land use (but ICs needed)
  - ITRC guidance: http://institutionalcontrols.itrcweb.org/

Base map aerial source: Google Earth © 2017 Google

No associated notes

102

Lead Case Study: Site-Specific Bioavailability Results Useful for Decisions

- Reduces:
  - Uncertainty in site risk and risk-based cleanup
  - Disruption of residents
  - Remediation-related risks (e.g., truck traffic, tree damage)
  - Remedial action costs
- Provides:
  - Additional site-specific data to supplement nature and extent sampling
  - Decisions protective of human health
  - Achievement of same target risk level
  - Flexibility of remedial options
  - Stakeholder outreach is important throughout

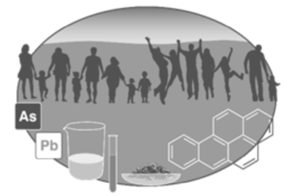
No associated notes

103

Today's Training Road Map

Importance of Evaluating Bioavailability in Soils

Bioavailability Basics



Case Study 1 (Arsenic Site)

Questions and Answers

Case Study 2 (Lead Site)

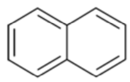
Discussion: Polycyclic Aromatic Hydrocarbons (PAHs)

Taking Action
Questions and Answers

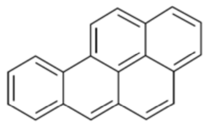
No associated notes.

104

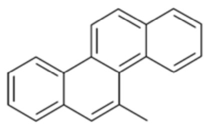
Bioavailability of PAHs from Soil



Naphthalene



Benzo[a]pyrene



5-Methylchrysene

SERDP PROJECT
ER-1743
January, 2017

- Polycyclic Aromatic Hydrocarbons (PAHs)
  - Over 10,000 individual chemicals
- Seven PAHs currently considered carcinogenic by USEPA
  - 4 rings: benz(a)anthracene, chrysene
  - 5 rings: benzo(a) pyrene, benzo(b)fluoranthene, benzo(k)fluoranthene, dibenz(a,h)anthracene
  - 6 rings: Indeno(1,2,3-c,d)pyrene
- Lipophilic, log Kow range from 5.2 to 6.6
- Low water solubility (0.01 to 0.00076 ug/mL)
- Low vapor pressure (6.3E-7 to 9.6E-11 mm Hg)

ITRC BCS-1 Section 8

Images from Final Report SERDP Project ER-1743 “PAH Interactions with Soil and Effects on Bioaccessibility and Bioavailability to Humans.”

105

Sources of PAHs in Soil

Type	PAH Source	Primary PAH-bearing Materials
Natural	Forest fires	Soot, char
	Grass fires	Soot, char
	Volcanic eruptions	Soot, char
	Oil seeps	Weathered crude oil
Industrial	Manufactured gas plants	Coal tar, pitch, coal, char, soot
	Coking operations	Coal tar, coal, coke, soot
	Aluminum production	Coal tar pitch (making and disposing of anodes)
	Foundries	Coal tar pitch, creosote, fuel oil (used in making sand casts), soot
	Wood treating	Creosote
	Refineries	Soot, various NAPLs (crude oil, fuel oil, diesel)
	Carbon black manufacture	Soot, oil tar
	Fuel spills and/or disposal	Various NAPLs (crude oil, fuel oil, waste oil, diesel)
Non-industrial Sources	Skeet	Coal tar pitch or bitumen (used as binder in targets)
	Asphalt sealants	Coal tar
	Landfills	Creosote (treated wood), soot, char
	Incinerators (municipal, hospital)	Soot
	Open burning	Soot, char
	Fire training	Soot
	Fires	Soot, char
	Auto/truck emissions	Soot

Photos: publicdomainpictures.net; pxhere.com; wikimedia.org

Table Source: Reprinted with permission from (Ruby, M.V., Y.W. Lowney, A.L. Bunge, S.M. Roberts, J.L. Gomez-Eyles, U. Ghosh, J. Kissel, P. Tomlinson, and C.A. Menzie. "Oral Bioavailability, Bioaccessibility, and Dermal Absorption of PAHs from Soil – State of the Science." Environmental Science & Technology 50, no. 5 (2016): 2151-64. Table 1), Copyright 2016 American Chemical Society.

Table Source: Reprinted with permission from (Ruby, M.V., Y.W. Lowney, A.L. Bunge, S.M. Roberts, J.L. Gomez-Eyles, U. Ghosh, J. Kissel, P. Tomlinson, and C.A. Menzie. "Oral Bioavailability, Bioaccessibility, and Dermal Absorption of PAHs from Soil – State of the Science." Environmental Science & Technology 50, no. 5 (2016): 2151-64. Table 1), Copyright 2016 American Chemical Society.

106

State of the Science: Bioavailability of PAHs from Soil

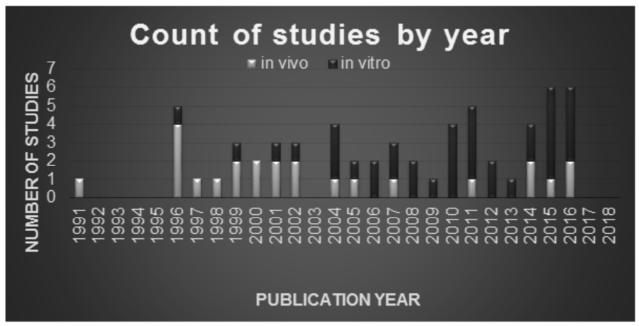
- Among the most common chemicals of concern at contaminated sites
- Current regulatory default is to assume that the RBA of PAHs in soil is 100%
  - Assumes absorption of PAHs from soil equivalent to absorption from PAH-spiked food

No associated notes.

State of the Science: Bioavailability of PAHs from Soil

- ▶ Considerable interest in incorporating bioavailability estimates in HHRA
- ▶ Over 60 studies performed (including in vivo and in vitro studies)
- ▶ Studies have supported site-specific RBA values for use in HHRA

- Elucidating factors controlling binding of PAHs to soil
- Still no consensus on in vitro nor even in vivo methods



Source: Alloy 2017

Alloy 2017. http://www.cleanupconference.com/wp-content/uploads/2017/09/CleanUp_2017_Proceedings_Low-Res.pdf

108

Evaluating RBA of Organics from Soil

Studying RBA of organic chemicals is harder than metals!

- Methods for estimating bioavailability
  - Lagged behind metals such as lead and arsenic
  - Assessment is complex
- Chemical Mixture
- Analytical costs
- Metabolism
  - Hepatic (in the liver)
  - Target tissue
  - Microbial
  - Multiple metabolites
- Enterohepatic recirculation
  - Most absorbed PAHs are returned to the GI tract through bile and some are reabsorbed
- IVBA requires simulated intestinal environment

ITRC BCS-1 Section 8

No associated notes

109 **Key Considerations in Study Design**

ITRC Document Provides Useful Information to Assess Studies

- Appropriate soil particle size
- Relevant comparison group
- Linearity of pharmacokinetics
- Repeated versus single dose
- Measurement of parent compound, metabolites, or both
- Adequate number of subjects
- Relevant concentrations/doses, number of different doses
- Ability to demonstrate full range of RBA
- Average versus individual subject RBA measurements
- Mass balance

ITRC BCS-1 Section 5

No associated notes

110

Key Considerations in Study Design

ITRC Document Provides Overview Specific to PAHs

- Sources
- Toxicity
- Factors influencing RBA from soil
- In vivo and in vitro methods
- Summary of research conducted to date
- Considerations for dermal absorption
- Case study

ITRC BCS-1 Section 8

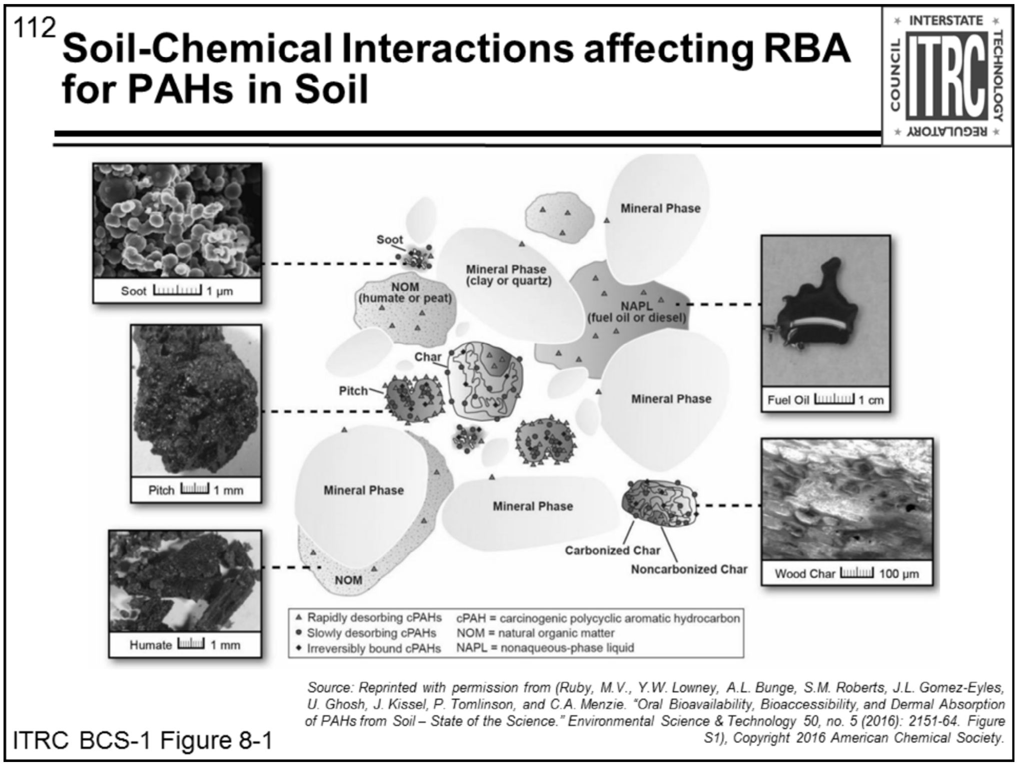
No associated notes

111

Bioavailability of PAHs from Soil What We Know

- Source of PAHs to soil dominates partitioning (in vitro) and RBA (in vivo)
- Some sources have higher RBA, others significantly reduced relative to soluble forms
  - Lower RBA: Soot, Skeet, Pitch
  - Higher: Fuel oil, Non-aqueous phase liquid (NAPL)
- Soil characteristics are less important to controlling RBA (peat, clay content)
- Addition of charcoal to the soil reduces RBA
- Dermal exposure pathway important to calculated exposures
- More work to be done – and is being done!

No associated notes



Source: Reprinted with permission from (Ruby, M.V., Y.W. Lowney, A.L. Bunge, S.M. Roberts, J.L. Gomez-Eyles, U. Ghosh, J. Kissel, P. Tomlinson, and C.A. Menzie. "Oral Bioavailability, Bioaccessibility, and Dermal Absorption of PAHs from Soil – State of the Science." Environmental Science & Technology 50, no. 5 (2016): 2151-64. Figure S1), Copyright 2016 American Chemical Society.

113

Today's Training Road Map

Importance of Evaluating Bioavailability in Soils

↓

Bioavailability Basics

↓

Case Study 1 (Arsenic Site)

↓

Questions and Answers

↓

Case Study 2 (Lead Site)

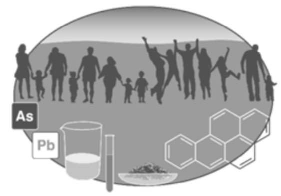
↓

Discussion: Polycyclic Aromatic Hydrocarbons (PAHs)

↓

➡ Taking Action

Questions and Answers



No associated notes.

114

Online Document – ITRC BCS-1
http://bcs-1.itrcweb.org/

Bioavailability of Contaminants in Soil: Considerations for Human Health Risk Assessment HOME

This ITRC guidance describes how to integrate bioavailability information into the human health risk assessment to improve the decision-making process.
Regulators, practitioners, and stakeholders will find help performing the following tasks:

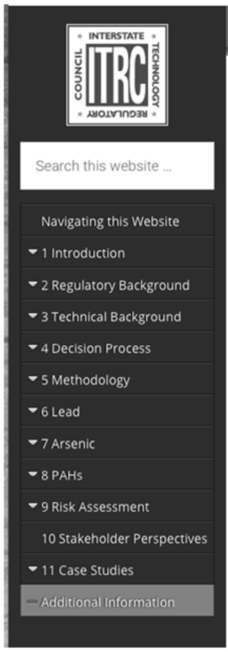
- select and properly interpret site-specific bioavailability testing information
- understand the strengths and weaknesses of different in vivo and in vitro methods
- consider the factors for selecting the most appropriate approaches for a site-specific evaluation of bioavailability of contaminants in soil without compromising the level of protectiveness for human health
- use the appropriate tools to develop site-specific bioavailability values in human health risk assessment.

If you are visiting this site for the first time please review the **Introduction** of this guidance.
All users may find **Navigating this Website** helpful.

No associated notes

115

Bioavailability of Contaminants in Soil: Considerations for Human Health Risk Assessment

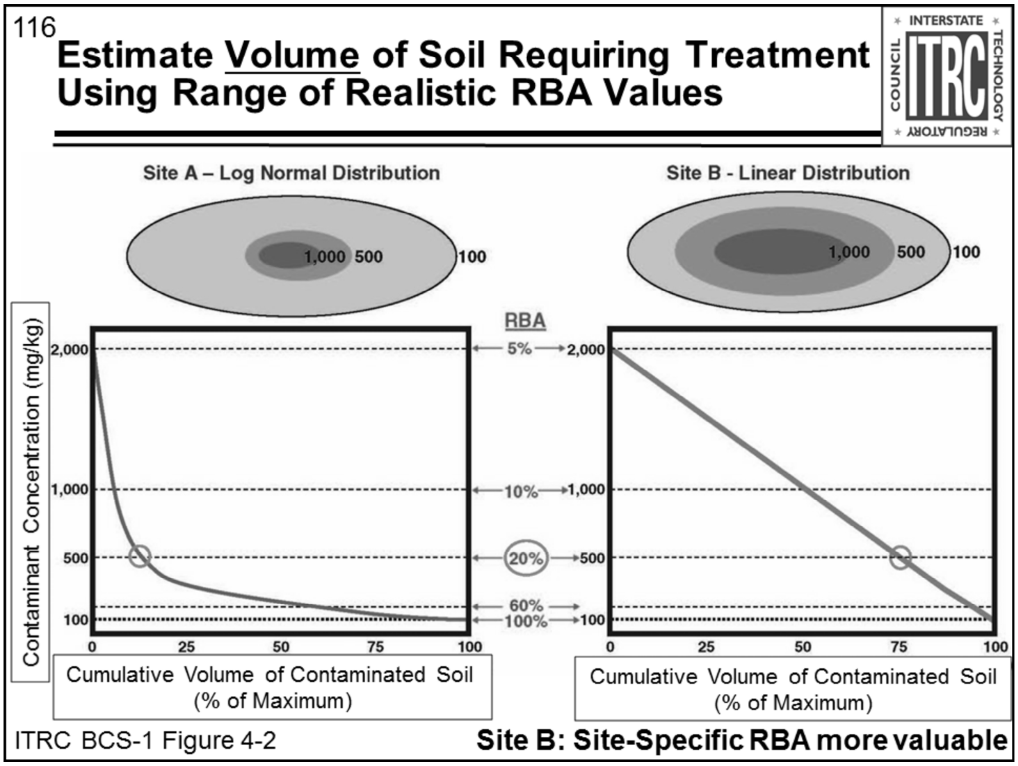


- Introduction: Definitions and Theory
- Regulatory Background: Existing Guidance, State Acceptance
- Technical Background: Soil Science, Mineralogy
- Decision Process: Decision Tree, Cost Benefit Analysis
- Methodology: In Vivo, In Vitro, In Vivo - in Vitro Correlations
- Chemical Specific Chapters: Lead, Arsenic, PAHs
- Risk Assessment: Incorporating RBA into Risk Assessment
- Stakeholder Perspectives: Engagement, Outreach, Communication
- Case Studies:

Case Study	Contaminant	Soil Type	Source Type	State

ITRC BCS-1 online guidance: http://bcs-1.itrcweb.org

No associated notes



Two sites are shown in Figure 4-2, each with a maximum concentration of 2,000 mg/kg of a contaminant that has a cleanup level of 100 mg/kg (at an RBA of 100%). The RBA values are overlaid, to illustrate the cleanup levels corresponding to a given RBA.

As an example, the green circles indicate the volumes impacted if an RBA of 20% were accepted, effectively raising the cleanup level to 500 mg/kg.

At Site A, only 15% of the total contaminated soil volume is above 500 mg/kg, (contaminant distribution is log normal) and therefore would require cleanup. In contrast, with a different distribution (linear distribution) of the contaminant concentrations (Site B), 75% of the total volume would still require remediation at an RBA of 20%.

Site-specific conditions will vary, but some key features of the analysis of volume and RBA in Figure 4-2 are worth pointing out:

Risk-based criteria, such as cleanup levels, increase significantly at RBA values of approximately 25% or less. For example:

an RBA of 25% yields a cleanup level that is 4x higher

an RBA of 10% yields a cleanup level that is 10x higher

The typical default value of a 60% RBA results in a relatively modest increase in cleanup levels: 1.67x higher.

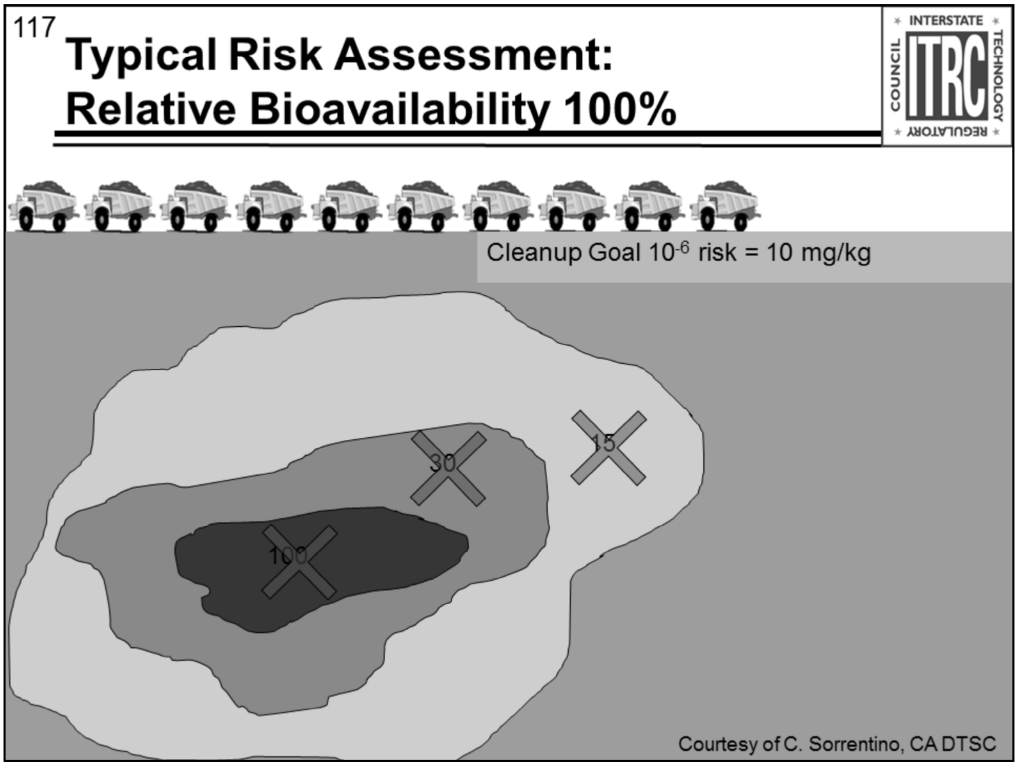
Estimating the volume requiring treatment at a range of realistic RBAs before beginning a site-specific bioavailability study may be valuable.

Some general observations regarding the value of incorporating site-specific RBA values include the following:

Small sites may not justify the expense of testing and increased regulatory costs.

At sites where discrete hot spots account for most of the risk (like Site A), or at sites with only a small volume of soil above cleanup goals, site-specific bioavailability assessment may be less valuable.

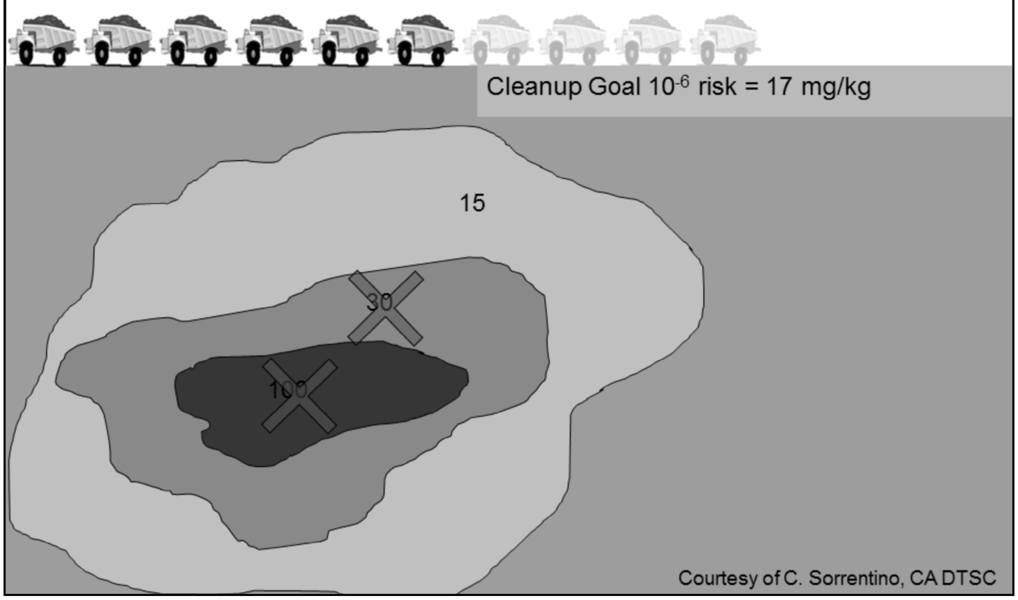
Bioavailability assessment is more valuable at sites with relatively high volumes of soil, and where most of the soil is contaminated at concentrations between the default cleanup levels and cleanup levels that incorporate an estimated RBA value (based on prior literature or experience with the specific soils or waste materials).



No associated notes

118

Applying US EPA Default: Relative Bioavailability 60%

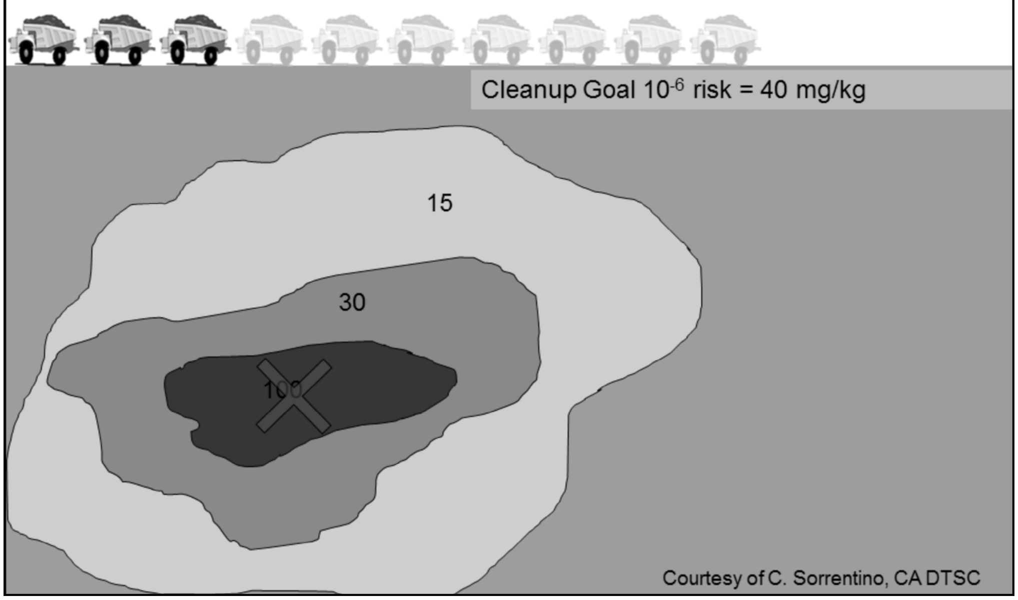


Courtesy of C. Sorrentino, CA DTSC

No associated notes

119

Site-Specific Evaluation: Relative Bioavailability 25%



No associated notes

120

ITRC Document: Review Checklist http://bcs-1.itrcweb.org

Bioavailability of Contaminants in Soil: Considerations for Human Health Risk Assessment

HOME

Review Checklist

This checklist summarizes elements that should be considered when developing or reviewing a risk assessment that uses a site-specific bioavailability or relative oral bioavailability (RBA) value. The checklist can be completed by a risk assessor or project manager or used by a reviewer to document that the information contained in the bioavailability assessment is complete and justified. Each site will vary depending on the chemical of interest, objectives, and purpose of the risk assessment.

☐ Are the methods used for soil sampling, chemical analysis and bioavailability testing including rationale for their selection and limitations, adequately described? [**Lead**, **Arsenic**, and **PAH**]

- What soil sampling methods (for example, discrete, ISM) were used? What sieving was performed and what sieve size was used, if applicable?
- What analytical methods for the contaminants were used?
- Identify the bioavailability and bioaccessibility methods (type of in vivo, in vitro, or combination models) used.
- Identify the in vivo – in vitro correlation (IVIVC) used

☐ Is bioavailability assessment beneficial (feasibility; logistical and technical constraints)? [**Decision Process** and **Stakeholder Perspectives**]

- Is the site-specific bioavailability likely to affect the remedial decisions?
- Is the cost of the bioavailability assessment justified with respect to the cost of remediation?
- Are validated bioavailability methods available?
- Has the use of site-specific bioavailability been accepted by the regulatory agency?

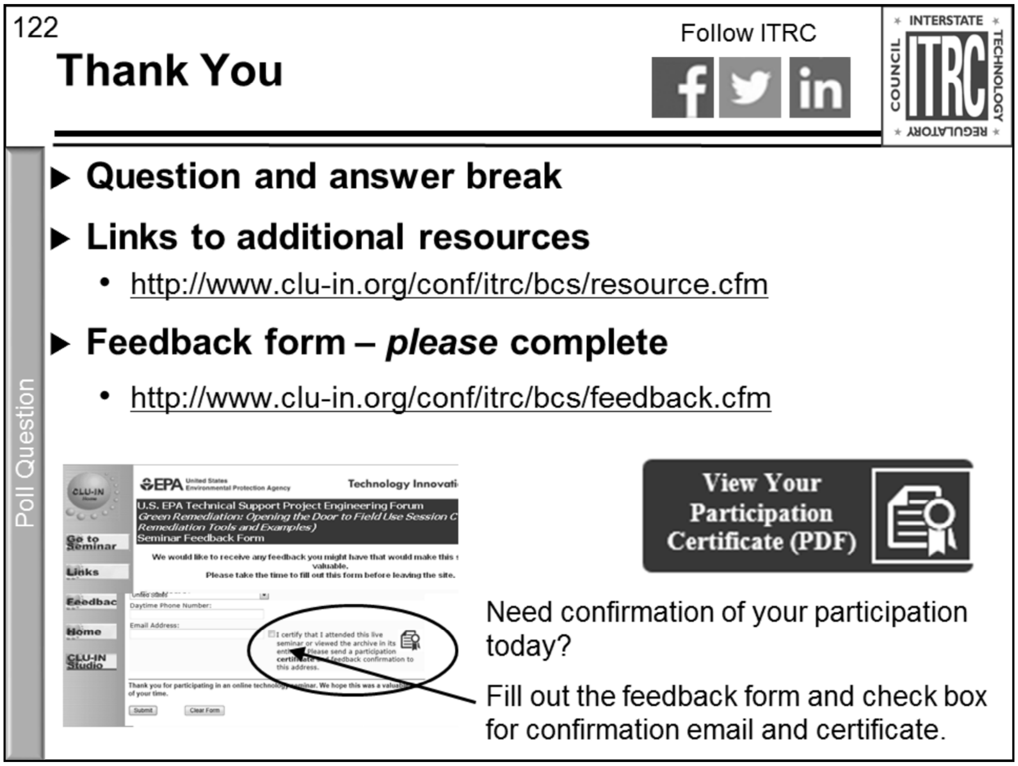
No associated notes

121

Site-Specific RBA Evaluation Take Home Messages

- Decrease the uncertainty of the risk assessment
- Maintains the Target Risk Level
- Improve Remedial Decision Making
- Often lead to significant savings of the resources available for remediation
- Multidisciplinary: Involve the Whole Team Early!
    - Regulatory: Project Managers, Geologists, Risk Assessors/Toxicologists
    - Consultants
    - Stakeholders: Responsible Parties, Public

No associated notes



Links to additional resources:
http://www.clu-in.org/conf/itrc/bcs/resource.cfm

Your feedback is important – please fill out the form at:
http://www.clu-in.org/conf/itrc/bcs/feedback.cfm

The benefits that ITRC offers to state regulators and technology developers, vendors, and consultants include:

✓Helping regulators build their knowledge base and raise their confidence about new environmental technologies

✓Helping regulators save time and money when evaluating environmental technologies

✓Guiding technology developers in the collection of performance data to satisfy the requirements of multiple states

✓Helping technology vendors avoid the time and expense of conducting duplicative and costly demonstrations

✓Providing a reliable network among members of the environmental community to focus on innovative environmental technologies

How you can get involved with ITRC:

✓Join an ITRC Team – with just 10% of your time you can have a positive impact on the regulatory process and acceptance of innovative technologies and approaches

✓Sponsor ITRC's technical team and other activities

✓Use ITRC products and attend training courses

✓Submit proposals for new technical teams and projects