4 Decision Process

This section is a general guide to determining whether and when a site-specific bioavailability assessment may be appropriate. A simplified flow chart illustrates basic decisions that can be addressed at any time within a cleanup project or risk assessment. Various factors that affect the cost or impact of site-specific bioavailability values are discussed. These factors include the nature and distribution of the contaminants, the soil properties, the exposure pathways, and the site size and volume of contaminated soil. In addition, external factors such as competing regulatory requirements, public perception, or land use issues are also discussed to illustrate how site-specific bioavailability values might be perceived by stakeholders or why these values might not be accepted. This section also provides some general costs for both in vitro and in vivo analysis, along with other nonanalytical costs associated with completing a risk assessment using site-specific bioavailability.

▼*Read more*

The decision to conduct a site-specific bioavailability assessment for a project is usually based on a cost-benefit analysis. This analysis can be considered at various stages of an environmental project (see Using Bioavailability Information in Risk Assessment), when sufficient information is obtained regarding the feasibility and costs of meeting default risk-based cleanup values at a site. The decision process is often iterative, with key questions revisited over time as the risks and costs become better defined.

A bioavailability assessment can have several uses, such as for developing site-specific screening levels in a risk assessment or incorporating the assessment results into a forward risk assessment to determine risk estimates. Note that most risk assessments examine both current and future risk and that bioavailability of contaminants in soil may change with time. A more detailed discussion on how to incorporate bioavailability into various aspects of a human health risk assessment is presented in Using Bioavailability Information in Risk Assessment.

Projects that might benefit from a site-specific bioavailability assessment generally have one or more of the following characteristics:

- Risks are driven largely by oral exposure to contaminants in soil.
- Chemical forms or soil properties are different from those used in the default assumptions.
- A contaminant level slightly exceeds the risk-based acceptable level and thus triggers a requirement for remediation.
- Risk-based cleanup goals require extensive or expensive remediation, or both.
- Remediation is not technically feasible.
- Remediation activities will adversely affect the environment.

These characteristics are addressed in more detail in this section, as well as in Using Bioavailability Information in Risk Assessment.

This guidance addresses site-specific bioavailability values only for scenarios involving human exposure to soil (ecological risks are not considered) and focuses primarily on the direct oral ingestion pathway, although dermal exposure is discussed for PAHs. In this guidance, bioavailability is also not considered for the inhalation exposure pathway or for ingestion of plants grown in contaminated soil. The inhaled fraction and ingested fraction are discussed in Human Exposure Pathways for Soil. The homegrown produce exposure pathway, however, may be of interest for stakeholders and the public and may require additional explanation when presenting information about bioavailability. Information on the homegrown produce exposure pathway can be found in Human Exposure Pathways from Homegrown Produce.

In theory, assessment of bioavailability of contaminants in soil is applicable both to human and ecological receptors. There is great variation, however, in how chemicals in ingested soil are digested and absorbed by ecological receptors because of the variation in their digestive systems and metabolism. The results of a bioavailability assessment for one species thus may not be applicable to others. This guidance only considers site-specific bioavailability for human receptors.