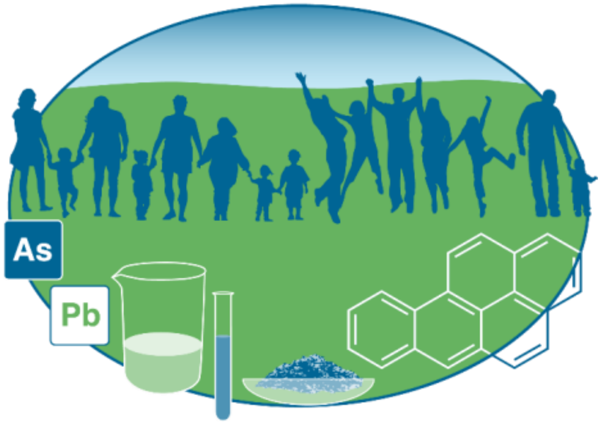
Starting Soon: Bioavailability of Contaminants in Soil: Considerations for Human Health Risk Assessment

- 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

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)

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- Course time is 2¼ hours
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ITRC (www.itrcweb.org) – Shaping the Future of Regulatory Acceptance

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  - Academia
  - Community stakeholders
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  - Technical and regulatory guidance documents
  - Online and classroom training schedule
  - More…

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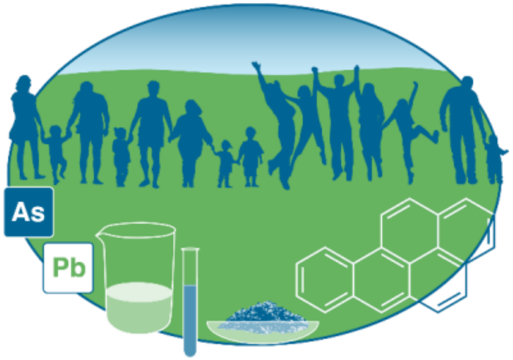
Read trainer bios at https://clu-in.org/conf/itrc/bcs/

Today's Training Road Map

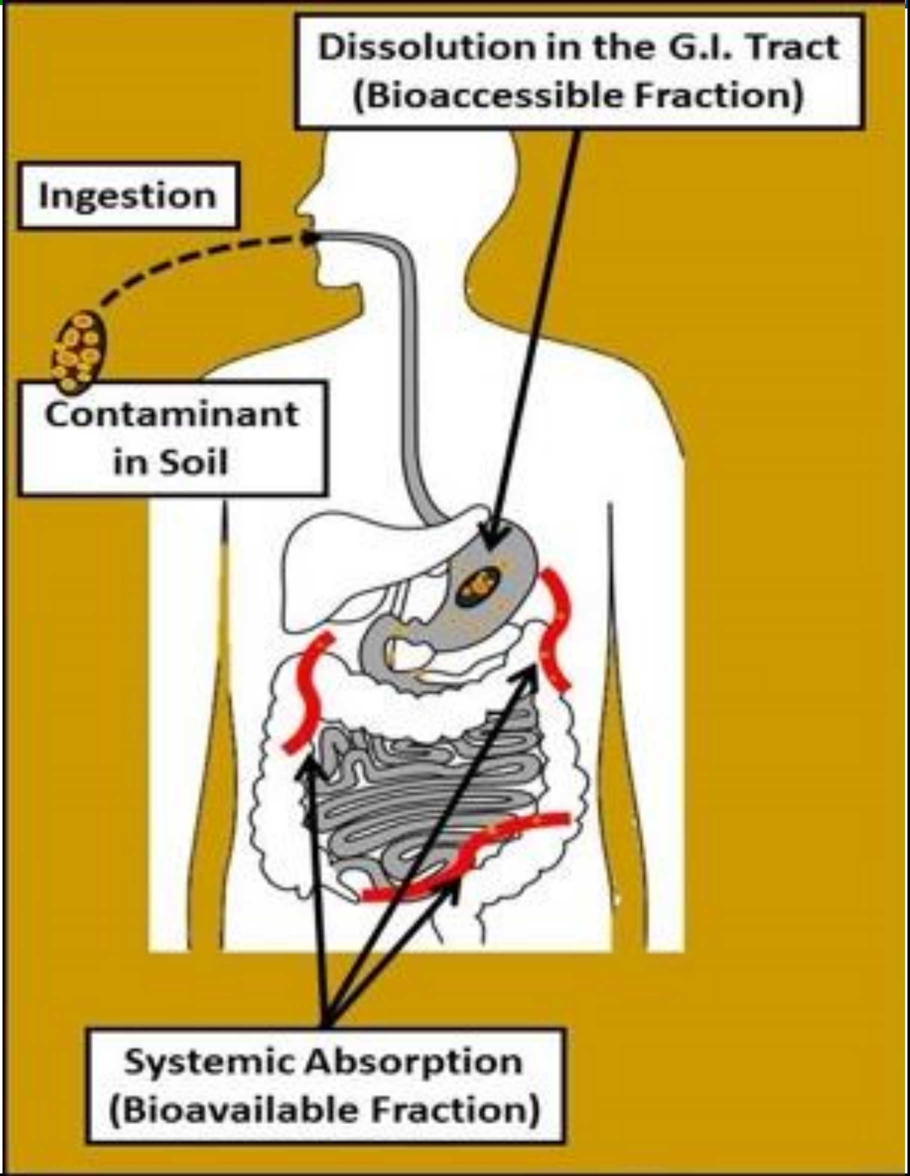
- Importance of Evaluating Bioavailability in Soils
- Bioavailability Basics
- Case Study 1 (Arsenic Site)
- Questions and Answers
- Case Study 2 (Lead Site)
- Discussion: Polycyclic Aromatic Hydrocarbons (PAHs)
- Taking Action
- Questions and Answers



Concept of Bioavailability

Poll Question

- Often not all of the contaminant ingested with soil moves into the bloodstream



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

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

Your Resource for Bioavailability in Soils – ITRC Guidance

Search this website ...

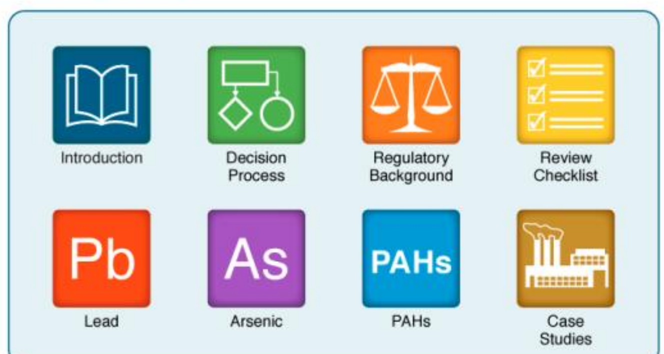
- Navigating this Website
- 1 Introduction
- 2 Regulatory Background
- 3 Technical Background
- 4 Decision Process
- 5 Methodology
- 6 Lead
- 7 Arsenic
- 8 PAHs
- 9 Risk Assessment
- 10 Stakeholder Perspectives
- 11 Case Studies
- Additional Information

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.



Publication Date: November 2017

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

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

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

A Regulator's Experience with Bioavailability – Learning Opportunities

- 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

Today's Training Road Map

Importance of Evaluating Bioavailability in Soils

Bioavailability Basics

Case Study 1 (Arsenic Site)

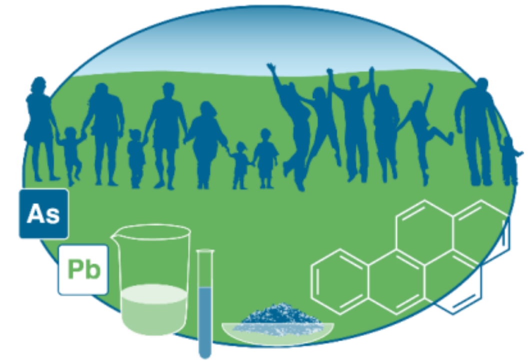
Questions and Answers

Case Study 2 (Lead Site)

Discussion: Polycyclic Aromatic Hydrocarbons (PAHs)

Taking Action

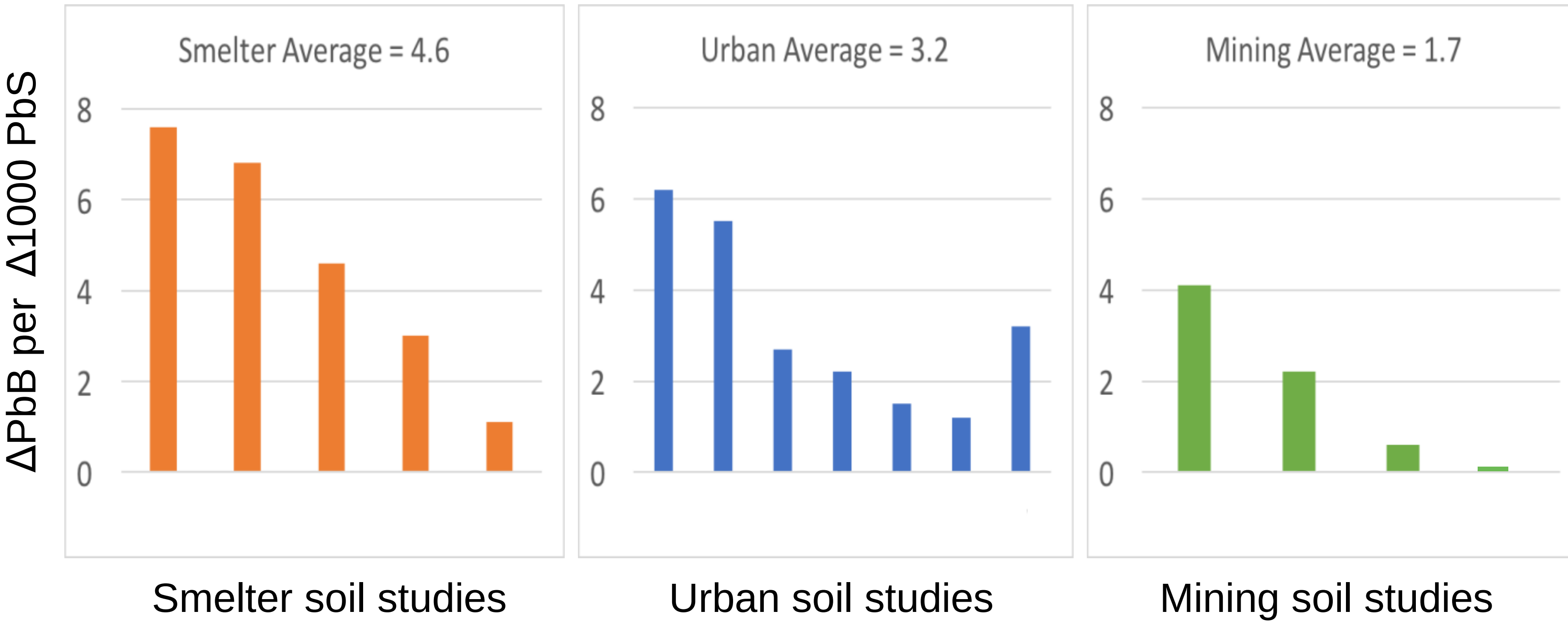
Questions and Answers



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

Studies relating soil lead and blood lead: Source of lead makes a difference

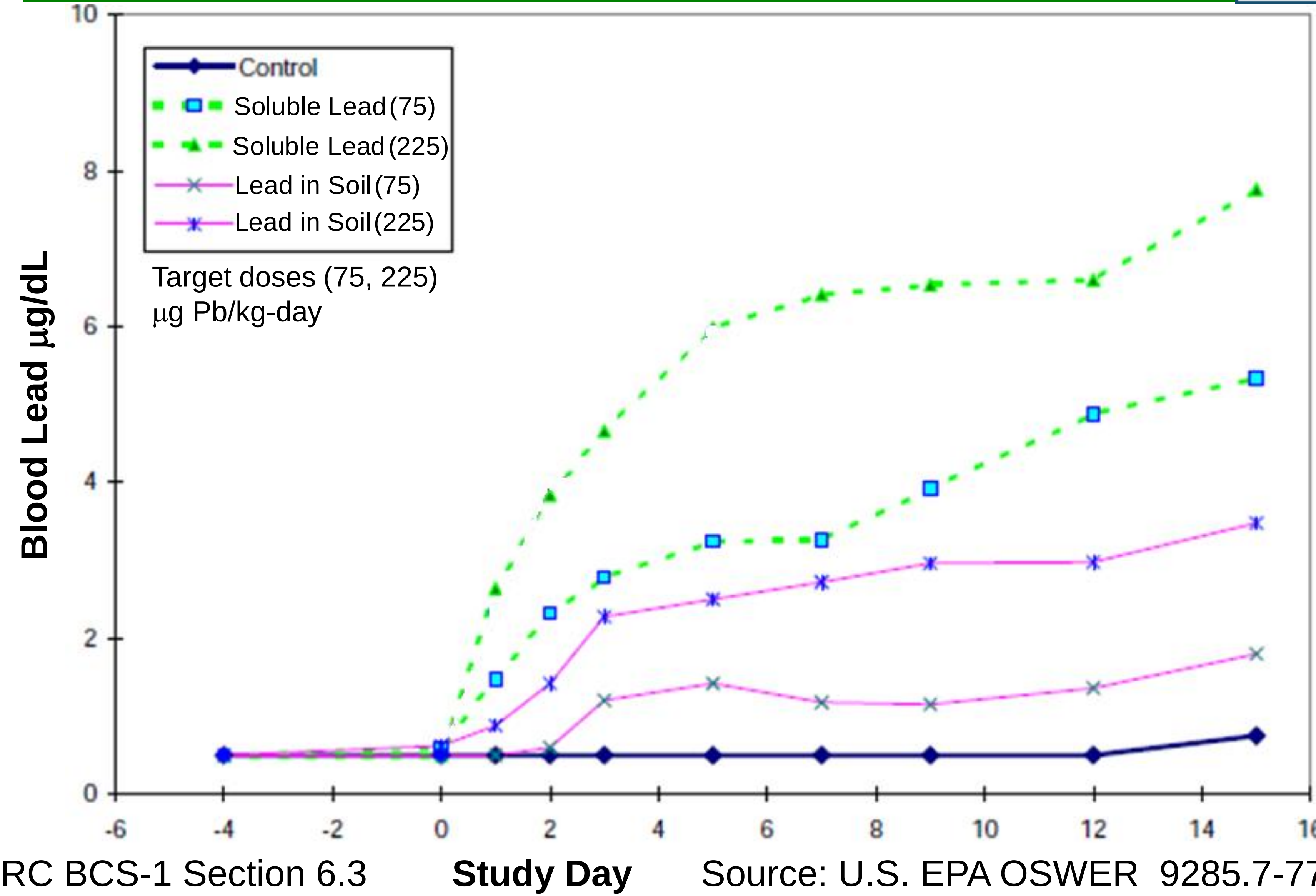


PbB – lead blood (µg/dL)
PbS – lead soil (mg/kg)

Data presented in Steele et al.1990

Demonstrating RBA of Lead in Soil with Animal Models

RBA – Relative Oral Bioavailability

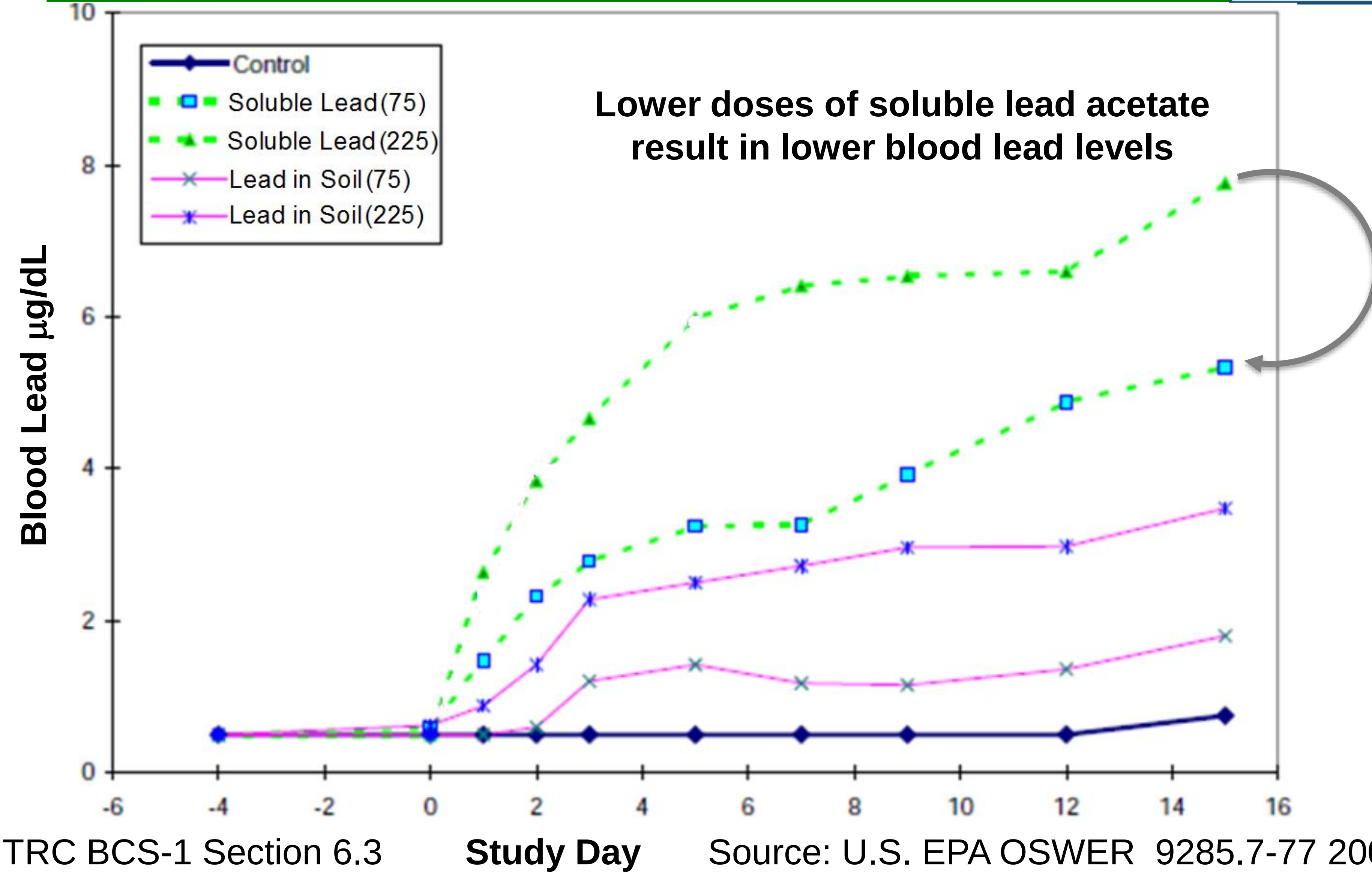


ITRC BCS-1 Section 6.3

Source: U.S. EPA OSWER 9285.7-77 2007.

Demonstrating RBA of Lead in Soil with Animal Models

RBA – Relative Oral Bioavailability



Source: U.S. EPA OSWER 9285.7-77 2007.

Demonstrating RBA of Lead in Soil with Animal Models

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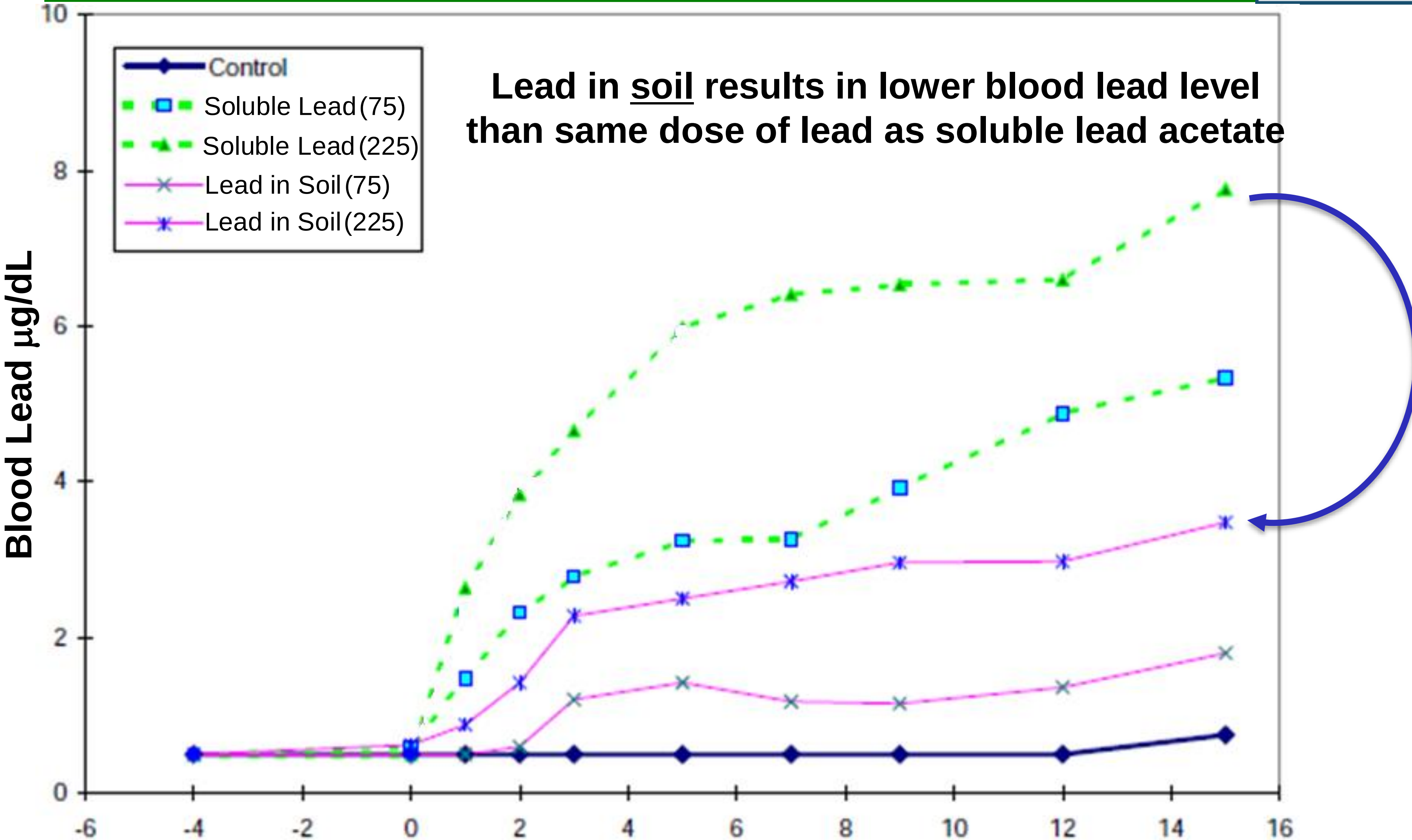
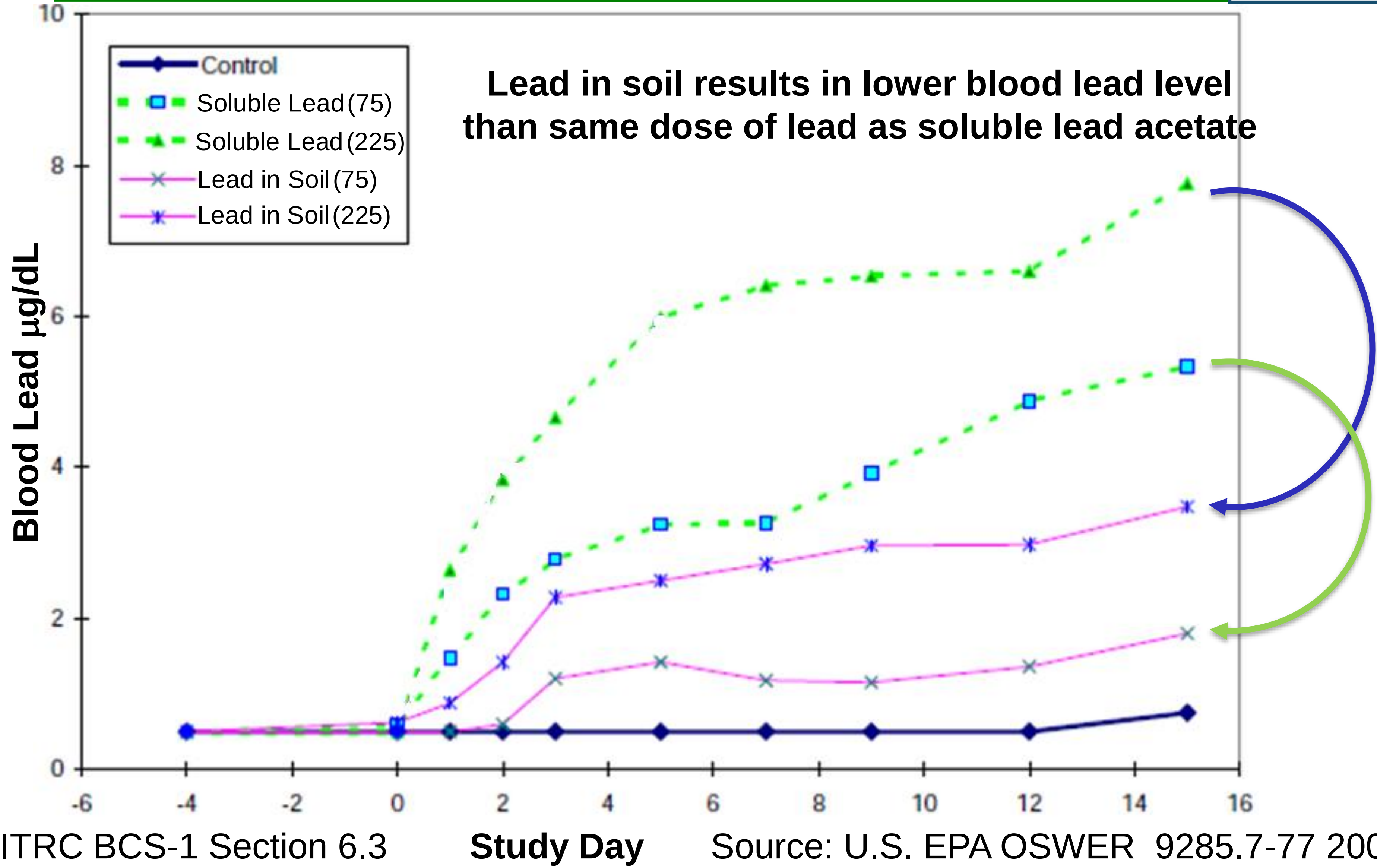


ITRC BCS-1 Section 6.3 **Study Day** Source: U.S. EPA OSWER 9285.7-77 2007.

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.

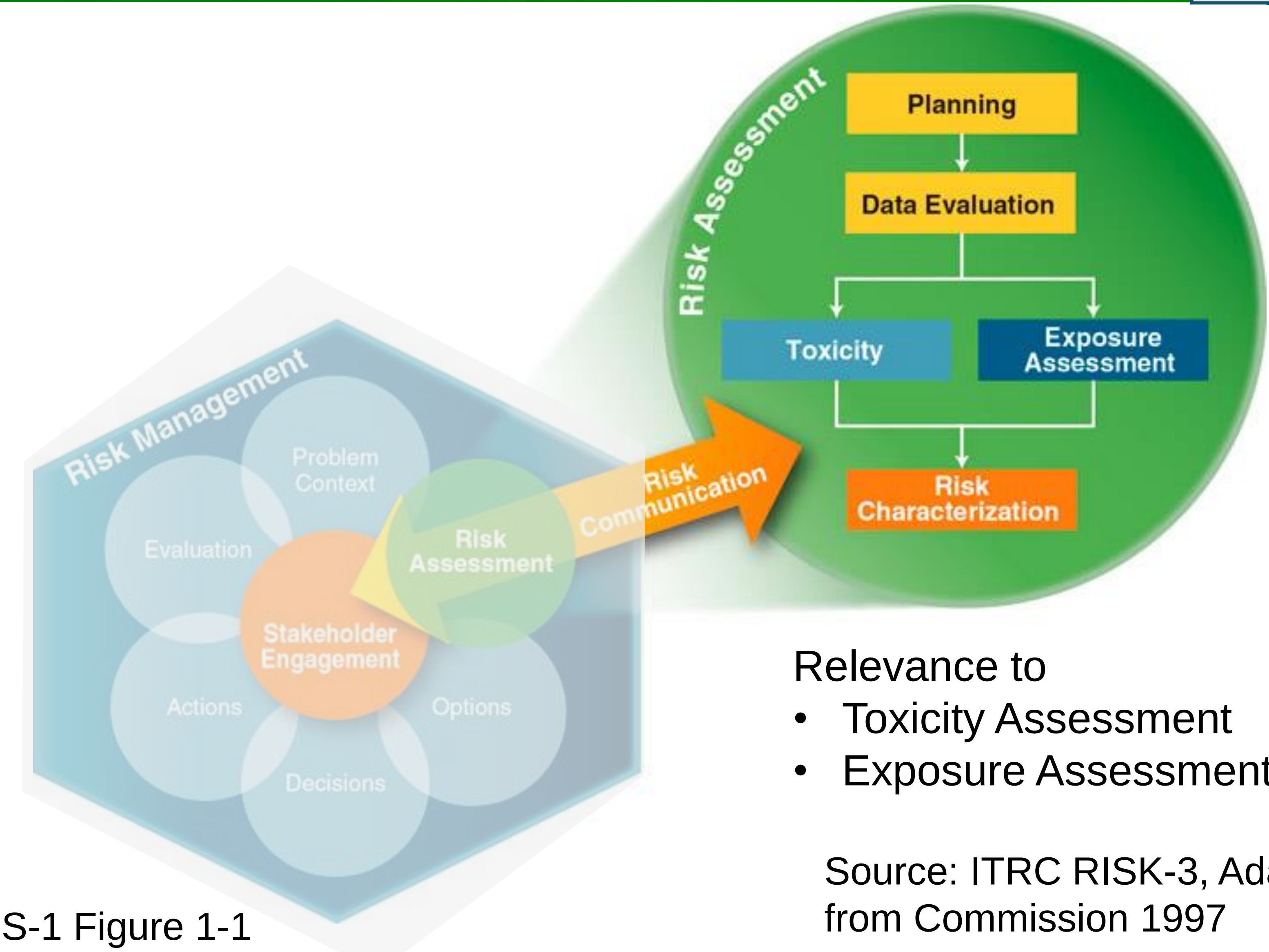
Regulatory Recognition of Using Bioavailability for Risk Assessment

"*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

Bioavailability: Relevance to Human Health Risk Assessment

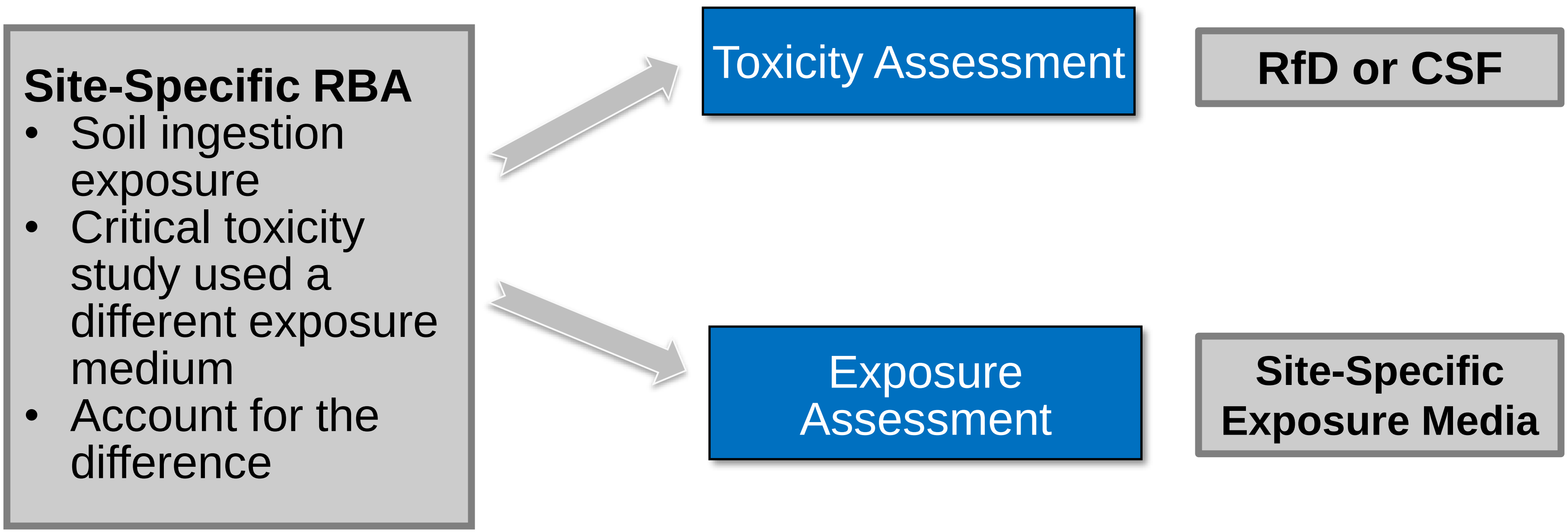


Relevance to
- Toxicity Assessment
- Exposure Assessment

Source: ITRC RISK-3, Adapted from Commission 1997

ITRC BCS-1 Figure 1-1

Bioavailability: Relevance to Toxicity Assessment and Exposure Assessment



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

Definition: Relative Oral Bioavailability (RBA)

- Comparison of bioavailability of a chemical in different dosing media

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

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

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

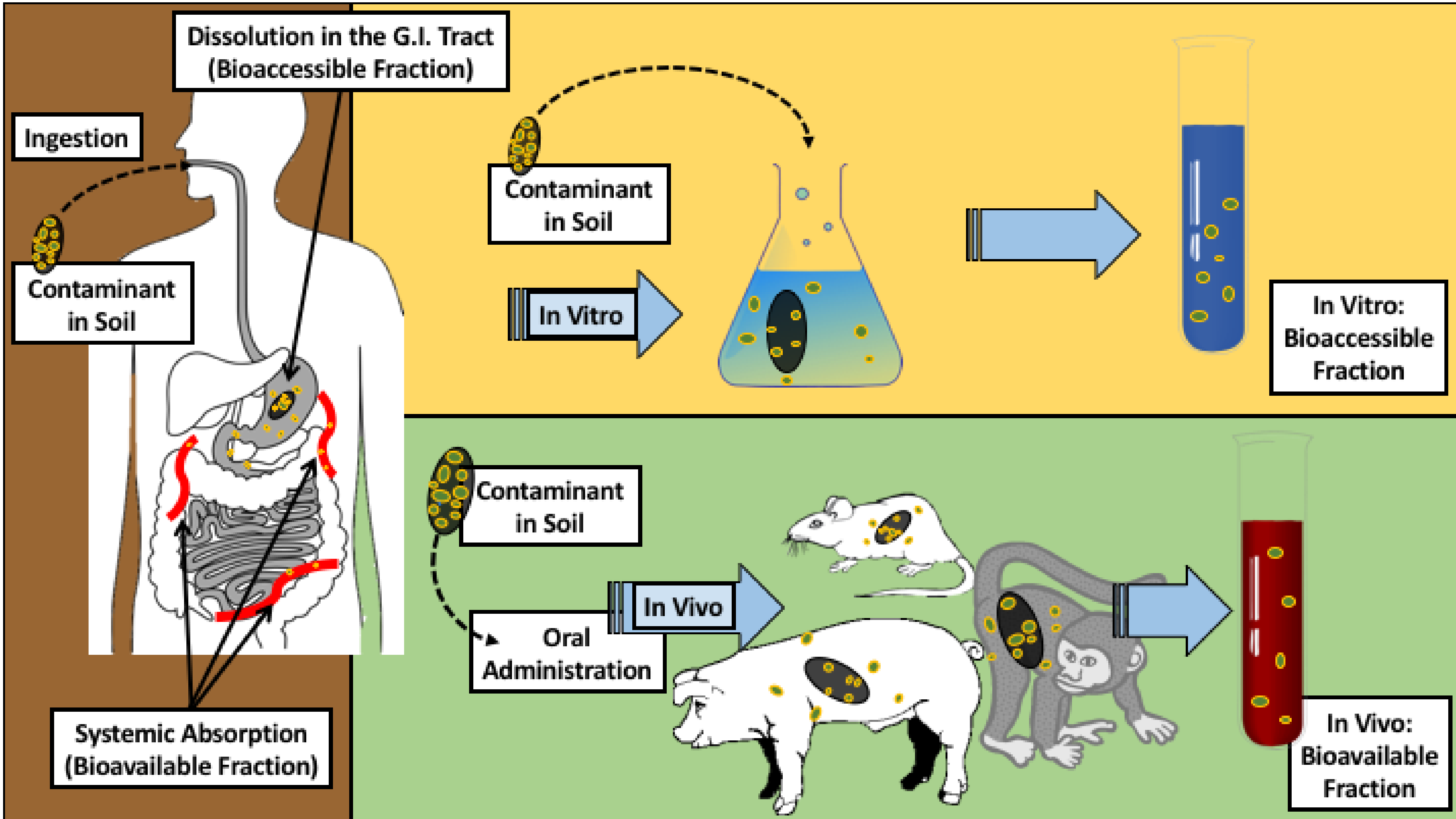
- Although current default assumes RBA of 100% for all chemicals in soil except arsenic and lead (default 60%)

Definition: Bioaccessibility

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

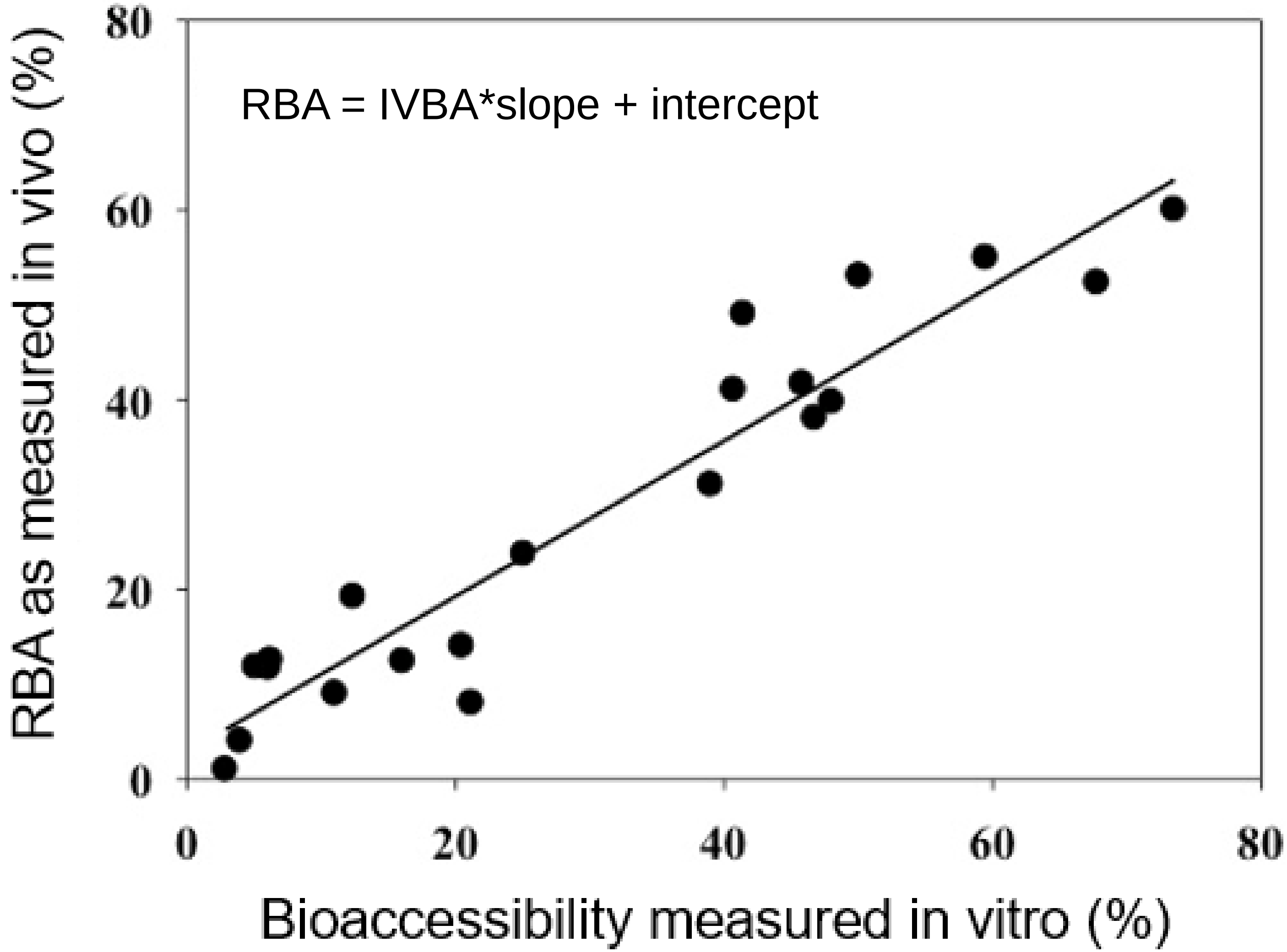
- Fraction of total amount of chemical present that is soluble / available for uptake
- In vitro methods attempt to characterize this parameter
  - In vitro bioaccessibility (IVBA)

Schematic of Bioavailability and Bioaccessibility



ITRC BCS-1 Figure 1-2

Developing an IVIVC to Predict RBA



(IVBA)

RBA: Relative Oral Bioavailability

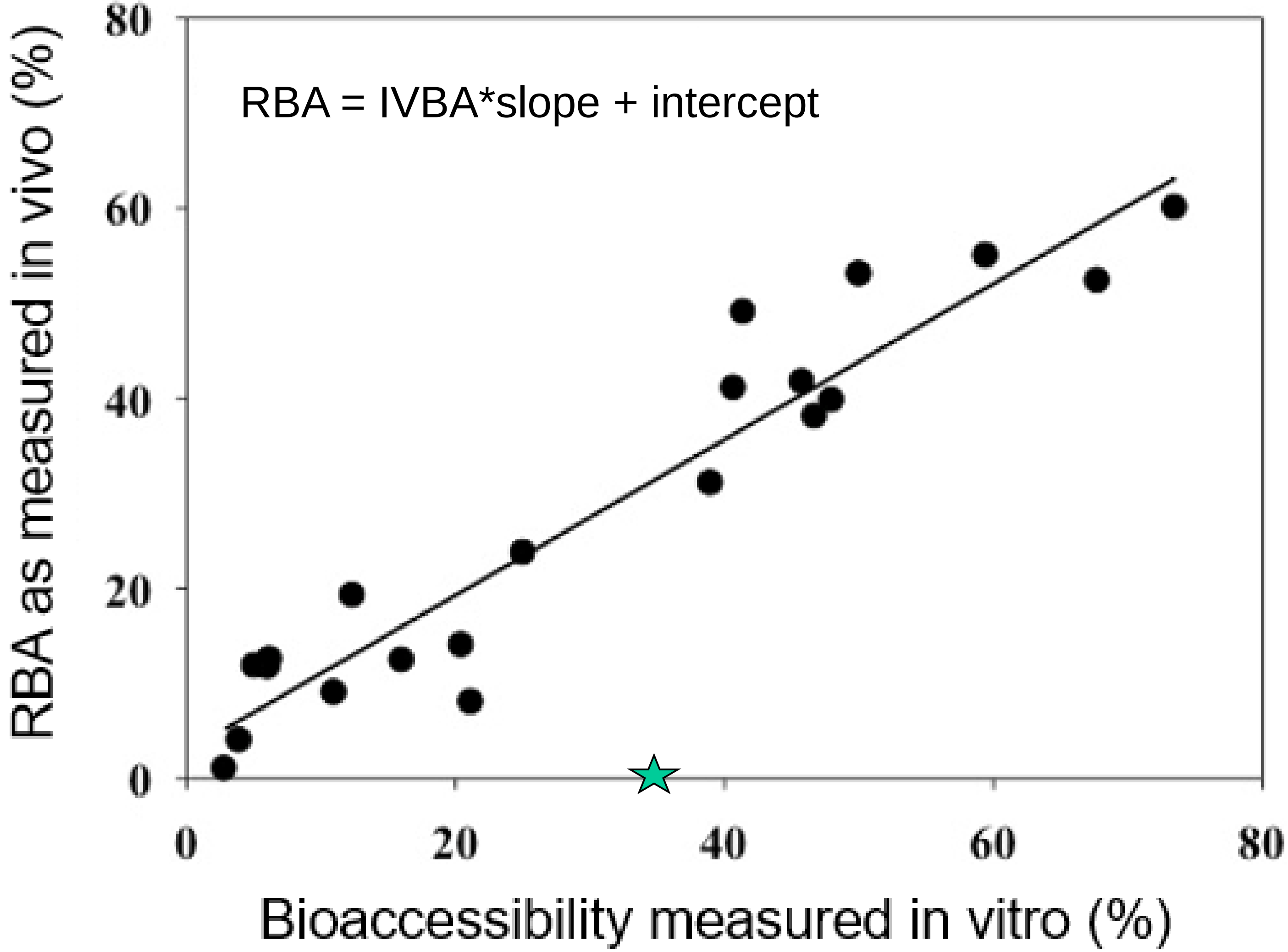
IVBA: In Vitro Bioaccessibility

IVIVC: In Vivo - In Vitro correlation

ITRC BCS-1 Figure 7-2 and Section 5.2.3

Source: DTSC 2016

Using an IVIVC to Predict RBA



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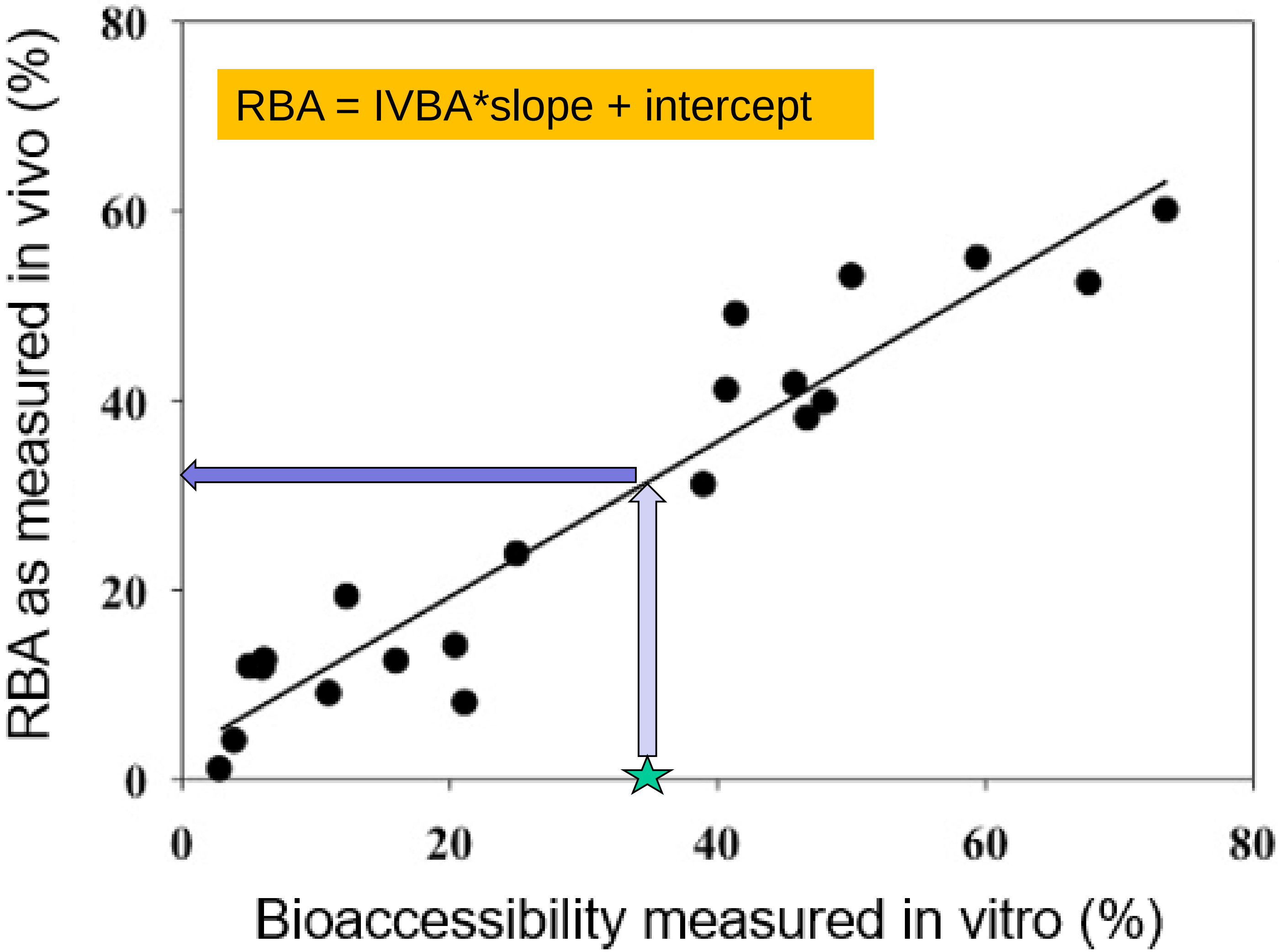
ITRC BCS-1 Figure 7-2

Source: DTSC 2016

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

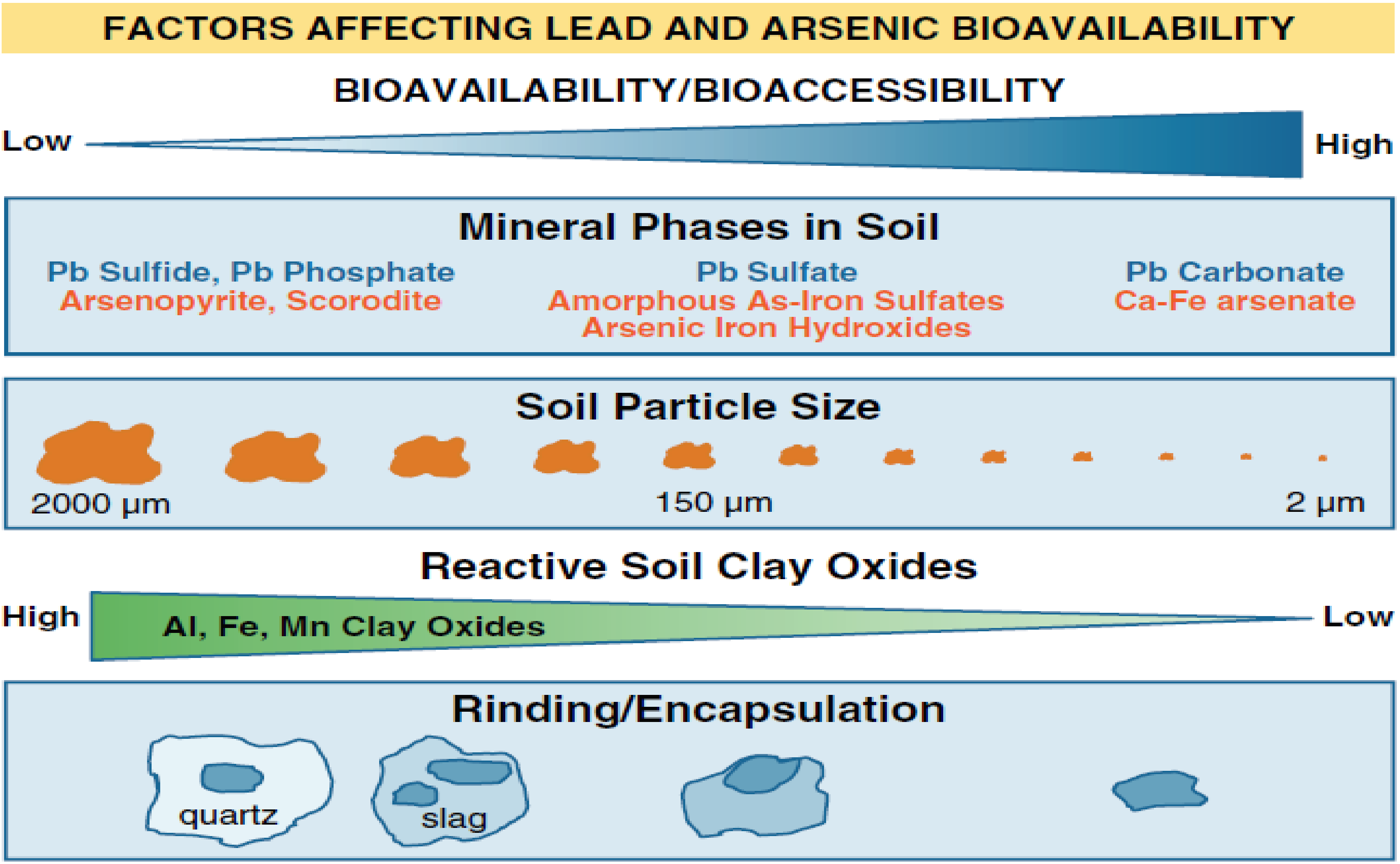
Source: DTSC 2016

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

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



ITRC BCS-1 Figure 3-1

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.

Today's Training Road Map

Importance of Evaluating Bioavailability in Soils

Bioavailability Basics

Case Study 1 (Arsenic Site)

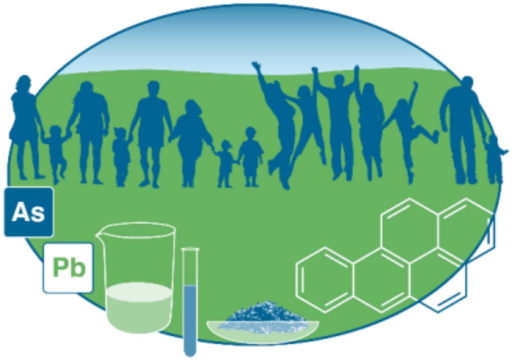
Questions and Answers

Case Study 2 (Lead Site)

Discussion: Polycyclic Aromatic Hydrocarbons (PAHs)

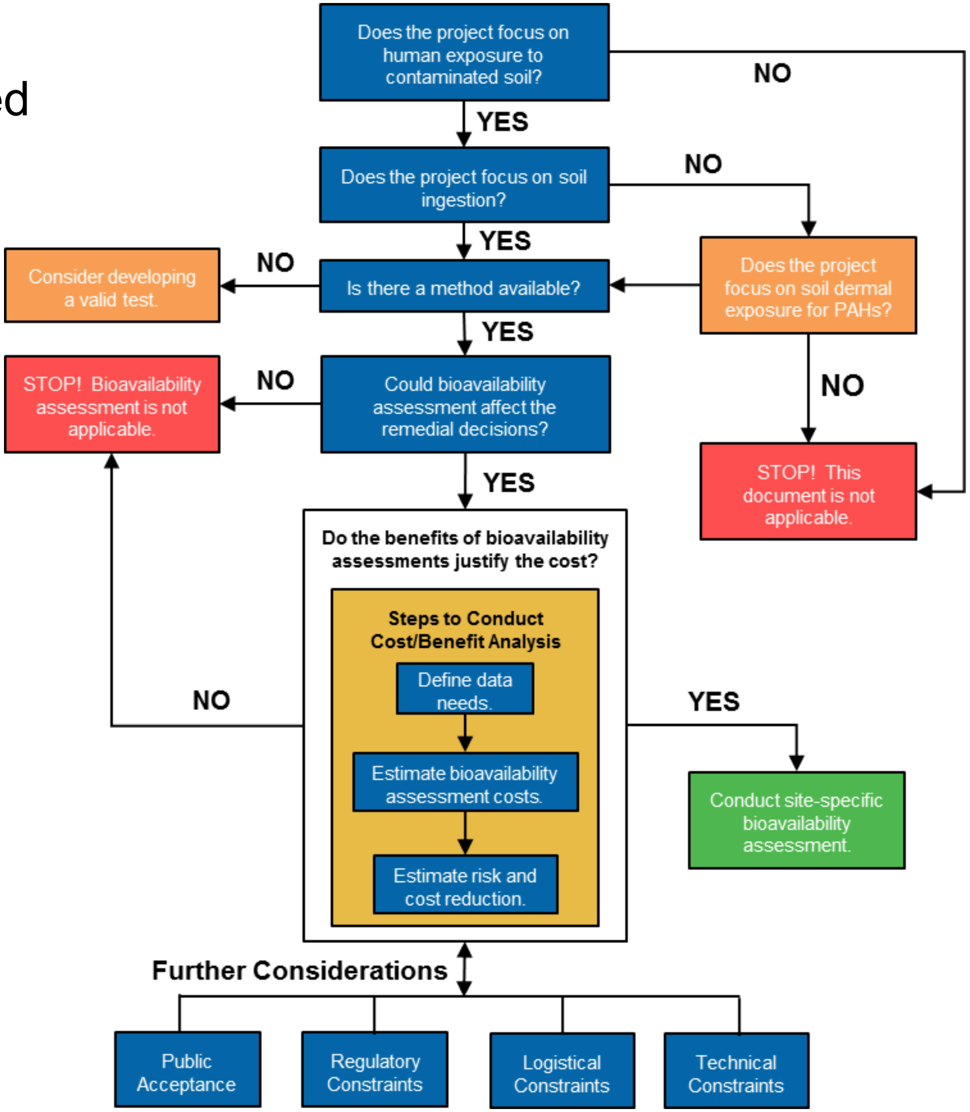
Taking Action

Questions and Answers



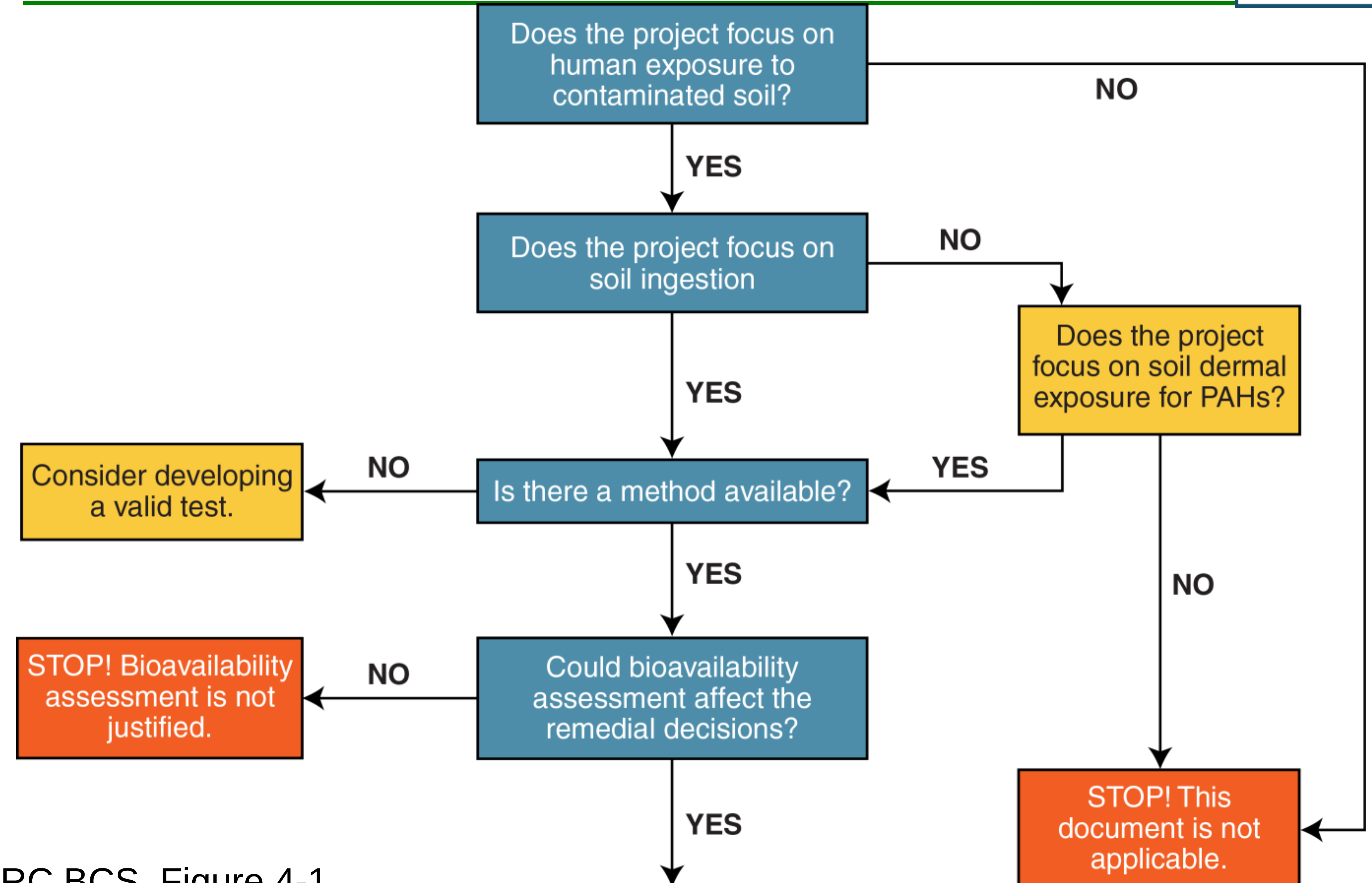
Considerations for Bioavailability Decision Process Flowchart

Full size flow chart available in "Related Links"



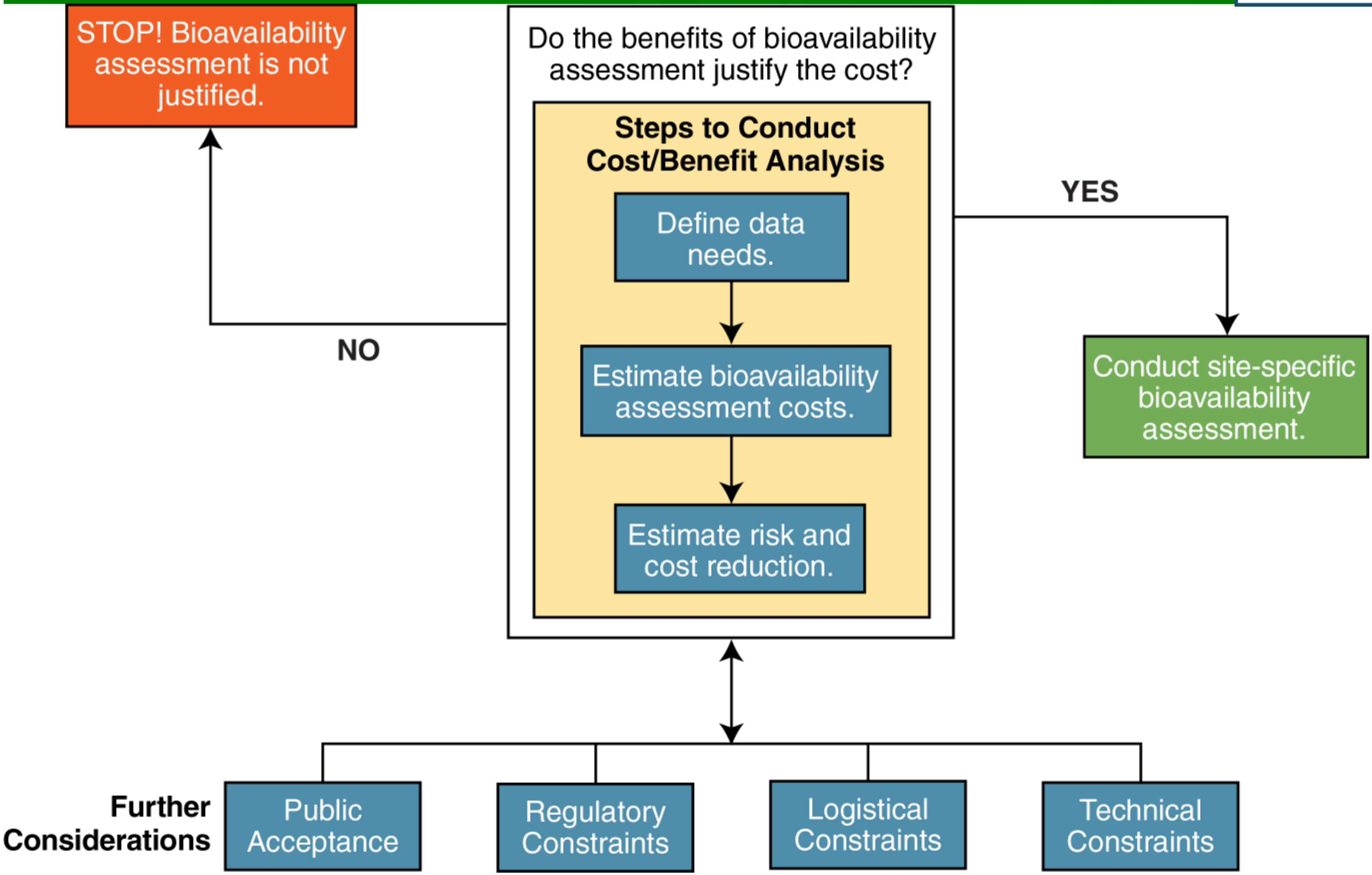
ITRC BCS-1 Figure 4-1

Considerations for Bioavailability Decision Process Flowchart- Part 1



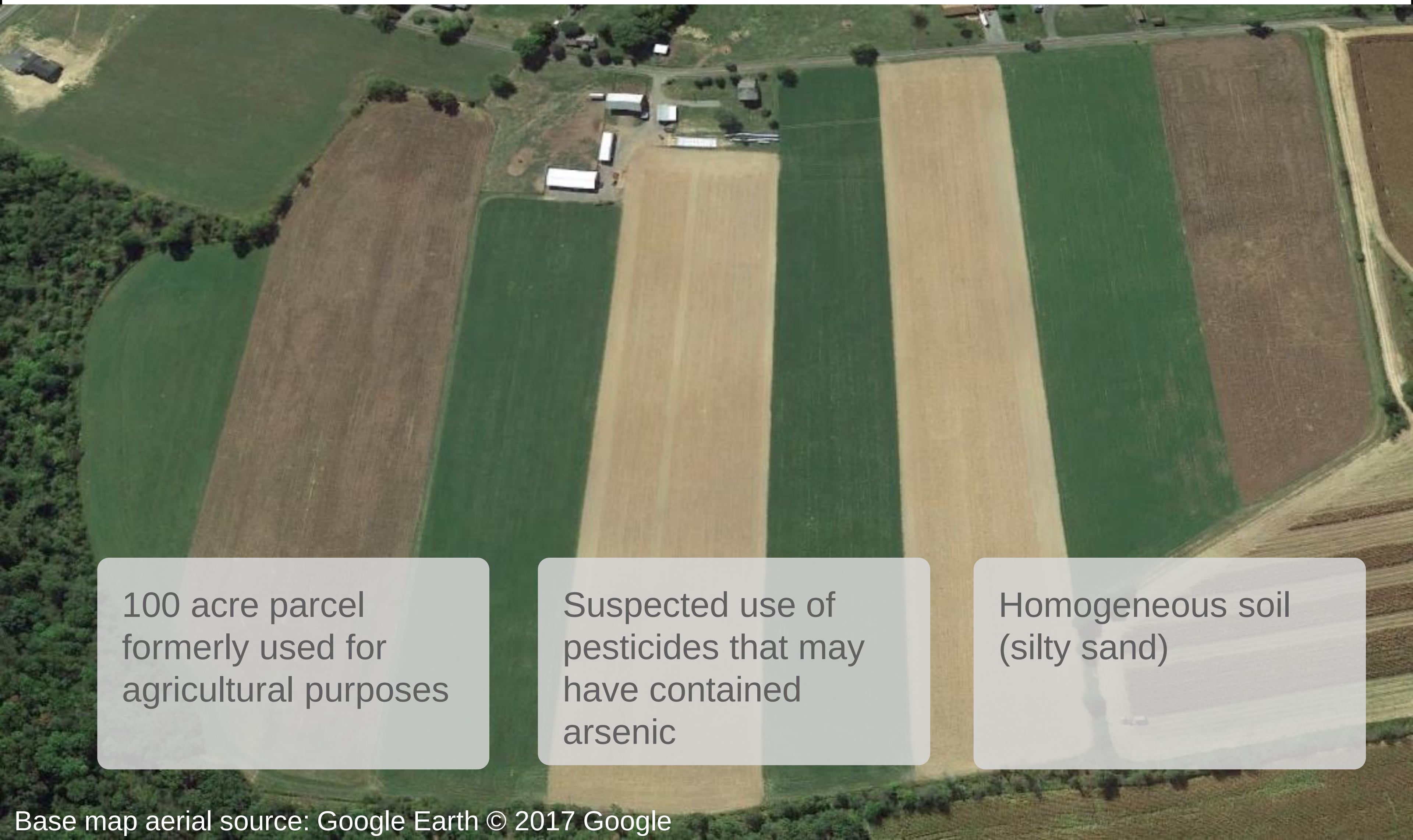
ITRC BCS Figure 4-1

Considerations for Bioavailability Decision Process Flowchart- Part 2



ITRC BCS Figure 4-1

Arsenic Case Study: Former Agricultural Parcel



100 acre parcel formerly used for agricultural purposes

Suspected use of pesticides that may have contained arsenic

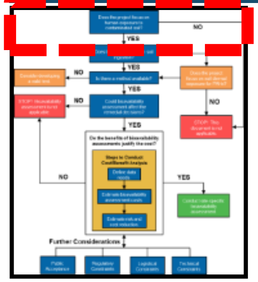
Homogeneous soil (silty sand)

Base map aerial source: Google Earth © 2017 Google

Arsenic Case Study: Usage and Activity Boundaries

Base map aerial source: Google Earth © 2017 Google

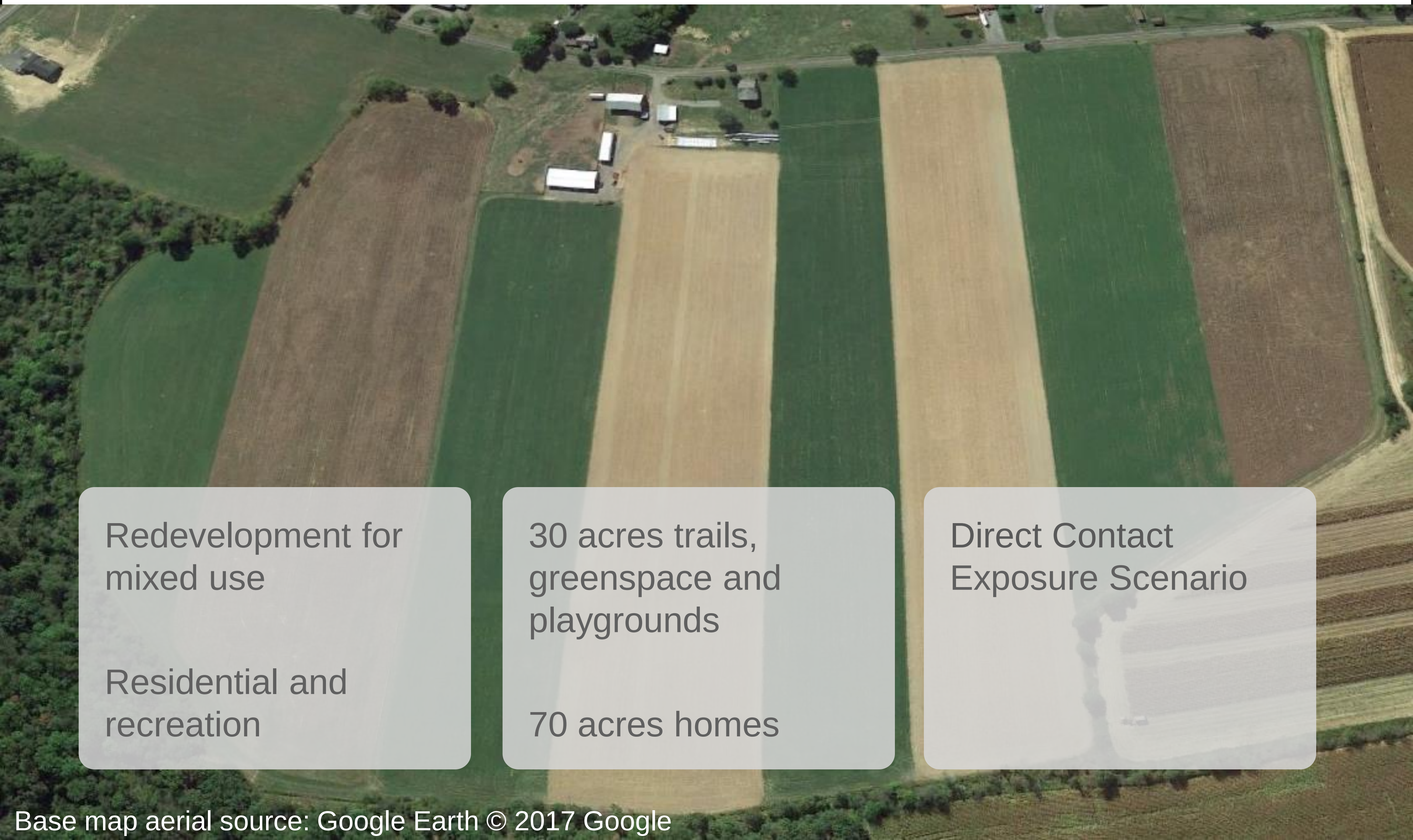
Considerations for Bioavailability Decision Process Flowchart



Does the project focus on human exposure to contaminated soil?

ITRC BCS Figure 4-1

Arsenic Case Study: Planned Mixed Use Redevelopment



Redevelopment for mixed use

Residential and recreation

30 acres trails, greenspace and playgrounds

70 acres homes

Direct Contact Exposure Scenario

Base map aerial source: Google Earth © 2017 Google

Arsenic Case Study: Residential Land Use

Photo courtesy of K. Long

Arsenic Case Study: Residential Land Use

Photo courtesy of K. Long

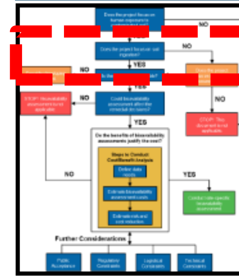
Arsenic Case Study: Residential Land Use

Photo courtesy of V. Hanley

Arsenic Case Study: Recreational Land Use

Photo courtesy of K. Long

Considerations for Bioavailability Decision Process Flowchart



Does the project focus on soil ingestion

ITRC BCS Figure 4-1

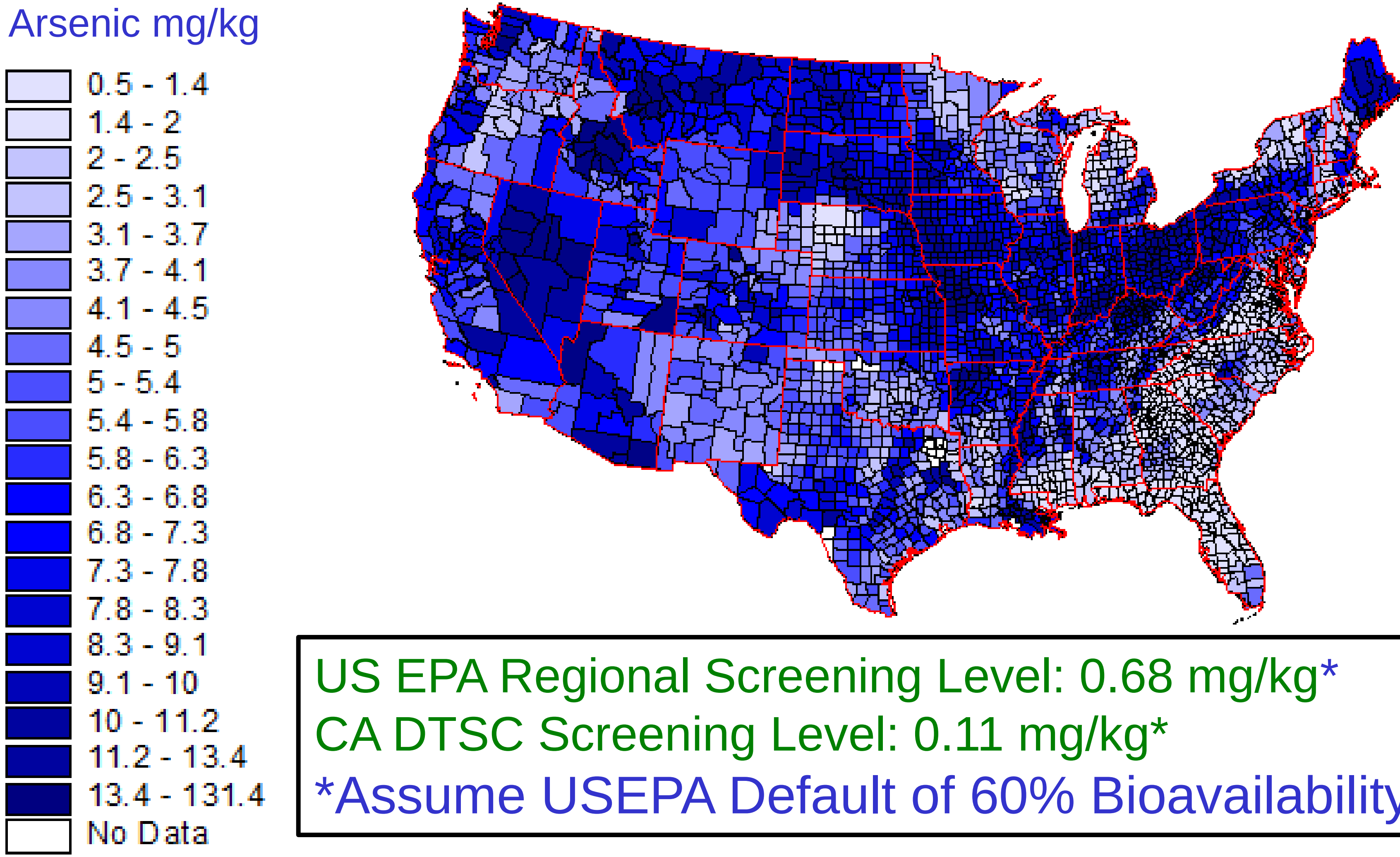
Incorporation of RBA Results into Human Health Risk Assessment (HHRA)

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

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*

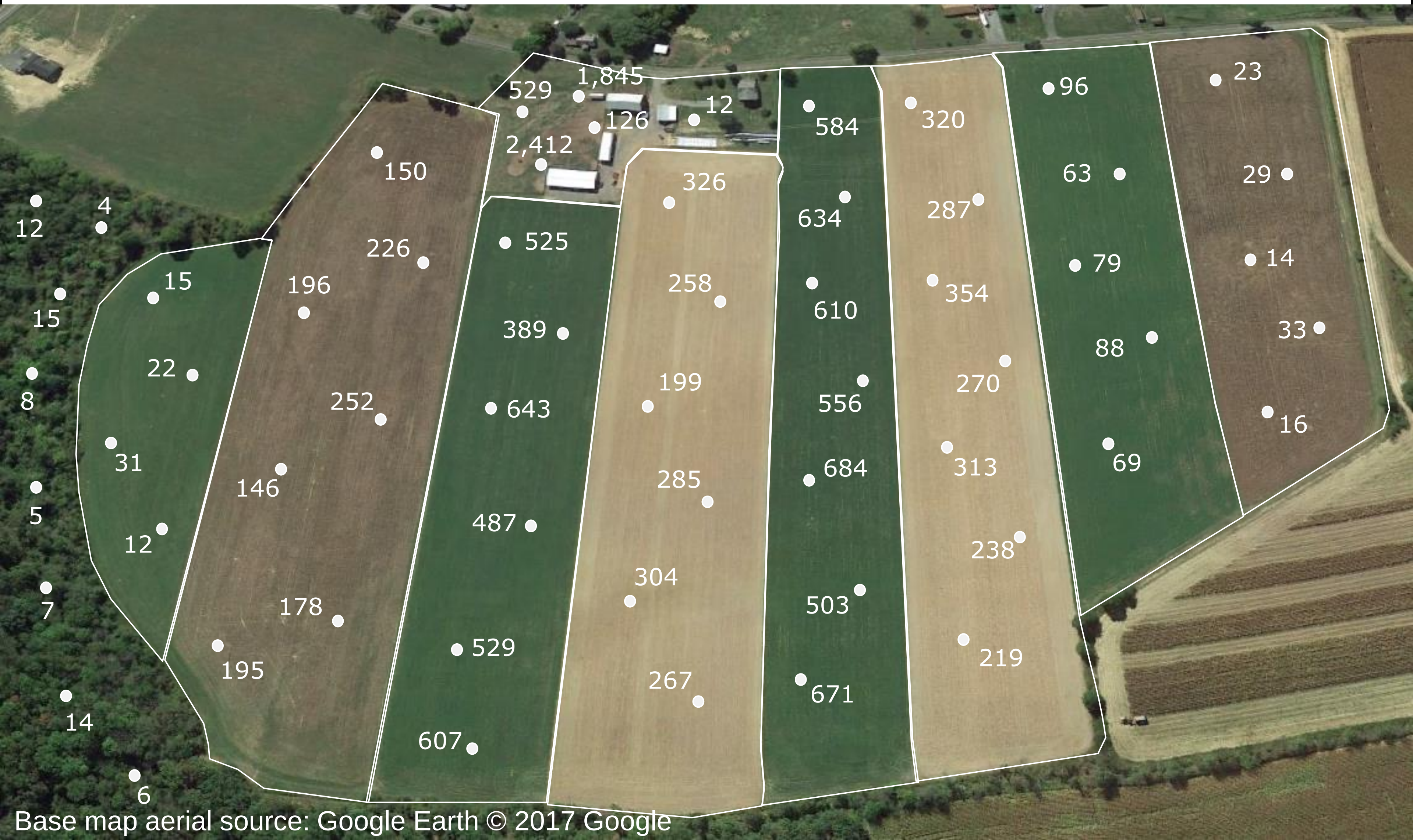
CA DTSC Screening Level: 0.11 mg/kg*

*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

Arsenic Case Study: Measured Concentrations (mg/kg)

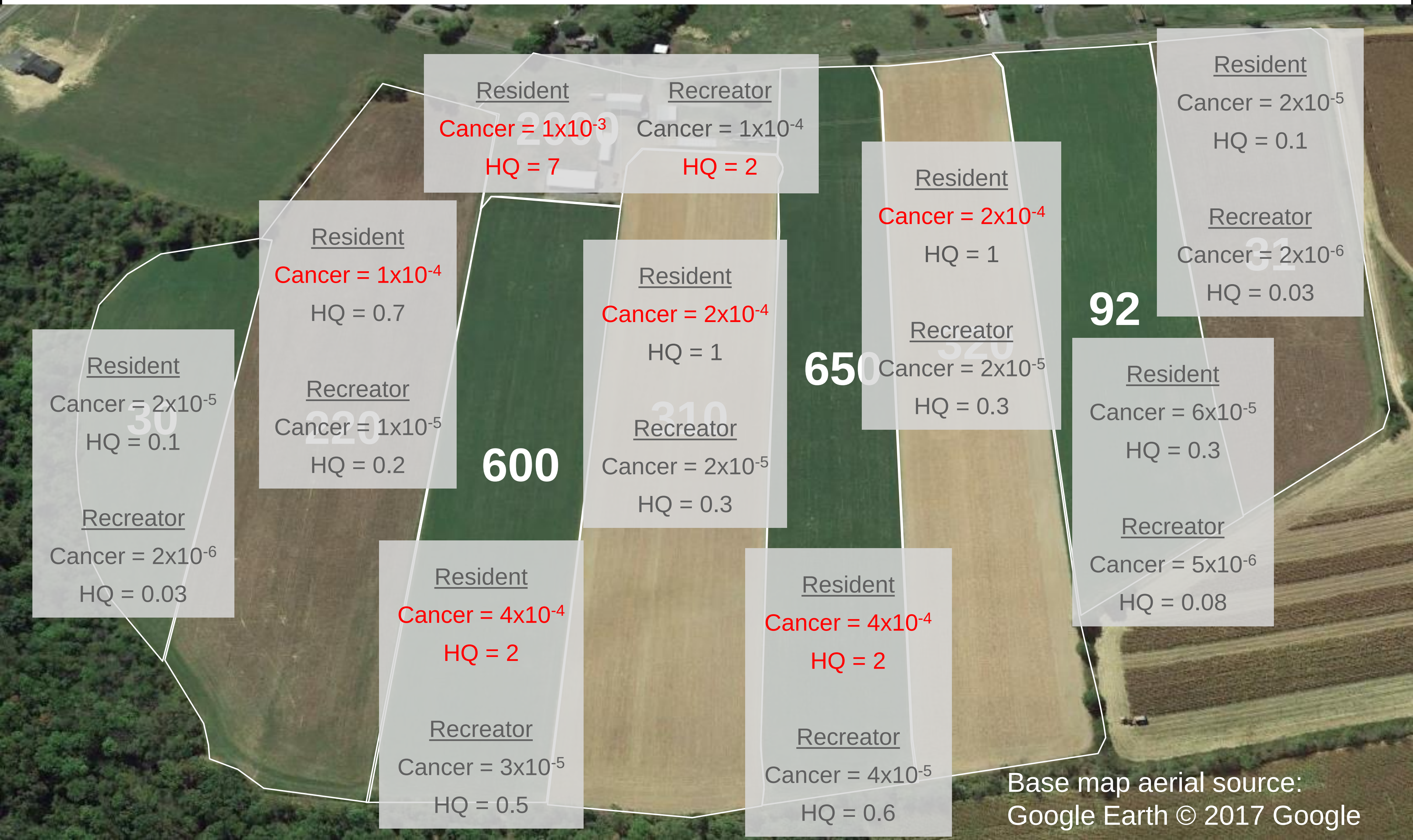


Base map aerial source: Google Earth © 2017 Google

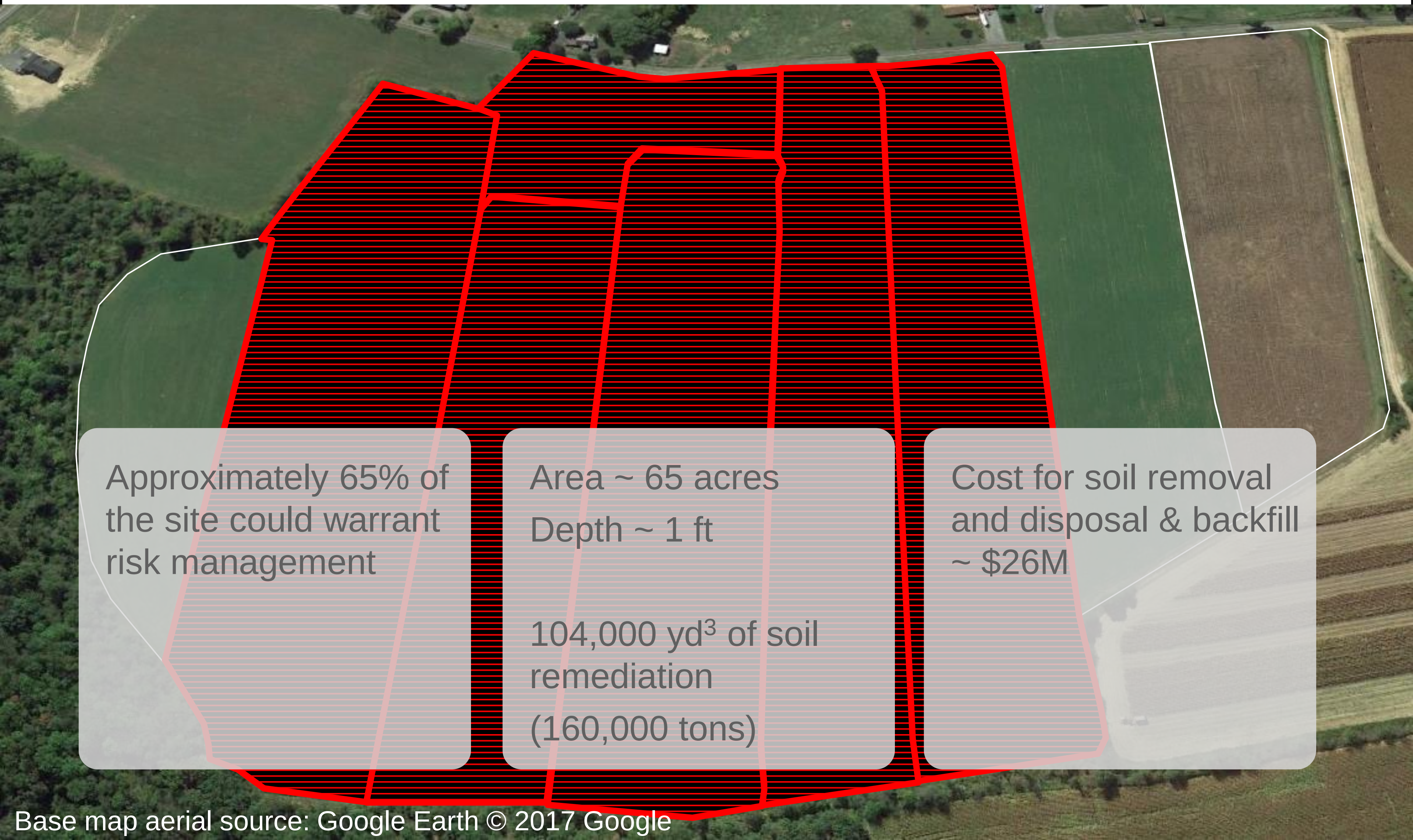
Arsenic Case Study: Average Concentrations (mg/kg)

Base map aerial source: Google Earth © 2017 Google

Arsenic Case Study: Risk Characterization (60% RBA)



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



Approximately 65% of the site could warrant risk management

Area ~ 65 acres

Depth ~ 1 ft

104,000 yd^3 of soil remediation

(160,000 tons)

Cost for soil removal and disposal & backfill ~ $26M

Base map aerial source: Google Earth © 2017 Google

Considerations for Bioavailability Decision Process Flowchart

Is there a method available?

ITRC BCS Figure 4-1

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

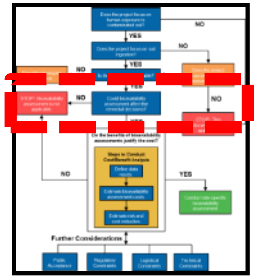
ITRC BCS-1 Table 7-1

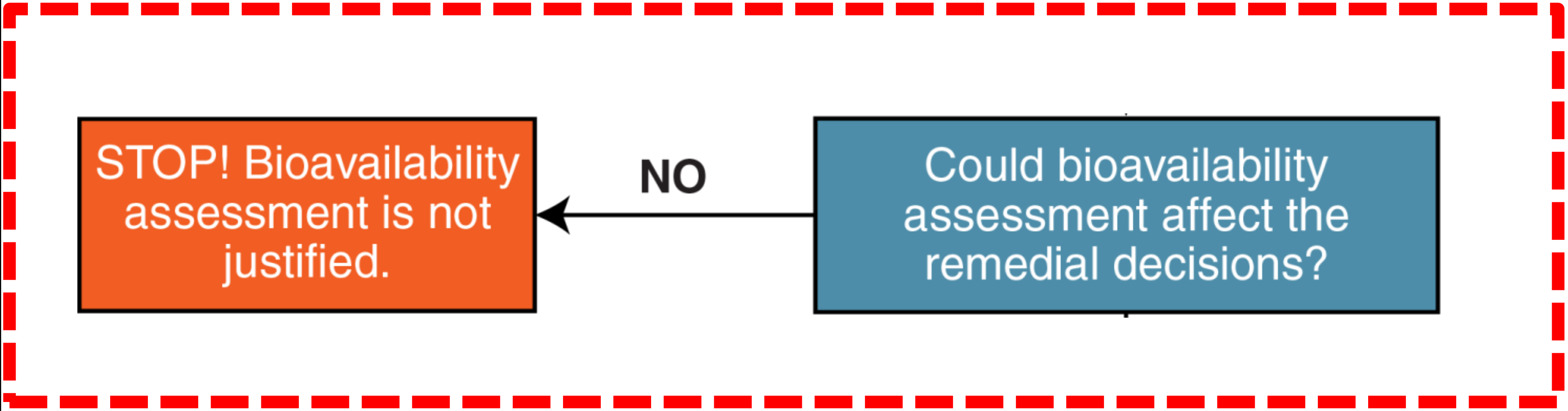
Available Methods for Determining Arsenic Bioavailability In Vitro

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

Considerations for Bioavailability Decision Process Flowchart

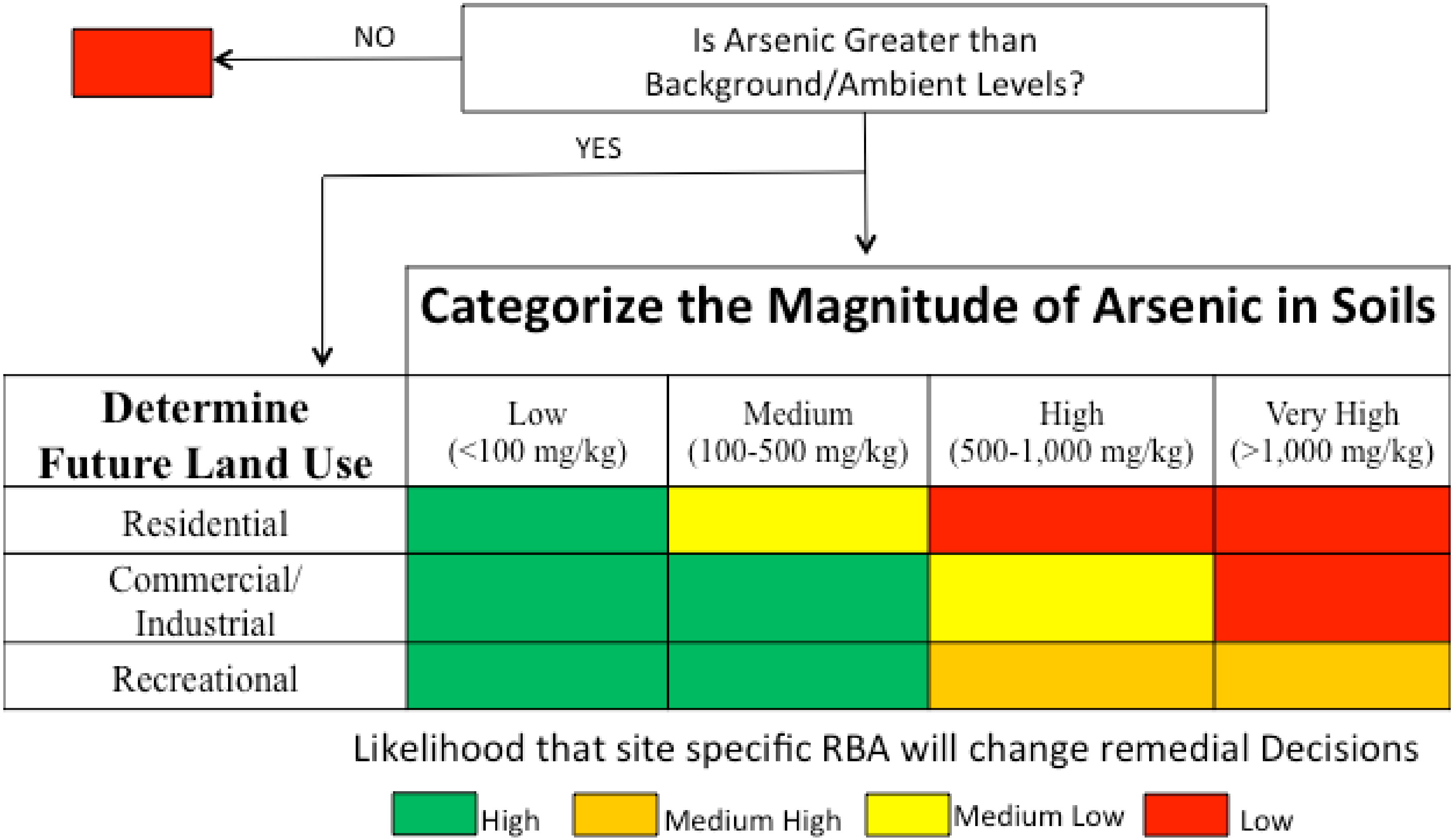




ITRC BCS Figure 4-1

Likelihood of RBA Affecting Remediation Decisions for Arsenic-contaminated Sites

RBA – Relative Oral Bioavailability

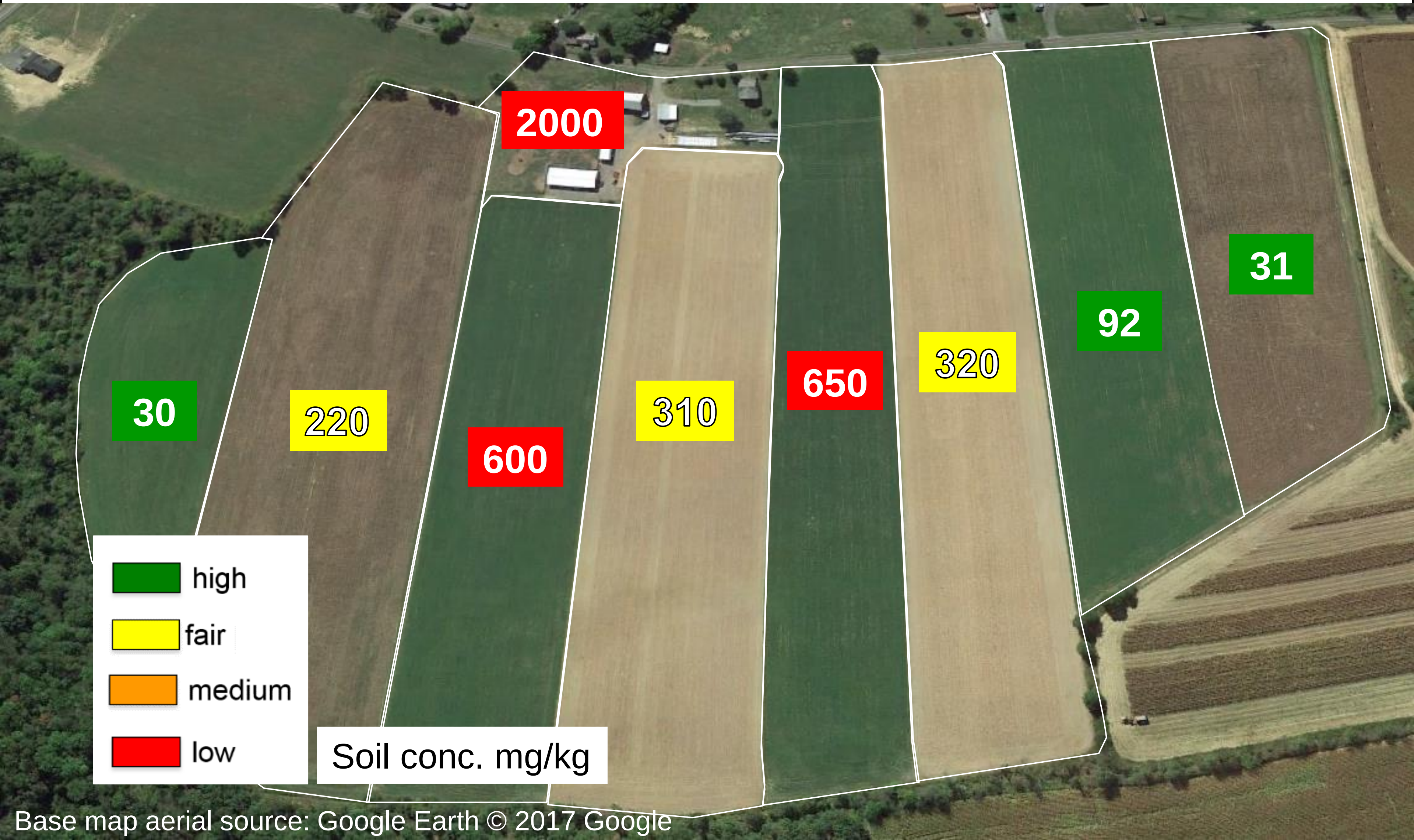


ITRC BCS Figure 7-3

Source: Adapted from California DTSC 2016

Will RBA Affect Remediation Decisions? Residential Exposure

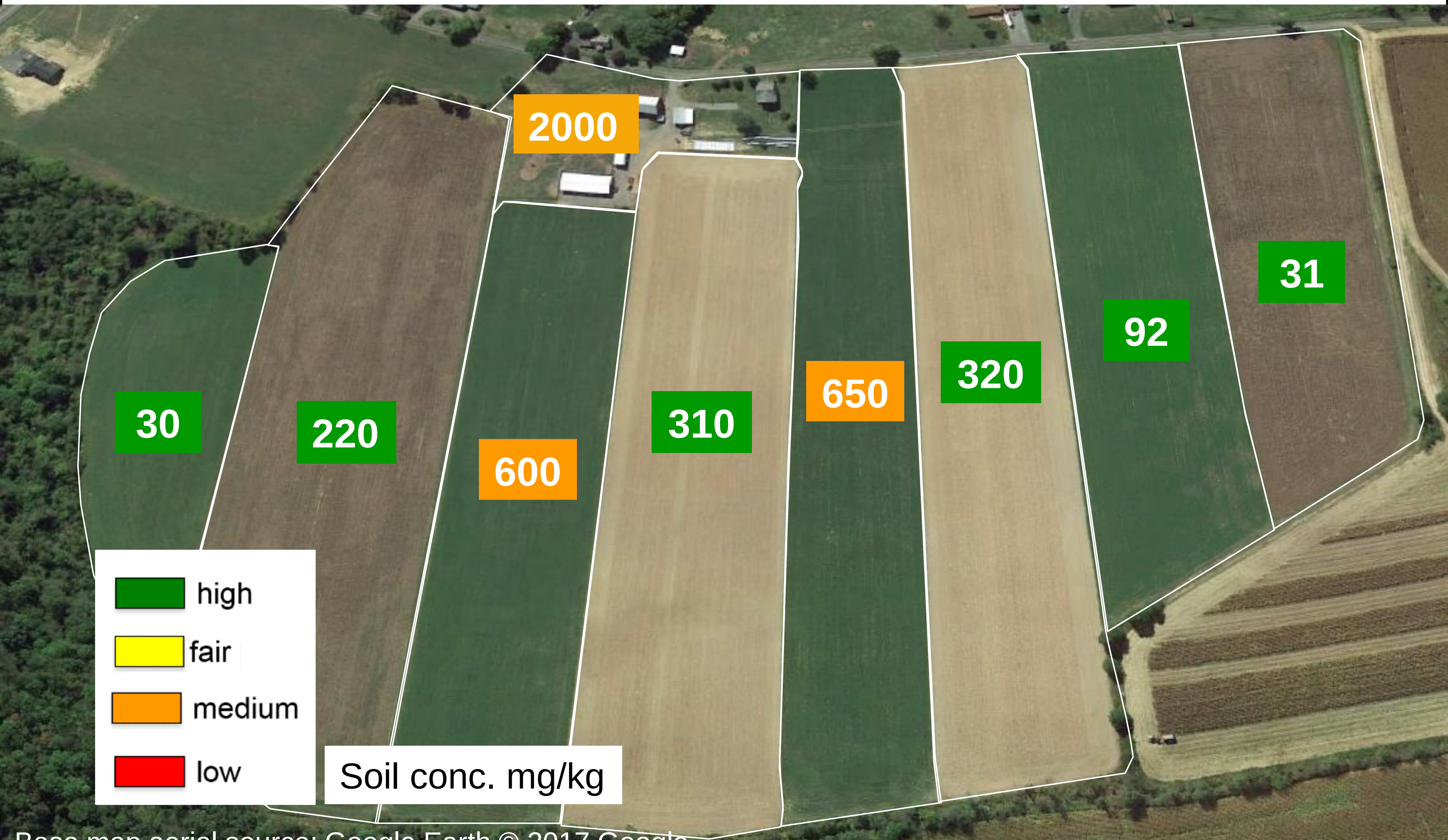
RBA – Relative Oral Bioavailability



Base map aerial source: Google Earth © 2017 Google

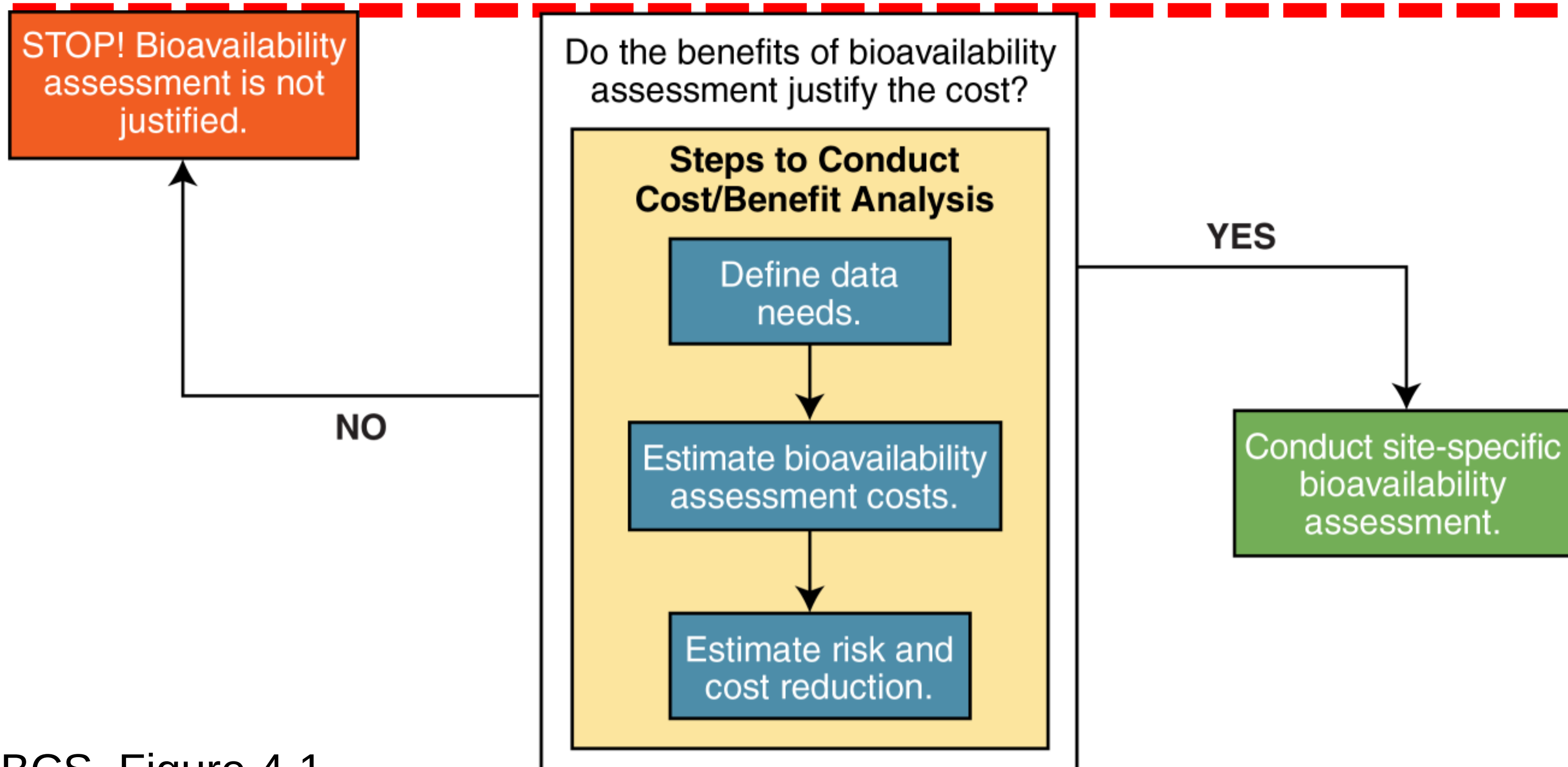
Will RBA Affect Remediation Decisions? Recreational Exposure

RBA – Relative Oral Bioavailability



Base map aerial source: Google Earth © 2017 Google

Considerations for Bioavailability Decision Process Flowchart



ITRC BCS Figure 4-1

Poll Question

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

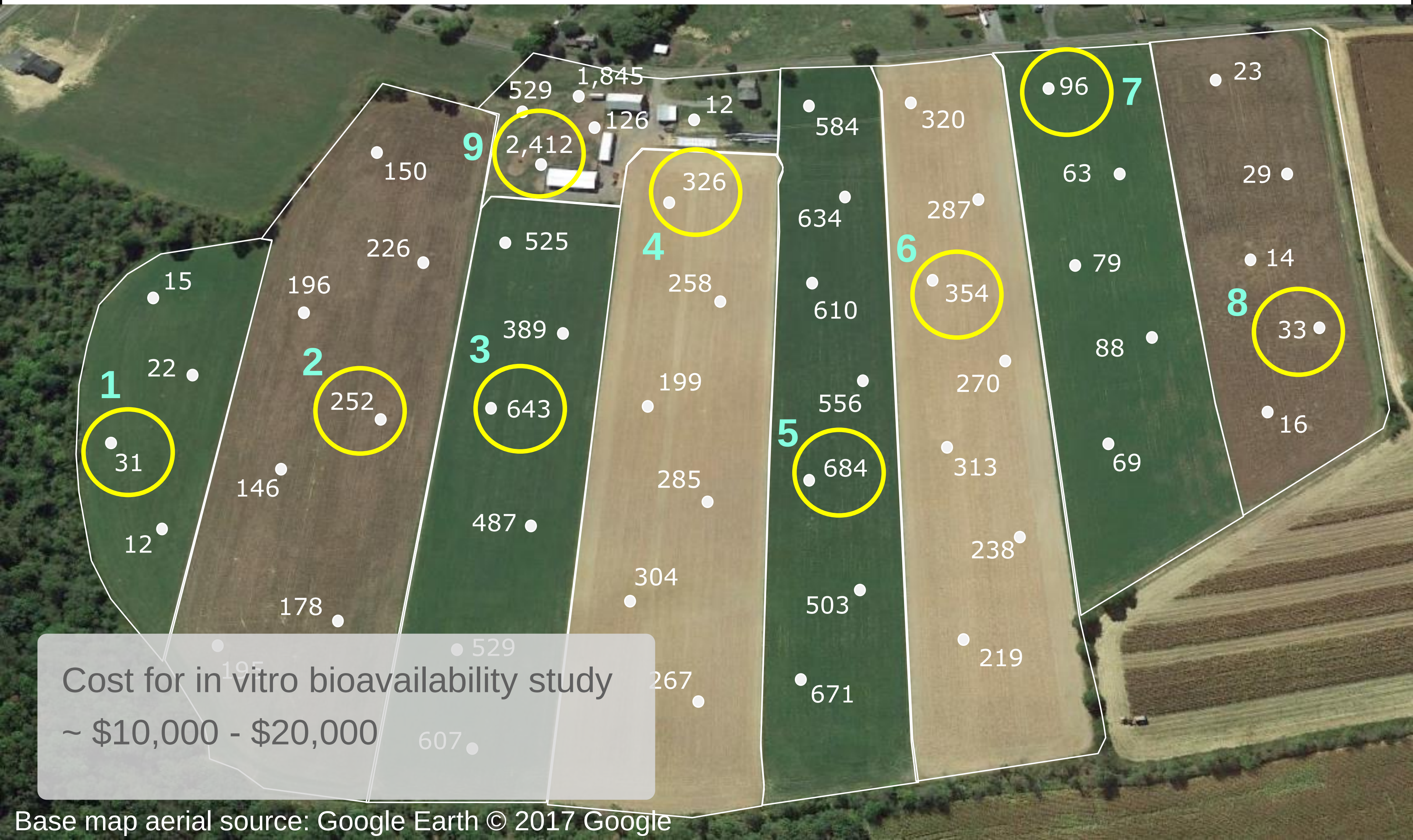
Approximate Costs for Bioavailability Analysis

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

Arsenic Case Study: Conducting Bioavailability Study

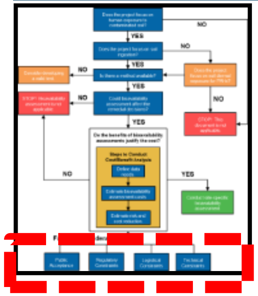


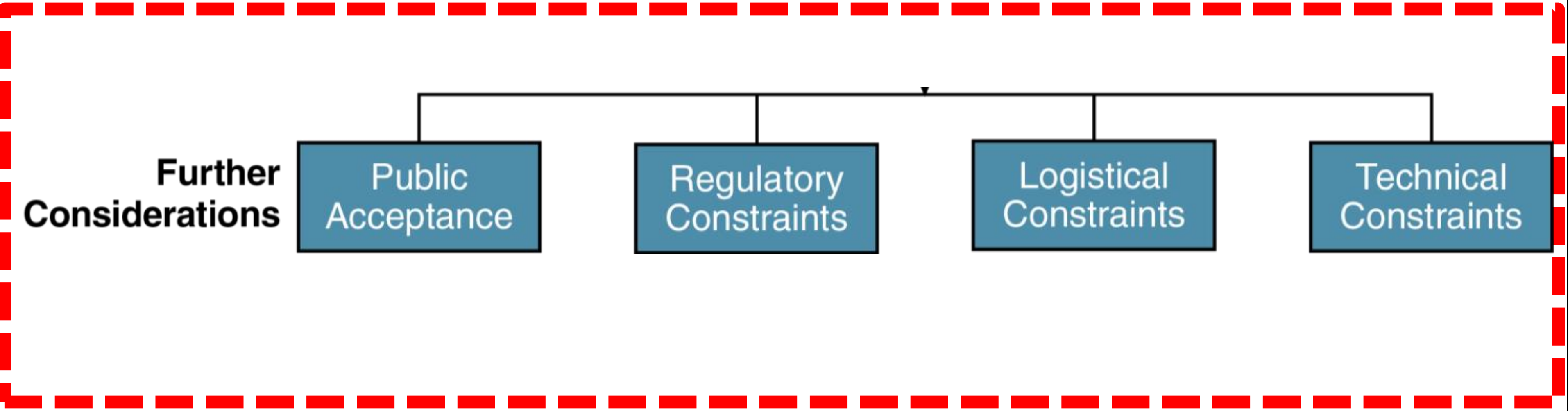
Cost for in vitro bioavailability study

~ $10,000 - $20,000

Base map aerial source: Google Earth © 2017 Google

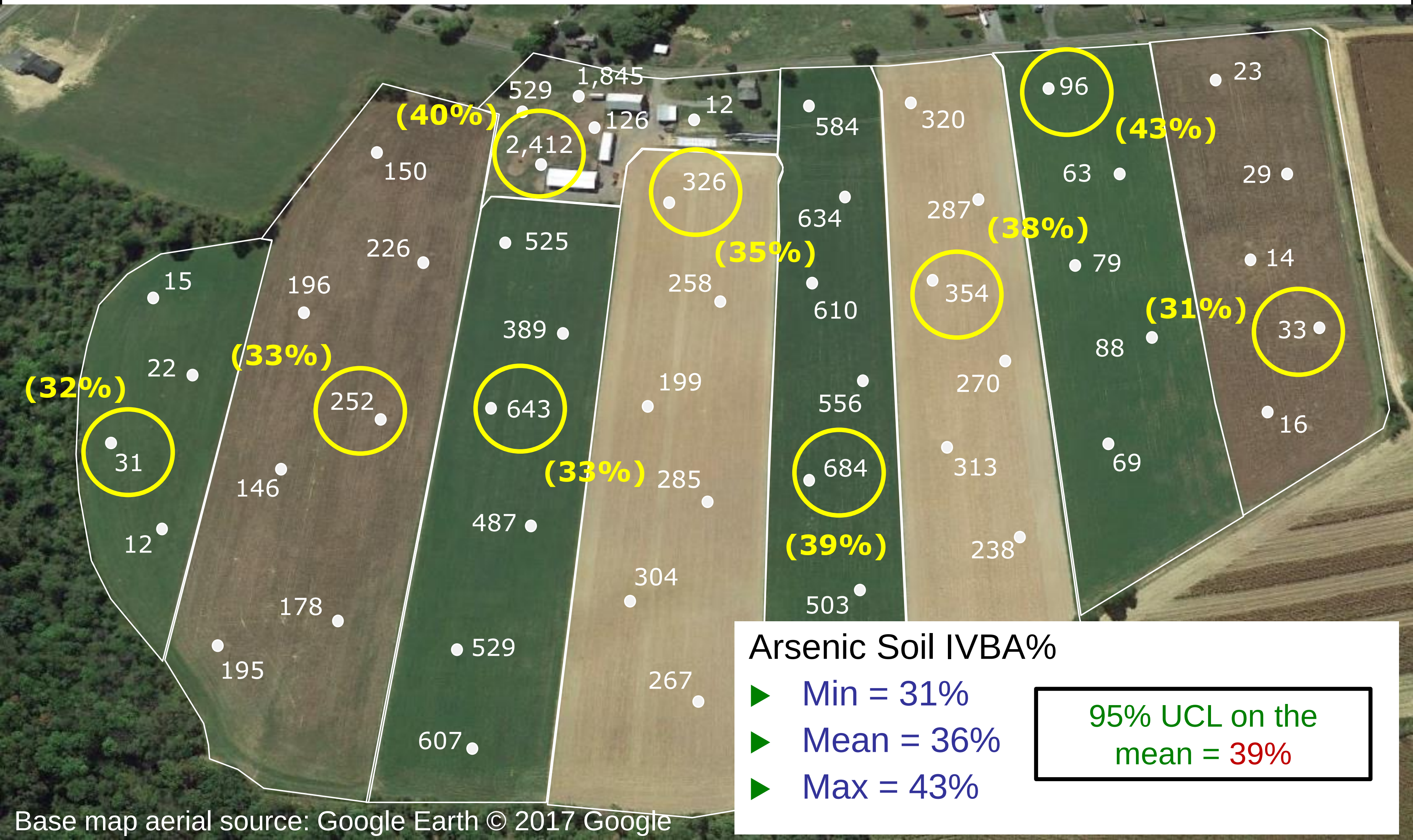
Considerations for Bioavailability Decision Process Flowchart





ITRC BCS Figure 4-1

Arsenic Case Study: Conducting Bioavailability Study



Base map aerial source: Google Earth © 2017 Google

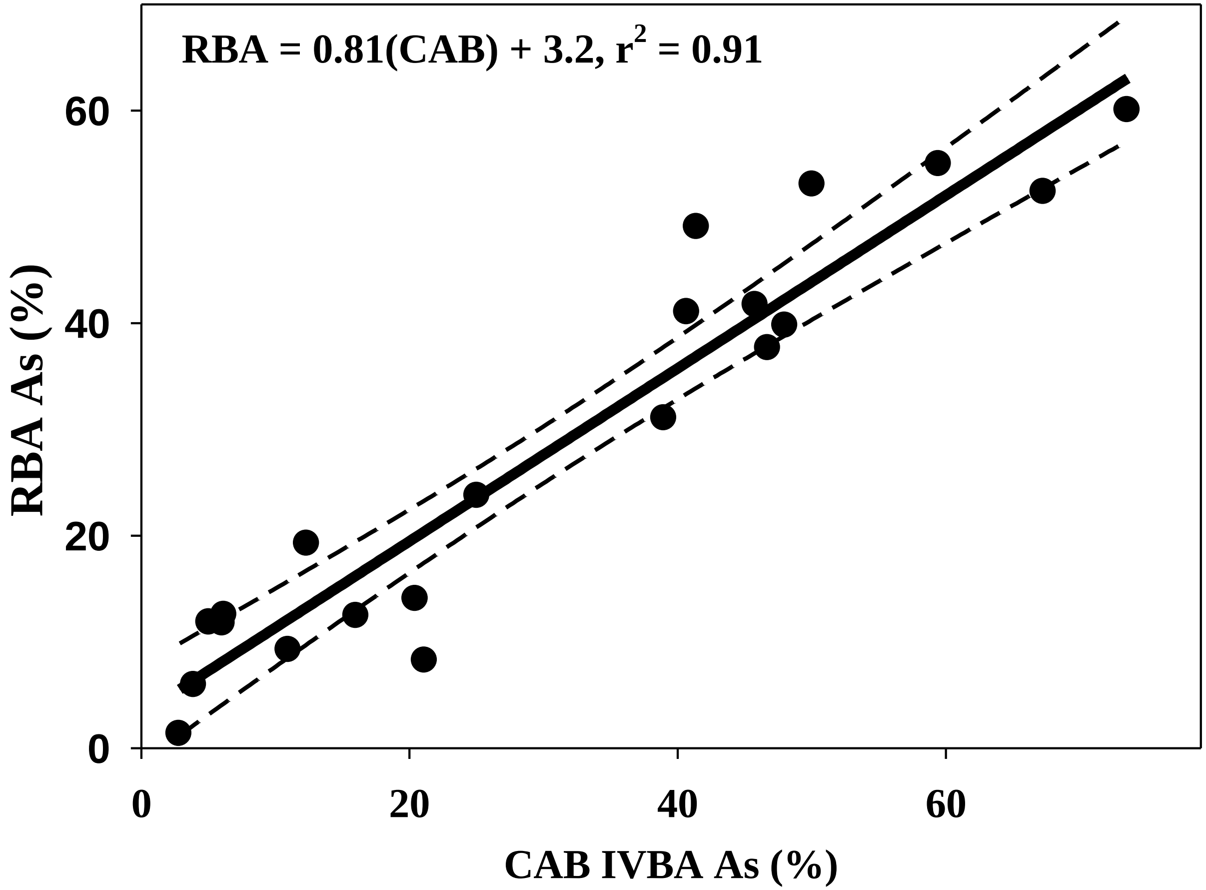
Arsenic Soil IVBA%

- Min = 31%
- Mean = 36%
- Max = 43%

95% UCL on the mean = 39%

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

IVIVC for California Arsenic Bioaccessiblity Method



IVBA = 39%
RBA = 35%

ITRC BCS-1 Figure 7-2

Source: DTSC 2016

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

- Cancer Risk
- Non-Cancer Hazard

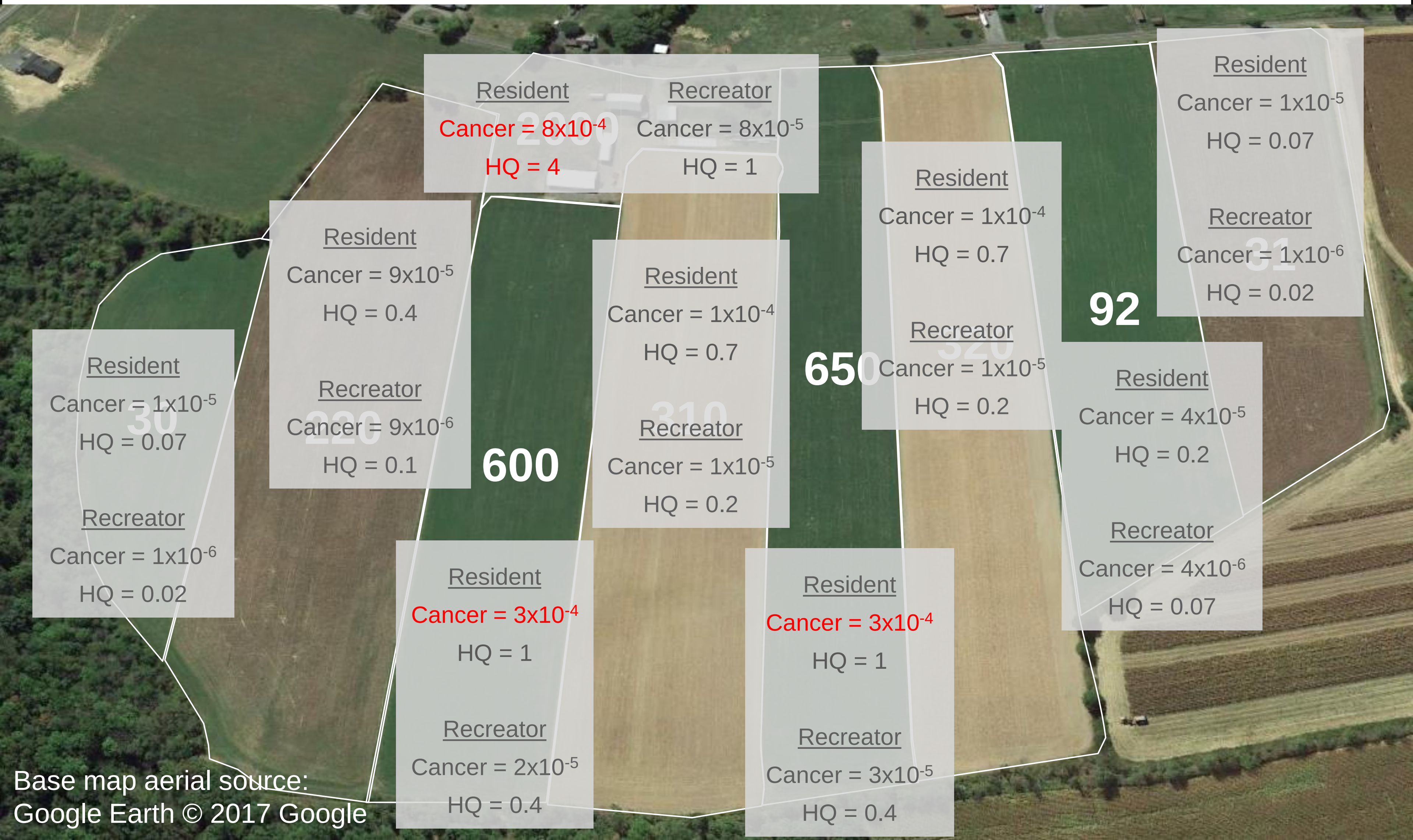
$$ELCR = \frac{C_s \times RBA \times IR \times EF \times ED}{(1/CSF) \times BW \times AT \times CF}$$

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

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 CSF	(Conversion factor) (Cancer slope factor)	= =	1.0E+6 mg/kg chemical-specific, $(mg/kg\text{-}day)^{-1}$
ED EF	(Exposure duration) (Exposure frequency)	= =	years 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

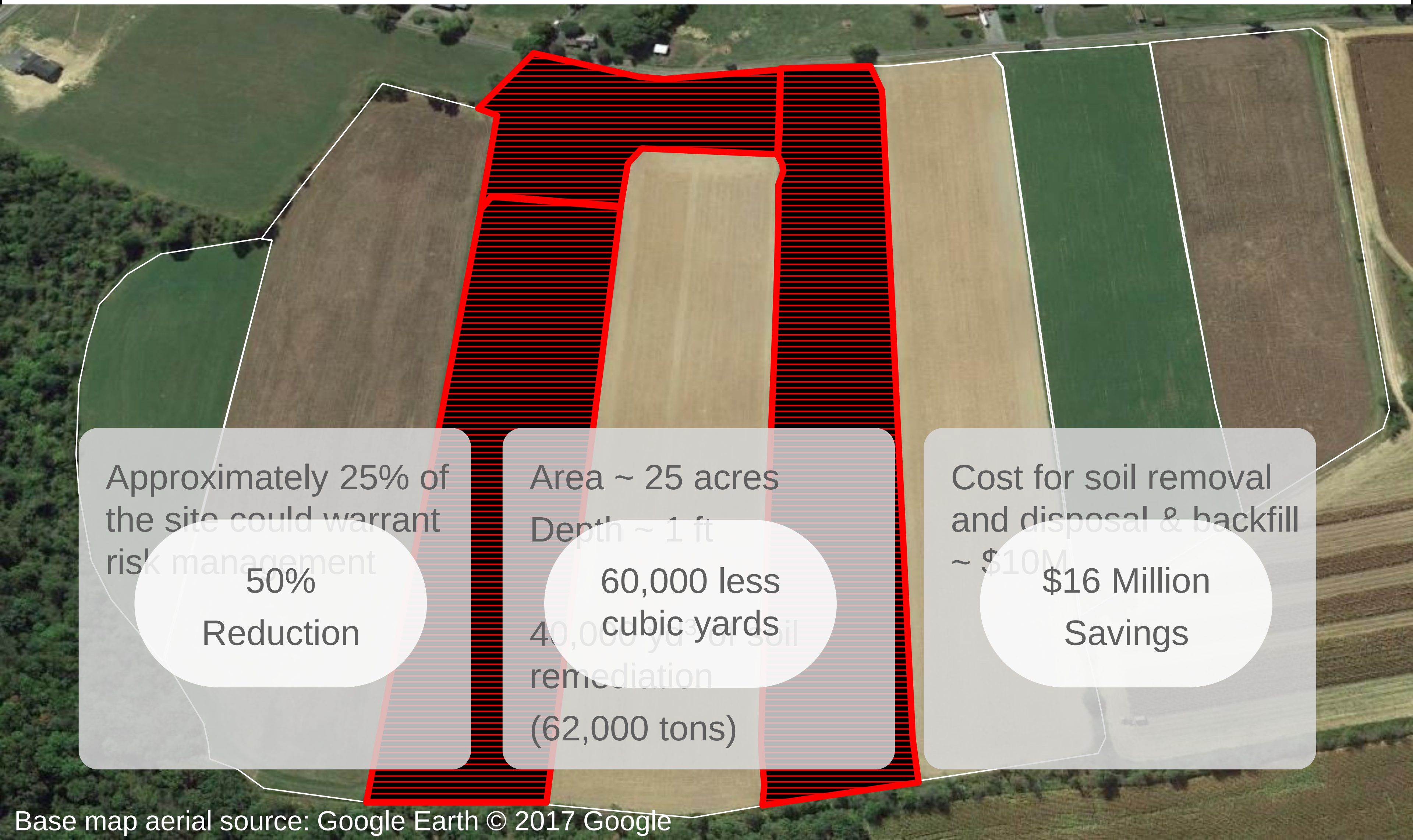
Arsenic Case Study: Risk Characterization (35% RBA)

RBA – Relative Oral Bioavailability



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

RBA – Relative Oral Bioavailability



Approximately 25% of the site could warrant risk management

50% Reduction

Area ~ 25 acres

Depth ~ 1 ft

40,000 yd^3 of soil remediation

(62,000 tons)

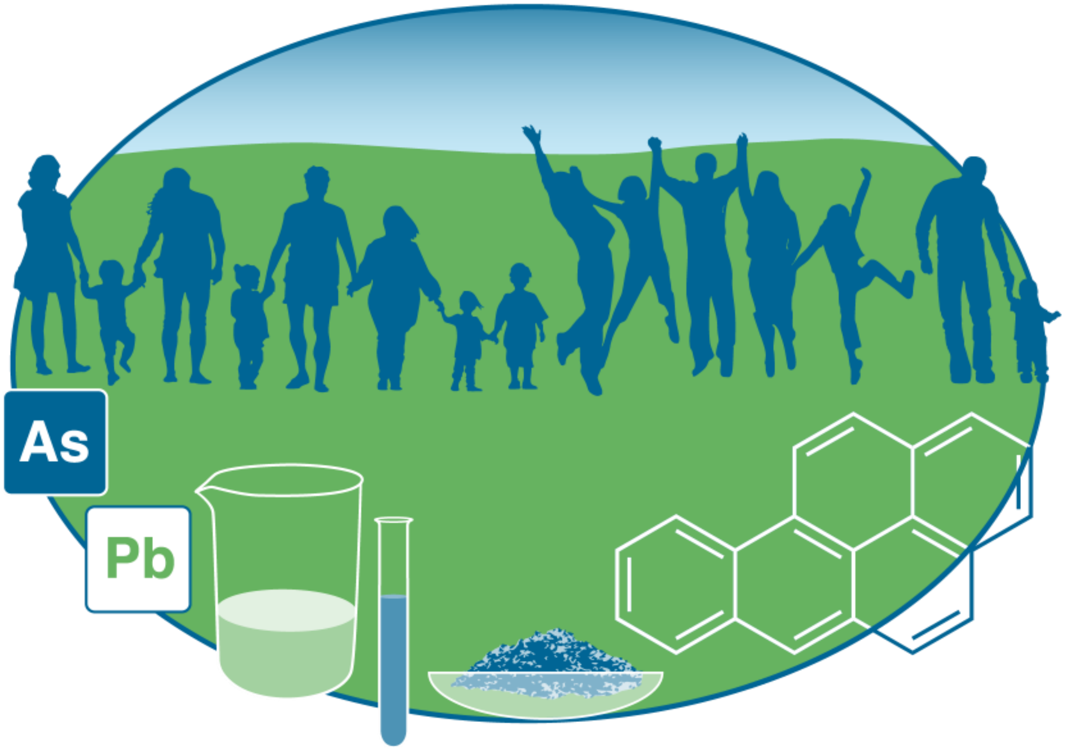
60,000 less cubic yards

Cost for soil removal and disposal & backfill ~ $10M

$16 Million Savings

Base map aerial source: Google Earth © 2017 Google

Question and Answer Break



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)**

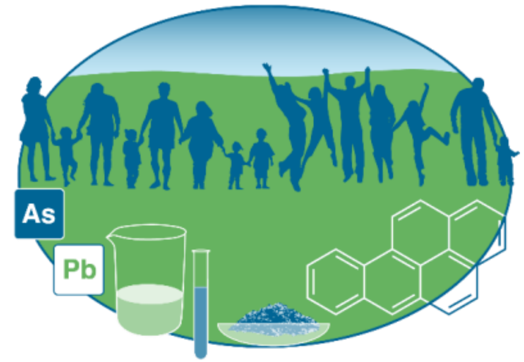
↓

Discussion: Polycyclic Aromatic Hydrocarbons (PAHs)

↓

Taking Action

Questions and Answers

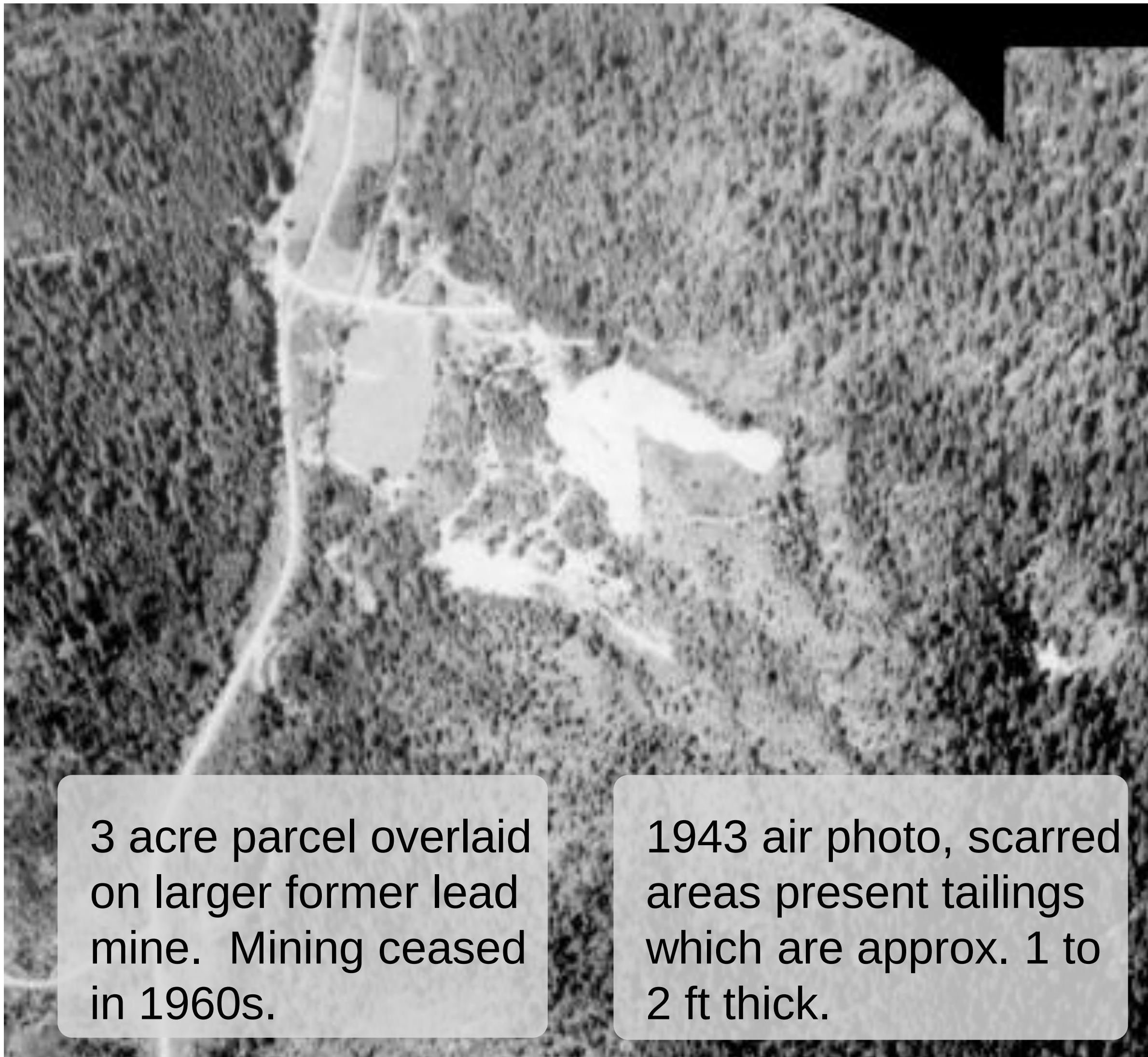


Lead Case Study

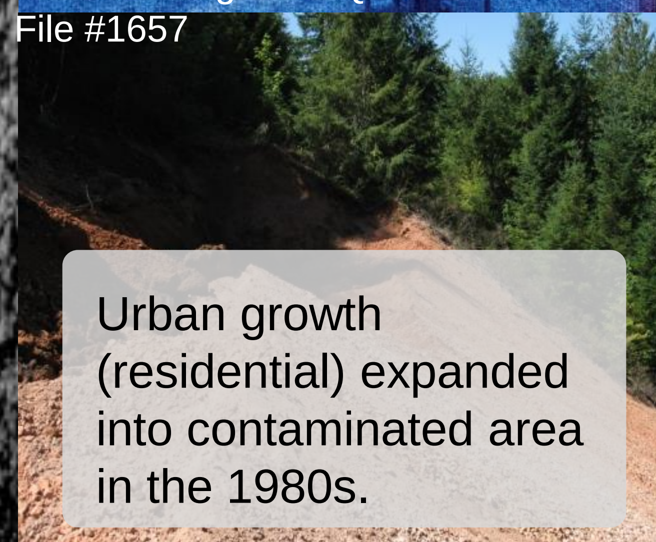
- Case study is presented as a series of meetings between regulator and consultant
- Historic lead mining area
- Contaminant source – lead tailings
- Residential area
- Future land uses are residential and commercial

Source: Pixnio.com

Lead Case Study: Former Lead Mining Area



Source: Oregon DEQ Black Butte Mine File #1657



3 acre parcel overlaid on larger former lead mine. Mining ceased in 1960s.

1943 air photo, scarred areas present tailings which are approx. 1 to 2 ft thick.

Urban growth (residential) expanded into contaminated area in the 1980s.

Lead Case Study: Site is Now a Residential Area

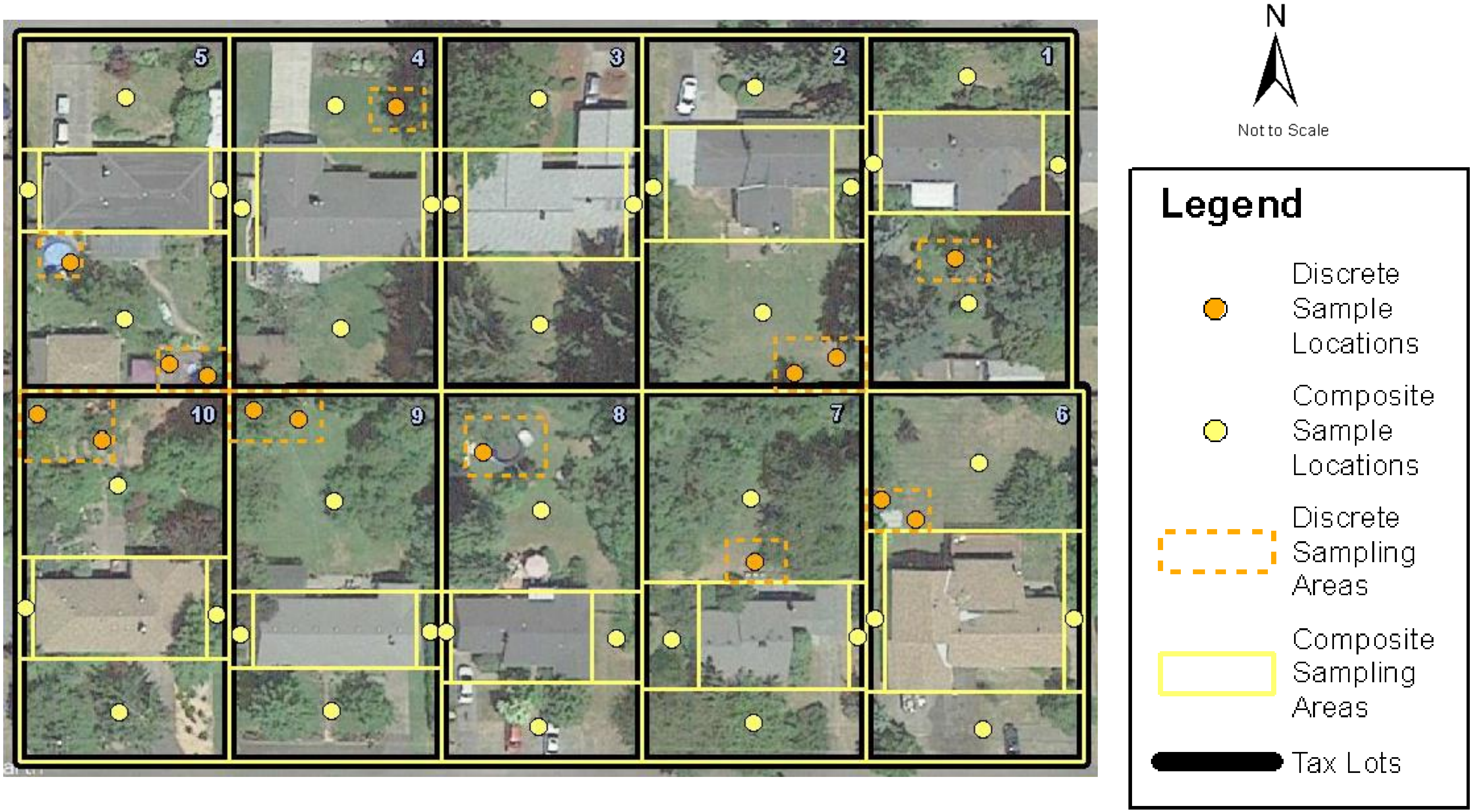
1980s development, with 1/3 acre or smaller lots

Includes play areas and gardens

Each parcel has front, back, and 2 side yards

Base map aerial source: Google Earth © 2017 Google

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



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

Base map aerial source: Google Earth © 2017 Google

Lead Case Study: Total Lead Sampling Complete

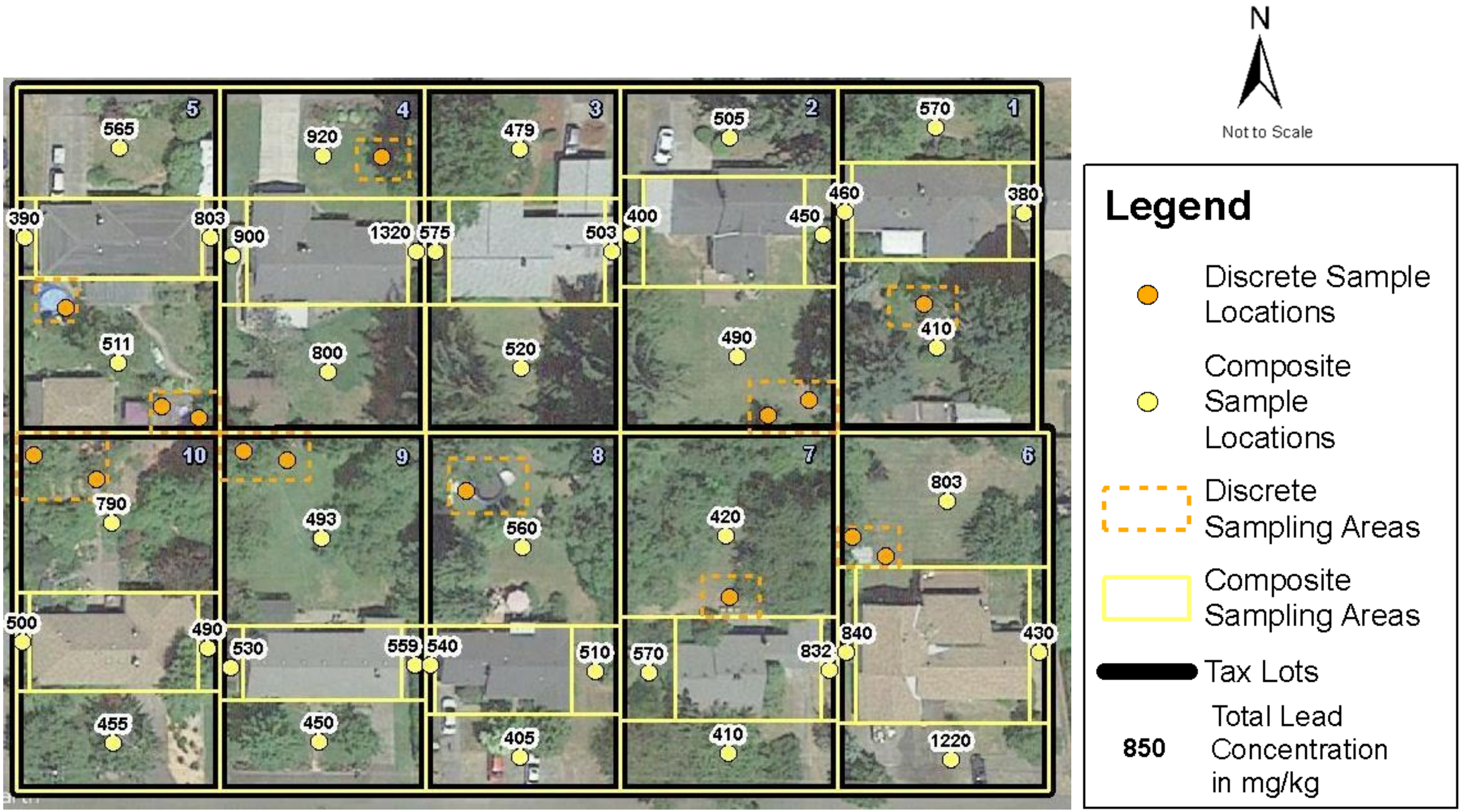
- Available samples for nature & extent
  - 10 properties; 4 yards each (1 composite sample/yard) = 40 samples
  - 5 properties with gardens (2 discrete samples/garden) = 10 samples
  - 5 properties with play areas (1 discrete sample/play area) = 5 samples
- Total lead concentrations
  - 380 to 1,321 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

Lead Case Study: All Properties Exceed Default Cleanup Level



Base map aerial source: Google Earth © 2017 Google

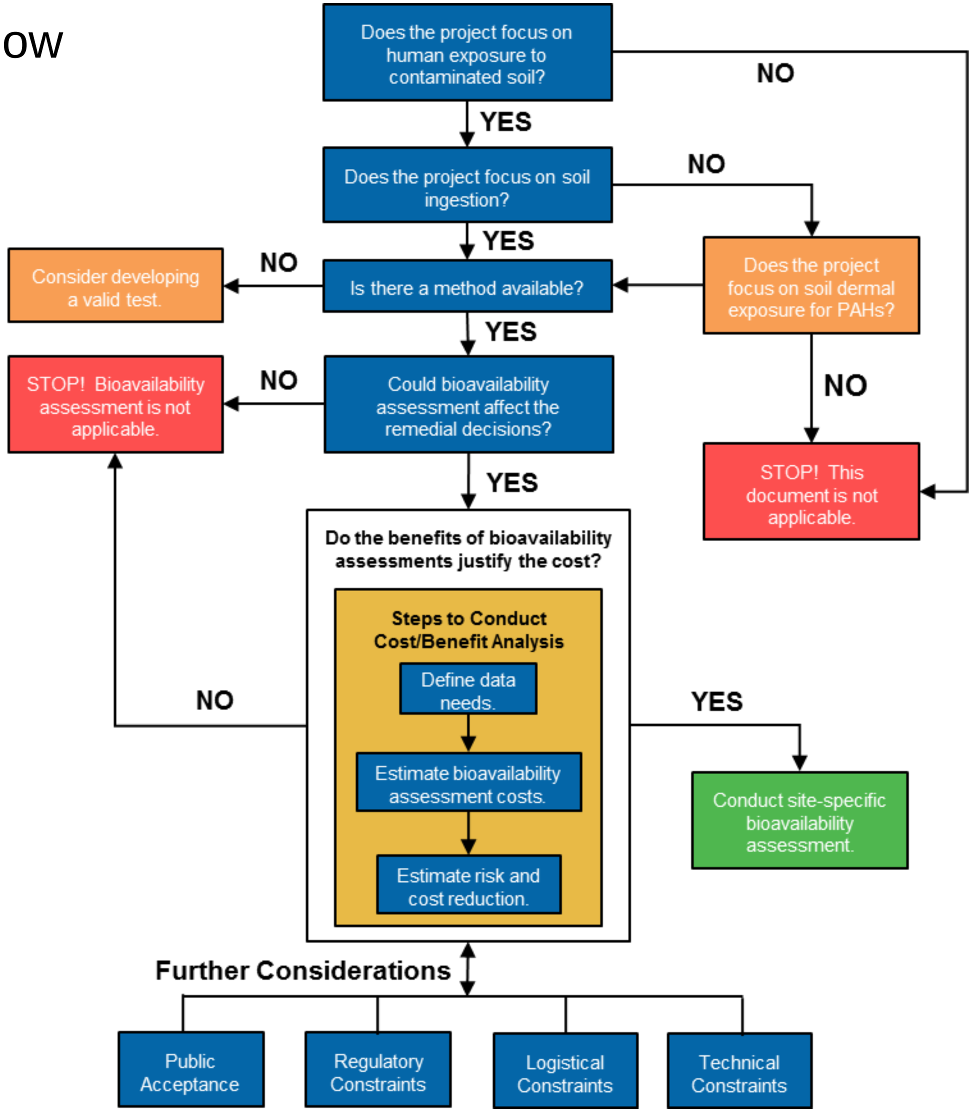
Current state residential screening level = 400 mg/kg

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

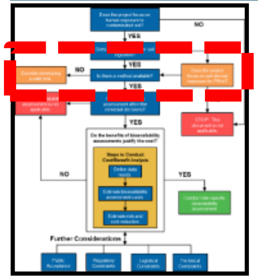
Lead Case Study: Need to Determine if Bioavailability Study is Worthwhile

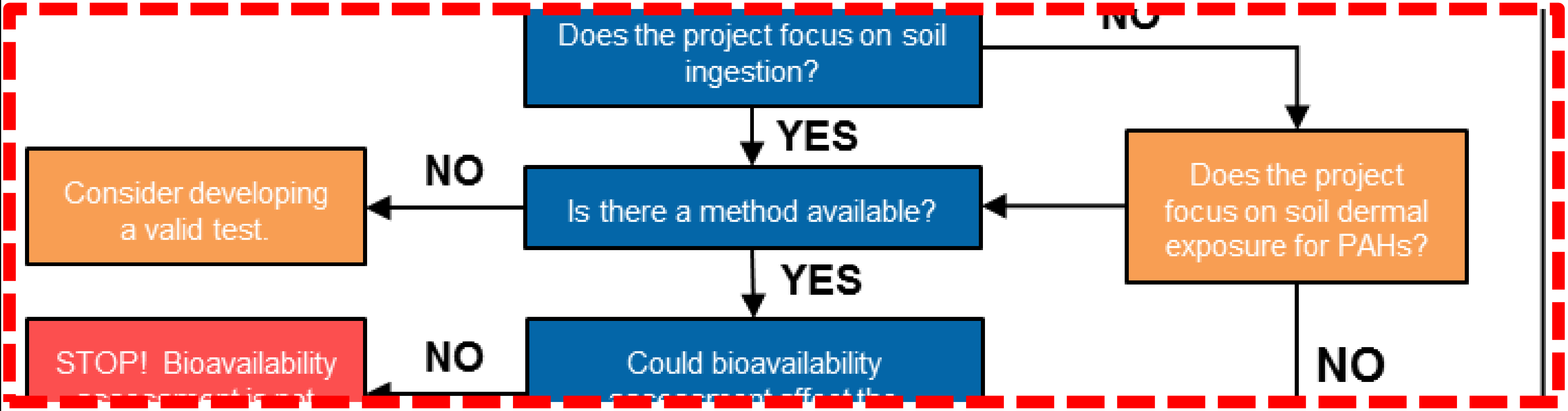
Full size decision flow chart available in "Related Links"



ITRC BCS-1 Figure 4-1

Lead Case Study: Methodology?





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

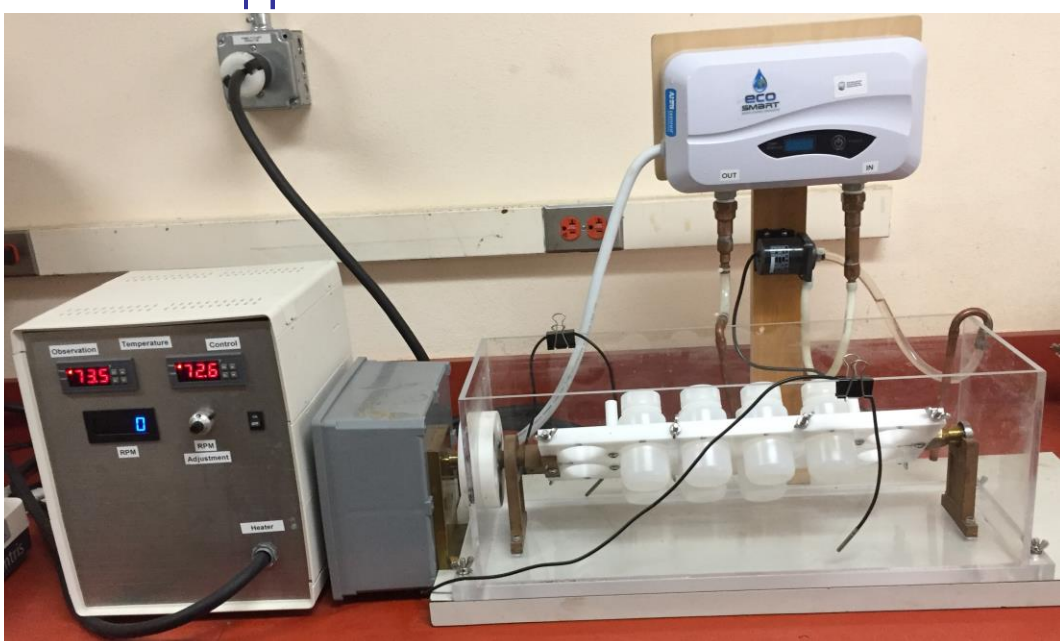
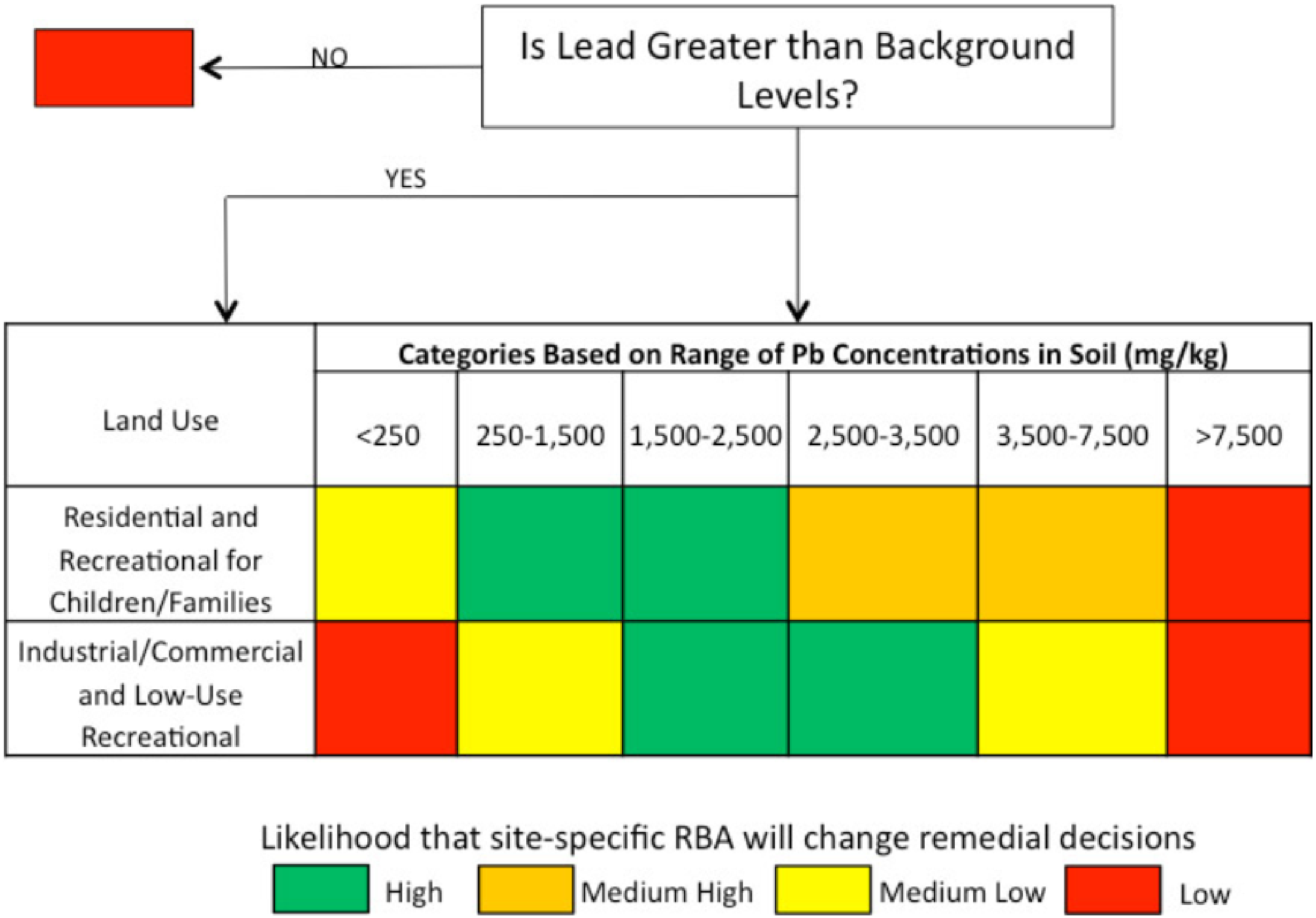


Photo courtesy of Geoff Siemering, University of Wisconsin, 2017

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

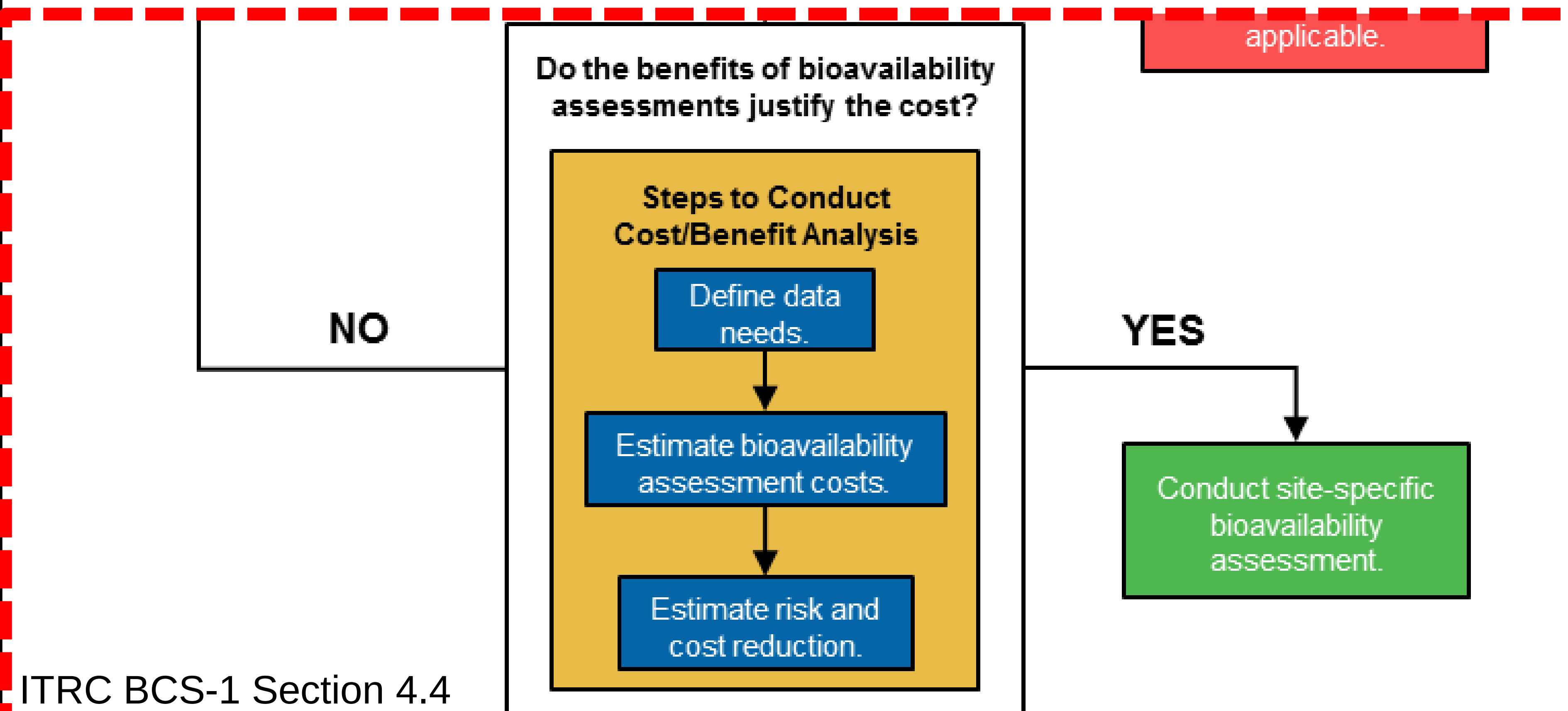
- Reasons we don’t need in vivo
  - Lead has been well studied with a variety of soils with good in vivo - in vitro correlation
  - Site soil is well-characterized
  - Site soil type & waste type are similar to those tested by USEPA
  - Site soil type has an established in vivo – in vitro correlation

Lead Case Study: Bioavailability Study Could Affect Remediation Decisions



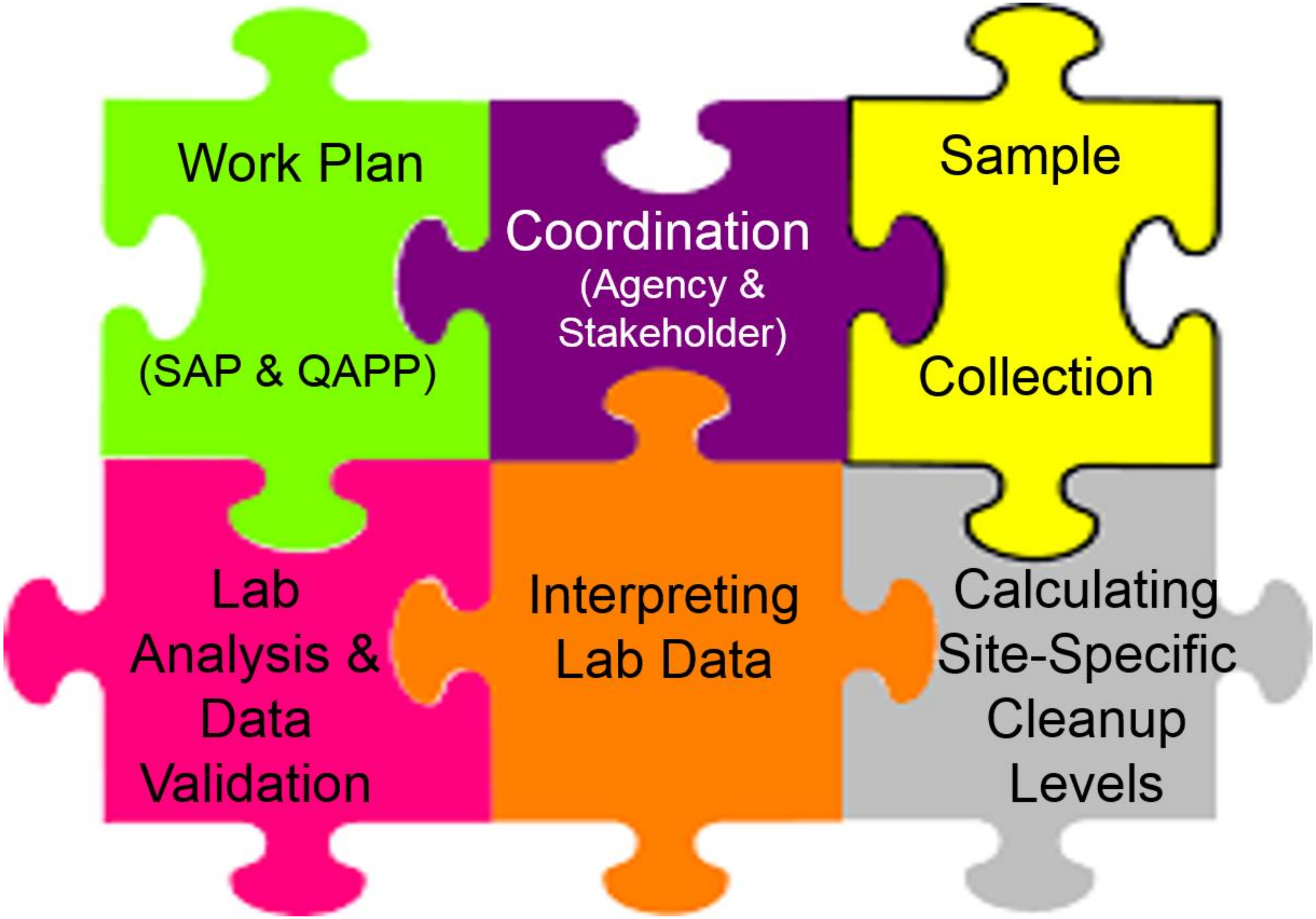
ITRC BCS-1 Figure 6-3

Lead Case Study: Cost Benefit Analysis



ITRC BCS-1 Section 4.4

Lead Case Study: Bioavailability Study has Various Components



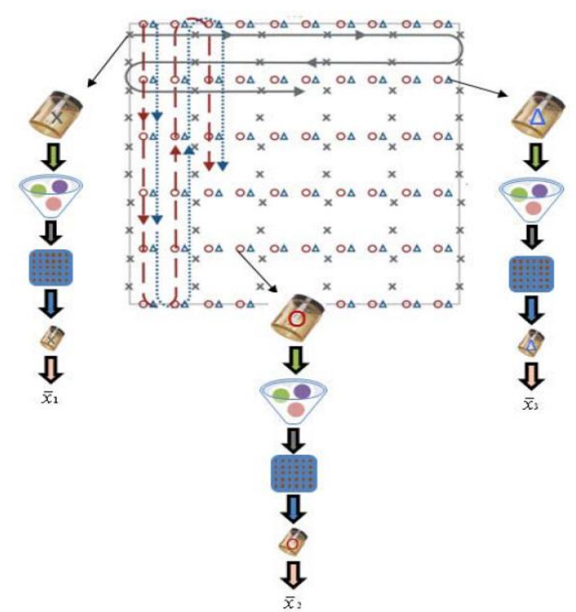
Poll Question

- 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

Lead Case Study: Guidance on Lead Sampling for IVBA Testing

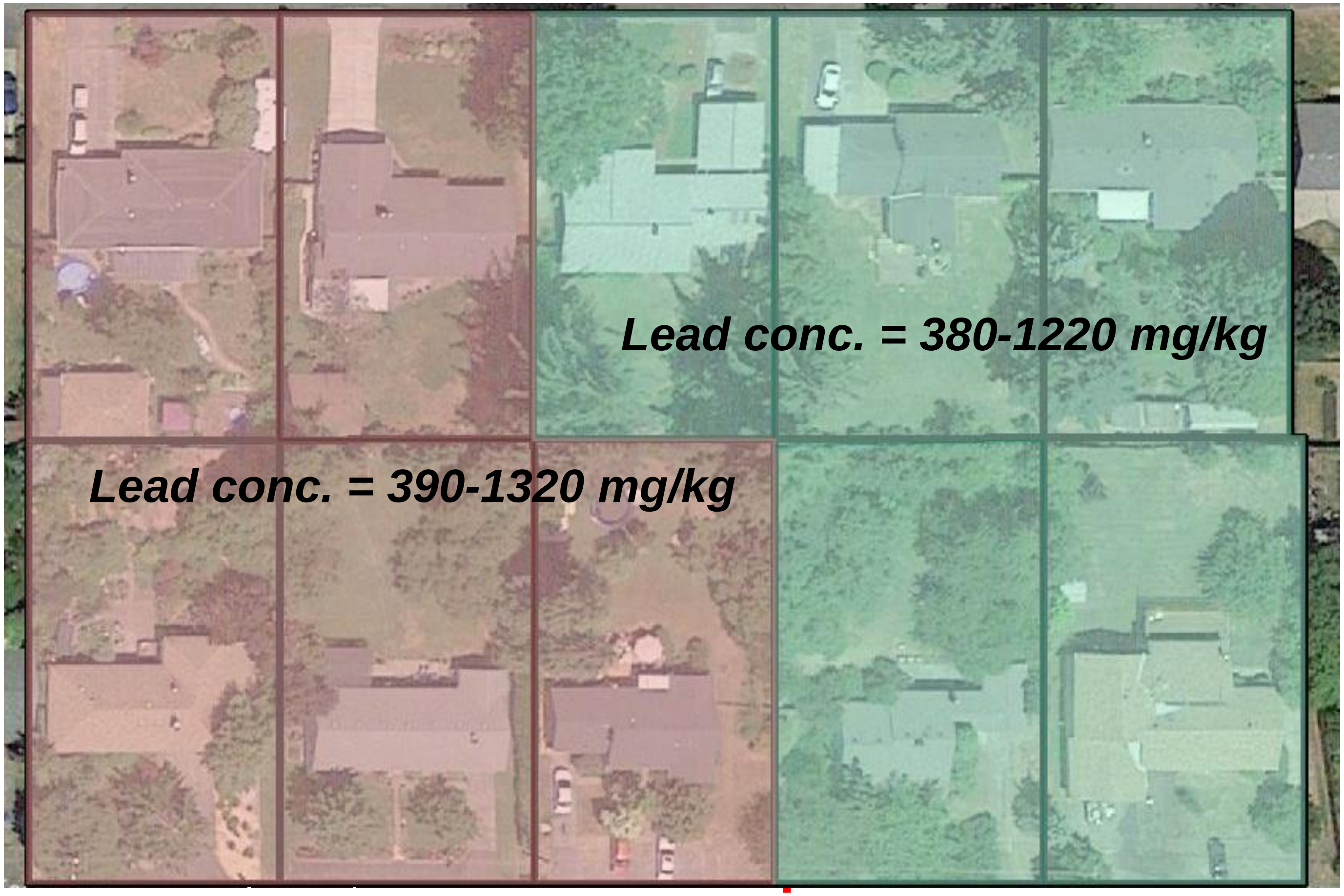
- USEPA "Guidance for Sample Collection for In Vitro Bioaccessibility Assay for Lead (Pb) in Soil" (2015)
  - "2 composites made up of 30 increments"
  - "In general, for most risk assessment applications, acceptable Type I error rate can be expected if ITRC (2012) recommendations are followed (30 increments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



ITRC BCS-1 Section 9.1.6

ITRC ISM-1 Figure 1-2

Lead Case Study: Where Should IVBA Samples be Collected?



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

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

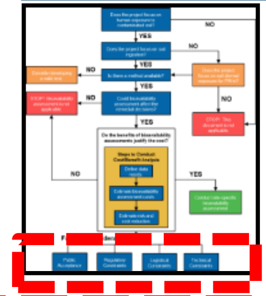
Photo courtesy of Geoff Siemering, University of Wisconsin, 2017

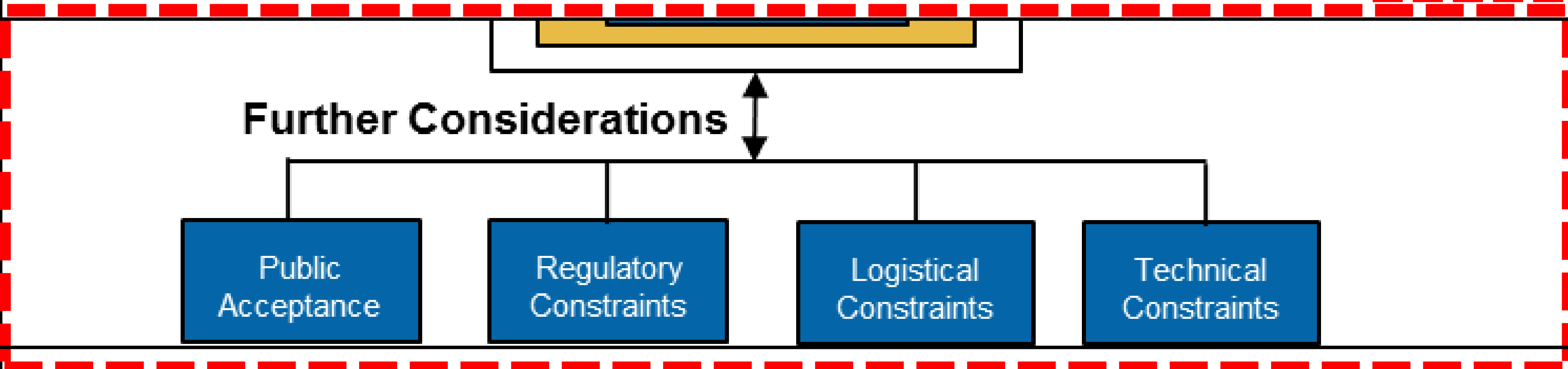
Lead Case Study: Potential Cost Impacts on the Project

- 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

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

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

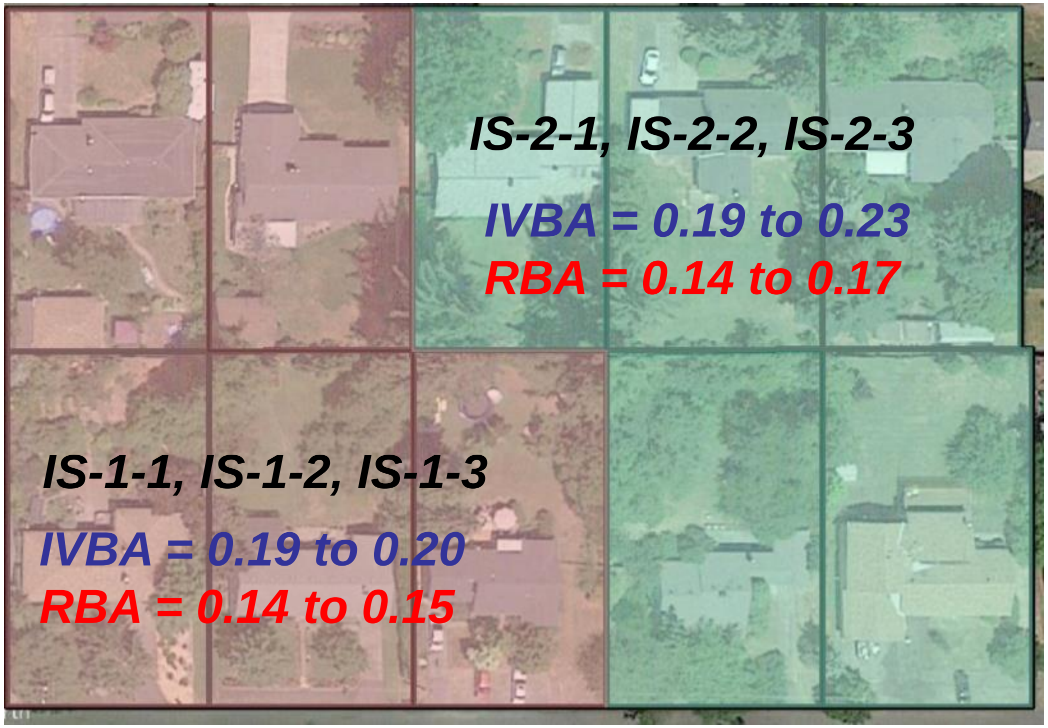
Lead Case Study: Follow-up Meeting Held to Discuss Study Results

- 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

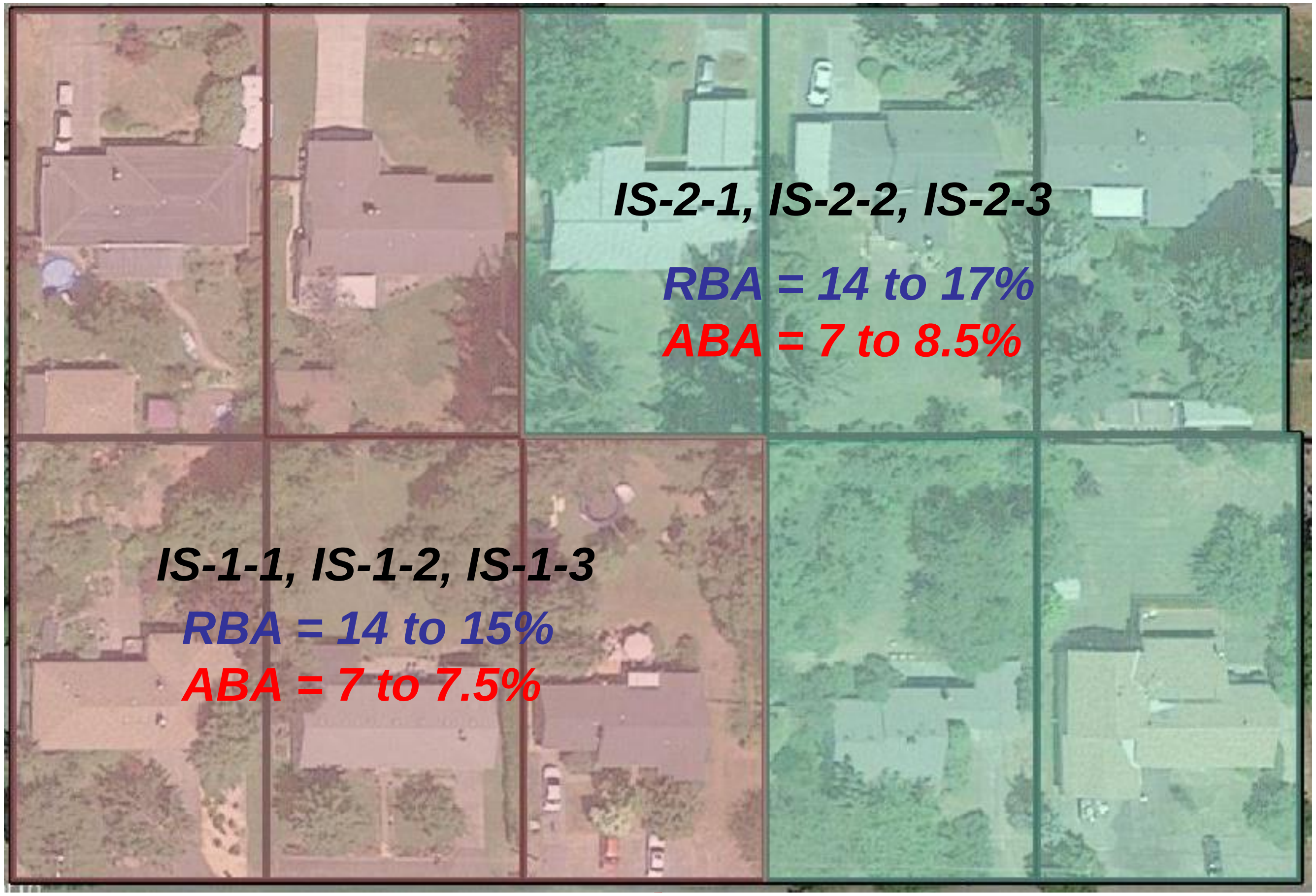
Lead Case Study: RBA Predicted from IVBA

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



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

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



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

Base map aerial source: Google Earth © 2017 Google

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%)

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

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)

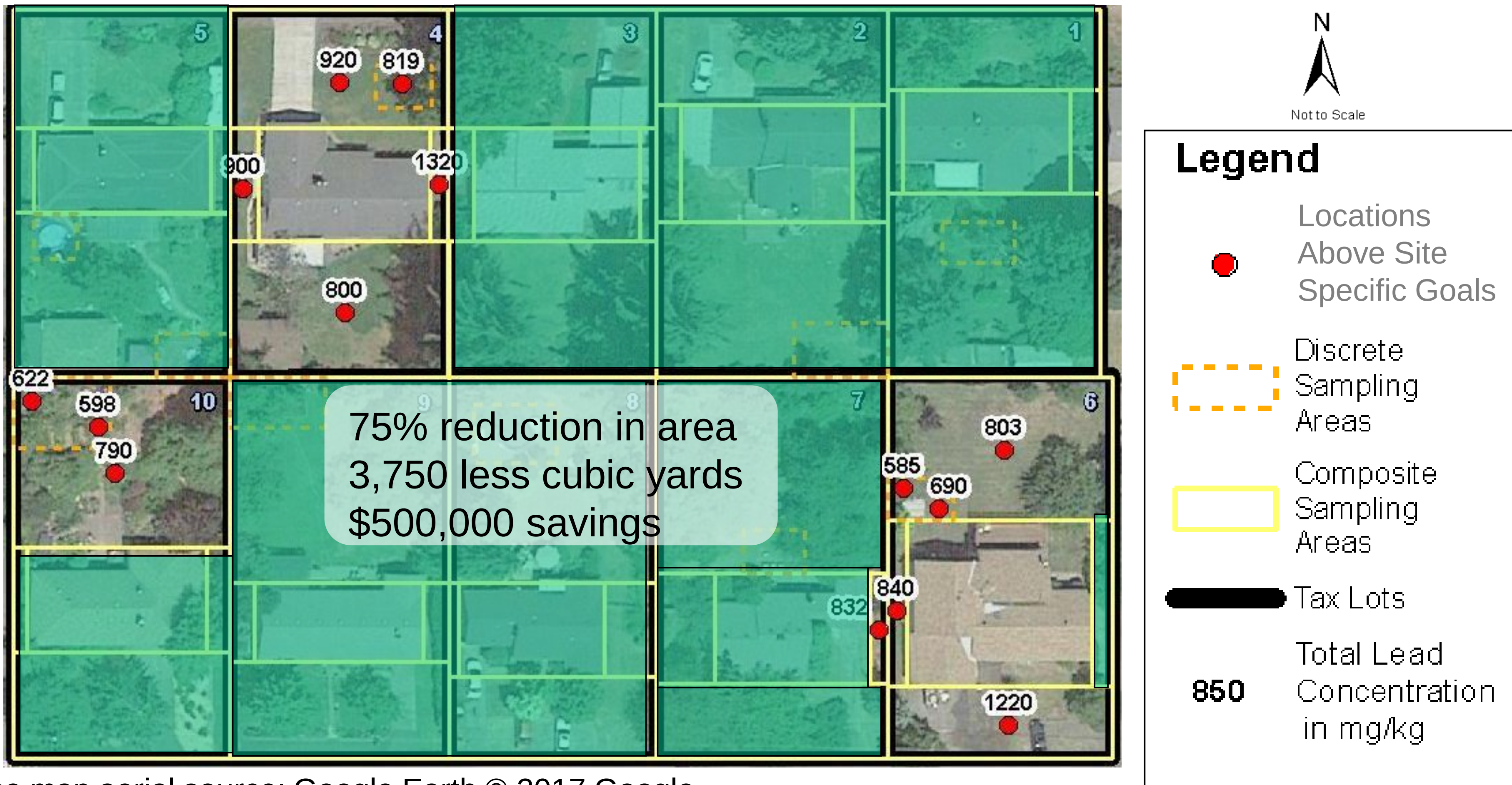
  "OLEM recognizes adverse health effects as blood lead concentrations below 10 ug/dL. Accordingly, OLEM is updating the soil lead strategy to incorporate this new information."

  (OLEM = USEPA Office of Land and Emergency Management)

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

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

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/

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

Today's Training Road Map

Importance of Evaluating Bioavailability in Soils

Bioavailability Basics

Case Study 1 (Arsenic Site)

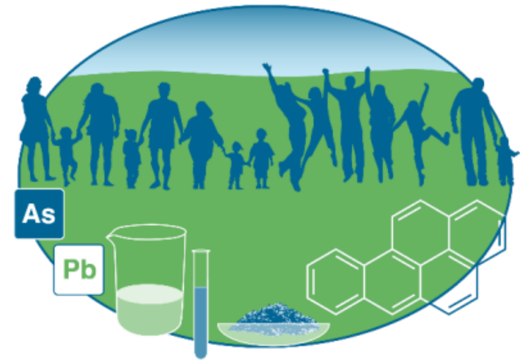
Questions and Answers

Case Study 2 (Lead Site)

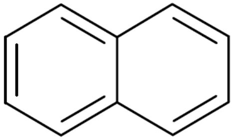
Discussion: Polycyclic Aromatic Hydrocarbons (PAHs)

Taking Action

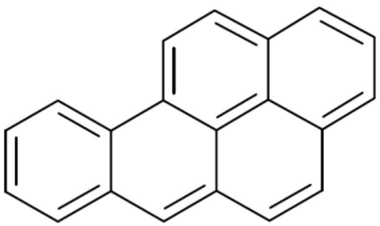
Questions and Answers



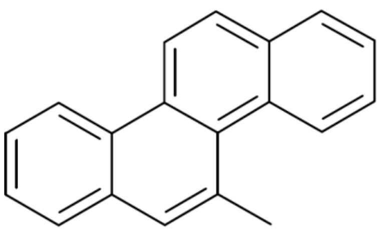
Bioavailability of PAHs from Soil



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)

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

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.

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

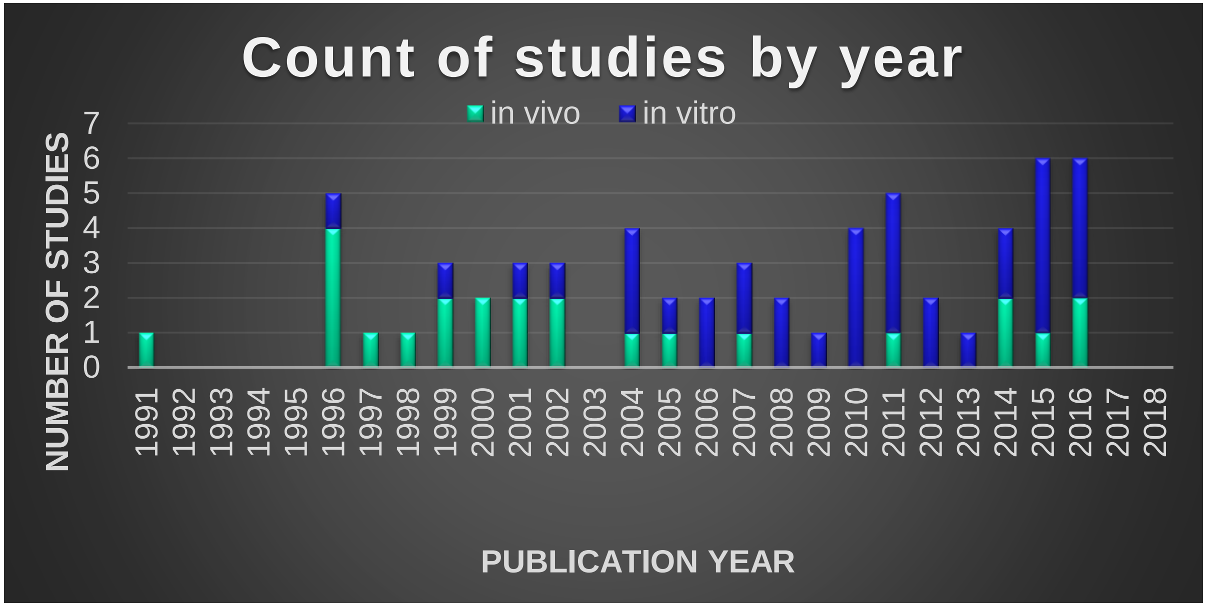
State of the Science: Bioavailability of PAHs from Soil

- 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

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

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

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

Key Considerations in Study Design

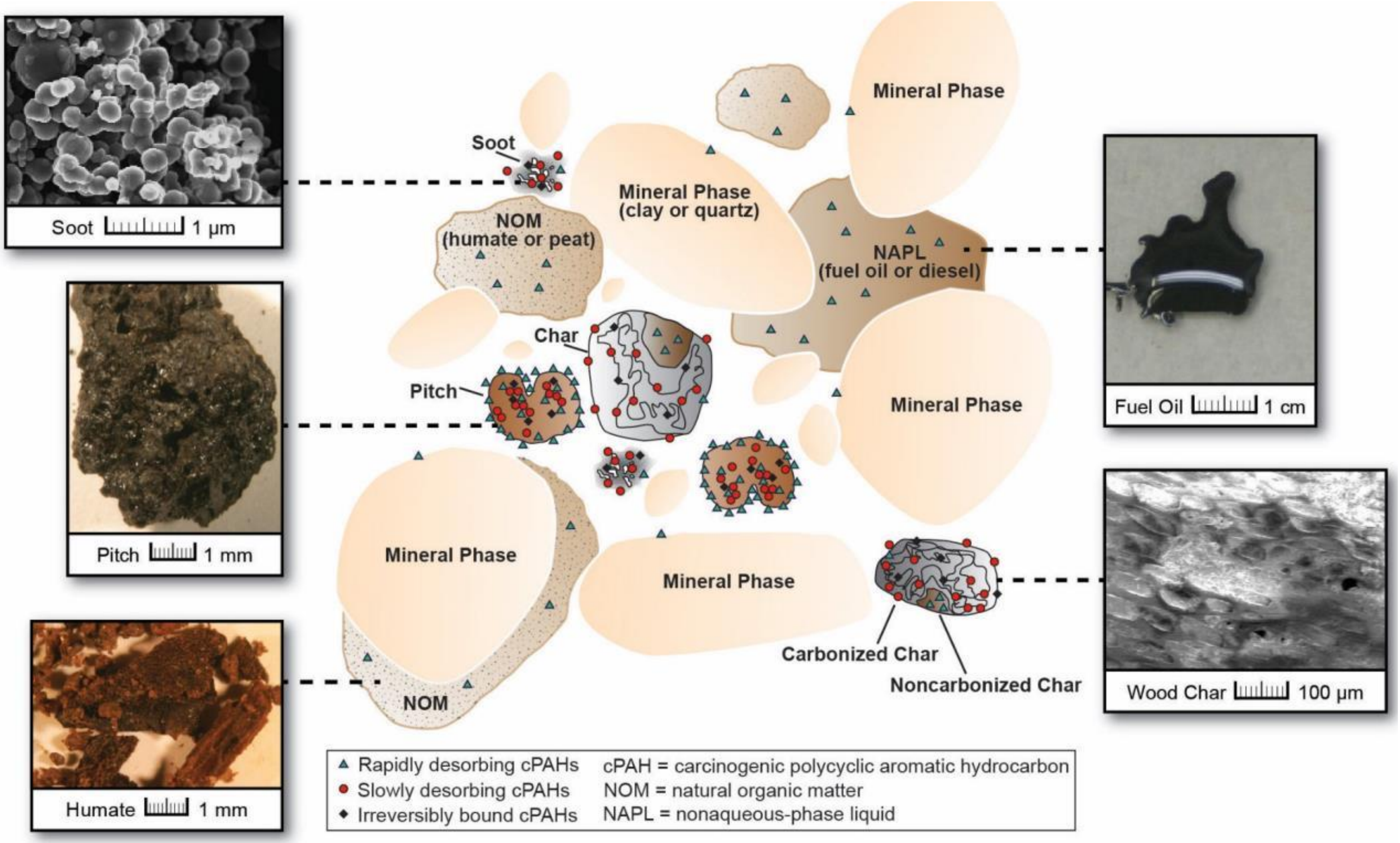
ITRC Document Provides Overview Specific to PAHs

- 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

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!

Soil-Chemical Interactions affecting RBA for PAHs in Soil



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ITRC BCS-1 Figure 8-1

Today's Training Road Map

Importance of Evaluating Bioavailability in Soils

Bioavailability Basics

Case Study 1 (Arsenic Site)

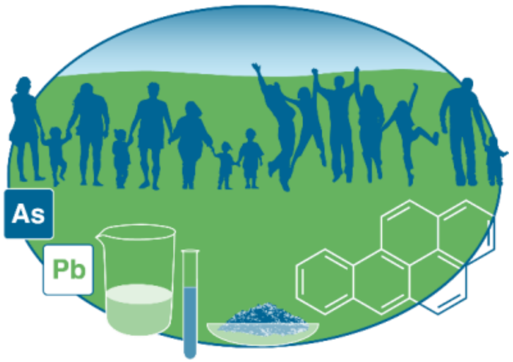
Questions and Answers

Case Study 2 (Lead Site)

Discussion: Polycyclic Aromatic Hydrocarbons (PAHs)

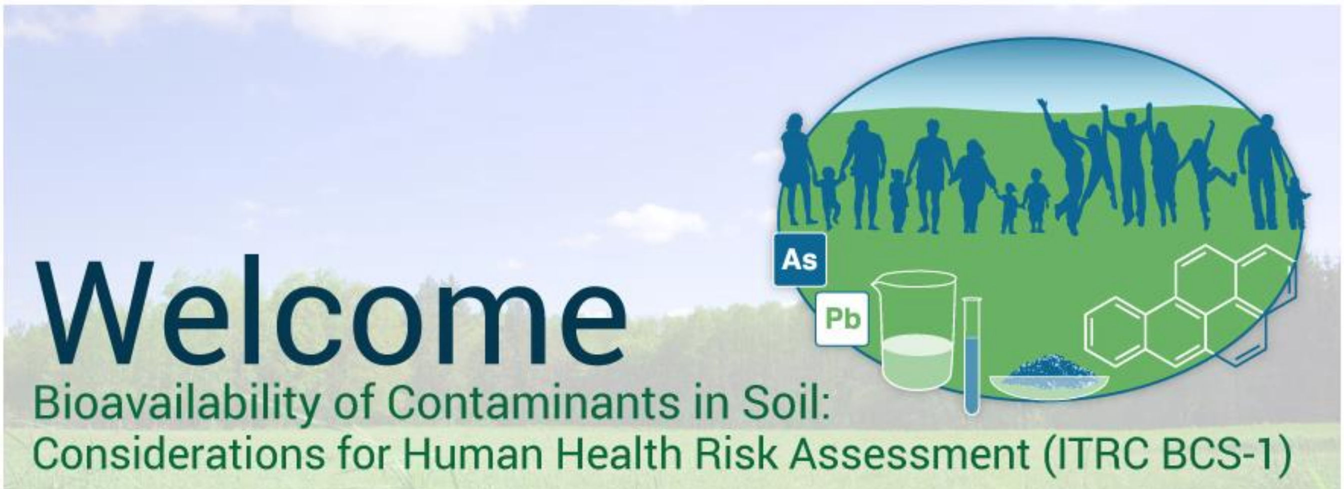
Taking Action

Questions and Answers



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.

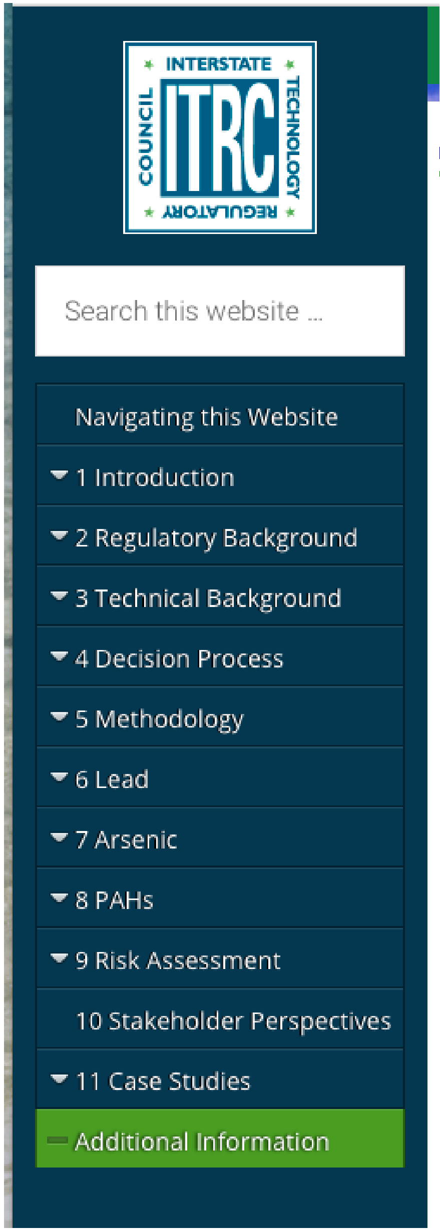
Regulators, practitioners, and stakeholders will find help performing the following tasks:

- 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.

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

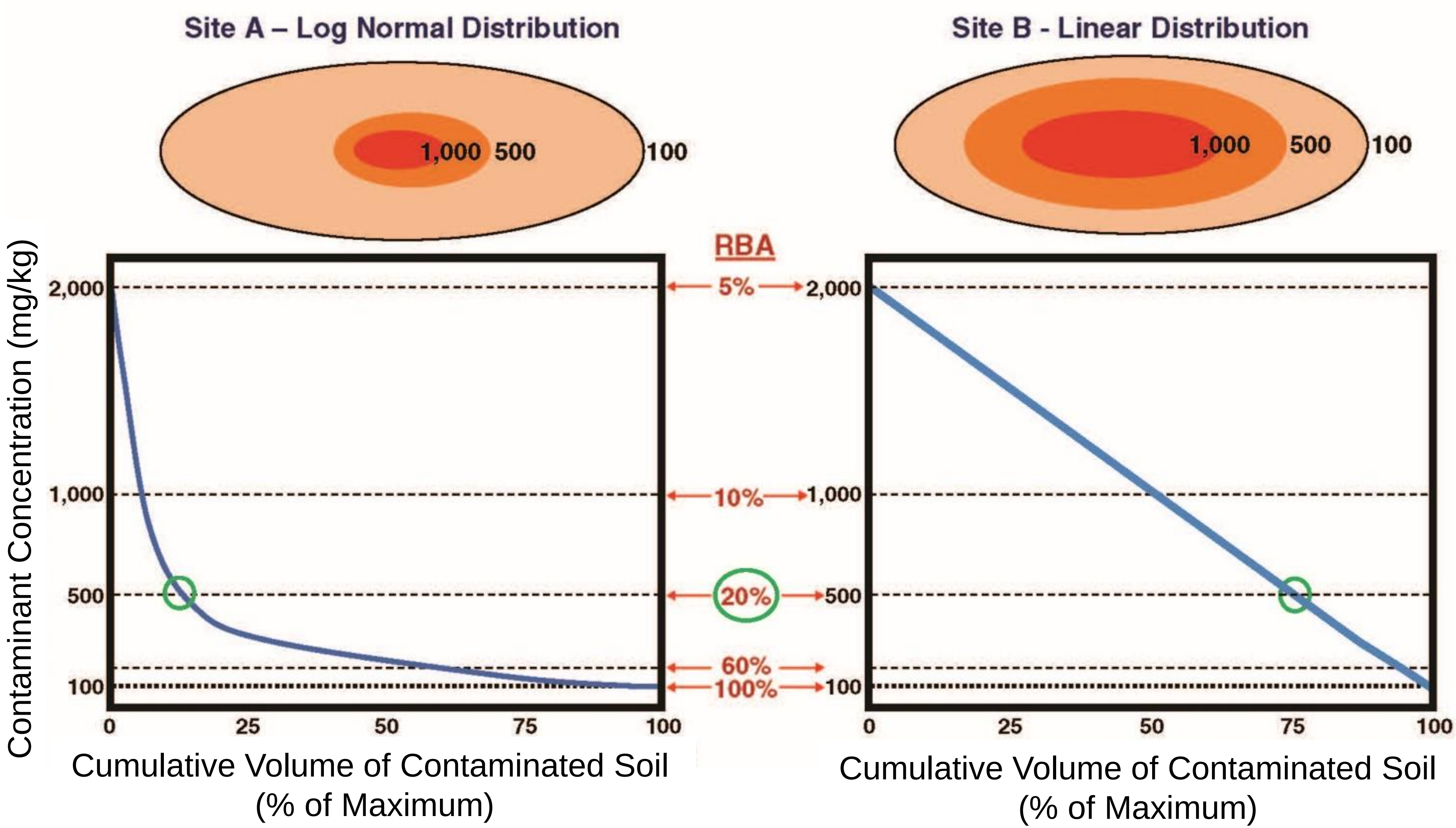


- Introduction: Definitions and Theory
- Regulatory Background: Existing Guidance, State Acceptance
- Technical Background: Soil Science, Mineralogy
- Decision Process: Decision Tree, Cost Benefit Analysis
- Methodology: In Vivo, In Vitro, In Vivo - in Vitro Correlations
- Chemical Specific Chapters: 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

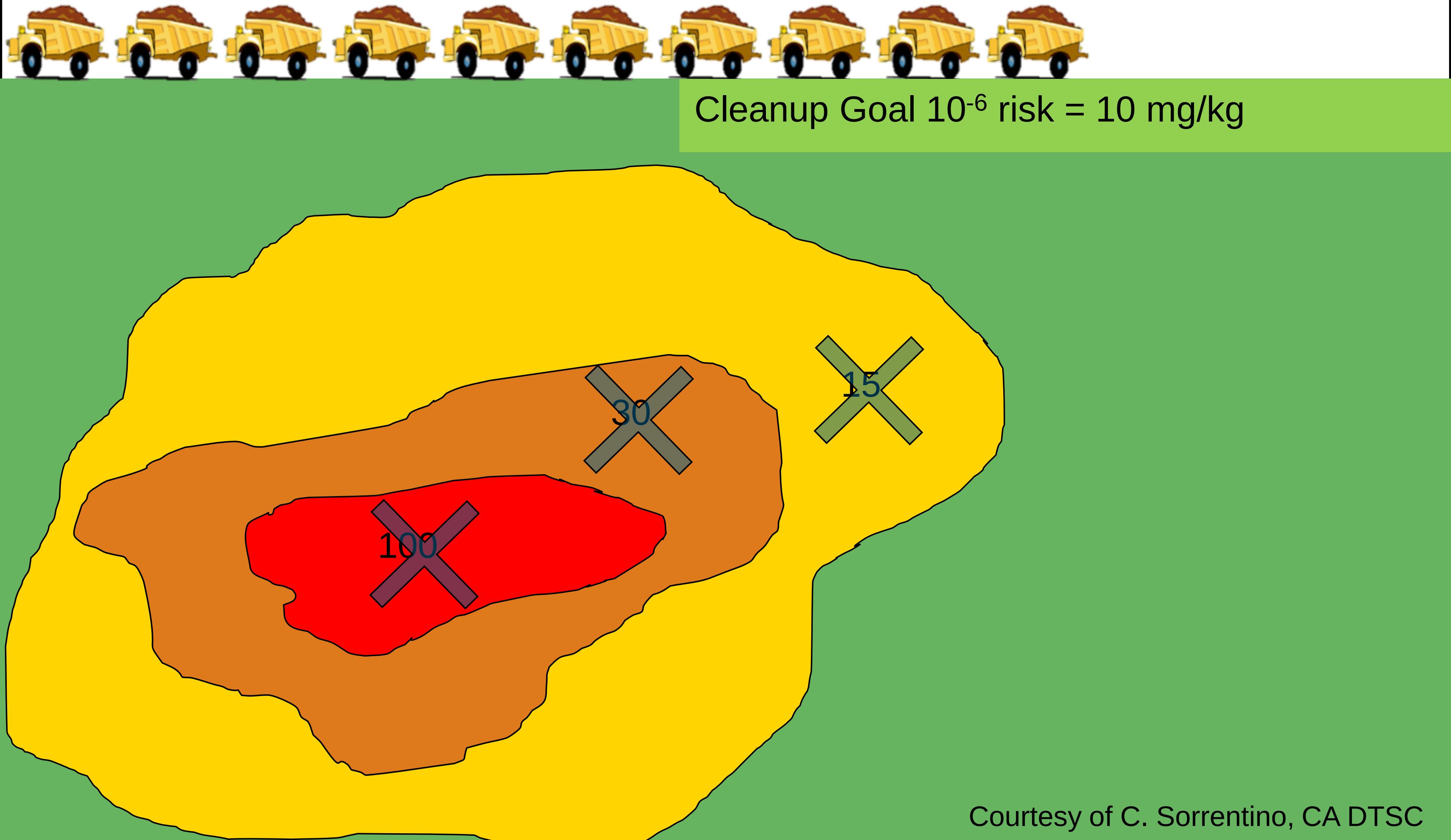
Estimate Volume of Soil Requiring Treatment Using Range of Realistic RBA Values



ITRC BCS-1 Figure 4-2

Site B: Site-Specific RBA more valuable

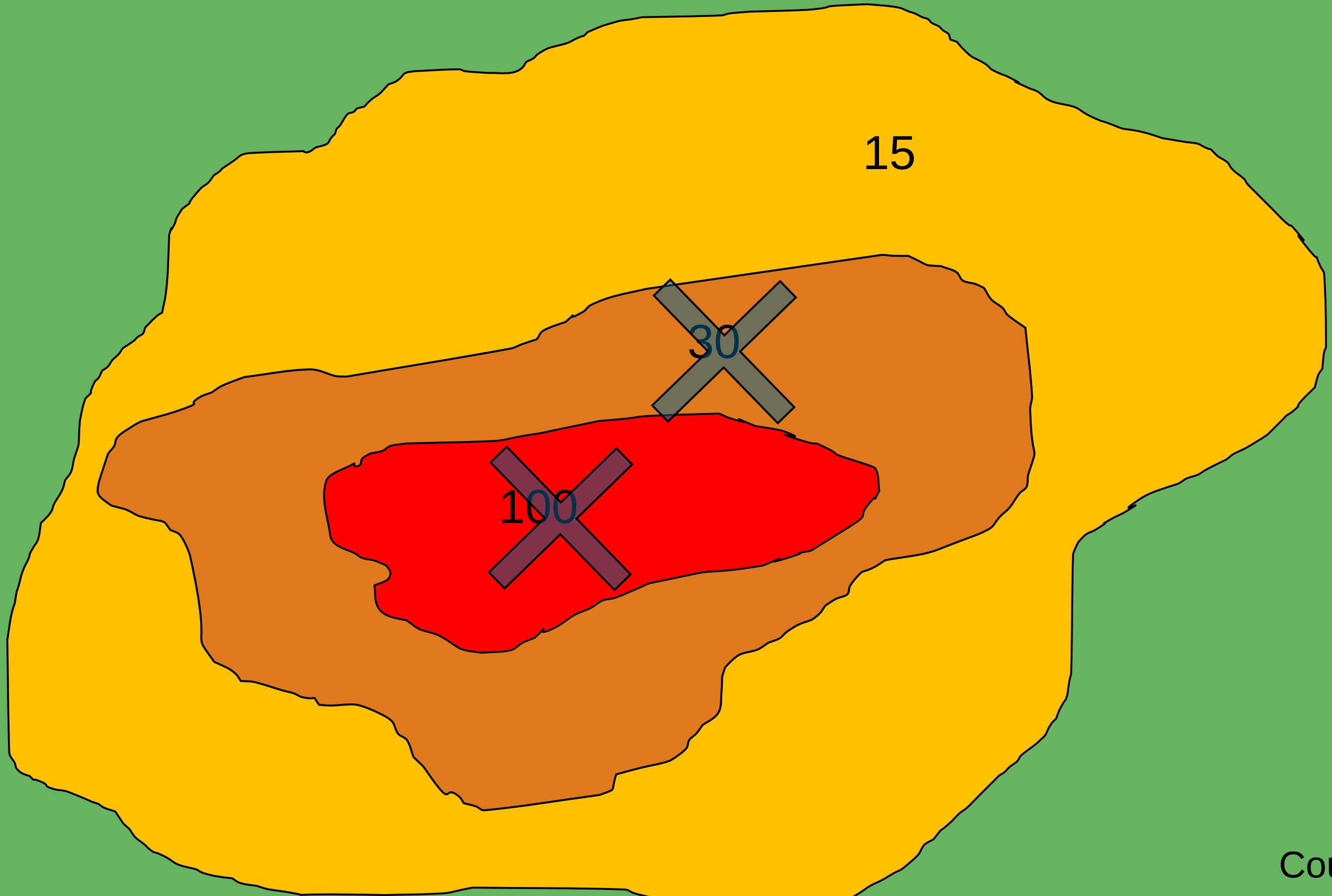
Typical Risk Assessment: Relative Bioavailability 100%



Courtesy of C. Sorrentino, CA DTSC

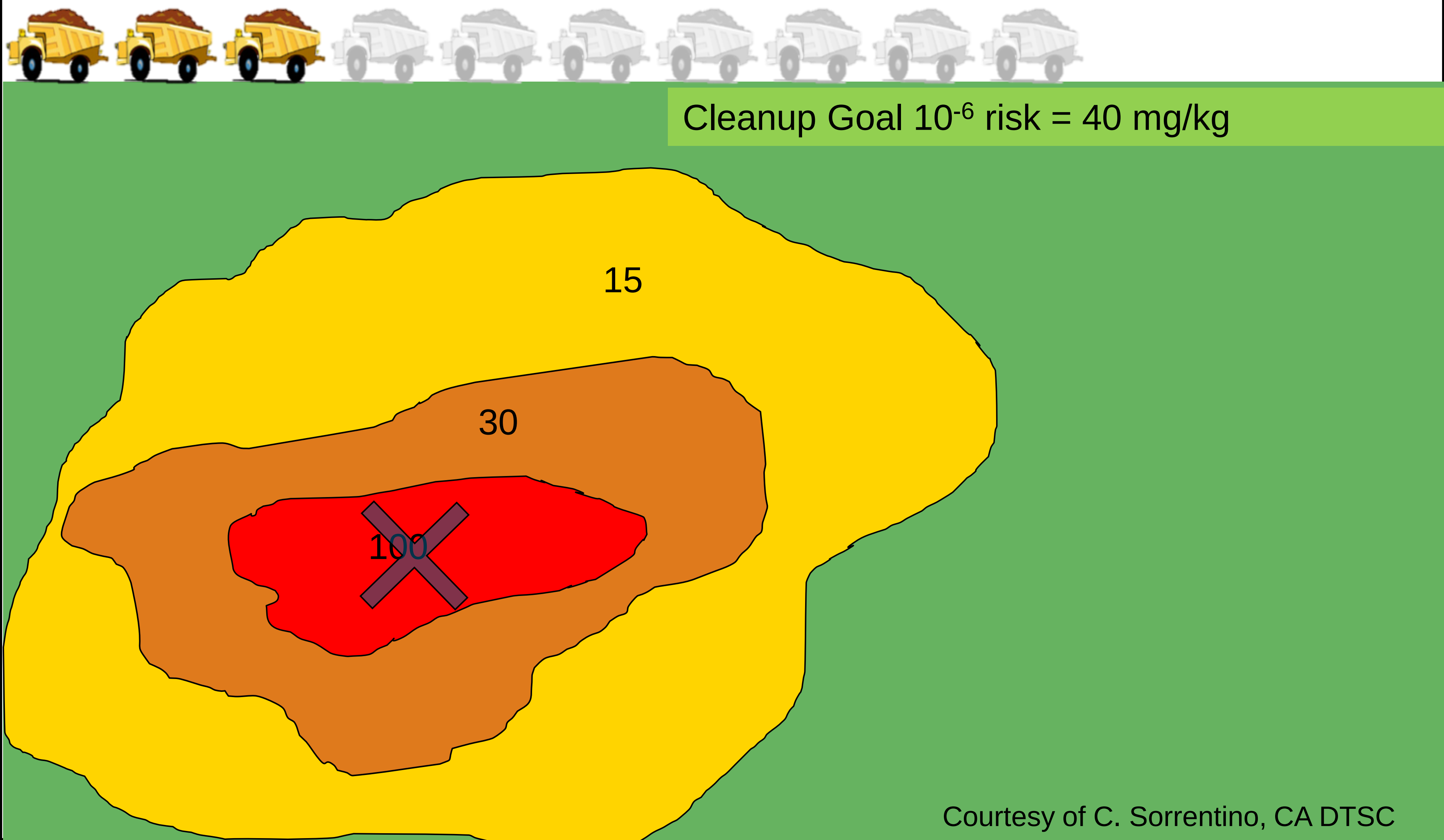
Applying US EPA Default: Relative Bioavailability 60%

Cleanup Goal 10^{-6} risk = 17 mg/kg



Courtesy of C. Sorrentino, CA DTSC

Site-Specific Evaluation: Relative Bioavailability 25%



Courtesy of C. Sorrentino, CA DTSC

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?

Site-Specific RBA Evaluation Take Home Messages

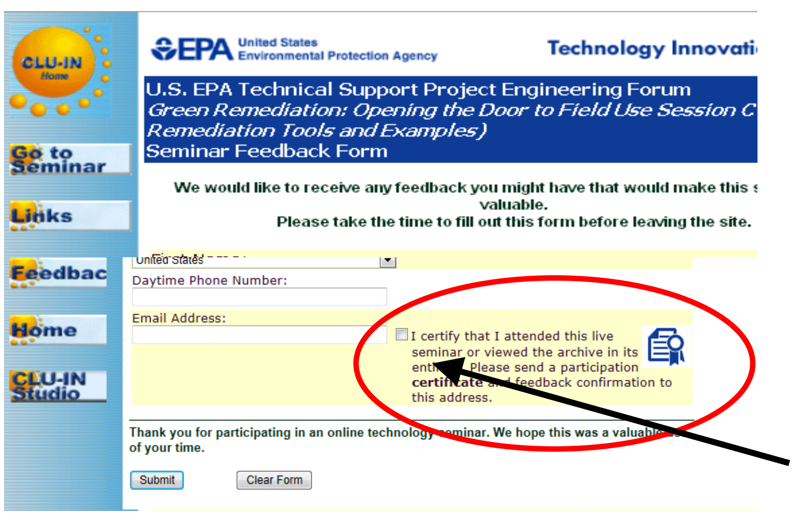
- Decrease the uncertainty of the risk assessment
- Maintains the Target Risk Level
- Improve Remedial Decision Making
- Often lead to significant savings of the resources available for remediation
- Multidisciplinary: Involve the Whole Team Early!
  - Regulatory: Project Managers, Geologists, Risk Assessors/Toxicologists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

Thank You

Follow ITRC

Poll Question

- **Question and answer break**
- **Links to additional resources**
  - http://www.clu-in.org/conf/itrc/bcs/resource.cfm
- **Feedback form – *please* complete**
  - http://www.clu-in.org/conf/itrc/bcs/feedback.cfm



Need confirmation of your participation today?

Fill out the feedback form and check box for confirmation email and certificate.