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2 Regulatory Background

This section provides a list of documents that offer technical background, regulatory perspective, and guidance relevant to understanding and using bioavailability in risk assessment. This section also includes the information collected from state risk assessors and ITRC Bioavailability in Contaminated Soil (BCS) team members about the use of bioavailability in their states.

▼*Read more*

Regulatory guidance is available for evaluating site-specific bioavailability in HHRAs; Table 2-1 summarizes several key guidance documents. These documents establish a broad precedent for incorporating bioavailability values into the risk assessment process, beginning with foundational documents such as USEPA's 1989 (USEPA 1989b) *Risk Assessment Guidance for Superfund* (RAGS).

Table 2-1. Regulatory guidance

Organization and Citation	Title	Comments
California Department of Toxic Substances Control (DTSC 2016b; Whitacre et al. 2017)	*Human and Ecological Risk Office (HERO): Human Health Risk Assessment (HHRA) Note Number 6. Recommended Methodology for Evaluating Site-Specific Arsenic Bioavailability in California Soils*	
Canadian Council of Ministers of the Environment (CCME 2008)	*Canadian Soil Quality Guidelines for Carcinogenic and Other Polycyclic Aromatic Hydrocarbons (Environmental and Human Health Effects)*	Scientific Supporting Document
Florida Department of Environmental Protection (Roberts et al. 2002)	*Measurement of Arsenic Bioavailability in Soil Using a Primate Model*	Guidance for arsenic default RBA value
Hawaii Department of Health (Hawaii DOH 2014)	*Technical Guidance Manual, Section 9-Supplemental Guidance for Select Contaminants of Concern, Appendix 9-E, Arsenic Screening Levels and Recommended Bioaccessibility Test Method*	
Health Canada (Health Canada 2011)	*Guidance Manual on Consideration of Oral Bioavailability of Chemicals in Soil for Use in Human Health Risk Assessment*	
Interstate Technology & Regulatory Council (ITRC 2015)	*Decision Making at Contaminated Sites, Issues and Options in Human Health Risk Assessment* (2015)	Section 6.1.3 of the ITRC guidance notes that assumptions of 100% bioavailability may lead to overestimations of exposure and risk. To address this issue, it describes use of bioavailability factors in the exposure assessment, it lists information the factors should consider and cites USEPA guidance for lead and arsenic bioavailability.
National Research Council (NRC 2003)	*Bioavailability of Contaminants in Soils and Sediments: Processes, Tools, and Applications*	

Organization and Citation	Title	Comments
Naval Facilities Engineering Service Center (Exponent 2000)	*Guide for Incorporating Bioavailability Adjustments into Human Health and Ecological Risk Assessments at U.S. Navy and Marine Corps Facilities*	
Ohio Environmental Protection Agency (Ohio EPA 2009)	*Application of Bioavailability in the Assessment of Human Health Hazards and Cancer Risk*	
United States Environmental Protection Agency (USEPA) (USEPA 1989b)	*Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part A) Interim Final*. EPA/540/1-89/002.	"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."
(USEPA 2004)	*Supplemental Guidance for Dermal Risk Assessment, RAGS, Part E*. OSWER 9285.7-02 EP.	
(USEPA 2007b)	*Estimation of Relative Bioavailability of Arsenic in Soils and Soil-like Materials by In Vivo and In Vitro Methods*	
(USEPA 2007c)	*Guidance for Evaluating the Oral Bioavailability of Metals in Soils for Use in Human Health Risk Assessment*	
(USEPA 2011a)	*Final Report: Bioavailability of Dioxins and Dioxin-like Compounds in Soil*	"[to] adjust a food or soil ingestion exposure estimate to match a RfD or slope factor based on... drinking water..."
(USEPA 2012e)	*Standard Operating Procedure for an In Vitro Bioaccessibility Assay for Lead in Soil*	
(USEPA 2012d)	*Recommendations for Default Value for Relative Bioavailability of Arsenic in Soil*. OSWER 9200.1-113.	
(USEPA 2012a)	*Compilation and Review of Data on Relative Bioavailability of Arsenic in Soil*	
(USEPA 2014d)	*Soil Dioxin Relative Bioavailability Assay Evaluation Framework.* OSWER 9200.2-136.	
(USEPA 2017c)	*Method 1340 In Vitro Bioaccessibility Assay for Lead in Soil*. SW-846 Update VI.	New in vitro Method 1340 SOP for lead
(USEPA 2017g)	*Validation Assessment of In Vitro Arsenic Bioaccessibility Assay for Predicting Relative Bioavailability of Arsenic in Soils and Soil-like Materials at Superfund Sites.* OLEM 9355.4-29.	Validation report for in vitro Method 1340 for arsenic
(USEPA 2017e)	*Standard Operating Procedure for an In Vitro Bioaccessibility Assay for Lead and Arsenic in Soil.* OLEM 9200.2-164.	Updated in vitro method 1340 SOP that includes arsenic
(USEPA and BARC 2008)	*Standard Operating Procedure for an In Vitro Bioaccessibility Assay for Lead in Soil*	

Regulatory constraints are also discussed in this guidance in the context of a site-specific decision to conduct a bioavailability assessment. The chemical-specific sections also include information about existing guidance.

2.1 Current Practices: Survey of State Regulators

▼*Read more*

In October 2015, ITRC informally surveyed risk assessors in state regulatory agencies throughout the country to understand how bioavailability is used in **human health risk assessments** within their jurisdiction. The following questions were

asked:

- Does the state use bioavailability or relative bioavailability of contaminants in soil in risk assessments?
- If so, does the state have any guidance or policy regarding the development and application of bioavailability or RBA of contaminants in soil?

Responses were received from 14 individuals from 12 states. Additional information has been provided by state members of the BCS team for states that did not respond to the initial survey. Table 2-2 summarizes the information provided by respondents. The responses indicate that lead is the chemical for which site-specific RBA values are most often incorporated. The responses summarized in Table 2-2 should be interpreted as anecdotal experience of the individuals who responded rather than as the official position of the respective states. There also may be multiple programs within a state which have different experiences. These responses also often indicated emerging policy or precedents. The responses are included in Detailed Survey Responses.

Table 2-2. Summary of current practices

State	Does your state use bioavailability?	Does the state have guidance or policy?
Alaska	Yes, with limitations.	The information is in our Risk Assessment Procedural Manual which is adopted in regulation.
California	Yes, in certain cases.	New guidance document for Arsenic, August 2016.
Florida	Florida is using an RBA of 0.33 for arsenic when calculating risk. Site-specific bioavailability evaluations have been completed for a small number of sites.	No official guidance.
Georgia	Yes, but only for human health risk evaluations and on a site-specific basis contingent upon the amount of well-supported and credible data provided.	Georgia has not yet issued guidance on bioavailability, but is in the process of updating its risk assessment guidance to clarify our current stance on bioavailability.
Kentucky	No, with the possible exception of lead.	Currently, no guidance or policy.
Massachusetts	We have allowed a relative bioavailability (RBA) approach at one site in Massachusetts for human health risks related to arsenic soil exposures.	We do not have a formal policy for RBA.
Michigan	Michigan DEQ used the IEUBK model which includes a default value for bioavailability of lead in soil, in developing the direct contact criteria for lead. MDEQ has allowed the use of site-specific RBA for arsenic or in vivo BA for dioxin.	No state guidance or policy; however, MDEQ uses USEPA guidance on bioavailability or RBA.
Missouri	Yes, bioavailability has been used in soil risk assessments prepared by USEPA on Superfund sites in Missouri (and reviewed by Missouri DNR and DHSS).	Currently no guidance or policy.
Montana	Montana uses RBA for lead and arsenic and we use USEPA guidance. If it were proposed for other contaminants, we would consider it.	
New York	In the Department of Health, depending upon the purpose of the evaluation and the amount and quality of information available to us, we would either implement a generic approach, or tailor the evaluation as warranted and supportable. In the Department of Environmental Conservation cleanup program, site-specific risk assessments are not commonly used when determining remedies for site.	No.

State	Does your state use bioavailability?	Does the state have guidance or policy?
Oklahoma	It is not common for us to run into this issue, we can look at bioavailability on a site-specific basis, but it needs to be well supported.	We do not have specific guidance on this issue.
Oregon	On a couple of projects in the Oregon Department of Environmental Quality's Cleanup Program, we used the results of laboratory relative bioavailability studies. In both cases, arsenic was the chemical of interest. These studies were done on a site-specific basis.	We do not have state guidance on RBA.
Pennsylvania	Generally, what we tell remediators is that they should assume 100% bioavailability unless they can demonstrate a site-specific value is more accurate. Remediators can use USEPA's default value of 60% for arsenic, but a site-specific number using an approved USEPA method is preferred.	We do not have specific guidance yet for how to handle bioavailability of contaminants in soil.
Utah	We have used site specific lead and arsenic bioavailability estimates in the soil risk assessments for the CERCLA activities.	The State of Utah has not developed guidance and rely on USEPA guidance.
Virginia	Bioavailability is not used, except for USEPA value for arsenic.	There is no guidance or similar on bioavailability.
Washington State	For mixtures of dioxins and furans, we allow the use of 60% bioavailability from soil. For lead, where we have set remediation levels using the IEUBK model, the model default of 60% was used. For arsenic, we use 100 % bioavailability.	