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9.2 Other Considerations and Limitations

This section discusses key aspects of using site-specific RBA values in HHRAs, including the importance of communicating the limitations and assumptions, the potential for RBA values to change, how to account for bioavailability of background soil, soil and source characteristics, and variability and validity of bioavailability results.

9.2.1 Communicating Limitations and Assumptions

In addition to characterizing the risks associated with potential receptor exposure, an HHRA should discuss its key assumptions and uncertainties.

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This discussion should address how bioavailability for any chemical has been determined and subsequently used in the HHRA. For example:

- The HHRA should explain whether the calculations included the use of generic default values for RBA or site-specific data collected during the investigation. If site-specific data were used, the HHRA should clearly explain the methods used to determine RBA and the values used and why.
- If a single RBA value was used for an exposure unit or area, the HHRA should explain the basis of the value used (for example, arithmetic mean, 95% upper confidence limit on the mean, 95th percentile, or maximum), the rationale for selecting the value, and how this affects the risk estimates or cleanup goals. Such a discussion might benefit from a quantitative sensitivity analysis which could show how sensitive key decisions might be to the RBA value used. For example, while it would be appropriate to use a conservative estimate of the average RBA (for example, 95% UCL on the mean), would the conclusion of the HHRA change (that is, change from acceptable to unacceptable risk for example) if the maximum RBA value were used?
- The HHRA should discuss, even qualitatively, the degree of uncertainty introduced from the bioavailability test methods themselves (such as **validation** issues or inter- and intra-species extrapolations). For example, few studies of arsenic bioavailability from soil have been conducted in animal models with GI anatomy and function similar to humans, such as nonhuman primates. The HHRA could also consider discussing other lines of evidence that would support the RBA value used (for example, site-specific mineralogical results, site-specific data regarding soil geochemical properties, grain size fractions, or historical data defining the source).
- The HHRA should explain what underlying assumptions are reflected in the samples and methods used to determine bioavailability (such as those based on juvenile swine or fasting of the animal) and how that might influence the values (for example, biased high in order to ensure protectiveness for sensitive subpopulations).
- If an RBA value was determined via site-specific sampling data, the HHRA should discuss the rationale for the sampling performed and the adequacy of the sampling. For example, it would be important to explain why the sample size was sufficient given the potential for site heterogeneity (for example, various sources, soil types, chemical concentrations).

This information should be discussed and explored in the uncertainty section of the HHRA because it is critical in informing HHRA reviewers and allows better decision making for risk management.

9.2.2 Potential for Bioavailability to Change in the Future

In order to support risk management decisions, HHRAs often seek to characterize current and reasonably expected future risks for each potential receptor. Because of the concern about potential future risks, HHRAs that use site-specific RBA values should account for potential factors that could alter the bioavailability of a chemical in soil in the future (Chaney, Basta, and Ryan 2008).

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Factors that affect bioavailability include soil chemistry, particle size, matrix effects, biological effects, and the stability of the chemical form (NRC 2003). Bioavailability can vary depending on the environmental matrix, aging of contaminants in soil, the interaction between the environmental matrices, the human interface, and human physiological processes. Most changes would be expected to have little effect on bioavailability, and many may decrease bioavailability over time (NRC

2003). Certain site activities or actions, however, could potentially increase bioavailability by modifying the geochemical setting of the contaminated soil. These activities include adding amendments to soil (such as fertilizing gardens) or flooding land, which could liberate some chemicals from soil and enhance their bioavailability. Table 5-3 of (NRC 2003) summarizes potential factors that may affect change in bioavailability over time.

9.2.3 Accounting for Background Bioavailability

While many regulatory agencies offer specific guidance on how HHRAs should account for background soil concentration and background risk, few provide any guidance on how RBA could be considered in the characterization of background risk. This section describes one approach for how background RBA could be considered during the site investigation process and used in the HHRA.

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Under USEPA risk management policy, which many states follow or adopt, remedial action to chemical concentrations below background (natural and anthropogenic) is generally not warranted (USEPA 2002a). USEPA's (2002a) *Role of Background in the CERCLA Cleanup Program* provides specific guidance regarding how site-specific background should be accounted for in HHRAs. This document recommends addressing site-specific background in the risk characterization component of the HHRA. More specifically, it recommends that the contribution of background to site risk be distinguished to help risk managers make informed decisions about risk management (for example, refining specific levels that warrant remedial action). As a result, the risk characterization of a HHRA should consider and potentially quantify site-related and background-related risks, which may include background bioavailability:

$$\mathrm{Total_{Risk}} = \mathrm{SiteRelated_{Risk}} + \mathrm{Background_{Risk}}$$

For the background risk to be separated from site-related risk, the HHRA should define background levels versus site-related concentrations. Likewise, the HHRA should characterize the RBA values of soil at the site (or in a given exposure area) and in background soil. Just as background soil may exhibit a different average contaminant concentration from soil in an exposure area, background soil may also exhibit different RBA values for that contaminant.

Background levels (concentrations and RBA values) can then be calculated to facilitate estimates of background risks separately from site-related risks. For this purpose, background exposure concentrations and RBA values may be determined similarly to exposure concentrations. RBA is then determined for the site contaminated soil within an exposure unit (for example, as 95% UCL on the mean), ensuring a consistent basis for comparison of the two values (apples-to-apples). If the exposure concentrations for both the site, as well as background, are calculated in the same way then the following relationship holds true and can be used to efficiently segregate background risk from site-related risk:

$$\mathrm{Total_{Risk}} - \mathrm{Background_{Risk}} = \mathrm{SiteRelated_{Risk}}$$

Background risks are calculated using the same methods and assumptions as site related risks. Because background risks are not typically used in determining whether corrective measures would be warranted at a site, the risk assessment should address background risk and site-related risk separately in the risk characterization. Note that the acceptability of using background levels (concentrations and bioavailability) to define site-related risk may vary depending on state regulations.

Other types of statistical limits, such as prediction limits, may be useful for other purposes in the site investigation and data evaluation process (for example, determining whether a concentration or an RBA value differs from background at a statistically significant level). Sometimes, however, it may not be appropriate to use upper estimates of background concentrations or RBA values (for example, UCL on the mean) in estimating background risks or in establishing site-related risks as detailed above.

9.2.4 Soil and Source Characteristics

The sampling design must capture the heterogeneity of the soils and meet data quality objectives. For example, the solubility of arsenic in soil varies depending on the origin of the soil, the source of the arsenic, and the chemical interaction of arsenic with other minerals present within the soil (see Arsenic). This variability can produce arsenic forms that are more tightly bound within the soil and less available for absorption. Site history also plays an important role in characterizing the soil contamination. Furthermore, the use of proper sampling techniques and methods could reduce uncertainty in the bioavailability results. Similarly, bioavailability could be influenced by particle size as demonstrated for lead (USEPA 2003b). (See the discussion of lead sources and soil type)

9.2.5 Variability and Validity of Bioavailability Results

Uncertainty can stem from the bioavailability tests and methods themselves, validation and quality assurance criteria used for testing, and the choice of correlation model. See Section 5.2.3. Other uncertainties include the extent to which bioavailability test results of a given protocol are reproducible within and between laboratories. If results are not comparable, uncertainties with the sample preparation and testing should be discussed in the uncertainty analysis.