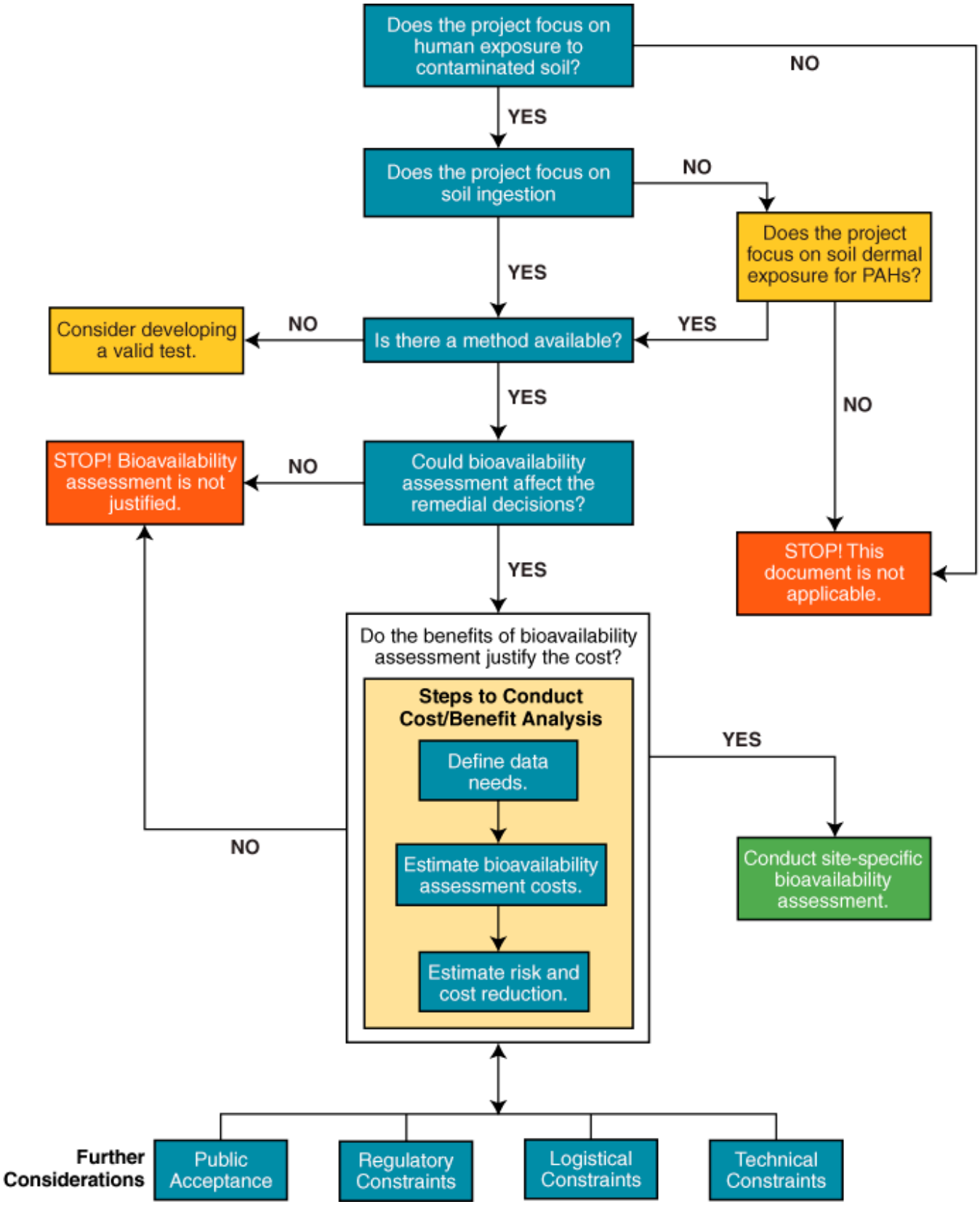
4.1 Decision Process Flowchart

Determining whether a bioavailability assessment is applicable to a given site involves answering a series of questions, as shown in Figure 4-1. The first three questions address applicability of the information in this document for the specific site, as discussed above and in the Introduction. The remaining questions are discussed in the sections following the figure.


Does the project focus on human exposure to contaminated soil?
NO
YES
Does the project focus on soil ingestion
NO
Does the project focus on soil dermal exposure for PAHs?
YES
Consider developing a valid test.
NO
Is there a method available?
YES
YES
NO
STOP! Bioavailability assessment is not justified.
NO
Could bioavailability assessment affect the remedial decisions?
STOP! This document is not applicable.
YES
Do the benefits of bioavailability assessment justify the cost?
Steps to Conduct Cost/Benefit Analysis
Define data needs.
Estimate bioavailability assessment costs.
Estimate risk and cost reduction.
YES
NO
Conduct site-specific bioavailability assessment.
Further Considerations
Public Acceptance
Regulatory Constraints
Logistical Constraints
Technical Constraints

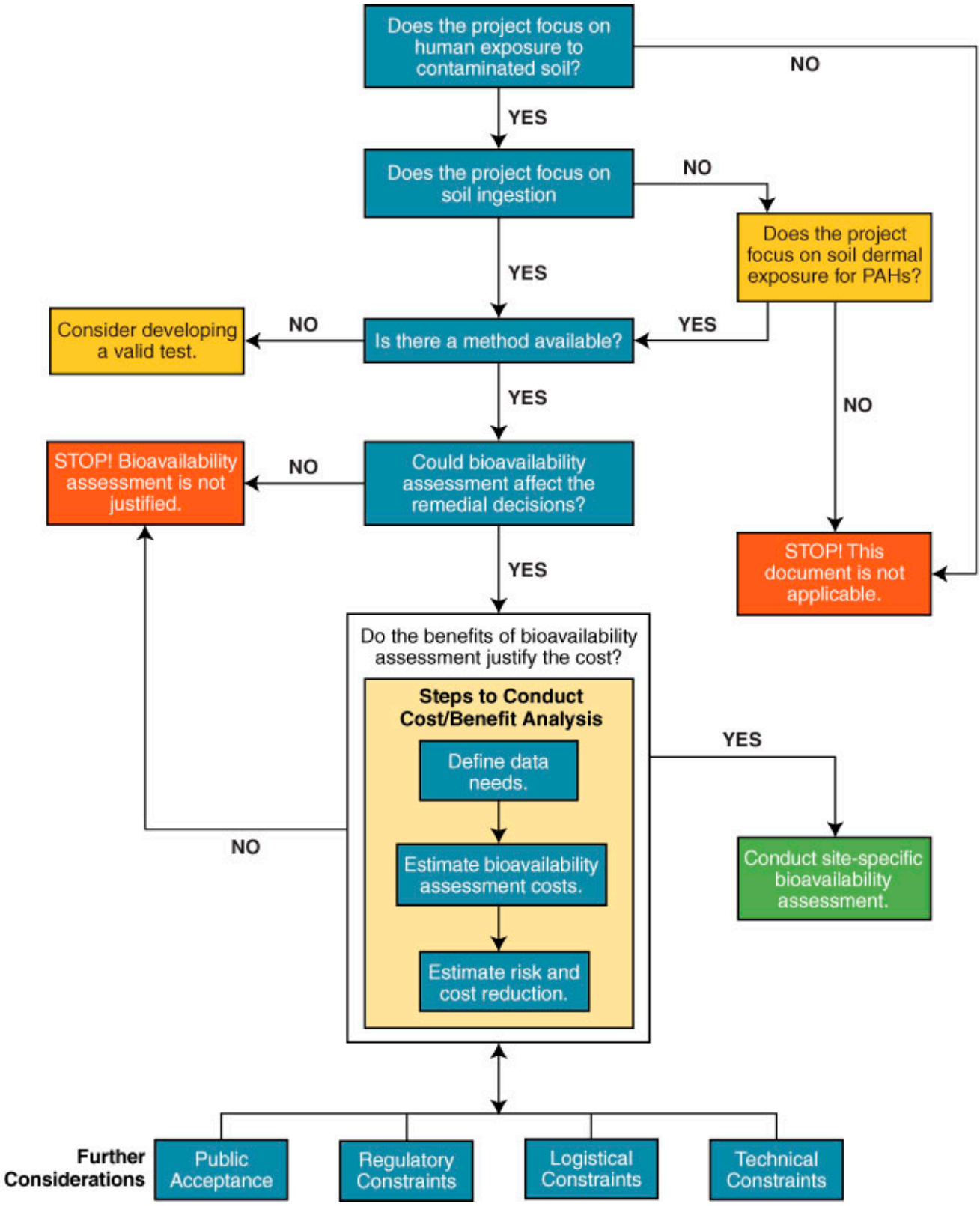


Figure 4-1. Early decision process: Is bioavailability testing warranted for a site?

4.2 Is There a Method Available?

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To conduct a bioavailability assessment, the primary site contaminants must have validated bioavailability test methods. Suitable test methods, however, do not yet exist for many contaminants. Currently, the best methods and information are available for lead, arsenic, and PAHs. Methods are also available for other contaminants (such as dioxins, polychlorinated biphenyls or PCBs, cadmium, and nickel), and method development remains an active area of research for these and other organic and inorganic chemicals (see also 9.1.10). The most important aspect of the initial decision process is to determine

whether bioavailability considerations are feasible to consider for a given project. This determination depends on the risk posed by the individual contaminant.

4.2.1 Applicable Contaminants

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Currently, site-specific bioavailability assessment is most easily achieved for lead, arsenic, or PAHs by the soil ingestion pathway for human receptors because an extensive research base, peer-reviewed methods, and regulatory precedence are available. Other contaminants might be suitable if methods are scientifically supported. The most reliable methods for bioavailability have been developed over many years for lead and arsenic. Methods for PAHs are still under development, although much literature exists regarding the viability of bioavailability considerations for PAHs. Therefore, although a variety of chemicals may contribute to risk at a site, currently site-specific bioavailability assessment may require significant original research unless lead, arsenic, or PAHs are the dominant contributors to risk. Site-specific bioavailability assessment for other organic chemicals or metals (cadmium, chromium, mercury, or others) may require additional effort to demonstrate the validity of the findings.

4.2.2 Applicable Receptors

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During the preliminary decision process, site-specific bioavailability considerations are based only on human receptors but not specifically for any one type of exposure scenario. Site-specific bioavailability values can be applied to residential, commercial, recreational, or any other type of human exposure scenario that includes incidental soil ingestion. While most human health risk assessments are generic and conservative with regards to physiologic parameters of the receptors, in some instances more refined physiologic parameters are used to protect a sensitive population.

4.2.3 Applicable Exposure Pathways

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Currently, bioavailability assessment is most applicable when the primary exposure pathway is ingestion of soils by human receptors. Examples of such exposures include human contact with surface soils during routine residential and occupational outdoor activities such as gardening, sports, and walking. During these activities, soil particles typically adhere to the face, hands, and forearms and are then ingested during normal hand-to-mouth contact. Soil particles can also deposit on clothing and shoes and be ingested during subsequent normal hand-to-mouth contact. The actual absorption of the chemicals following ingestion of soil is a factor that refines risk estimates because calculations are based on the absorbed dose rather than the ingested dose. Dermal uptake is a separate consideration, particularly for PAHs.

4.2.4 Applicable Sources

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While site-specific bioavailability assessment may be attractive because of its potential to reduce risk estimates or increase remedial goals, both the nature of the soil and the nature of the original source can influence the results of a site-specific bioavailability assessment. In some cases, a site-specific bioavailability assessment may yield higher values than the default RBA values published in the literature or adopted by agencies. For example, such a result might occur if a highly bioavailable form of arsenic such as pesticidal arsenic was released to sandy soils with low binding capacity. This potential is discussed in more detail in the sections on individual chemicals. In general, bioavailability literature and methodology are most extensive for the following sources:

- arsenic: mine soils, orchard soils, and pesticides
- lead: mine soils, residential soils, and shooting ranges
- PAHs: manufactured gas plant (MGP) residue soils, combustion, and other ambient anthropogenic sources

4.3 Could Bioavailability Assessment Affect the Remedial Decisions?

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A general understanding of bioavailability of the contaminants and some basic soil factors may be sufficient to determine

whether the assessment will affect remedial decisions; however, additional site information is sometimes needed. A preliminary in vitro analysis on a small sample set may be needed to support this evaluation. This may be an iterative question, with the answer changing as new data become available.

Answering this question also relies heavily on understanding other risk pathways for the site. This guidance focuses on bioavailability values in soil that primarily influence the soil ingestion pathway (and to a lesser extent dermal exposure), but does not address other pathways, such as plant uptake/food ingestion. Thus, the risk pathways for the site should be defined and assessed well enough to understand what the potential risks are for each pathway. This overall assessment is important because significant resources could be spent assessing bioavailability, only for the risk assessment to later show that a different pathway greatly outweighs the risk from the soil ingestion pathway. Typically, the risk assessment must be well developed to determine whether site-specific bioavailability values for the soil ingestion pathway will significantly change the risk levels or remediation goals. Additional information is presented in the lead and arsenic sections about when a bioavailability study makes sense.

4.4 Do the Benefits of Bioavailability Assessment Justify the Costs?

Two primary issues affect the cost/benefit analysis: the effects of a site-specific bioavailability value on the site risks and remediation requirements and the costs of the bioavailability assessment itself. Answering cost/benefit questions can be an iterative process, and several additional considerations may affect the outcome (Exponent 2000), including:

- number of contaminants driving risk
- chemical form of the contaminant or the exposure medium for the site compared to the chemical form or medium used to derive the reference dose
- potential for regulatory acceptance
- whether the bioavailability assessment can be completed within the required time frame
- the cost of bioavailability testing compared to the cost of cleanup
- whether existing site data support a bioavailability assessment

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The effect of site-specific bioavailability values on remediation costs may be easy to evaluate for small and relatively simple sites, but many sites require detailed evaluations of several remediation options. These sites benefit from a thorough risk assessment and detailed conceptual site model (CSM). The economic benefits of site-specific bioavailability values may include a finding that no remediation is needed at a site or decision unit or may support broader risk management options. In many cases, however, the benefit is less stringent cleanup goals, which reduces the volume requiring remediation or supports a less costly remediation technology.

Using RBA Values

As an example, consider a proposed risk-based target level of 450 mg/kg (RBA = 100% applied) for total arsenic, based on occasional recreational exposures in a remote area and a target cancer risk of 1×10^{-6} (depending on the regulatory agency the target range could be 1×10^{-4} to 1×10^{-6}). Site-specific RBA values for arsenic in soils typically range from 10% to 60%. Applying these RBA values to the unadjusted recreational target level (450 mg/kg) would then provide cleanup goals for total arsenic that could range from 750 mg/kg (60% RBA) to 4500 mg/kg (10% RBA). Clearly, this change in the RBA value would affect the volume of excavation needed and the costs of remediation, while still adequately protecting recreational receptors. For additional details, see Using Bioavailability Information in Risk Assessment.

Reduced remediation costs are not the only benefit that bioavailability assessment offers. Other considerations can include reduced uncertainty in the risk assessment, improved public perception, faster remediation, ease of property transfer or

development, and long-term applicability of the site-specific bioavailability values. Another indirect benefit of bioavailability assessment, regardless of the site-specific benefits, is that it supports broader improvement of the analytical methods. Significant progress on laboratory methods for bioavailability assessment has been made in academia based on projects that were not specifically focused on reduction of remedial costs.

The costs of performing bioavailability assessments can vary widely. Sometimes, testing may require only inexpensive **in vitro methods** for a small number of samples. In other cases, costly **in vivo methods** may be needed to establish defensible site-specific RBA values, or to validate less costly in vitro tests. One-time sampling may be sufficient, or iterative ongoing characterization may be needed. The testing may be performed on a subset of the same samples used for characterization, or separate sampling may be required because sample preparation requirements differ.

Additionally, bioavailability testing may require different samples, such as when different types of materials or soils exist within a given decision unit. Collecting data on supporting lines of evidence such as soil properties and mineralogy may be appropriate. Finally, significant costs may be incurred for negotiations and meetings to gain acceptance from regulators and affected communities or to defend any recommendations.

If contaminant concentrations are only marginally above the preliminary action level and site conditions are a good fit for site-specific bioavailability assessment, then potential RBA values can be evaluated using inexpensive in vitro tests (the results of in vitro tests are referred to as measurements of **bioaccessibility**). This testing can be accomplished on samples collected using incremental sampling methodology (ISM) or discrete sampling. The cleanup project team decides on a representative dataset for a particular decision unit; see the risk assessment discussion for more information about data representativeness as it applies to bioavailability.

If an immediate bioavailability decision is not possible, then soil samples can be archived for future testing (if contaminant levels are found to warrant additional site-specific risk considerations). In vitro testing on background soil samples may also be relevant if background concentrations complicate interpretation of the testing (although bioavailability testing probably is not applicable in cases where the natural background concentrations are greater than risk-based screening levels). Other early data considerations include tests to assess suitability of contaminant sources (such as for specific species of metal) and soil conditions. These practices can help project managers decide whether to pursue bioavailability assessment, as well as support discussions with regulators and stakeholders early in the site assessment process. For additional details on using soil sampling results, see Using Bioavailability Information in Risk Assessment.

Once a remedial action cost is estimated, a cost estimate should be prepared for refining the risk assessment using bioavailability assessment. It is important to include not only analytical and consulting costs, but to also include the cost to communicate the use of site-specific RBA values to the regulatory agency and stakeholders. Projects that might use site-specific RBA values can range from a simple screening level project with a handful of in vitro analyses to a large project with several iterations of a risk assessment, which may include in vitro and in vivo analyses and supporting physical and chemical analyses. RBA values can be incorporated into treatability studies as well, which might support a treatment remedy or aid in understanding long term stability of soil. The Road 1815 Cattle Dip Vat Site case study provides a good example of a cost-effective, screening-level bioavailability assessment.

4.4.1 Conducting a Cost/Benefit Analysis

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The costs and benefits of a bioavailability assessment should be evaluated in terms of the potential effects on the site remediation costs. Even before bioavailability testing is considered, many projects will have developed preliminary cost estimates for typical soil remediation methods, including physical removal, encapsulation, stabilization, capping, and institutional controls. Evaluating the costs and benefits can be a relatively simple volume/removal calculation or can require a more detailed estimate addressing a variety of cleanup options which may incorporate balancing of carbon footprint or loss of habitat from excavation, community disruption, or other project-specific balancing factors. Finally, the stage of a site in the overall remediation life cycle can affect the cost of the bioavailability assessment. The following steps outline a standard approach to determine the costs and benefits of a site-specific bioavailability assessment.

4.4.1.1 Step 1. Define Data Needs *Read More*

When considering bioavailability assessment, it is important to review the overall CSM and evaluate the likely data needs. This process starts by defining one principal study question and then later expanding considerations to other issues and questions; see (USEPA 2006a). Because project goals seek to protect human health and the environment, sites with contaminated soil have principal study questions that ask what risk the soil contamination in an exposure area poses.

A typical data need for these sites is the representative concentration of the contaminant over a given exposure area. With

contaminants that tend to bind to soil, consider the potential site-specific RBA value and the representative concentration to determine the risk from soil contamination; see Using Bioavailability Information in Risk Assessment for more information. This approach allows project managers and stakeholders to make well-informed decisions regarding appropriate response actions. Using site-specific RBA values can make the difference between action and no-action or containment and treatment. Because RBA is a ratio and results in a percentage of total contaminant concentration, however, as concentrations increase above risk screening levels, the effect of site-specific RBA values on decisions decreases. The Empire Mine State Historic Park case study provides an example of how elevated concentrations decrease the usefulness of a site-specific RBA value.

When bioavailability assessment is appropriate, early data can be used to assess the potential site-specific RBA values. When using ISM to collect average concentrations of a contaminant over a decision unit, gathering representative samples can be as simple as collecting representative subsamples from the ISM samples (including replicates) for in vitro testing. Issues such as appropriate sample preparation methods for chemical analysis and for bioavailability testing should be considered during the planning process. These tests are relatively low-cost, so early testing may be easier than archiving soil for testing later.

In some cases, it may also be prudent to determine background concentrations, which may represent alternative cleanup criteria. Background concentration analysis can be especially important for arsenic, due to the levels of naturally occurring arsenic in soils. It may also be important to measure the bioavailability of the background chemicals, for comparison with site bioavailability measurements. See Using Bioavailability Information in Risk Assessment for more information on incorporating bioavailability assessments into a CSM. Finally, it is often helpful to examine any historical information on bioavailability for similar contamination in similar soils.

4.4.1.2 Step 2. Estimate Bioavailability Assessment Costs *Read More*

The costs of incorporating site-specific bioavailability assessment into a project extend beyond the laboratory costs for analysis. The costs to consider when deciding to use bioavailability at a specific site may include the following:

- initial evaluation of applicability of site-specific bioavailability assessment to project needs
- work plan development and discussion and approval from concerned agencies
- sample collection and preparation
- in vitro analyses
- supplemental analyses (for example, mineralogy or soil properties)
- in vivo testing (for example, mouse, rat, or swine tests)
- interpretation of results, development of cleanup goals, and report preparation
- engagement with interested parties, regulators, and stakeholders (including the public)

Many of these costs are highly variable depending on the size and complexity of the project, the number and nature of chemicals for the bioavailability assessment, and level of engagement needed with the agencies and stakeholders. Some of these costs may not be necessary for each project. For example, mineralogy analyses typically examine the soil sample attributes that may affect bioavailability. By comparison, analysis of soil properties includes a more general assessment of the physical and chemical properties of a soil that could influence bioavailability such as particle size distribution, pH, redox, soil water-holding capacity, and organic carbon content.

The costs for bioavailability assessment can vary greatly, but a simple preliminary screening project for using bioavailability in a risk assessment can cost as little as $10,000. This screening project might include work plan preparation, sample collection, simple in vitro extractions for several samples, and a final report with evaluation of the results. A more thorough bioavailability assessment including 10 to 20 in vitro samples, using a more detailed and possibly more advanced extraction method, and coordination with the regulatory agency, might cost as much as $50,000. A bioavailability assessment that includes in vitro and in vivo analysis, and more involved regulatory and public outreach could cost $100,000 or more.

Researchers have developed and validated many analytical methods for bioavailability assessment. Commercial laboratories are now beginning to offer these analyses as part of their suite of routine and specialty services. Approximate costs provided by commercial and research laboratories for the analyses specific to bioavailability assessment are provided in Table 4-1. These costs are expected to change as more commercial laboratories begin to offer these analyses. Note that laboratories often give bulk discounts on a specialty analysis, because they must modify their standard processes for that specific method. Once the laboratory is set up for the method, it can run more samples through the process with limited additional cost.

The estimated costs provided below for in vitro bioaccessibility (IVBA) analyses for metals assume that the laboratory performs drying and sieving. The estimates below represent approximate costs during 2015 and 2016.

Table 4-1. Approximate costs for laboratory analyses

Analysis	Approximate Cost (USD)	Provider
Soil properties	$500–$1,000 (per sample)	Commercial labs
Soil mineralogy	$200–$1,000 (per sample)	Academic and commercial labs
IVBA for lead and arsenic	$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 three soils, metals only)	Academic labs
In vivo (primate)	$90,000 (for three soils, metals only)	Academic labs

The per sample costs may or may not include quality control samples (replicates, blanks, spikes, reference materials) and the in vivo study costs can vary greatly. These costs do not include site characterization or sample collection. The costs for an in vitro study are generally simpler to determine than those for an in vivo study, because in vivo studies include parameters that add to the overall cost and complexity of the study.

Conducting RBA studies in animals (in vivo) is both time consuming and expensive. The exact costs are difficult to specify, because these are not standard methods that can be easily contracted with a commercial laboratory. Additionally, some university-based scientists who have conducted this work have recently retired or moved on to other areas of research, so estimating costs from a new generation of scientists is difficult. Animal studies for RBA in soil for inorganics (such as lead or arsenic) can cost approximately $30,000 to $100,000 for a few soils. The lower end of this range is for work conducted in rodents, while the higher end represents larger animal research models such as swine or nonhuman primates.

As discussed in Other Factors in Developing In Vitro Methods for Predicting Bioavailability, additional complexities exist for studying the RBA of organic contaminants in soil, and these complexities in study design and analytical efforts affect both schedule and costs. Two recent, government-funded research efforts to assess the RBA of PAHs from soil cost at least $300,000, and it is not yet clear whether these studies resulted in estimates of RBA that will be accepted by regulatory agencies.

Actual costs of RBA studies in animals depend on the number of soils to be evaluated, the animal model selected, whether the work is performed by a commercial or academic lab, and the target contaminant. These constraints (cost and time) are among the factors driving the development of in vitro methods to estimate RBA for use in HHRA. However, under the existing regulatory environment in the United States, animal studies may still be warranted. For example, these studies may be appropriate when in vitro methods have not been established for a particular contaminant or to assess site-specific factors that were not adequately accounted for in the development of existing in vitro methods (such as when the in vitro method is not validated for a particular source material or for the soil characteristics of a given site).

Approximate costs that have been reported for the development of work plans, interpretation of results and development of cleanup goals, and engagement with regulatory and public stakeholders are presented in Table 4-2. These costs represent rough estimates based on experience, and the costs can be higher in some cases. Costs for public and regulatory engagement, for example, can be much higher if multiple agencies or stakeholders are involved.

Table 4-2. Approximate costs for professional services

	Approximate Reported Costs (USD)	
Task	**Small/Simple Site**	**Large/Complex Site**
Preliminary internal evaluation of project	$5,000–$10,000	$10,000–$15,000
Regulatory engagement	$5,000–$10,000	$10,000–$50,000
Work plan development	$5,000–$15,000	$10,000–20,000
Work plan execution/laboratory interaction/results interpretation/development of remedial goals/report preparation	$20,000–$30,000	$50,000–$100,000
Engagement with public and other stakeholders	$5,000–$10,000	$20,000–$50,000
Total	$5,000–$30,000	$10,000–$100,000

Approximate cost of excavation, hauling and disposal at hazardous waste landfill are shown in Table 4-3.

Table 4-3. Approximate costs for physical removal

Task	**Approximate Reported Costs (USD)**	**Approximate Reported Costs (USD)**
	100 cubic yards	1000 cubic yards
Workplan preparation, confirmation sampling, oversight, disposal coordination, documentation	$1,000–$5,000	$5,000–$10,000
Excavation in silty material with easy access Includes mobilization to site ($1500), $10/cubic yard	$2,500	$11,500
Hauling to landfill (100 miles from site at $25/ton), assumes 1.6 tons/cubic yard	$4,000	$40,000
Disposal at Subtitle D landfill (100 cubic yards or 160 tons) at $40/ton	$6,400	$64,000
Clean fill material and placement	$1,000–$5,000	$10,000–$50,000
Final report (including residual risk evaluation and regulatory interaction for closure)	$10,000	$20,000
Total	$24,900–$32,900	$150,500–$195,500

All reported costs are approximate and are presented only as a general estimate.

4.4.1.3 Step 3. Estimate Risk and Cost Reduction *Read More*

Ultimately, bioavailability testing is valuable because it more accurately assesses the site-specific risks and broadens risk management options. However, this increased accuracy comes at a cost, and the potential benefits of a more accurate risk assessment should outweigh the costs of testing. The most obvious benefit of bioavailability assessment occurs when the results show that a given decision unit does not require remediation because the concentrations do not exceed the cleanup goals, while remaining protective of human health. In many cases, however, the results do not show that the entire site is below risk criteria, but rather that a reduced area or volume requires cleanup or management. The size, complexity (for example, past historical uses, contaminant sources, soil types) and intended future use of the site (number of potential future exposure areas) are typically used to determine the number of decision units necessary to characterize a site, and therefore affect the cost of conducting a site evaluation, including any bioaccessibility or bioavailability testing.

Determining the value of these reductions generally requires a thorough CSM. Several factors affect the evaluation, including the volume and depth of contaminated soil, the exposure pathways, and the concentration of the contaminants, as well as the distribution of the contamination (the volumes impacted within different concentration ranges). For example, Figure 4-2 illustrates the effects of site-specific RBA values on the soil volume that requires treatment, and how these effects depend on the distribution of the contaminants.

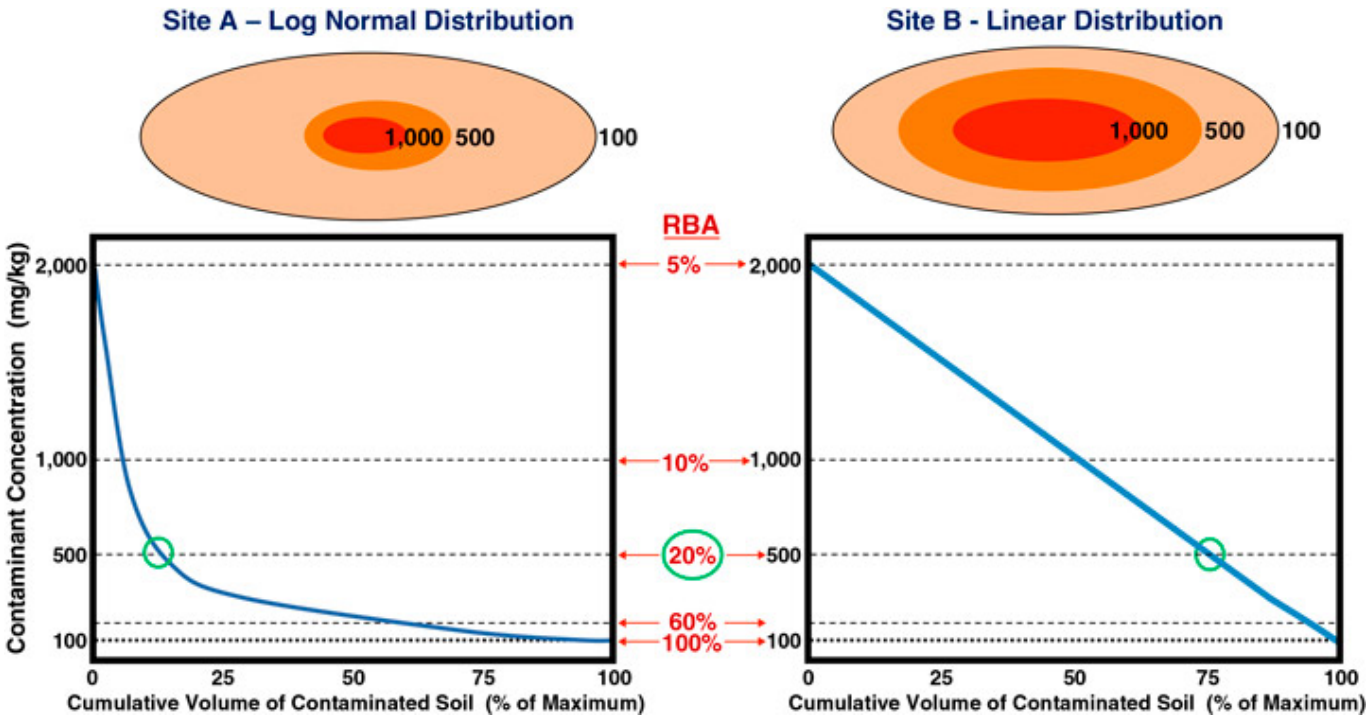

Figure 4-2. Relationship between RBA values, cleanup criteria and remedial volumes.

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:

1. Risk-based criteria, such as cleanup levels, increase significantly at RBA values of approximately 25% or less. For example:
    1. an RBA of 25% yields a cleanup level that is 4x higher
    2. an RBA of 10% yields a cleanup level that is 10x higher
2. The typical default value of a 60% RBA results in a relatively modest increase in cleanup levels: 1.67x higher.
3. Estimating the volumes 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).

Determining the value of site-specific RBA values also may require initial remedial designs for a range of options. For example, some areas of a site may be capped or excavated during remediation, regardless of bioavailability. Other examples include cases where the ultimate criteria for a site are based on the average concentration over an entire site or where some contaminated soils are considerably more difficult to remediate because of depth or access. The effects on remediation costs may be easy to evaluate (such as for small and simple sites), or detailed evaluations of several remediation strategies may be needed. This analysis can often be an iterative process, requiring several evaluations over time as more information becomes available.

Reduced remediation costs are not the only consideration. For some sites, pursuing site-specific RBA values may not be

worthwhile considering the time and resources that would be spent to gain community acceptance. In other cases, the added time before remediation can be completed may not be justified from an economic redevelopment perspective.

The value of a bioavailability assessment depends on the actual site-specific RBA value adopted. Estimating the ultimate RBA value can be difficult, because the RBA value is affected by a range of site-specific properties. Literature results offer some insight. For example, measured RBA values for lead in 19 different soils ranged from 6 to 105% (Casteel et al. 2006; USEPA 2007b), compared to the default value of 60%. A survey of 29 arsenic-impacted sites showed a range of RBA values from 8 to 60%, which USEPA used to support the recommended default value of 60% (USEPA 2010f). Given these wide ranges, there may be value in an initial estimate derived from models based on soil properties or simple extraction tests.

In most cases, it is preferable to use site-specific bioavailability tests (Griffin and Lowney 2012; Drexler and Brattin 2007; USEPA 2012e; USEPA 2017c, e, g). The specific tests used should be standardized (as identified in the Methodology section) and in vitro tests should be calibrated to in vivo bioassays for similar materials, if possible. These in vitro extraction tests are inexpensive and can indicate the possible site-specific RBA values, as well as the heterogeneity in RBA values for different soils across the site. Such heterogeneity may result from differences in source materials contributing to contamination at a site, and characteristics of the soils or environmental conditions at different areas across the site. These tests are most developed for arsenic and lead. Further details on the test methods and likely findings of bioavailability assessments are provided in the lead, arsenic, and PAH chapters.

4.5 Further Considerations

In addition to the initial key questions of whether validated methods exist and whether the benefits of RBA outweigh its costs, a variety of further considerations can affect the decision-making process. These considerations include community and regulatory acceptance, as well as several technical factors.

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Potential public concerns and regulatory issues should be assessed at several points in the process. In some cases, acceptance may be likely, given prior history or regulatory comfort. In other cases, significant outreach efforts may be needed to gain acceptance from affected parties. Also, significant outreach and coordination may be needed to develop consensus with regulatory staff and to develop the technical justifications for recommended values. Related logistical issues may also affect the decision process, such as project delays due to conducting a more involved or detailed risk assessment analysis that incorporates bioavailability. However, if ISM techniques are required by a regulatory agency or are being used for standard assessment work, the same sampling techniques can be applied to bioavailability testing thereby increasing the overall project efficiency.

Technical factors can also affect the decision to pursue bioavailability assessment. Many of these factors depend on the specific contaminant. Soil factors such as clay content or organic matter content can affect feasibility, as can the pH or redox status. The source of the contamination also can be important, because some materials are more bioavailable than others. Most of the technical factors are compound-specific, and therefore are discussed in more detail in the lead, arsenic, and PAH sections.

4.5.1 Public Acceptance

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Several factors may affect the public's acceptance of site-specific bioavailability values, including:

- how effectively the responsible parties or regulatory agency explains what bioavailability is and how it fits into a risk assessment
- the degree to which the public has been involved in the process and feels comfortable with the assumptions made (was the public involved early in the process and did the public have input before decisions were made?)
- the history of the site, including whether other health-based standards have been presented previously

A potential issue that may arise when communicating with the public and tribal stakeholders is that the stakeholders may see the use of bioavailability as a means of reducing the responsible party's liability and costs, thus potentially increasing the risk to the public. It is important to communicate that reducing the uncertainty in the risk assessment (such as using a site-specific RBA value) does not compromise protection of human health. Outreach efforts should emphasize that the bioavailability assessment is another means of better understanding potential human exposures to contaminants.

Also, technical aspects of a cleanup, such as using bioavailability assessment, can be misconstrued by the public. If not

explained well, the public might perceive regulators and consultants as using overwhelming technical details to lobby for a limited cleanup. How bioavailability assessment is communicated and presented, just like any technical aspect of a cleanup project, can be vital to the success of the project. Examples of these issues are presented in more detail in the Stakeholder Perspectives chapter.

4.5.2 Regulatory Constraints

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Different agencies may have different regulatory constraints on using site-specific bioavailability values. The use of site-specific bioavailability should be discussed with the regulatory agencies early in the project, before any assessment of bioavailability is conducted. An increasing number of federal and state agencies are considering or incorporating site-specific bioavailability assessments in risk management decisions, but in-depth communication with regulators may be required to ensure acceptance for a given site. The Red Rock Road case study presents an example of the extended regulatory negotiations that can be required to satisfy two regulatory agencies with differing views on using site-specific RBA values.

Note that a regulatory agency may not allow the use of the default RBA for a contaminant if a site-specific RBA analysis has been conducted, if appropriate methods were used. For example, a bioavailability assessment may find that the site-specific RBA value for arsenic is higher than the USEPA default value of 60%. The site-specific value, rather than the default, should now be used in the risk assessment. Conversely, a regulatory agency may accept the use of a site-specific RBA result lower than the default value if the analytical methods are appropriate. Finally, a regulatory agency may request a level of conservatism when deciding on the final site RBA values to account for uncertainty in the sampling and the laboratory analyses.

Early communication and additional education about and awareness of site-specific conditions improve the chances that agencies will accept site-specific RBAs. For small sites, however, there may be a point at which the cost to explain and support the RBA outweighs its benefit.

In addition to the constraints within a Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) or state cleanup program, other regulatory constraints may apply. Examples include states where Applicable or Relevant and Appropriate Requirements (ARARs) might require excavation or treatment, or another federal program that might require excavation or treatment is in place. Future land use plans or local rules also might not allow leaving contamination in place. These types of jurisdictional requirements should be assessed early in the project, before resources are spent on bioavailability assessment.

Information from an informal survey of state risk assessors about current practices in using bioavailability assessment is presented in Table 2-2; detailed responses are included in Survey Responses. Additional information is presented for lead (Deviation from Bioavailability Default Values) and for arsenic (Existing Guidance).

4.5.3 Logistical Constraints

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Whether site-specific bioavailability assessment is appropriate for a project may depend on several factors more related to project logistics than to specific bioavailability issues. One of the initial questions to resolve is whether the cost of the bioavailability assessment is less than the cost of physical removal. For smaller sites, the relatively lower cost of physical removal might be equal to or less than the relatively higher cost of conducting bioavailability analysis and related work (see Cost/Benefit Analysis). The project schedule may present another logistical challenge, since a required schedule for completion may be shorter than the time required to complete bioavailability analysis and regulatory approval.

Some general issues that should be considered prior to use of bioavailability include the following:

- **Land use** – Do local land use requirements require the removal of contamination regardless of the site-specific RBA values? An example might be a municipality that has a future development plan for an area and may be unwilling to allow contaminated soil to remain in place, or may have plans to remove a given thickness of soil for other reasons. Or the contaminated soil may be useful as is, such as in a road bed that is contaminated. In this case, it may be better to simply cap the road and use an institutional control so that the road can still be used, with the public protected. Additionally, subsurface soils may be brought to surface as part of new development grading requirement. This activity may change the potential soil exposure pathway. In each of these cases, the value of a site-specific bioavailability assessment should be considered in light of the land use.
- **Schedule** – The time required to conduct bioavailability analysis and gain regulatory and public acceptance is sometimes longer than the entire project schedule. For a simple bioavailability assessment with limited in vitro

analysis, little public involvement, and regulatory acceptance prior to conducting the bioavailability assessment, the timeframe may be two to six months. In some cases, this time frame is too long for completion of the project. Fast-paced property transactions or developments may similarly preclude the use of bioavailability assessment. For very large sites, remediation may take several years, yet a bioavailability assessment may help define interim risks prior to complete remediation. Although presumptive remedies often offer the means to quickly identify a remedy and complete a cleanup, there is no similar presumptive approach for bioavailability assessments. As new data and guidance become available, presumptive bioavailability approaches for specific contaminants may emerge in the future.

- **Colocated contaminants** – As with any cleanup project, colocated contaminants may drive risk. Some of these contaminants may have limited bioavailability information and may not have accepted analytical methods. If so, then these contaminants may become the risk driver and bioavailability assessment may become less useful.
- **Other considerations** – Site-specific constraints can limit the usefulness of bioavailability assessment. Other considerations may include geotechnical issues at the site, such as a vegetated layer that may require removal if it is in the zone with the highest contaminant concentration. Additionally, before embarking on these studies stakeholders must agree on the appropriate particle size for estimation of RBA, because smaller particles contribute most to incidental ingestion exposure. Agreement must also be reached on how the results from this lower particle size may alter the broader CSM (for example, for assessing estimate of total source load, or other pathways such as migration to water).

4.5.4 Technical Constraints

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There are several technical issues to consider when deciding whether to pursue a site-specific bioavailability assessment. These issues include the soil properties that affect bioaccessibility, the physical and chemical nature of the contaminant sources, and the nature and toxicity of the contaminants present at the site. These potential constraints on the use of bioavailability assessments are discussed in the following sections.

4.5.4.1 Soil Properties

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Various soil properties can influence bioavailability, including mineralogy, grain size distribution, and organic carbon content, as well as the balance of water and gases. More information is included in the Technical Background chapter. The influence of these soil factors can be unique for specific contaminants and is discussed in detail in the individual contaminant sections. In general, increased carbon, the presence of mineral oxides, and organic content of the soil tend to promote binding of contaminants and decrease bioavailability. On the other hand, the effects of soil pH can vary; for example, lead tends to be more soluble and bioavailable in low pH conditions, while arsenic is more readily mobilized in alkaline soils. Greater detail on the influences of soil properties is provided in the chemical-specific chapters (lead, arsenic, and PAH).

When deciding whether to pursue bioavailability assessment, consider whether the soil at the site exhibits any of the properties that tend to restrict bioavailability. Biogeochemistry is complex, however, and bioavailability is hard to predict based on soil factors alone. Relative in vitro tests may provide the best insight into potential RBA values.

4.5.4.2 Contaminant Source

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Bioavailability is affected by the source of the contaminant. It is important not only to characterize the source materials, but also to recognize that multiple sources may be present. The chemical and physical nature of the source material can affect the bioavailability and may also determine the most appropriate test.

For example, the arsenic in arsenical pesticides is generally more bioavailable than arsenic in mine tailings. For lead, bioavailability can differ for different mineral phases (for example, lead sulfides versus lead carbonates), matrices (free metal grains versus lead in the vitreous phase of slag), and particle sizes. For PAHs, bioavailability is generally lower for highly condensed materials, such as lampblack, than in materials that sorb the PAHs less strongly, such as fuels. These source factors are discussed in detail in the chemical-specific sections. It is critical to know what kinds of sources are present and to design the sampling and analysis plans to reflect the nature of the sources. The duration of contact with soil can also affect bioavailability. Over a period of years, the bioavailability of the originally released source chemical may change with weathering and with changes in soil properties such as the amount of organic carbon present. Different tests and criteria

may apply to different areas at sites with more than one source material present.

4.5.4.3 Contaminant-Specific Issues

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Certain contaminant-specific issues may help in deciding whether to conduct a site-specific bioavailability assessment. More detailed contaminant-specific information is provided in the lead, arsenic, and PAH chapters.

Lead is the best-studied contaminant addressed in this guidance, followed by arsenic, and then PAHs. In vitro studies of arsenic bioavailability were designed following lead studies; specific studies related to lead, arsenic, and PAHs are ongoing. It may be necessary to conduct more detailed analysis and assessment for site-specific RBA values for PAHs than for lead or arsenic, because of the larger family of compounds in PAHs and the greater uncertainty in PAH bioavailability at present.

The toxicity of a chemical may also influence the decision on whether to use a site-specific RBA value. For instance, because the oral cancer slope factor for arsenic is high, the risk-based soil screening levels for arsenic are often lower than background, especially for residential land use scenarios, and cleanup goals for residential land use may be based on background levels. In these instances, incorporating an RBA in the calculation of a health-based soil screening criterion may not affect the calculation of a final site-specific cleanup goal, especially for residential land use scenarios. This analysis may be more useful, however, for nonresidential scenarios. With the recent interest in lowering lead cleanup values, this situation may also be true for lead.