

January 4, 2021

ATTACHMENT C: Relative Bioavailability Adjustment of Decision Unit Exposure Point Concentrations for Arsenic and Lead: Upper Columbia River Case Study

Site description: As part of human health risk assessment (HHRA), residential soils and beach sediments were sampled for arsenic and lead concentrations and relative bioavailability (RBA) at 162 decision units, along a 25-mile stretch of the Upper Columbia River (Integral, 2014; SRC, 2014; TAI, 2016; U.S. EPA, 2017a). Contamination was thought to have occurred predominantly by aerial deposition from local smelter operations, historic dumping of smelter waste into the river, and possibly by other local sources.

Data Quality Objective (DQO): The complete DQO for sampling can be found in the Quality Assurance Project Plans (QAPPs) for the residential soil studies (SRC, 2014; TAI, 2016). An objective of the study was to collect data that would provide a basis for adjusting EPC for arsenic and lead at each decision unit for RBA.

Sampling approach: Sampling locations for the residential soil studies were decision units varying in size from approximately <1 to 5 acres. The sampling design was incremental composite sampling (ICS). For approximately 40% of residential decision units, 3 composites of 30 increments each were collected. At residential properties in which there were multiple decision units of the same type (e.g., more than one garden), three incremental composite (IC) samples were collected at one decision unit and single composites (30 increments) were collected at the other decision units of the same type on the same property. Sampling depths were tilled depth for gardens (generally 0–12 inches), 0–3 inches for disturbed areas (e.g., animal activity areas), 0–1 inch for other residential soils, and 0–6 inches for beaches. Residential sampling was conducted in two time periods (referred to as 2014 and 2016), which covered overlapping areas along the river (Figures C-1 and C-2). In the 2014 sampling, out of 201 decision units sampled (not including driplines), decision units were selected for *in vitro* bioaccessibility (IVBA) measurement if the concentration in a composite sample exceeded either 20 mg arsenic/kg or 100 mg lead/kg. One IC sample was selected for IVBA analysis from each eligible decision unit. In addition, all IC samples with relative percent differences for lead or arsenic concentration that were >30% were selected for IVBA measurement. This resulted in a total of 114 decision units (57%) being characterized for IVBA. In the 2016 sampling, a random sample of 20% of decision units that met the above concentration criteria were selected for IVBA measurement, resulting in a total of 41 decision units (9%) being characterized for IVBA. As in the 2014 sampling, IVBA was measured in a single IC sample from each decision unit. Concentrations and IVBA (U.S. EPA, 2017b, 2017c, 2017d) were measured in residential soil samples that were sieved to <150 µm; beach sediment samples were sieved to <250 µm (U.S. EPA, 2017a). Altogether, IVBA was assayed on a total of 138 residential soil decision units and 23 beach decision units, representing approximately 20% of all residential decision units and approximately 75% of all beach decision units.

RBA adjustments of arsenic and lead concentrations: For each decision unit with IVBA data, an RBA-adjusted soil lead concentration was calculated using the following equations (U.S. EPA, 2017f):

$$RBA\% = (0.878 \times IVBA\% - 2.8)$$

$$RBA\text{-adjusted lead concentration} = RBA/0.6 \times \text{measured lead concentration}$$

where IVBA is in percent format (i.e., not as a fraction), 0.6 is the default soil RBA in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model) ($0.6 = 0.3/0.5$), and the measured lead concentration is based on the IC sample result (or average, if replicate IC samples were collected).

RBA-adjusted soil arsenic concentration was calculated using the following equations (U.S. EPA, 2017f):

$$RBA\% = (0.79 \times IVBA\% + 3)$$

$$RBA\text{-adjusted arsenic concentration} = RBA \times \text{measured arsenic concentration}$$

where IVBA is in percent format (i.e., not as a fraction).

RBA results from 2014 and 2016: Mean RBA for decision units sampled in 2016 were significantly lower for both lead and arsenic than the means for decision units sampled in 2014 (*t*-test, $p < 0.001$). The difference between the mean arsenic RBA in residential soils measured at decision units sampled in 2014 ($n = 100$) and 2016 ($n = 38$) was 11.6 (95% confidence interval [CI]: 9, 14); and the difference between the 2014 and 2016 mean lead RBA was 12.6 (95% CI: 8, 17).

Several factors may have contributed to the differences in the RBA means from the 2014 and 2016 sampling events, including the chemical form of arsenic or lead in the soil as well as physical-chemical characteristics of arsenic- or lead-bearing soil particles in soils. The 2016 samples were collected, in general, further to the south than the 2014 samples and further from lead and arsenic smelter emission sources located in the northern stretches of the river (Figures C-1 and C-2). Given that the above factors may have contributed to the variability in RBA, area mean RBAs were estimated for soils and beaches located within or outside of the 2014 soil study boundary (Tables C-1 and C-2).

Application of the IVBA information for HHRA: When decision unit-specific IVBA information was available, it was used to adjust RBA for that specific decision unit. For those decision units where IVBA was measured, the sample of RBAs estimated from IVBA was used to assign RBA values to decision units, as follows: decision units located within 2014 boundary were assigned the mean measured RBA of all decision units within the 2014 boundary and decision units outside of the 2014 boundary were assigned the mean measured RBA of all decision units outside the 2014 boundary (Tables C-1 and C-2).

Table C-1. Summary Statistics for Decision Unit RBAs (Excluding Beaches)					
	N	Mean	SD	SE	CV
Lead RBA %					
Outside 2014 Boundary	32	50.5	13.6	2.4	0.27
Inside 2014 Boundary	107	63.9	7.6	0.7	0.12
Arsenic RBA %					
Outside 2014 Boundary	32	16.4	6.6	1.2	0.41
Inside 2014 Boundary	107	27.6	7.4	0.7	0.27

CV, coefficient of variation (SD/mean); RBA, relative bioavailability; SD, standard deviation; SE, standard error

Table C-2. Summary Statistics for Beach Decision Unit RBAs					
	N	Mean	SD	SE	CV
Lead RBA %					
Outside 2014 Boundary	5	50.2	9.7	4.3	0.19
Inside 2014 Boundary	18	56.8	5.8	1.4	0.10
Arsenic RBA %					
Outside 2014 Boundary	5	21.2	6.2	2.8	0.29
Inside 2014 Boundary	18	30.0	5.1	1.2	0.17

CV, coefficient of variation (SD/mean); RBA, relative bioavailability; SD, standard deviation; SE, standard error

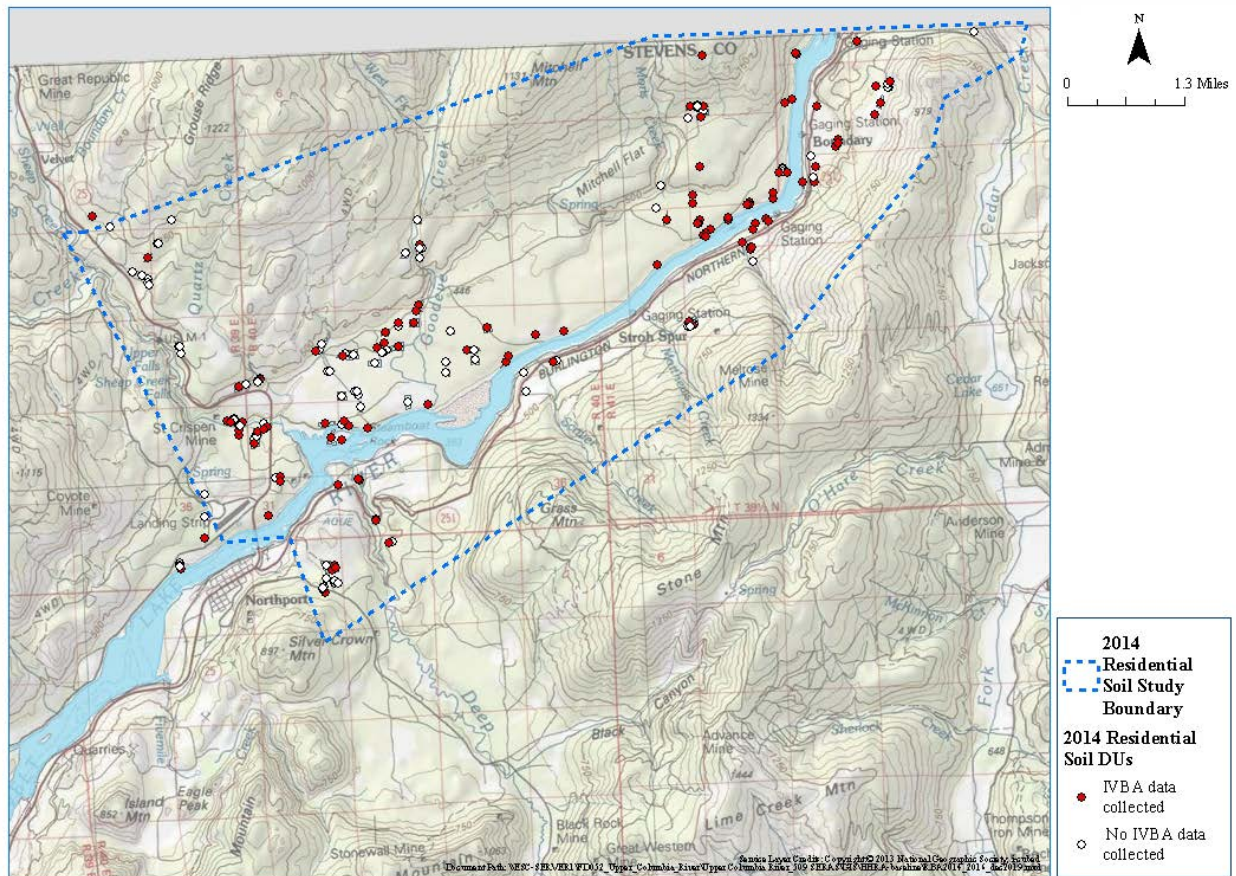


Figure C-1. Location of 2014 Residential Soil Decision Units Sampled for Lead and Arsenic IVBA.

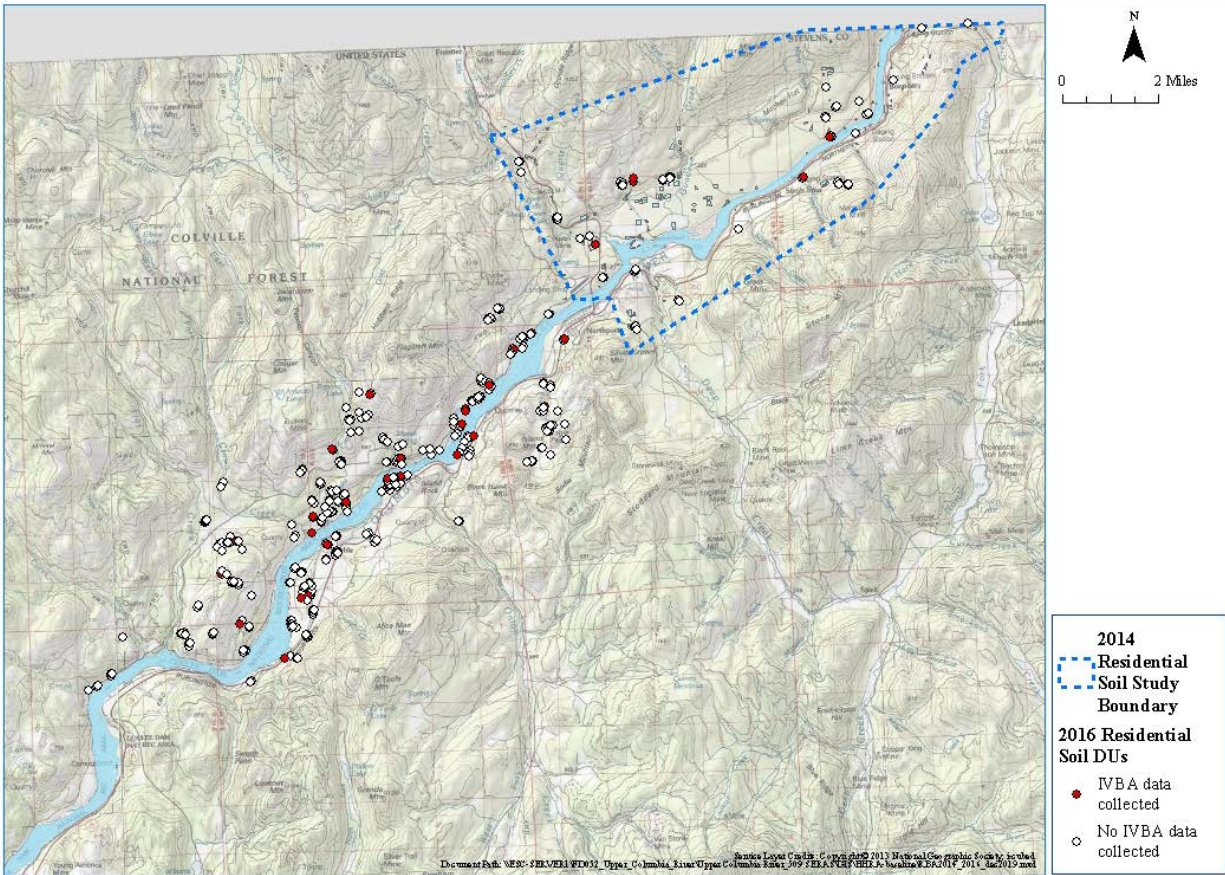


Figure C-2. Location of 206 Residential Soil Decision Units Sampled for Lead and Arsenic IVBA.

References:

Integral. (2014) Upper Columbia River Final Beach Sediment Study Field Sampling and Data Summary Report. Prepared for Teck American Incorporated. December.

SRC. (2014) Quality Assurance Project Plan. Upper Columbia River Residential Soil Study. Washington State. Prepared for U.S. Environmental Protection Agency Region 10 and Environmental Response Team. Prepared by SRC, Inc. for Lockheed Martin. Scientific Engineering Response & Analytical Services Program. August.

TAI. (2016) Final 2016 Residential Soil Study, Quality Assurance Project Plan Addendum No. 1 to the 2014 Residential Soil Study Quality Assurance Project Plan. Prepared for Teck American Incorporated. July.

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U.S. EPA (U.S. Environmental Protection Agency). (2017b) Validated Test Method 1340: *In Vitro* Bioaccessibility Assay for Lead in Soil. U.S. Environmental Protection Agency. Available online at: https://www.epa.gov/sites/production/files/2017-03/documents/method_1340_update_vi_final_3-22-17.pdf.

U.S. EPA (U.S. Environmental Protection Agency). (2017c) Validation Assessment of *In Vitro* Arsenic Bioaccessibility Assay for Predicting Relative Bioavailability of Arsenic in Soils and Soil-like Materials at Superfund Sites. U.S. Environmental Protection Agency. OLEM 9355.4-29. April 20, 2017.

U.S. EPA (U.S. Environmental Protection Agency). (2017d) Release of Standard Operating Procedure for an *In Vitro* Bioaccessibility Assay for Lead and Arsenic in Soil and Validation Assessment of the *In Vitro* Bioaccessibility Assay for Predicting Relative Bioavailability of Arsenic in Soils and Soil-like Materials at Superfund Sites. Transmittal Memorandum from Schatzi Fitz-James to Superfund National Program Managers, Regions 1-10. May 5, 2017. U.S. Environmental Protection Agency. Available online at: <http://semspub.epa.gov/src/document/HQ/196751>.

ATTACHMENT D: Bioavailability Adjustment of Daily Oral Intake of Arsenic in a Baseline Human Health Risk Assessment: A Case Study

The issue of bioavailability of arsenic is especially important at mining, milling, and smelting sites. This is because the arsenic at these sites often exists, at least in part, as a poorly soluble sulfide, and may occur in particles of inert or insoluble material. These factors collectively tend to reduce the bioavailability of arsenic. The oral bioavailability of soil-bound arsenic largely depends on the rate at which it dissociates from the soil matrix in the gastrointestinal tract. Soil-bound arsenic is usually absorbed by the gastrointestinal tract to a lesser degree than when in more soluble forms. This reduced absorption results from the affinity between arsenic and the soil matrix, the low solubility of the chemical form of arsenic associated with the soil, or both. Thus, the bioavailability of arsenic from site soil is expected to be low for constituents that are tightly bound within the soil matrix and/or are in a form that is insoluble in the gastrointestinal tract under physiological conditions.

During the remedial investigation data collection, a site-specific bioavailability study was conducted to provide a better understanding of the oral bioavailability of arsenic in soil, which may have been affected by site-related releases. Soil arsenic relative bioavailability (RBA) was estimated from *in vitro* bioaccessibility (IVBA) measured using U.S. Environmental Protection Agency (U.S. EPA) Method 1340 (U.S. EPA, 2017a, 2017b).

The total arsenic concentrations in the test samples ranged from 29 to 6,899 mg/kg, spanning the range of levels typically seen during the Remedial Investigation. The bioaccessible fraction of arsenic does not appear to be concentration dependent with respect to total arsenic. The highest IVBA values were 57% and 54% at two locations where known efflorescent salts have been observed during site investigations; therefore, these values were considered outliers and were not used to estimate the site-wide RBA. A site-specific bioavailability adjustment factor was estimated using test results from 72 soil samples collected across the site from a combination of residential and non-residential areas (gulch areas, smelter area, and mine tailings). For this pooled data set, the RBA 50th, 90th, 95th, and 99th percentiles were estimated to be 14%, 21%, 22%, and 28%, respectively. To ensure that site risk was not underestimated at a residence and provide a health-protective estimate of site-specific bioavailability, 22% was selected as the site-specific oral bioavailability adjustment factor for use in this human health risk assessment (HHRA). The adjustment was as follows:

$$\text{adjusted DI} = \text{DI} \times \text{RBA (fraction)}$$

where DI is the daily oral intake of arsenic in soil (mg/kg/day).

This bioavailability adjustment factor was used to adjust the oral exposure from total arsenic measured in all soil samples. The test results indicate that the forms of arsenic in soil at the site are of relatively low bioavailability, when compared to U.S. EPA default value of 60% (U.S. EPA, 2012). It should be noted that the oral bioavailability adjustment factor derived herein is intended to be a site-specific value and is not intended for unvalidated use at other sites.

References:

U.S. EPA (U.S. Environmental Protection Agency). (2012) Compilation and Review of Data for Relative Bioavailability of Arsenic in Soil and Recommendations for Default Value for Relative Bioavailability. OSWER 9200.1-113. Washington, DC. December. Available online at: <http://semspub.epa.gov/src/document/HQ/175339>.

U.S. EPA (U.S. Environmental Protection Agency). (2017a) Standard Operating Procedure for an *In Vitro* Bioaccessibility Assay for Lead and Arsenic in Soil. U.S. Environmental Protection Agency, Office of Superfund Remediation and Technology Innovation: Washington, DC. OLEM 9200.2-164. July. Available online at: <https://semspub.epa.gov/src/document/HQ/100000153>.

U.S. EPA (U.S. Environmental Protection Agency). (2017b) Validation Assessment of the *In Vitro* Bioaccessibility Assay for Predicting Relative Bioavailability of Arsenic in Soil and Soil-like Materials at Superfund Sites. U.S. Environmental Protection Agency, Office of Superfund Remediation and Technology Innovation: Washington, DC. OLEM 9355.4-29. April 20, 2017. Available online at: <http://semspub.epa.gov/src/document/HQ/196751>.

ATTACHMENT E: Retrospective RBA assessment to Support a Removal Decision: A Case Study

Site description: Arsenic-contaminated sediment from an industrial facility was dispersed into a residential neighborhood (most likely as fill). Sampling of residential yards revealed contamination that was largely restricted to a depth of <1 foot. Properties having soil arsenic levels greater than the action level (AL) of 40 mg/kg were identified for potential removal actions. Subsequent to the sampling for concentration, the decision was made to estimate arsenic relative bioavailability (RBA) in archived soil samples to determine which properties exceeded the AL after adjustment for RBA.

Soil arsenic concentrations, IVBA, and RBA at the site: Arsenic concentrations and *in vitro* bioaccessibility (IVBA) (Method 1340) were measured for 22 soils, each representing a residential property at the site (Table E-1). The mean arsenic concentration was 66 ± 54 (mean \pm standard deviation [SD]) mg/kg (95% confidence limit [CL]: 42–90; range: 1–219). The mean IVBA \pm SD was $26 \pm 9\%$ (range: 10–38).

Arsenic RBA was predicted from each IVBA by applying the validated regression model relating arsenic IVBA and arsenic RBA (U.S. EPA, 2017a, 2017b, 2017c). Arsenic IVBA was reported in units of percent; therefore, the conversion to RBA% is as follows (Equation E-1):

$$RBA\% = IVBA\% \times 0.79 + 3 \quad \text{Eq. (E-1)}$$

The mean \pm SD arsenic RBA for the 22 soils was $24 \pm 7\%$ (95% CL: 21–27; range: 11–33; 95th percentile [PCT95]: 32; Table E-1). Five of the soils had RBAs that were $\leq 15\%$ (range: 11–15); the other 17 RBAs were all $>20\%$ (range 21–33). Four samples collected at depth had a mean RBA that was not significantly different from surface samples ($27 \pm 10\%$; range: 13–33; *t*-test $p > 0.05$).

The subset of five surface soils that had RBAs $\leq 15\%$ are statistical outliers; however, it suggests the possibility of clustering of soil arsenic RBA into a lower and higher category. Since this could be an indication of heterogeneity of RBA across the sampled locations, it would be reasonable to further explore the geographic distribution of the lower RBA soils as well as the nature of the arsenic contamination of the soils at the site. Heterogeneity of site RBAs can be observed when there are multiple sources of contamination and the arsenic from the different sources have different RBAs. An example of this would be a site in which soil is contaminated with smelter source material along with smelter stack emissions. Evidence for heterogeneity of contamination sources may support deriving more than one RBA to represent different locations within the site. No evidence could be obtained for multiple arsenic sources at this site (based on the nature of the industrial processes to which the contamination was attributed).

Any of several statistical metrics could be selected to represent RBA at the site, but in practice, the mean, the 95% upper confidence limit (95UCL), and the PCT95 are the most common metrics. The mean or 95UCL are typically used when calculating a central tendency exposure and the PCT95 may be used as a reasonable maximum exposure or where there is much uncertainty or heterogeneity in the measured IVBA or calculated RBA values (U.S. EPA, 1989, 2002, 2019). Factors to be considered in selecting which metric to use include uncertainty in the estimated mean (CI), evidence or concerns for source heterogeneity or spatial heterogeneity of RBA, and risk management objectives. The risk assessor selects a metric that is appropriate for the site. At this site, the 95UCL or PCT95 were considered as metrics to represent the site-wide RBA. This was based mainly on two considerations: (1) uncertainty about how well the IVBA data represented the site (it was not based on a statistical sample) and (2) the site RBA estimate was going to support removal decisions.

RBA-adjusted AL: The method used to adjust the AL will depend on the RBA assumptions that underlie the soil AL. If the RBA assumption embedded in the soil AL is 100%, then the following adjustment would be made (Equation E-2):

$$\text{soil } AL_{\text{adjusted}} = \text{soil } AL / (\text{RBA}\% / 100) \quad \text{Eq. (E-2)}$$

If the RBA assumption embedded in the soil AL is 60% (U.S. EPA, 2012b), then the following adjustment would be made (Equation E-3):

$$\text{soil } AL_{\text{adjusted}} = \text{soil } AL / (\text{RBA}\% / 60) \quad \text{Eq. (E-3)}$$

In either case, the 95UCL or PCT95 could be used to adjust the AL. Adjusted ALs based on the above equations are shown in in Table E-2. Adjustment of the AL for RBA decreased the number of properties that exceeded the AL from 12 of 18 to ≤ 2 of 18, depending on the specific RBA adjustment.

Soil ID	Soil Arsenic mg/kg	SD mg/kg	Arsenic IVBA %	SD mg/kg	Arsenic RBA %
1	53	0	24	0	22
2	55	5	24	0	22
3	40	0	33	1	29
4	38	1	33	1	29
5	110	1	25	2	23
6	36	1	23	1	21
7	54	1	31	1	27
8	72	2	25	1	23
9	36	1	36	1	31
10	53	1	29	1	26
11	46	2	36	1	31
12	147	1	35	0	31
13	49	1	26	0	24
14	47	1	27	1	24
15	68	9	12	0	12
16	34	4	15	0	15
17	4	1	10	1	11
18	4	0	12	3	12
19 ^a	127		38		33
20 ^a	155		36		32
21 ^a	219		36		31
22 ^a	1		13		13
N	22		22		22
Mean	66		26		24
SD	54		9		7
LCL95	42		22		21
95UCL	90		30		27
PCT95	155		36		32

^aCollected at depth.

LCL95, 95% lower confidence limit on the mean; IVBA, *in vitro* bioaccessibility; N, number of estimates; PCT95, 95th percentile; RBA, relative bioavailability; SD, standard deviation; 95UCL, 95% upper confidence limit on the mean

RBA Assumption in AL	Unadjusted AL^a (ppm)	Properties Exceeding AL	Adjusted AL Based on 95UCL RBA= 27%^b (ppm)	Properties Exceeding AL	Adjusted AL Based on PCT95 RBA= 32%^b (ppm)	Properties Exceeding AL
RBA = 100%	40	12 of 18	148 ^c	0 of 18	125 ^c	1 of 18
RBA = 60%	40	12 of 18	89 ^d	2 of 18	75 ^d	2 of 18

^aUnadjusted AL is the State of Connecticut Removal Management Level.

^bRegional risk assessor would select a metric most appropriate for the site.

^cCalculated from Equation E-2.

^dCalculated from Equation E-3.

AL, action level; PCT95, 95th percentile; RBA, relative bioavailability; 95UCL, 95% upper confidence limit on the mean

References:

U.S. EPA (U.S. Environmental Protection Agency). (1989) Risk Assessment Guidance for Superfund Volume 1 Human Health Evaluation Manual (Part A). U.S. Environmental Protection Agency, Office of Emergency and Remedial Response: Washington, DC. EPA/540/1-80/0023. December. Available online at: <https://www.epa.gov/risk/risk-assessment-guidance-superfund-rags-part>.

U.S. EPA (U.S. Environmental Protection Agency). (2002) Calculating Upper confidence Limit for Exposure Point Concentrations at Hazardous Waste Sites. U.S. Environmental Protection Agency, Office of Emergency and Remedial Response: Washington, DC. OSWER 9285.6-10. July. Available online at: <https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100CYCE.txt>.

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U.S. EPA (U.S. Environmental Protection Agency). (2017c) Release of Standard Operating Procedure for an *In Vitro* Bioaccessibility Assay for Lead and Arsenic in Soil and Validation Assessment of the *In Vitro* Bioaccessibility Assay for Predicting Relative Bioavailability of Arsenic in Soils and Soil-like Materials at Superfund Sites. Transmittal Memorandum from Schatzi Fitz-James to Superfund National Program Managers, Regions 1-10. May 5, 2017. U.S. Environmental Protection Agency. Available online at: <https://semspub.epa.gov/src/document/HQ/100000153>.

U.S. EPA (U.S. Environmental Protection Agency). (2019) Guidelines for Human Exposure Assessment. U.S. Environmental Protection Agency, Risk Assessment Forum: Washington, DC. EPA/100/B-19/001 October. Available online at: https://www.epa.gov/sites/production/files/2020-01/documents/guidelines_for_human_exposure_assessment_final2019.pdf.

ATTACHMENT F: Relative Bioavailability Adjustment of a Risk-Based Concentration for Lead: A Case Study – Adjusting RBA in the IEUBK Model and ALM

Once site-specific relative bioavailability (RBA) has been determined, adjustments can be applied to the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model) absorption fraction percent of soil lead parameter (AFP_{soil} , Figure F-1). This adjustment is as follows (Equation F-1):

$$\text{adjusted } AFP_{soil} = RBA \text{ fraction} \times 50 \quad \text{Eq. (F-1)}$$

where the value 50 is the IEUBK model default value for the absorption fraction percent of lead in drinking water (AFP_{water}).

Site-specific adjustment of the absorption fraction percent parameters in the IEUBK model should be applied only to the corresponding medium tested for RBA (e.g., soil). Once adjustments have been applied to the AFP_{soil} parameter, the model will predict a site-specific risk-based soil lead concentration that reflects the site-specific RBA of soil lead. Concentrations of lead found throughout the site can then be compared to the adjusted risk-based concentration for decision-making purposes.

Note that different sources (i.e., smelting, foundries) may result in the need for source-specific, risk-based concentrations at one site. For example, if the source of lead contamination on one part of the site is from smelting processes and the other is from lead shot, the soil RBA (and AFP_{soil}) may vary with location. A conceptual site model is needed prior to sampling and testing for RBA to ensure accurate representation of RBA and AFP_{soil} at the site.

An average AFP_{soil} throughout the site or range-specific value can be used in the IEUBK model. Region 4 recommends using an average AFP_{soil} if the source of contamination at the site is consistent.

Example of risk-based concentration adjustment: A Region 4 site in Chattanooga, Tennessee, hereafter referred to as “the Site” applied site-specific bioavailability to adjust the risk-based concentration used for decision-making purposes. Thirty-three surface soil samples were sent to the laboratory for IVBA measurement using Method 1340 (U.S. EPA, 2017a). Samples ranged in lead concentrations from 130 to 2000 mg/kg. RBA was predicted from IVBA (U.S. EPA, 2017b). The AFP_{soil} for each soil sample was calculated using Equation F-1. The mean of AFP_{site} of all samples analyzed, 36%, was selected to represent the Site because the contamination was from one main source, which was spent foundry sands (see Table F-1). After an appropriate blood lead level had been selected (8 µg/dL), the average site-specific AFP_{soil} was used in the IEUBK model to derive an RBA-adjusted risk-based concentration (see Figure F-2). Updated parameters were also applied to the IEUBK model, resulting in a final risk-based concentration of 361 mg/kg. The concentration of 361 mg/kg then became the site-specific clean-up goal.

Table F-1. Thirty-three Soil Samples Analyzed by Method 1340 and Their Corresponding AFP_{soil}

Total Lead (mg/kg)	IVBA Lead (mg/kg)	IVBA Fraction^a	RBA^b	AFP_{soil}
290	335	1.16	99%	49%
330	234	0.71	59%	30%
360	355	0.99	84%	42%
360	279	0.78	65%	33%
390	269	0.69	58%	29%
400	319	0.80	67%	34%
430	400	0.93	79%	39%
490	519	1.06	90%	45%
500	472	0.94	80%	40%
590	469	0.79	67%	33%
630	476	0.76	64%	32%
670	736	1.10	94%	47%
700	790	1.13	96%	48%
700	593	0.85	72%	36%
710	550	0.77	65%	33%
730	638	0.87	74%	37%
740	589	0.80	67%	34%
890	660	0.74	62%	31%
920	723	0.79	66%	33%
970	785	0.81	68%	34%
1200	992	0.83	70%	35%
1200	836	0.70	58%	29%
1200	880	0.73	62%	31%
1200	906	0.76	63%	32%
1700	1290	0.76	64%	32%
2000	1880	0.94	80%	40%
	Mean	0.85	71%	36%

^aCalculated as IVBA fraction = IVBA lead/total lead.

^bRBA calculated as RBA percent = 100 × (0.878 × IVBA fraction - 0.028).

AFP_{soil}, is the IEUBK model parameter absorption fraction percent for soil; IEUBK, Integrated Exposure Uptake Biokinetic Model for Lead in Children; IVBA, *in vitro* bioaccessibility; RBA, relative bioavailability

GI Values/Bioavailability Information

MEDIA	ABSORPTION FRACTION PERCENT	Access alternate bioavailability parameters?	FRACTION PASSIVE/TOTAL ACCESSIBLE	HALF SATURATION Level ($\mu\text{g}/\text{day}$)
Soil	30	<input checked="" type="radio"/> No <input type="radio"/> Yes		
Dust	30			
Water	50		0.2	100
Diet	50			
Alternate	0			

TRW Homepage: <http://www.epa.gov/superfund/health/contaminants/lead/index.htm>

Buttons: OK, Cancel, Reset, Help?

Figure F-1. Default Parameters in the IEUBK Model; Adjustments Specific to Media Tested for Bioavailability.

GI Values/Bioavailability Information

MEDIA	ABSORPTION FRACTION PERCENT	Access alternate bioavailability parameters?	FRACTION PASSIVE/TOTAL ACCESSIBLE	HALF SATURATION Level ($\mu\text{g}/\text{day}$)
Soil	36	<input checked="" type="radio"/> No <input type="radio"/> Yes		
Dust	36			
Water	50		0.2	100
Diet	50			
Alternate	0			

TRW Homepage: <http://www.epa.gov/superfund/health/contaminants/lead/index.htm>

Buttons: OK, Cancel, Reset, Help?

Figure F-2. Site-specific AFP_{soil} Adjustment of Soil and Dust.

References:

U.S. EPA (U.S. Environmental Protection Agency). (2017a) Standard Operating Procedure for an *In Vitro* Bioaccessibility Assay for Lead and Arsenic in Soil. U.S. Environmental Protection Agency, Office of Superfund Remediation and Technology Innovation: Washington, DC. OLEM 9200.2-164. July. Available online at: <https://semspub.epa.gov/src/document/HQ/100000153>.

U.S. EPA (U.S. Environmental Protection Agency). (2017b) Validation Assessment of the *In Vitro* Bioaccessibility Assay for Predicting Relative Bioavailability of Arsenic in Soil and Soil-like Materials at Superfund Sites. U.S. Environmental Protection Agency, Office of Superfund Remediation and Technology Innovation: Washington, DC. OLEM 9355.4-29. April 20, 2017. Available online at: <http://semspub.epa.gov/src/document/HQ/196751>.

ATTACHMENT G: Relative Bioavailability Adjustment of Absorption Fraction Parameters in the Integrated Exposure Biokinetic Model for Lead in Children and Adult Lead Methodology: Cherokee County Railroad Site Case Study

Site description: As part of the human health risk assessment (HHRA), soils were sampled at 34 locations along a historic rail line (U.S. EPA, 2014). Contamination of the rail lines occurred predominantly from use of chat from surrounding mine waste piles as ballast in the railbeds. Various sources of chat may have been used at different times in the construction of the railbeds.

Data Quality Objective (DQO): One of several objectives of the soil sampling study was to collect data on lead *in vitro* bioaccessibility (IVBA) that would provide a basis for adjusting the absorption fraction percent for soil lead (AFP_{soil}) in the U.S. Environmental Protection Agency (U.S. EPA) Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model) (U.S. EPA, 1994) and absorption fraction for soil and dust (AF_{S+D}) parameter in the U.S. EPA Adult Lead Model (ALM) (U.S. EPA, 2003) for RBA at the site. The IEUBK model was used to assess risks to children exposed to rail-line soils during recreational visits to the area. The ALM was used to assess risk to workers and adolescent and adult recreational visitors.

Sampling approach: IVBA testing (U.S. EPA Method 1340, U.S. EPA, 2017) was conducted on 43 soil samples collected from the rail lines in 2013 and 2014. The samples included 31 surface soil samples (0–6 inches) and 12 subsurface samples (6–48 inches).

RBA Predicted from IVBA and Adjustments of Absorption Fraction Parameters:

IVBA was converted to RBA as follows:

$$RBA \text{ percent} = (IVBA \text{ fraction} \times 0.878 - 0.028) \times 100$$

where RBA is expressed as a percent and IVBA is expressed as a fraction.

The IEUBK model AFP_{soil} parameter was calculated as follows:

$$AFP_{soil} = (RBA \text{ percent} / 100) \times 50$$

where the value 50 is the IEUBK model default value for the absorption fraction percent of lead in drinking water (AFP_{water}).

The ALM AF_{S+D} parameter was calculated as follows:

$$AF_{S+D} = (RBA \text{ percent} / 100) \times 0.20$$

where the value 0.20 is the ALM default value for the absorption fraction for lead in water.

Results from 2013 and 2014 sampling: Table G-1 presents the lead IVBA, RBA predicted from IVBA, and AFP_{soil} for each sample. IVBA in surface soils ranged from 23% to 96%, corresponding to an RBA range of 18–82%. For locations identified as high-frequency use areas, IVBA in surface soils ranged from 23% to 86%, corresponding to an RBA range of 18–73%. For locations identified as low frequency use areas, IVBA values in surface soils ranged from 39% to 96%, corresponding to an RBA range of 32–82%. Although it is known that the ballast used in the railroad beds was originally composed of chat from surrounding mine waste piles, it is unknown whether the same lead-contaminated material

was used in constructing all railbeds. Based on uncertainty regarding the source materials, and high variability in RBA (18–82%), separate RBA, AFP_{soil}, and AF_{S+D} values were estimated based on exposure areas as follows:

IEUBK Model Adjustments to AFP_{soil}					
Exposure Point	Population	Soil	Average IVBA (Fraction)	Estimated RBA	Adjusted AFP _{soil}
High-frequency use	Child recreational visitor	Surface soil	0.535	44%	22%
Low-frequency use			0.721	61%	30%

ALM Adjustments to AF_{S+D}					
Exposure Point	Population	Soil	Average IVBA (fraction)	Estimated RBA	Adjusted AF _{S+D}
High-frequency use	Adolescent/adult recreational visitor	Surface soil	0.535	44%	9%
Low-frequency use			0.721	61%	12%
Site	Future worker	Surface + subsurface soil	0.608	51%	10%

Table G-1. *In vitro* Bioaccessibility and Estimated Relative Bioavailability of Lead in Rail Line Soil Samples Collected in 2013 and 2014

Sample Year	Location	Exposure Area	Depth (inch)	Total Lead (mg/kg)	IVBA (fraction)	RBA ^a	AFP _{soil} ^b
2013	CCR-SS-25B	HFR	0–6	1860	0.564	47%	23%
	CCR-SS-11A	LFR	0–6	2330	0.700	59%	29%
	CCR-SS-12B	LFR	0–6	1690	0.551	46%	23%
	CCR-SS-1A	LFR	0–6	1640	0.639	53%	27%
	CCR-SS-26A	LFR	0–6	3240	0.643	54%	27%
	CCR-SS-13A	HFR	6–12	1990	0.460	38%	19%
	CCR-SS-24B	HFR	6–12	1860	0.450	37%	18%
	CCR-SS-28A	LFR	6–12	1800	0.483	40%	20%
	CCR-SS-33A	LFR	6–12	2280	0.521	43%	21%
	CCR-SS-6A	LFR	6–12	964	0.752	63%	32%
	CCR-SS-27B	LFR	12–18	2070	0.549	45%	23%
	CCR-SS-31B	LFR	12–18	1970	0.470	38%	19%
	CCR-SS-13E	HFR	18–24	518	0.263	20%	10%
	CCR-SS-26B	LFR	18–24	1680	0.498	41%	20%
	CCR-SS-29B	LFR	18–24	1150	0.516	43%	21%
	CCR-SS-32A	LFR	18–24	2690	0.663	55%	28%
CCR-SS-1C	LFR	24–30	637	0.764	64%	32%	
2014	17A	HFR	0–6	856	0.518	43%	21%
	17B	HFR	0–6	1025	0.768	65%	32%
	17C	HFR	0–6	1833	0.863	73%	36%
	13-Baxter Springs A	HFR	0–6	2631	0.559	46%	23%
	13-Baxter Springs B	HFR	0–6	2552	0.695	58%	29%
	13-Baxter Springs C	HFR	0–6	2187	0.604	50%	25%

Table G-1. *In vitro* Bioaccessibility and Estimated Relative Bioavailability of Lead in Rail Line Soil Samples Collected in 2013 and 2014

Sample Year	Location	Exposure Area	Depth (inch)	Total Lead (mg/kg)	IVBA (fraction)	RBA ^a	AFP _{soil} ^b
	25A	HFR	0-6	1028	0.597	50%	25%
	25B	HFR	0-6	1035	0.407	33%	16%
	24A	HFR	0-6	1280	0.397	32%	16%
	24B	HFR	0-6	1994	0.486	40%	20%
	15A	HFR	0-6	184	0.233	18%	9%
	15B	HFR	0-6	372	0.267	21%	10%
	14A	HFR	0-6	246	0.537	44%	22%
	32A	LFR	0-6	1553	0.690	58%	29%
	32B	LFR	0-6	1876	0.913	77%	39%
	32C	LFR	0-6	1917	0.745	63%	31%
	8C	LFR	0-6	844	0.921	78%	39%
	8B	LFR	0-6	917	0.961	82%	41%
	8A	LFR	0-6	788	0.944	80%	40%
	1A	LFR	0-6	1256	0.729	61%	31%
	1B	LFR	0-6	841	0.609	51%	25%
	1C	LFR	0-6	707	0.588	49%	24%
	26A	LFR	0-6	1515	0.759	64%	32%
	26B	LFR	0-6	1460	0.814	69%	34%
	13-Lawton A	LFR	0-6	223	0.391	32%	16%
	13-Lawton B	LFR	0-6	167	0.665	56%	28%

^aRBA = (IVBA × 0.878-0.028) × 100.

^bAbsorption fraction percent for soil for use in IEUBK model, AFP = RBA × 0.50.

AFP_{soil} is the IEUBK model parameter absorption fraction percent for soil; HFR, high-frequency recreational use area; IEUBK, Integrated Exposure Uptake Biokinetic Model for Lead in Children; IVBA, *in vitro* bioaccessibility; LFR, low-frequency recreational use area; RBA, relative bioavailability

Surface Only (0-6")	Average Lead (mg/kg)	Average IVBA (fraction)	Average RBA	Average AFP _{soil}
High-Frequency Use	1363	0.535	44%	22%
Low-Frequency Use	1351	0.721	61%	30%
Site	1356	0.637	53%	27%

Across All Depths	Average Lead (mg/kg)	Average IVBA (fraction)	Average RBA	Average AFP _{soil}
High-Frequency Use	1379	0.510	42%	21%
Low-Frequency Use	1469	0.672	56%	28%
Site	1434	0.608	51%	25%

References:

U.S. EPA (U.S. Environmental Protection Agency). (1994) Technical Support Document for the Integrated Exposure Uptake Biokinetic Model for Lead in Children (v0.99d). U.S. Environmental Protection Agency, Office of Emergency and Remedial Response: Washington, DC. EPA 9285.7-22. December. Available online at: <https://www.epa.gov/superfund/lead-superfund-sites-software-and-users-manuals>.

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U.S. EPA (U.S. Environmental Protection Agency). (2014) Baseline Human Health Risk Assessment for the Cherokee County Railroad Site Operable Unit 8 – Located in Cherokee County, Kansas. Final Draft. May 14, 2015.

U.S. EPA (U.S. Environmental Protection Agency). (2017) Release of Standard Operating Procedure for an *In Vitro* Bioaccessibility Assay for Lead and Arsenic in Soil and Validation Assessment of the *In Vitro* Bioaccessibility Assay for Predicting Relative Bioavailability of Arsenic in Soils and Soil-like Materials at Superfund Sites. Transmittal Memorandum from Schatzi Fitz-James to Superfund National Program Managers, Regions 1-10. May 5, 2017. U.S. Environmental Protection Agency. Available online at: <https://semspub.epa.gov/src/document/HQ/100000153>.

ATTACHMENT H: Relative Bioavailability Adjustment of Soil Lead Exposure Point Concentrations for a Time-Weighted Exposure to Soil

This example illustrates an approach to adjusting time-weighted average (TWA) soil lead exposure point concentrations (EPCs) for relative bioavailability (RBA) for use in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model). Time weighting can be useful for assessing lead risks in exposure scenarios in which the child receptor spends time at two different locations having different soil concentrations and RBA. The calculations shown below are based on recommendations of the Technical Review Workgroup (TRW), *Assessing Intermittent or Variable Exposures and Lead Sites* (U.S. EPA, 2003) as amended by more recent recommendations of the TRW made in several site consultations. These recommendations are extended in the example calculations that follow, by incorporating RBA into the calculation of the TWA soil concentration.

Exposure scenario: Assumptions for the scenario that are pertinent to calculating the TWA soil lead concentration and RBA-adjusted TWA concentration are as follows (Table H-1):

1. Children spend 2 out of every 7 days at a camp and 5 out of 7 days at home, 3 months of each year.
2. The fraction of waking hours spent outdoors are the same at camp and at home.
3. The M_{SD} (fraction of door dust contributed by soil) is 0.7 at both locations (IEUBK model default value).
4. The air lead concentration is 0.1 mg/m^3 at both location (IEUBK model default value).
5. The soil/dust ingestion rate is the same at home and at camp (IEUBK model default values).
6. The mean soil lead concentration at the home is 100 ppm and the concentration at the camp is 700 ppm.
7. The RBA of soil at home is 0.6 (60%) and the RBA of soil at the camp is 0.8 (80%).
8. All other exposures are assumed to be the same at home and camp (IEUBK model default values).

Calculation of RBA-adjusted TWA soil and dust lead concentration: The TWA exposure is calculated by weighting the soil lead concentrations at the two locations by a weighting factor, F , representing the fraction of exposure that occurs at the two locations. For this scenario, F is calculated as follows:

$$F_{camp} = \frac{2}{7} = 0.286 \quad \text{Eq. (H-1)}$$

$$F_{home} = 1 - F_{camp} = 0.714 \quad \text{Eq. (H-2)}$$

Note that F_{camp} is calculated based on the exposure frequency that represents the smallest repeated exposure averaging time, in this case, 2 days per 7 days, rather than the frequency for the larger averaging time (3 months per 12 months). This approach will tend to overestimate the 12-month average lead daily intake (DI) and corresponding average blood lead, but it will not underestimate the average DI and blood

lead for the 3-month seasonal period of exposure (Lorenzana et al., 2005). Therefore, this is the more health-protective approach to time averaging the exposures.

The TWA soil exposure concentration (ppm) is calculated by apportioning the soil lead concentration according to F_{camp} and F_{home} , as follows:

$$\text{Soil}_{TWA} = 0.286 \times 700 + 0.714 \times 100 = 271 \quad \text{Eq. (H-3)}$$

The corresponding TWA indoor dust lead concentration (ppm) is calculated as the product of the Soil_{TWA} and M_{SD} , plus the contribution from air lead, as follows:

$$\text{Dust}_{TWA} = \text{Soil}_{TWA} \times 0.7 + 100 \times 0.1 = 200 \quad \text{Eq. (H-4)}$$

The analogous calculation for the RBA-adjusted Soil_{TWA} adjusts the location-specific soil concentrations by the corresponding RBAs relative to the default RBA in the IEUBK model (e.g., camp RBA/0.6). The adjustment is as follows:

$$\text{RBA adjusted Soil}_{TWA} = 0.286 \times 700 \times \frac{0.8}{0.6} + 0.714 \times 100 \times \frac{0.6}{0.6} = 338 \quad \text{Eq. (H-5)}$$

The corresponding TWA indoor dust lead concentration is as calculated as the product of the RBA-adjusted Soil_{TWA} , M_{SD} , and air lead concentration, as follows:

$$\text{RBA adjusted Dust}_{TWA} = \text{RBA adjusted Soil}_{TWA} \times 0.7 + 100 \times 0.1 = 247 \quad \text{Eq. (H-6)}$$

In this scenario, the higher RBA at camp (0.8) relative to the IEUBK model default RBA (0.6) contributes to a higher TWA soil concentration after adjustment for RBA at home and camp (338 ppm compared to 271 ppm).

Application of RBA-adjusted TWA soil lead concentrations in the IEUBK model: To predict the probability of exceeding a given blood lead concentration decision point (e.g., 5 $\mu\text{g}/\text{dL}$), the RBA-adjusted TWA soil lead concentration would be used as input to the IEUBK model. The default bioavailability parameters in the IEUBK model (AFP_{soil} , AFP_{dust}) should not be adjusted when RBA-adjusted soil concentrations are inputs to the model.

References

Lorenzana, R.M., Troast, R., Klotzbach, J.M., Follansbee, M.H., Diamond, G.L. (2005) Issues related to time averaging in modeling risks associated with intermittent exposures to lead. *Risk Anal.* 25(1):169–178.

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Parameter	Unit	Value	Equation
Days at camp	day/week	2	
Days in exposure interval	day/week	7	
Soil lead at camp	ppm	700	
Soil lead at home	ppm	100	
RBA at camp		0.80	
RBA at home		0.60	
IEUBK model default M_{SD}		0.7	
IEUBK model default air lead	$\mu\text{g}/\text{m}^3$	0.1	
IEUBK model default RBA		0.60	
Fraction of time at camp		0.286	Eq. H-1
Fraction of time at home		0.714	Eq. H-2
Soil lead TWA	ppm	271	Eq. H-3
Dust lead TWA	ppm	200	Eq. H-4
RBA-adjusted soil lead TWA	ppm	338	Eq. H-5
RBA-adjusted dust lead TWA	ppm	247	Eq. H-6

M_{SD} , soil-dust mass transfer coefficient; RBA, relative bioavailability; TWA, time-weighted average