9.1 Risk Calculations

When site-specific RBA values are incorporated into a HHRA (or in the calculation of cleanup goals), several factors must be considered. One of the critical factors is ensuring that the risk estimates are representative of (or cleanup goals are protective of) the reasonable maximum exposure (RME) for a receptor group. This approach is consistent with USEPA and state objectives for risk-based decision-making.

▼*Read more*

Accounting for RME ensures that a reasonable and adequate margin of safety for most of the potentially exposed population, including susceptible subpopulations, is reflected in the HHRA's risk characterization conclusions. The RME is estimated based on current and future land use and the receptor selected for the site (USEPA 1989b). For RME estimates to be achieved for risk estimates or cleanup goals, the exposure values used in calculating risk or cleanup goals must represent a combination of high-end and mid-range values. For example, in accounting for soil ingestion exposure risk, high-end estimates of soil ingestion rates and other exposure factors can be used in combination with estimates of the average soil concentration (for example, the 95% upper confidence limit on the mean).

Site-specific RBA values in HHRA are particularly useful because they decrease uncertainty in the risk-based decisions that are made at a given site. Often, accounting for RBA can reduce risk management costs. Other benefits include improved speed of remediation, ease of property transfer or development, and favorable public perception of HHRA. For the responsible party, the desired outcome of using site-specific RBA values for the HHRA is a more realistic estimate of the risk that can lead to more suitable, less costly, remedial decisions. For regulators, using site-specific RBA values reduces the level of uncertainty associated with the risk assessment without changing the point of departure for risk management decisions.

9.1.1 Conceptual Site Model

A conceptual site model (CSM) describes the potential contaminant sources, release mechanisms, fate and transport pathways, affected environmental media, receptors, and exposure pathways relevant to current and potential activities and land uses for a site. The CSM documents current and potential future site conditions and explains the relationship between sources and receptors by considering potential or actual migration and exposure pathways.

▼*Read more*

The bioavailability in soil affects the significance of the soil ingestion exposure route; with low RBA values, the exposure route may become insignificant or at least not the driving route of exposure for determining the need for soil cleanup. The CSM assists in organizing the HHRA, helping to identify uncertainties and data gaps, and focusing soil sample collection for bioavailability assessment within the potential exposure areas. Soil samples should be collected from representative exposure areas at various depths consistent with the exposure assumptions of the particular receptor population, because bioavailability can vary by depth and area of the site.

The preliminary CSM for the site should be developed before using the RBA results. After the RBA results are available, the soil ingestion component of the CSM should be updated to incorporate the RBA data and indicate the relevance of the pathway. A detailed discussion of CSM development is provided in Section 3 of the RISK-3 guidance (ITRC 2015).

9.1.2 USEPA Guidance on Bioavailability Assessment and RBA Values

Bioavailability is identified as a component in estimating the health risk of chemicals in soil in several documents, including RAGS Part A (USEPA 1989b); Soil Screening Guidance (USEPA 1996b); and Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites (USEPA 2002c).

RAGS Part A (USEPA 1989b) indicates that site-specific HHRA may consider bioavailability estimates to account for the difference in absorption efficiencies of a chemical in different media (such as water and soil). In the absence of chemical- and site-specific RBA data, USEPA and state agencies use a default RBA of 100% for chemicals in soil. The use of soil RBA values in HHRA is evaluated in this guidance for the oral ingestion pathway only. Assessing bioavailability in dermal contact exposure to PAHs in soil is briefly discussed.

9.1.3 Incorporating RBA values in the Calculation of Risk Estimates or Cleanup Goals

The use of HHRA and the equations used in evaluating the potential significance of exposure to chemicals are explained in many USEPA and states guidance documents, including ITRC's RISK-1 and RISK-2 guidance. ITRC's RISK-3 guidance describes both forward and backward calculations of risk and cleanup goals, respectively.

The forward calculation for the oral exposure route derives a lifetime average daily dose (LADD, for cancer) or average daily dose (ADD, for noncancer) using the concentration of the chemical in soil to which a receptor is exposed over the exposure period (exposure concentration) and default or site-specific exposure assumptions (such as averaging time, exposure duration, exposure frequency, and soil ingestion rate).

Next, the noncancer hazard quotient (HQ) is established using the ratio of the calculated ADD to the appropriate chemical-specific oral reference dose (RfD). The cancer risk (CR) is established by multiplying the LADD by the cancer slope factor (CSF). Individual CR and HQ estimates for each chemical can be summed to form a cumulative CR and noncancer hazard index (HI), respectively. The calculated cumulative CR or HI is then compared to the regulatory acceptable target cancer risk (TCR) level or range (for example, 1×10^{-6} to 1×10^{-4}) or target noncancer hazard index (THI is generally 1) to determine if a site requires additional response activities. Different regulatory programs may have different risk management goals. Likewise, some programs do not account for cumulative risk and rely on evaluating single-chemical risk estimates to make decisions about risk management actions.

In a backward calculation, the screening level or soil cleanup goal for each chemical is derived using predetermined or regulatory acceptable TCR or target hazard quotient (THQ), appropriate toxicity value, and exposure assumptions similar to those used in the forward calculation. Site exposure concentrations (for example, the 95% UCL on the mean) can then be compared to the calculated risk-based screening levels or cleanup goals to evaluate whether a site requires additional response activities.

Lead calculations are performed differently from those presented above; see further discussion in the lead example section below.

9.1.3.1 Appropriate Oral Toxicity Values

The toxicity values used for evaluating exposures to soil by ingestion are the RfD and CSF. RfDs are toxicity endpoints/values used to evaluate potential human noncancer hazard from oral exposure; see ITRC's RISK-3 guidance (ITRC 2015). CSFs are toxicity endpoints/values used to evaluate potential human carcinogenic risks from oral exposure to carcinogens over a lifetime.

PAH CSF Determination

PAHs have different cancer potencies and are evaluated in HHRAs using a relative potency factor (RPF) approach. RPFs for PAHs describe the cancer potency value of individual PAHs relative to benzo(a)pyrene (BaP). RPFs may be applied to the measured soil concentrations to derive BaP toxicity equivalent concentrations, or the RPF may be applied to the BaP CSF to derive the CSF value for each carcinogenic PAH. Table 8-1 includes the RPF for some carcinogenic PAHs relative to the BaP CSF.

Mutagenic Mode of Action (MMOA)

When a chemical is determined to be a carcinogen with a potential MMOA, the CSFs are developed using chemical-specific modifications that address the differential potency caused by critical early life stage exposures (USEPA 2005b). Under USEPA's (2005a) *Guidelines for Carcinogen Risk Assessment*, BaP is "carcinogenic to humans." USEPA also considers BaP to have an MMOA; therefore, carcinogenic PAHs with CSFs based on RPFs applied to the BaP CSF are also considered mutagenic carcinogens (USEPA 2017f). When chemical-specific cancer toxicity data on the critical window of exposure are not available, CSF modifications are made using default adjustment values or age–dependent adjustment factors (ADAF). The USEPA default ADAF values are used when modifying the BaP CSF (USEPA 2005a; 2017f). See example calculations.

9.1.3.2 RBA and the Daily Intake Rate

In the forward risk (or hazard) calculation of the CR (or HQ), the RBA value is used to modify the daily dose of a chemical in soil considering the dosing medium used in the critical study for that chemical that provided the basis for the RfD or CSF value. The bioavailability of a chemical in soil is often lower than the unbound chemical or chemical form in water or diet due to varying chemical and soil properties including solubility, organic characteristics (diffusion and biodegradability), and chemical form (NRC 2003). PAHs are sparingly water soluble and tend to sorb strongly to soil. Modifications to the daily dose of chemicals in soil are therefore necessary when the toxicity value is based on a critical study that used water or food (something other than soil) as a delivery medium for the chemical. The equations below show how RBA is incorporated in the forward risk or hazard calculations:

Cancer risk:

$$ELCR = \frac{DI \times RBA}{(1/CSF) \times CF} \qquad \text{Or} \qquad ELCR = \frac{C_s \times RBA \times IR \times EF \times ED}{(1/CSF) \times BW \times AT \times CF}$$

Noncancer hazard:

$$HQ = \frac{DI \times RBA}{RfD \times CF} \qquad \text{Or} \qquad HQ = \frac{C_s \times RBA \times IR \times EF \times ED}{RfD \times BW \times AT \times CF}$$

Where:

AT (Averaging time)	=	days (for cancer – 70 years x 365 days/year; for noncancer – ED x 365 days/year)
BW (Body weight)	=	kg
C_s (Concentration in soil)	=	site-specific, mg/kg
CF (Conversion factor)	=	1.0E+6 mg/kg
CSF (Cancer slope factor)	=	chemical-specific, $(mg/kg\text{-}day)^{-1}$
DI (Daily intake)	=	chemical-specific, mg/kg-day
ED (Exposure duration)	=	years
EF (Exposure frequency)	=	days/year
ELCR (Excess Lifetime Cancer risk)	=	unitless
HQ (Hazard quotient)	=	unitless
IR (Ingestion rate)	=	mg/day
RBA (Relative bioavailability)	=	site-specific, unitless
RfD (Oral reference dose)	=	chemical-specific, mg/kg-day

Daily intake is the chemical intake based on body-weight-adjusted chemical concentration in soil for a site scenario that is adjusted to a daily intake rate by the averaging time. The soil exposure concentration is an estimate of the mean (for example, the 95% UCL on the mean), depending on the regulatory requirement and data quality needs.

All equations presented above assume that RBA is constant over the range of doses. However, RBAs vary with factors such as dose, presence of other chemicals, and soil exposure duration. Thus, the assumption that the RBA is a constant is valid only within the conditions under which it was derived.

9.1.3.3 RBA and the Oral Toxicity Values

Unlike the forward calculation of risk estimates, in a backward HHRA, the soil risk-based cleanup goals are calculated based on a target cancer risk or target hazard quotient. In this approach, RBA is used to modify the toxicity values (CSF or RfD):

For carcinogens:

$$CG = \frac{TCR \times AT \times BW \times CF}{CSF \times RBA \times IR \times EF \times ED}$$

For noncarcinogens:

$$CG = \frac{THQ \times AT \times BW \times CF}{\left(1/RfD\right) \times RBA \times IR \times EF \times ED}$$

Where:

AT	(Averaging time)	=	days (for cancer – 70 years x 365 days/year; for noncancer – ED x 365 days/yr)
BW	(Body weight)	=	kg
CF	(Conversion factor)	=	1.0E+6 mg/kg
CG	(Cleanup goal)	=	chemical-specific, mg/kg
CSF	(Cancer slope factor)	=	chemical-specific, $(mg/kg\text{-}day)^{-1}$
ED	(Exposure duration)	=	years
EF	(Exposure frequency)	=	days/year
IR	(Ingestion rate)	=	mg/day
RBA	(Relative bioavailability)	=	site-specific, unitless
RfD	(Oral reference dose)	=	chemical-specific, mg/kg-day
TCR	(Target cancer risk)	=	unitless
THQ	(Target hazard quotient)	=	unitless

9.1.4 Exposure Assumptions in Relation to Bioavailability

Integration of bioavailability into the risk or hazard (or soil cleanup goal) calculations still represents the RME. For ingestion of contaminants in soil, the RME for chronic exposure combines "an average exposure point concentration with reasonably conservative values for intake and duration in the exposure calculations" (USEPA 1996b).

▼*Read more*

The equations show that including RBA does not affect the RME assumption because RBA does not affect exposure assumptions that are receptor-activity or behavior-based factors (such as exposure frequency, exposure duration, or soil intake). Bioavailability relates to chemical-specific factors that influence the absorbed dose or fraction of ingested chemical that crosses the gastrointestinal epithelium. Thus, including RBA values in equations for estimating risks or cleanup goals does not affect the target level of protection built into the RME exposure scenario (risk estimates or cleanup goals that consider RBA meet the RME requirement).

Soil type and other soil characteristics may influence absorption efficiency, and consequently bioavailability. In a well-designed site-specific bioavailability assessment, these soil characteristics should be evaluated.

9.1.5 Use of Default RBA Values

USEPA has established default RBA values that can be used in evaluating the significance of exposures to lead (USEPA 1999) and arsenic (USEPA 2012d) from soil. Despite the availability of these defaults, agencies have advocated the use of site-specific data where possible. Agencies have adopted this position because default RBA values and the scenario they are based on may not be appropriate in some site-specific conditions or circumstances (NRC 2003). Note that when representative and valid site-specific RBA data are available, those data should be used in place of default RBA values in HHRA. This practice reduces uncertainty in the site-specific risk-based decisions.

▼*Read more*

For arsenic, USEPA has indicated that the generic RBA default of 60% could be used in screening-level assessments since the value is "not likely to be exceeded at most sites and is preferable to the assumption of an RBA equal to 100%" (USEPA 2012d). This empirical RBA of 60% is the 95th percentile of the RBA values from USEPA's current database (which means that less than 5% of the estimates exceed 60% RBA). For lead, USEPA established a default value of 60%, which is typically used to estimate blood lead levels from soil exposure and establish remediation goals for lead in soil. There are, however, studies that have noted that this empirical level may underestimate the RBA at some sites (NRC 2003). In USEPA's update of the IEUBK model, the proposed default RBA remains 60 % (USEPA 2016h). Generally, generic regulatory defaults for soil RBA may be appropriate and less costly, but their use should be confirmed with the regulatory agency. The default RBA from soil for PAHs is 100%.

Currently there is not enough soil type-specific data, correlated with source types and RBA measurements, to develop default RBA values by soil type for arsenic, PAHs, or lead (USEPA 2007c). Default values may be developed in the future as

additional RBA studies are published.

9.1.6 Determining the Site-Specific RBA for HHRA

The number of samples and sampling approach (for example, discrete or incremental samples) is a site-specific decision requiring professional judgement. Various site-specific aspects should be considered, such as site geology (how many different soil types are present), source areas (whether different source areas are present), exposure areas (whether various exposure areas are present and if some are representative of others), and chemical concentrations. ITRC's Incremental Sampling Methodology (ISM) guidance (ITRC 2012) and USEPA (2015a) guidance for lead sampling provide further information on considerations during project planning.

▼*Read more*

When estimating RME, high end soil ingestion rates are often used in combination with mid-range values for other exposure parameters (such as mean soil concentrations or 95% UCL on the mean concentrations) over an exposure period. The RBA effectively modifies the estimate of exposure point concentration. Consequently, as with sampling of soil, site-specific estimates of soil RBA values should provide representative coverage of the receptor's exposure area, to increase confidence in risk estimates (or cleanup goals) related to site-specific exposures (USEPA 2007b; 2015a). Thus, project teams can decide either to composite soil samples from across the site (USEPA 2007c) to obtain a representative estimate of the site's average RBA, or to collect enough discrete soil samples to calculate a statistically robust estimate of RBA for decision units (for example, receptor-specific exposure areas/units) at the site. Regardless of whether compositing or discrete sampling is used, various site-specific issues, such as soil type and depth of contamination, should be considered when combining RBA values for use in HHRA or cleanup goal calculations.

The specific exposure units for site receptors (exposure areas and depths) should be identified based on the site CSM, and the RBA data should be grouped consistent with the CSM. If background samples are available for the bioavailability assessment, the background RBA values should be addressed and grouped separately. Refer to the decision process chapter for issues to be considered in the bioavailability assessment.

9.1.6.1 Sampling and RBA Estimation *Read More*

When only one soil sample is submitted for RBA testing (usually a composite, or a sample from a small decision unit with homogeneous soils), only one RBA value will be available for use in the risk and cleanup goal calculations. Using only one soil sample for RBA testing, however, may not be appropriate, because soils are usually heterogeneous. Uncertainty may also exist about whether one RBA value adequately represents the RBA for an entire exposure area and depth range. In these cases, multiple soil samples should be submitted for RBA testing. When more than one soil sample is submitted for RBA analysis, multiple RBA values (one per sample) will be provided by the laboratory. Laboratory results for in vivo and in vitro methods are discussed in the Methodology section.

With multiple RBA analyses for the same exposure unit, several estimates of central tendency may be representative, including the mean, median, or some UCL on the mean. Currently, there is no clear guidance or precedent for which value to use. In choosing among these values, however, note that the RBA is usually applied to an estimate of the mean soil concentration and integrated into a final exposure estimate that contains the conservative RME exposure assumptions. Additionally, some USEPA guidance recommends using the straight arithmetic mean RBA value rather than a value that accounts for potential uncertainty (for example, the UCL on the mean). In the case of lead, for example, USEPA recommends using the arithmetic mean soil concentration as an exposure concentration in evaluating potential exposure to lead (USEPA 2015a). In doing so, it would be reasonable to also use the straight arithmetic mean lead RBA value in the exposure calculation.

If more conservatism is warranted due to concerns regarding the uncertainty in the RBA, a UCL on the mean RBA could be calculated. For example, a 90% or 95% UCL on the arithmetic mean could be used as the statistical measure for the RBA. In doing so, the most recent version of USEPA's ProUCL software (USEPA 2016d) could be used to generate the UCL value. Because the UCL on the mean RBA may be applied to the 95% UCL on the mean soil concentration, the use of multiple UCLs should be evaluated for consistency with the overall approach used for adequate site characterization and with USEPA guidance (USEPA 1992b). The RBA estimate chosen should adequately characterize the RBA but, when integrated into the other parameters (for example, UCL on the mean soil concentration), not cause the overall risk estimates to become overly conservative.

When ISM is used for site characterization, the soil samples submitted for RBA testing should also be collected using ISM for consistency. ISM yields an estimate of the average concentration across a decision unit (exposure area), which may include one or more sampling units. It is a site-specific decision whether to collect soil samples for RBA analysis from one incremental sample or from replicate incremental samples within the sampling unit. If the site characterization data are

available prior to submittal of samples for RBA testing, the degree of consistency between the triplicate results may be used to make this decision. Submitting IS samples for RBA analysis yields an average RBA across the sampling unit.

As indicated in Footnote 1 of Section 3.3.4 of the ITRC's ISM guidance (ITRC 2012), ISM may be used for RBA testing. The guidance also notes, however, that "… to be representative of exposure, bioavailability studies must be performed on ISM samples that have not been processed by grinding. If other data quality objectives (DQOs) being fulfilled by ISM samples in the exposure DU require grinding as part of sample processing, the comparability of ground vs. unground samples should be evaluated as part of the study."

Regardless of the estimate of central tendency, the variability in the individual RBA values should be discussed in the uncertainty analysis section of the HHRA. This discussion could entail a qualitative or quantitative sensitivity analysis (see Bioavailability in Risk Assessment).

9.1.6.2 Site-Specific RBA and Probabilistic Risk Assessment *Read More*

Probabilistic risk assessment (PRA) can help to capture uncertainty and variability (USEPA 2014c) in the risk characterization. This approach could be a useful tool when considering RBA. A PRA uses distributions rather than discrete variables for some or each parameter used to calculate risks. In doing so, a PRA provides a distribution or range of risks as its output rather than a single point estimate of risk. In a probabilistic framework, soil RBA would be represented by a probability distribution rather than a discrete value. PRA may be worth considering, however, the increased cost of doing so and likelihood of acceptability by the oversight regulatory agency should be weighed against the potential benefits. As USEPA explains (2014c), a "PRA generally requires more resources than standard Agency default-based deterministic approaches." As a result, this approach may be costlier to perform in comparison to a deterministic HHRA. The increased costs, however, may be offset by a reduction in the degree of risk management necessary to achieve acceptable risks.

9.1.7 RBA Based on Site-Specific Results

At sites where both **in vivo method** and **in vitro method** results are available, the project team should consider the quality and quantity of the results and determine whether to use the in vivo or in vitro results, or some combination of the information. If the results are equally representative of site conditions and valid, then typically the in vivo results are preferred over the in vitro results.

The information expected from the laboratory for an in vivo or in vitro study is presented in the Methodology section. Specific information for lead, arsenic, and PAHs is also discussed in each of the chemical-specific chapters.

9.1.8 Examples of RBA Use in HHRA

Exposure is quantified considering the magnitude, frequency, and duration of exposure for the receptors and pathways selected for quantitative HHRA. The exposure factors used in the example risk calculations below are based on the latest USEPA Office of Land and Emergency Management (OLEM), formerly Office of Solid Waste and Emergency Response (OSWER), (USEPA 2014a) and Regional Screening Level guidance. The RfD and CSF values are from the Integrated Risk Information System (IRIS) database (USEPA 2015b). USEPA and many states use the OSWER guidance and IRIS database values to calculate risk estimates and screening levels (USEPA 2017h).

The following sections use **hypothetical example site data** to illustrate the HHRA calculations for arsenic and BaP. When considering these examples in the context of a specific site, applicable requirements and regulations, and method limitations should be considered.

9.1.8.1 Arsenic Example Calculations ▼*Read more*

Site Background *Read More*

Portions of the site are known to have been used as farmland. The site was developed for use as a commercial center in 1980 and significant filling and grading occurred. Concentrations of arsenic have been detected in soil samples. The higher concentrations of arsenic are colocated with the area that was used for farming in the past. At adjacent sites, however, agriculture may not be the source because the arsenic concentrations do not decrease with depth. The source may be naturally occurring arsenic in the form of a locally prevalent arsenopyrite.

Site Description and Conceptual Site Model *Read More*

- Background soil concentrations: No background level for arsenic was established.
- Maximum and average concentrations in soils, size of the data set: A single site with 20 samples; total arsenic concentrations ranged from 30 to 980 mg/kg. The 95% UCL on the mean = 278 mg/kg.
- Soil type: Soil characteristics (pH, clay, organic content, dominant minerology) are not known. Geographical history indicates some localized deposits of the mineral arsenopyrite, which is naturally high in arsenic.

- Source of arsenic: Analysis to determine arsenic species indicate that arsenic at the site is likely from historical agricultural land use.
- Present and future land use scenarios: The present and potential land use scenarios are residential or commercial/industrial.

Methodology Used for Evaluating Bioavailability *Read More*

No in vivo bioavailability value was established for the site. An in vitro method was used to establish bioavailability. Arsenic was extracted using a fluid that has properties which resemble gastrointestinal fluid (pH 1.5). This extract represented the fraction of soluble arsenic and is referred to as the in vitro **bioaccessibility** (IVBA) fraction.

Methodology Used to Establish Site-Specific RBA Values *Read More*

The IVBA was used to predict the RBA using a correlation model by Brattin et al. (2013). Also, see Table 7-2 (in section 7.3.4.1) for other models in the literature for arsenic. This model is based on arsenic RBA measurements from in vivo juvenile swine studies. The RBA values estimated using the (Brattin and Casteel) regression equation (shown below) ranged from 20% to 28%. For samples where arsenic was nondetect (the arsenic concentration in the extracted fluid was below the method detection limit), the equation intercept of 19.7 (or 20%) was used as the default RBA.

$$\text{RBA} = 19.7 + (0.62 \times \text{IVBA}), \text{where } r^2 = 0.723$$

Incorporating RBA in Estimation of Risk *Read More*

The noncancer hazard estimates and cleanup goals for oral exposure to soil arsenic were calculated for a residential child, residential aggregate adult/child, and worker using 95% UCL on the mean and the maximum detected arsenic concentrations. Tables 9-1, 9-2, and 9-3 summarize these calculations.

Table 9-1. Arsenic: Calculated hazard using 95% UCL on the mean (278 mg/kg)

RBA Value	Residential-Child HQ	Residential-Aggregate HQ	Worker HQ
None (or 100%)	12	4	**0.7**
Default: 60%	7	2	**0.4**
Site-specific: 28%	3	1	**0.2**

Table 9-2. Arsenic: Calculated hazard using maximum detected concentration (980 mg/kg)

RBA Value	Residential-Child HQ	Residential-Aggregate HQ	Worker HQ
None (or 100%)	42	13	3
Default: 60%	25	8	2
Site-specific: 28%	12	4	**0.7**

Using backward calculation and assuming THQ = 1, the soil cleanup goals for arsenic calculated using different RBA values are shown in Table 9-3. The USEPA RSLs for arsenic are 39 and 650 mg/kg for residential (child) and outdoor worker, respectively.

Table 9-3. Arsenic: Calculated soil cleanup goal (CGs) for various RBA values (THQ = 1)

RBA Value	Residential-Child CG (mg/kg)	Residential-Aggregate CG (mg/kg)	Worker CG (mg/kg)
None (or 100%)	23.5	77	389
Default: 60%	39.1	129	649
Site-specific: 28%	83.8	**277**	1390

Analysis and Conclusion *Read More*

The use of site-specific 28% RBA generates more refined risk estimates and cleanup goals for the soil ingestion exposure pathway. The tables above show that if the property is maintained for industrial or nonresidential land use, using the 95% UCL on the mean arsenic concentration with site-specific RBA resulted in an acceptable HQ value for workers compared to the use of the conservative maximum detected concentration of arsenic.

Noncancer Hazard Estimate Equations and Assumptions *Read More*

The noncancer hazard estimates and cleanup goals for oral exposure to soil arsenic were calculated using the equations and assumptions shown below.

Residential child noncancer hazard equation:

$$HQ = \frac{C_s \times RBA \times IR_{child} \times EF \times ED_{child}}{RfD \times BW_{child} \times AT_{child} \times CF}$$

Residential aggregate noncancer hazard equation:

$$HQ = \frac{C_s \times RBA \times IF \times EF}{RfD \times AT_{aggregate} \times CF}$$

$$IF = \left(\frac{IR_{child} \times ED_{child}}{BW_{child}}\right) + \left(\frac{IR_{adult} \times ED_{adult}}{BW_{adult}}\right)$$

Where:

$AT_{aggregate}$	(Averaging time, aggregate)	=	26 yrs x 365 days/year
AT_{child}	(Averaging time, child)	=	6 yrs x 365 days/year
BW_{adult}	(Body weight, adult)	=	80 kg
BW_{child}	(Body weight, child)	=	15 kg
C_s	(Site soil concentration)	=	278 mg/kg
CF	(Conversion factor)	=	1.0E+6 mg/kg
ED_{adult}	(Exposure duration, adult)	=	20 years
ED_{child}	(Exposure duration, child)	=	6 years
EF	(Ingestion exposure frequency)	=	350 days/year
HQ	(Hazard Quotient)	=	1, unitless
IF	(Age-adjusted soil ingestion factor)	=	105 mg-year/kg-day
IR_{adult}	(Soil ingestion rate, adult)	=	100 mg/day
IR_{child}	(Soil ingestion rate, child)	=	200 days/year
RBA	(Relative oral bioavailability)	=	28%
RfD	(Oral reference dose)	=	0.0003 mg/kg-day

Worker noncancer hazard equation:

$$HQ = \frac{C_s \times RBA \times IR \times EF \times ED}{RfD \times BW \times AT \times CF}$$

Where:

AT	(Averaging time)	=	9125 (25 years x 365 days/year)
BW	(Body weight)	=	80 kg
C_s	(Soil concentration)	=	278 mg/kg
CF	(Conversion factor)	=	1.0E+6 mg/kg
ED	(Exposure duration)	=	25 years

EF	(Exposure frequency)	=	225 days/year
HQ	(Hazard quotient)	=	0.2, unitless
IR	(Soil ingestion rate)	=	100 mg/day
RBA	(Relative oral bioavailability)	=	28%
RfD	(Oral reference dose)	=	0.0003 mg/kg-day

Example of residential, noncancer soil cleanup goal equation and assumptions:

$$CG = \frac{THQ \times AT_{child} \times BW_{child} \times CF}{\left(\frac{1}{RfD}\right) \times RBA \times IR_{child} \times EF \times ED_{child}}$$

Where:

AT_{child}	(Averaging time, child)	=	6 years x 365 days/year
BW_{child}	(Body weight, child)	=	15 kg
CF	(Conversion factor)	=	1.0E+6 mg/kg
CG	(Cleanup goal)	=	83.8 mg/kg
ED_{child}	(Exposure duration, child)	=	6 years
EF	(Ingestion exposure frequency)	=	350 days/year
THQ	(Hazard Quotient)	=	1
IR_{child}	(Soil ingestion rate, child)	=	200 days/year
RBA	(Relative oral bioavailability)	=	28%
RfD	(Oral reference dose)	=	0.0003 mg/kg-day

9.1.8.2 Benzo(a)Pyrene (BaP) Example Calculations ▼*Read more*

Site Background *Read More*

An industrial plant has soil contaminated with PAHs, including BaP, at a limited area. The property was previously used as a manufactured gas plant. Based on initial risk estimates, BaP was the primary risk driver, so an in vivo bioavailability study was conducted for BaP.

Site Description and Conceptual Site Model *Read More*

- Background soil concentrations: No background level for BaP was established.
- Maximum and average concentrations in soils, size of the data set: The contaminated site has soil BaP concentrations ranging from 1 to 180 mg BaP/kg soil; 95% UCL on the mean = 11 mg/kg and mean = 1.1 mg/kg.
- Soil type: Soil characteristics are not known.
- Source of BaP: The potential sources of the PAHs are the manufactured gas process and waste materials including coal tar.
- Future land use: The potential future land use scenarios are residential or commercial/industrial.

Methodology Used for Evaluating Bioavailability *Read More*

An in vivo method using mice was used to evaluate bioavailability.

Methodology Used to Establish Site-Specific RBA *Read More*

The range of measured RBA values (25% – 75%) was used.

Incorporating RBA in Estimation of Risk *Read More*

BaP is a carcinogen with an MMOA; therefore, the cancer toxicity value (CSF) is adjusted using ADAFs, for residential

receptors only.

Tables 9-4 and 9-5 present the calculated ELCR estimates and the soil cleanup goals for various RBA values.

Table 9-4. BaP: Calculated ELCR using 95% UCL on the mean (11 mg/kg)

RBA	Residential ELCR	Worker ELCR
Default: 100%	7E-05	3E-06
Site-specific: 75%	5E-05	2E-06
Site-specific: 25%	2E-05	8E-06

Using backwards calculations and assuming a target cancer risk (TCR) = 1×10^{-6}, the soil cleanup goals for BaP using the range of RBA are shown below.

Table 9-5. BaP: Soil cleanup goals (CGs) for various RBA values (assumes TR = 1×10^{-6})

RBA	Residential CG (mg/kg)	Worker CG (mg/kg)
Default: 100%	0.2	4
Site-specific: 75%	0.2	5
Site-specific: 25%	0.6	15

Analysis and Conclusion *Read More*

The use of site-specific RBA refines the HHRA by lowering the uncertainty contributed by possible influence of the soil matrix on BaP bioavailability. As demonstrated above, the site-specific RBA decreases the ELCR estimate and increases the cleanup goal values. If the regulatory target ELCR is 1×10^{-6}, the use of site-specific bioavailability (and the 95% UCL on the mean concentration) does not change the outcome of the HHRA due to the high soil concentrations at the site. Where the regulatory target ELCR is 1×10^{-5}, however, site-specific bioavailability may affect the risk management decision for the site (using the 95% UCL on the mean concentration and a commercial/industrial land use scenario). Because of the mutagenic mode of action and high CSF of BaP, a bioavailability assessment may be useful if the soil concentrations are slightly above the cleanup goal or when the RBA value is expected to be less than 50%.

Cancer Risk Estimate Equations and Assumptions *Read More*

The ELCR estimates and cleanup goals for oral exposure to soil BaP were calculated using the equations and assumptions shown below.

Residential Child and Adult Aggregate Risk for a Carcinogen with an MMOA:

$$ELCR = \frac{C_s \times RBA \times IFM \times EF}{(1/CSF) \times AT \times CF}$$

$$IFM = \left(\frac{IR_{<2} \times ED_{<2} \times ADAF_{<2}}{BW_{<2}}\right) + \left(\frac{IR_{2-<6} \times ED_{2-<6} \times ADAF_{2-<6}}{BW_{2-<6}}\right) +$$

$$\left(\frac{IR_{6-<16} \times ED_{6-<16} \times ADAF_{6-<16}}{BW_{6-<16}}\right) + \left(\frac{IR_{16-26} \times ED_{16-26} \times ADAF_{16-26}}{BW_{16-26}}\right)$$

Where:

$ADAF_{<2}$	(Age-dependent adjustment factor for cancer potency, ages <2 years)	=	10, unitless
$ADAF_{2-<6}$	(Age-dependent adjustment factor for cancer potency, ages 2-<6 years)	=	3, unitless
$ADAF_{6-<16}$	(Age-dependent adjustment factor for cancer potency, ages 6-<16 years)	=	3, unitless
$ADAF_{16-26}$	(Age-dependent adjustment factor for cancer potency, ages 16-26 years)	=	1, unitless
AT	(Averaging time)	=	70 years x 365 days/year
$BW_{<2}$	(Body weight ages <2 years)	=	15 kg
$BW_{2-<6}$	(Body weight ages 2-<6 years)	=	15 kg
$BW_{6-<16}$	(Body weight, ages 6-<16 years)	=	80 kg
BW_{16-26}	(Body weight, ages 16-26 years)	=	80 kg
C_s	(Site-specific soil concentration)	=	11 mg/kg
CF	(Conversion factor)	=	1E+06 mg/kg
CSF	(Oral cancer slope factor)	=	1.0 $(mg/kg\text{-}day)^{-1}$
$ED_{<2}$	(Exposure duration, ages <2 years)	=	2 years
$ED_{2-<6}$	(Exposure duration, ages 2-<6 years)	=	4 years
$ED_{6-<16}$	(Exposure duration, ages 6-<16 years)	=	10 years
ED_{16-26}	(Exposure duration, ages 16-26 years)	=	10 years
EF	(Ingestion exposure frequency)	=	350 days/year
ELCR	(Excess lifetime cancer risk)	=	5.4E-05, unitless
IFM	(Mutagenic age-adjusted ingestion factor)	=	476.67 mg-year/kg-day
$IR_{<2}$	(Soil ingestion rate, ages <2 years)	=	200 mg/day
$IR_{2-<6}$	(Soil ingestion rate, ages 2-<6 years)	=	200 mg/day
$IR_{6-<16}$	(Soil ingestion rate, ages 6-<16 years)	=	100 mg/day
IR_{16-30}	(Soil ingestion rate, ages 16-26 years)	=	100 mg/day
RBA	(Site-specific relative bioavailability)	=	75%, unitless

Worker Risk for a Carcinogen (MMOA adjustment does not apply to adults):

$$\mathrm{ELCR} = \frac{\mathrm{CSF} \times \mathrm{C_s} \times \mathrm{RBA} \times \mathrm{IR} \times \mathrm{ED} \times \mathrm{EF}}{\mathrm{AT} \times \mathrm{BW} \times \mathrm{CF}}$$

Where:

AT	(Averaging time)	=	70 years x 365 days/year
BW	(Body weight)	=	80 kg
C_s	(Soil concentration)	=	11 mg/kg

CF	(Conversion factor)	=	1×10^{-6} kg/mg
CSF	(Oral cancer slope factor)	=	1.0 $(mg/kg\text{-}day)^{-1}$
ED	(Exposure duration, worker)	=	25 years
EF	(Ingestion exposure frequency)	=	225 days/year
ELCR	(Excess lifetime cancer risk)	=	2.3E-06, unitless
IR	(Soil ingestion rate, worker)	=	100 mg/day
RBA	(Site-specific relative bioavailability)	=	75%, unitless

Residential Soil Cleanup Goal for a Carcinogen with MMOA adjustment:

$$CG = \frac{TCR \times AT \times CF}{CSF \times RBA \times IFM \times EF}$$

Where:

AT	(Averaging time)	=	70 years x 365 days/year
CF	(Conversion factor)	=	1E+06 mg/kg
CG	(Cleanup goal)	=	0.028 mg/kg
CSF	(Oral cancer slope factor)	=	1.0 $(mg/kg\text{-}day)^{-1}$
EF	(Ingestion exposure frequency)	=	350 days/year
TCR	(Target cancer risk)	=	1×10^{-6}, unitless
IFM	(Mutagenic age-adjusted ingestion factor) See derivation above.	=	476.67 mg-year/kg-day
RBA	(Site-specific relative bioavailability)	=	75%, unitless

Worker Soil Cleanup Goal for a Carcinogen (MMOA adjustment does not apply to adults):

$$CG = \frac{TCR \times AT \times BW \times CF}{CSF \times RBA \times IR \times ED \times EF}$$

Where:

AT	(Averaging time)	=	70 years x 365 days/year
BW	(Body weight)	=	80 kg
CF	(Conversion factor)	=	1×10^{-6} kg/mg
CG	(Cleanup goal)	=	4.8 mg/kg
CSF	(Oral cancer slope factor)	=	1.0 $(mg/kg\text{-}day)^{-1}$
ED	(Exposure duration, worker)	=	25 years
EF	(Ingestion exposure frequency)	=	225 days/year
TCR	(Target cancer risk)	=	1×10^{-6}, unitless
IR	(Soil ingestion rate, worker)	=	100 mg/day
RBA	(Site-specific relative bioavailability)	=	75%, unitless

9.1.9 Lead

USEPA guidance addresses soil sampling for IVBA testing for lead, stating that lead RBA estimates are used in lead risk assessment models (USEPA 2015a).

9.1.9.1 Lead Models

Various lead models can help to evaluate lead exposures.

▼*Read more*

USEPA's Adult Lead Methodology (ALM) is used to estimate blood lead levels for adults in a nonresidential setting. The default oral RBA from soil used in the model is 60%. The model documentation (USEPA 2003b) states that site-specific RBA data are highly preferred, because variation in RBA is expected for different species of lead and different particle sizes, which may also vary from site to site. A recent version of the ALM spreadsheet USEPA 2017 (USEPA 2017a) and its supporting documentation (USEPA 2003b; 2017b) are available from USEPA.

USEPA's Integrated Exposure Uptake Biokinetic (IEUBK) Model is used to estimate blood lead levels for children in a residential setting. The default oral RBA from soil used in the model is 60% (USEPA 1999). The model documentation (USEPA 2007a) states that the gastrointestinal (GI) values/bioavailability option on the parameter input menu can be used to modify the GI absorption coefficient to account for site-specific information on bioavailability. The most recent version of the IEUBK model (USEPA 2010d) and its documentation (USEPA 2007d; 2017b) are available from USEPA.

California Department of Toxic Substances Control (DTSC) has developed the LeadSpread Model (DTSC 2011a; b). The default oral RBA from soil used in this model is 44%. The comments embedded in the model spreadsheet indicate that alternative site-or waste-specific RBA values can be used in the model if the RBA can be scientifically justified. For industrial and commercial settings, the default oral RBA of 60% is the basis for calculating cleanup goals using a modified ALM. See Section 6.4.3.

USEPA is developing the All Ages Lead Model (AALM) (USEPA 2016a). This model is currently being beta-tested by several groups. The model combines and expands the exposure and absorption modules of the IEUBK model with a comprehensive biokinetic model (Leggett 1993). Consistent with the IEUBK model, the default oral RBA from soil used in the AALM is 60%. Draft documentation has been developed describing the AALM. The model is being evaluated against paired exposure and blood lead data, and is used as a research tool to evaluate scenarios that cannot be evaluated using the IEUBK model. Some of these scenarios are discussed in Chapter 3 of the Integrated Science Assessment for Lead (USEPA 2013a).

9.1.9.2 Lead Example Calculations ▼*Read more*

The following section uses **hypothetical example site data** to illustrate the HHRA calculations for lead.

Background *Read More*

The site is currently a residential property. Fill material containing waste residues from a smelter were imported to the property and used to fill low-lying areas. Elevated concentrations of lead were detected in surface soil from zero to one foot below ground surface in the filled areas.

Site Description and Conceptual Site Model *Read More*

- Background soil concentrations: No background level for lead was identified.
- Maximum and average concentrations in soils, size of the data set: A single site with 10 soil samples analyzed for lead bioavailability. Each soil sample was collected in the field as a five-point composite. Each sample was sieved by the laboratory and the material less than 150 microns was used for IVBA testing. The measured concentrations of lead in site soil ranged from 637 mg/kg to 677 mg/kg (average = 649 mg/kg).
- Soil type: Soil characteristics are not known.
- Source of lead: Fill material on site contains metal slag from a smelter.
- Future land use: Residential or commercial use is anticipated.

Methodology Used for Evaluating Bioavailability *Read More*

Bioavailability was evaluated using the IVBA method presented in USEPA guidance (USEPA 2007b).

Methodology Used to Establish Site-Specific RBA *Read More*

The IVBA values reported by the laboratory ranged from 81% to 89%, with an average value of 85%.

Step 1—Estimation of In Vivo Relative Bioavailability

The following empirical linear regression model was previously established by USEPA (2007b) between RBAs derived using in vitro and in vivo (juvenile swine) procedures:

$$RBA = 0.878 \times IVBA - 0.028$$

Using this equation, the in vivo RBA of lead in site soil was estimated based on the site-specific IVBA values measured in soil samples collected from the site. A range of site-specific RBAs corresponding to the minimum, average, and maximum was calculated. The sample-specific RBAs range from 68% to 75%, with an average RBA of 72%.

Step 2—Absolute Bioavailability

An estimate of absolute bioavailability is needed for the IEUBK model. Based on available information in literature on lead absorption in humans, USEPA estimates that the absolute bioavailability of lead from water and the diet is usually about 50% in children (USEPA 2010d). When a reliable site-specific RBA value for soil is available, it may be used to estimate a site-specific absolute bioavailability in that soil, as follows:

$$ABA_{soil} = 50\% \text{ x } RBA_{soil}$$

Where:

ABA_{soil} = ABA of lead in site soil ingested by a child

RBA_{soil} = site-specific RBA of lead

The calculated ABA_{soil} for the site ranges from 34% to 38%, with an average ABA_{soil} of 36%, which is higher than USEPA's default ABA of 30% used in the IEUBK model.

Incorporating RBA in Estimation of Risk *Read More*

The percentage of the exposed population with a predicted blood lead level (BLL) exceeding 5 µg/dL from oral exposure to lead in soil was calculated. The target BLL used for this example was 5 µg/dL; however, other states and agencies may use a different target BLL. The site-specific RBA value was used in the lead models in place of the default RBA values as follows:

- IEUBK Model: The default soil and dust GI bioavailability values were modified in the IEUBK model. The average estimated site-specific ABA_{soil} value (36%) was used in place of the default value (30%) for soil and dust. The remaining default input values were left unchanged in the IEUBK model.
- ALM: The $AF_{S,D}$ input parameter value was modified in the ALM. The $AF_{S,D}$ is the product of 0.20 (the absorption factor for soluble lead) and the RBA. The average estimated site-specific RBA (0.72) was used in place of the default value (0.6). The remaining default input values were left unchanged in the ALM.

For comparison purposes, the models were also run using USEPA's default ABA_{soil} value (in the IEUBK Model) or RBA (in the ALM). The input assumptions used in the IEUBK Model and ALM for this lead example are presented in Table 9-6.

Table 9-6. Lead: Input Assumptions Used in the IEUBK Model and ALM

Input Parameter	IEUBK Model (Resident Child)	ALM (Worker)
Outdoor Soil Lead Concentration mg/kg	649 (site-specific average)	649 (site-specific average)
Soil/Dust Ingestion Weighting Factor (% Soil)	45 (default)	—
Soil Ingestion Rate (g/day)	default	0.050
Soil/Dust Absorption Fraction (unitless)	30% (default), 36% (site-specific average)	0.12 (default), 0.14 (site-specific average)
Fraction Passive/Total Accessible (unitless)	0.2 (default)	—
Exposure Frequency (days/yr)	default	219 (default)
Averaging Time (days/yr)	default	365 (default)
Water, Diet Absorption Fraction	default	—
Indoor Air, Outdoor Air, and Drinking Water Lead Concentrations	default	—
Dietary Lead Intake	default	—
Water Consumption Rate	default	—
Mother's BLL at Childbirth (µg/dL)	0.6 (default)	—
Fetal/maternal BLL ratio (unitless)	—	0.9 (default)

Input Parameter	IEUBK Model (Resident Child)	ALM (Worker)
Baseline BLL (µg/dL)	—	0.6 (default)
Biokinetic Slope Factor (µg/dL per µg/day)	—	0.4 (default)
Geometric Standard Deviation BLL (unitless)	1.6 (default)	1.8 (default)
Target BLL of concern (µg/dL)	5	5

The predicted results for a resident child and commercial worker using the average soil lead concentration and average site-specific RBA (in addition to the default RBA) are presented in Table 9-7.

Table 9-7. Lead: Probability that calculated BLL > 5 µg/dL for soil concentration of 649 mg/kg

RBA	Resident Child	Fetus of Worker
Default: 60%	70.4%	1.4%
Average site-specific: 72%	79.8%	2.1%

Assuming the target is 5% probability that BLL exceeds 5 µg/dL, the soil cleanup goals for lead were calculated using the IEUBK Model and ALM based on the default and average site-specific RBAs, as shown in Table 9-8.

Table 9-8. Soil cleanup goal (CG) for two RBA values (assumes target is 5% probability that BLL > 5 µg/dL)

RBA	Residential CG (mg/kg)	Worker CG (mg/kg)
Default: 60%	154	1050
Average site-specific: 72%	128	900

Analysis and Conclusion *Read More*

The site-specific RBA data for lead in soil provide more refined site-specific estimates of BLLs for potential site receptors. The site-specific RBA data, however, did not change the conclusions of the risk evaluation: the soil lead concentrations result in BLLs that are above USEPA-acceptable levels for a residential scenario and BLLs within USEPA-acceptable levels for a commercial scenario. The average site-specific RBA is higher than the default RBA, resulting in lower site-specific soil cleanup goals than the cleanup goals calculated using the default RBA.

9.1.10 Applicability to Other Chemicals

This guidance focuses on lead, arsenic, and PAHs. Other chemicals may be of interest at a site. When applying the risk assessment and cleanup goal calculations described in this section to other chemicals, note the following:

Other inorganics (for example, cadmium, cobalt, nickel). ▼*Read more*

In general, the concepts, decision process, and sampling considerations described in this guidance may apply to other inorganics when in vivo and in vitro results are correlated, considering methods and method requirements, sampling limitations, and other chemical-specific information that could affect bioavailability. See for example, Denys et al. 2012; Henderson et al. 2012a, b; Kang et al. 2016; Schoof and Nielsen 1997; Schroder et al. 2003.

Petroleum hydrocarbons. ▼*Read more*

Petroleum contaminants of interest are generally volatiles and semivolatile compounds, including PAH. For volatiles, inhalation is the principal pathway of exposure. For PAH, however, including benzo(a)pyrene, oral and dermal exposures significantly contribute to the risk from exposure to these contaminants. Soil ingestion and dermal exposures are estimated to contribute to 72% and 28% of the total potential cancer risk resulting from contact with PAH in soil. Note that the presence of hydrocarbons may affect the bioavailability of PAHs (see PAH section). The information presented here for bioavailability of PAH could be used at petroleum hydrocarbon sites. However, because the composition of petroleum hydrocarbons is a complex mixture and varies by site, other chemicals may be relevant at a petroleum cleanup site that are not currently addressed by the methods discussed here. As of publication of this guidance, few petroleum hydrocarbon bioavailability studies are available.

Dioxins and Furans. ▼*Read more*

Exposures from soil are typically to mixtures of 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD) congeners that have varying toxic potency and, very likely, different RBA values. These differences are evident between RBA estimates for test soils assayed in swine and rats (USEPA 2011a). Different RBA estimates may be obtained depending on the animal model and bioassay used, and congener composition of the dioxin mixture. Evidence indicates that mixtures of dioxins/furans with higher chlorinated congeners (hexa-, hepta-, octa-) are less bioavailable than the lower-chlorinated congeners (tetra- and penta-). In addition to soil type, congener-specific differences in bioavailability should be considered when determining RBA of dioxin mixtures. USEPA recently compiled and summarized studies conducted to estimate RBA of TCDD and polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofuran (PCDD/F) in soils (USEPA 2011a). However, the extent to which variations in experimental design affects RBA estimates has not been evaluated. One study compared RBA estimates for the same test materials in more than one assay; the outcome was dissimilar estimates of RBA for two soils based on a single dose rat bioassay and a multiple dose swine assay (USEPA 2011a). Some of this uncertainty has been attributed to influences on soil type (% carbon content), soil properties, and duration of contact with the soil. Note that there are also circumstances when soil characteristics may have no impact on RBA. For instance, the graphitic nature of dioxin contamination could provide a matrix where the low soil carbon content and very low black carbon results in no effect at all on RBA.

Washington State's Department of Ecology (DOE) proposed a default GI absorption fraction or RBA of 0.4 for the less bioavailable and typically more abundant dioxin/furan mixtures (Washington State Department of Ecology 2007). This value (0.4) was derived by dividing 30% ABA (value used to characterize absorption of soil-bound dioxins and furans) by 80% (value used to characterize ABA of dioxin/furan in the toxicological studies used to calculate the CSF). Final guidance published by Washington DOE recommended a weighted RBA for TEQ dioxins of 0.6, based on typical mixtures of dioxin/furan congeners identified in soil (Washington State Department of Ecology 2007).

Several states including Oregon, Massachusetts, West Virginia, and Florida have state-specific soil action levels approximating or lower than 10 parts per trillion, based on the administered dose used in the critical studies to develop the TCDD CSF by USEPA, which corresponds to an ABA factor of 80%. Michigan has set 90 ppt soil action level which uses a 50% default estimate for ingestion absorption efficiency, a parameter that is equivalent to bioavailability. This value is similar to the 50% estimate for bioavailability of dioxins assumed in the World Health Organization (WHO) Permissible Tolerable Monthly Intake factors that are intended to limit long-term, body burden to levels that are assumed not to be associated with significant cancer or noncancer health risks (WHO 2001; 2002). The 50% value is used to adjust the oral RfD of all organic hazardous substances which exhibit two characteristics: (1) log octanol water partitioning coefficient greater than five and a molecular weight greater than 200 grams per mole, or (2) nonionizing organic hazardous substance (MDEQ 2006). International organizations recognize a wide range of estimates (approximately 30-90%), with most using a default 50% estimate for RBA. The Minnesota dioxin soil action level of 200 parts per trillion reflects a 55% estimate for bioavailability (USEPA 2011a).

Due to limited dioxin/furan in vitro bioavailability studies, assessing bioavailability of dioxins and dioxin-like compounds in soil is not addressed in this guidance. Several guidance documents on estimating RBA of dioxin in soil are available and are listed below:

- (USEPA 2014d). *Soil Dioxin Relative Bioavailability Assay Evaluation Framework*, February 2014.
- (USEPA 2011a). Bioavailability of Dioxins and Dioxin-Like Compounds in Soil; Transmission Memo. January 2011. This document notes the limitations of estimating RBA for dioxin.
- (USEPA 2010b). *Bioavailability of Dioxins and Dioxin-Like Compounds in Soil*, Final Report, December 2010.
- Michigan Department of Environmental Quality (MDEQ) (MDEQ 2006). RRD Operational Memorandum No. 1: Technical Support Document – Attachment 6: Part 201 Soil Direct Contact Criteria and Part 213 Tier I Soil Direct Contact Risk-Based Screening Levels.