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?

▢ Consider potential variability of bioavailability between areas where source types or historical releases to the environment may be different, soil characteristics may be different, and background areas.

- Are soil and source types of various exposure units homogeneous or different from each other?
- Is the site-specific RBA value applicable to the area? (if the soil tested was not specifically from the area)
- What are the soil characteristics (soil type, pH)?
- What are the contaminant source types (for example, a highly bioavailable form such as, pesticidal arsenic)?
- What historical use and releases are present?

▢ What is the focus of the risk assessment?

- soil ingestion exposure evaluation, soil dermal exposure evaluation, site-specific cleanup goal, or other purpose
- conceptual site model (CSM) presents exposure pathways and receptors for various exposure units/areas
- land use scenarios
- regulatory (default) cleanup goals

▢ Did bioavailability and risk assessments consider potential differences in RBA values for different exposure units/areas being used for different receptor exposure scenarios?

▢ Does the risk assessment discuss the basis of the site-specific bioavailability, RBA value(s) used?

- RBA estimate basis, mean, 95% upper confidence limit (UCL) of the mean, maximum and rationale
- differences in risk assessment outcomes using different types of RBA estimates
- RBA estimation method consistent with soil concentration statistics (mean, 95% UCL of the mean, maximum)

▢ Is the use of the site-specific bioavailability in the calculation of risk/hazard levels or cleanup goals including assumptions and their rationale clearly presented?

- calculation equation
- assumptions
- calculated values

▢ Did the risk evaluation present analysis/conclusion that includes limitations or uncertainties in the use of bioavailability?

- variability of the RBA and concentrations data and sources of variability
- method-related uncertainties (sampling, bioavailability tests, IVIVC model)
- chemical properties and presence of other chemicals
- background level(s)

▢ Was the public engaged and was there a general understanding about bioavailability and acceptance? [Stakeholder Perspectives]

- Note the participants.
- Identify the feedback mechanism.
- Did the investigation and risk assessment consider post-assessment stakeholder engagement and feedback with regards to the use of bioavailability in the risk assessment?

▢ Other