

Problem Formulation

1. Examine site investigation data and if needed collect, sieve<sup>1</sup>, and analyze soil for CoCs.

2. Are all risks below a level of concern?

Yes

Stop. Site-specific risk analysis not necessary

No

3. Could a site specific RBA adjustment impact decision-making?<sup>2</sup>

No

Yes

Bioaccessibility Testing

4. Is an *in vitro* method available for estimating site specific RBA that meets the following criteria?  
a. Method with *in vivo* validation in literature;<sup>3</sup> or  
b. Own method with in-lab *in vivo* validation<sup>3</sup>; or  
c. Method validated for contaminants that behave similarly<sup>4</sup>.

No

Is an *in vivo* study feasible?<sup>5</sup>

No

Yes

Yes

5. Seek stakeholder input and confer with regulators regarding sampling and method implementation.

6. Proceed with RBA study and evaluate RBA using appropriate guidance<sup>7</sup>.

Risk Analysis

7. Incorporate RBA values into DQRA using appropriate guidance.

Assume RBA is 100%

<sup>1</sup>Justification for choice of particle size must be provided. See more information on this topic in checklists.

<sup>2</sup>Scenarios where bioavailability adjustments will have the most benefit should consider factors such as concentration of the CoC, average % BA value, contaminant source and end use, with comprehensive literature review where available and necessary.

<sup>3</sup>Correlation of in vivo results with an in vitro method requires that: a) The in vivo study includes controls; b) The method is used on a minimum of three soils representing a range of soil types; and c) The in vivo-in vitro comparisons produce a slope of close to 1 and a statistically significant r value. See checklists for more details. Note that BARC is recommending four approved methods for lead and arsenic, based on sufficient validation. The points regarding the definition of “validation” including appropriate correlations for the same method, on different data sets generated by different groups, as detailed by Juhasz, Basta and Smith (Environmental Pollution 2013, 180, 372-375) may need to be considered.

<sup>4</sup>Assumptions regarding similar behaviour of contaminants to known validated elements must be justified through a comprehensive review of the literature.

<sup>5</sup>It should be determined if the added benefit of the RBA analysis exceeds the cost of conducting the RBA data. This will require estimating the range of possible RBA values and evaluating the potential added benefit of incorporating these values into the risk assessment.