UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION II
290 BROADWAY
NEW YORK, NEW YORK 10007-1866

June 14, 2017

BY ELECTRONIC MAIL

Robert Law, Ph.D.
CPG Project Coordinator
de maximis, inc.
186 Center Street, Suite 290
Clinton, New Jersey 08809

Re: Lower Passaic River Study Area (LPRSA) Revised Draft Final Baseline Human Health Risk Assessment (BHHRA) – Administrative Settlement Agreement and Order on Consent for Remedial Investigation/Feasibility Study (AOC) CERCLA Docket No. 02-2007-2009

Dear Dr. Law:

The U.S. Environmental Protection Agency (EPA) has completed a review of the Cooperating Parties Group's (CPG) March 2017 submission of the revised draft final BHHRA. In accordance with Section X of the AOC, please revise the BHHRA in accordance with the direction provided in the enclosed comment set and resubmit to EPA.

Also enclosed with this letter is a memorandum to the file regarding review of lead modeling results from the BHHRA for the LPRSA in consideration of EPA's December 2016 memorandum titled, "Updated Scientific Considerations for Lead in Soil Cleanups."

Please let me know if you have any questions and/or would like to schedule a conference call to discuss EPA's comments or the memorandum to the file.

Sincerely,

Jennifer LaPoma, Remedial Project Manager
Lower Passaic River Study Area RI/FS

Enclosures

616135

Cc: M. Sivak, EPA (by email)
M. Olsen, EPA (by email)
F. Zizila, EPA (by email)
W. Potter, demaximis (by email)

EPA JUNE 14, 2017 COMMENTS
REVISED DRAFT FINAL BASELINE HUMAN HEALTH RISK ASSESSMENT REPORT
FOR THE LOWER PASSAIC RIVER STUDY AREA
DATED MARCH 2017

No.	Comment
1	Most of the comments on the Revised Draft BHHRA have been fully addressed.
2	Per response to EPA General Comment 2, the use of statements like "at the direction of USEPA" was to be eliminated in the document except for two places in the text (in Sections 4.3 and 7.3.2.1). However, such statements have not been removed from exposure point concentration tables (Tables 4-8 through 4-21 and 4-23 through 4-28) which all have the footnote: "Per USEPA direction, the exposure point concentration used to evaluate Reasonable Maximum Exposure (RME) is also used to evaluate Central Tendency Exposure (CTE)." This practice is consistent with standard RAGS guidance. Replace the phrase "Per USEPA direction" with "Consistent with risk assessment guidance"
3	Per response to EPA General Comment 18, the term "target endpoint" was to be replaced with "target organ effect" throughout the document. This replacement was completed through most of the text, but "target endpoint" remains on many tables and several figures. Make the replacement on Tables ES-3, 6-2, 6-4, 6-8, 6-12, 6-15 through 6-20, and on Figures 8-2 through 8-4.

No.	Page No.	Specific Technical Comments
4	Page 6-36, Section 6.4 Potential COC Identification, Table	Per response to Comment 63 on the Revised Draft BHHRA, the COC table was revised, but has one editorial error. Under RME Mixed Fish Diet, Heptachlor Epoxide is listed under two columns for cancer risk: "$>10^{-5}$ to $<10^{-4}$" and "$>10^{-6}$ to $<10^{-5}$". The risk for the combined child/adult angler receptor was $>10^{-5}$. Remove Heptachlor Epoxide from the column "$>10^{-6}$ to $<10^{-5}$" for the fish diet.
5	Page 7-28, Section 7.2.3.1 Default Dermal Absorption Fractions	Per response to Comment 86 on the Revised Draft BHHRA, add the following statement after the table of f_{oc} values on page 7-28: "While a lower DAF may be applicable if accessible areas with sediment f_{oc} > 10% are found, it is important to note that estimated cancer risks and noncancer hazards from dermal exposures to TCDD-TEQ in sediment are already within the NCP risk range and less than or equal to the goal of protection of an HI of 1."
6	Page 8-11, Section 8.2 Conclusions, last paragraph	Per response to Comment 106 on the Revised Draft BHHRA, Section 8.2 should have been revised consistent with Attachment A to the comments (and consistent with Section E.3 Conclusions). However, three sentences were added to the end of this paragraph that were not included in Attachment A. These sentences repeat information regarding background levels that was presented in the preceding paragraph. Remove the three sentences, beginning with "Further, and consistent with USEPA guidance…"

No.	Page No.	Specific Technical Comments
7	Table 3-12 Analysis of Tissue COPCs Not Identified as Surface Water or Sediment COPCs	Per response to Comment 107 on the Revised Draft BHHRA, Table 3-12 was inadvertently omitted from the previous draft and is now included in the Revised Draft Final BHHRA. However, upon review of this table, it seems that several references in the text incorrectly refer to Table 3-12. • Page 3-10, Footnote 10: "…mixed diet COPCs are summarized in Table 3-12" should refer to Table 3-13 instead. • Page 3-11, first sentence in Section 3.4.1: "…were retained as COPCs in one or more media, as summarized below and in Table 3-12" should refer to Table 3-13 instead. • Page 3-11, third paragraph: "As shown in Table 3-11, all of these chemicals were detected in surface water or sediment…" should refer to Table 3-12 instead.

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DATE: June 14, 2017

SUBJECT: Refinements to Lead Models for the Lower Passaic River Study Area (LPRSA) Human Health Risk Assessment

FROM: Jennifer LaPoma, Remedial Project Manager
Lower Passaic River Study Area, RI/FS

TO: File

The attached memorandum titled "Refinements to Lead Models for the LPRSA Human Health Risk Assessment" dated May 30, 2017 documents the U.S. Environmental Protection Agency's (EPA) evaluation of lead for the LPRSA (OU4) with consideration of the EPA's December 22, 2016 release of "Updated Scientific Considerations for Lead in Soil Cleanups" OLEM Directive 9200.2-167.

Memorandum

To: *Jennifer LaPoma, EPA Region 2*
Elizabeth Franklin, USACE

From: *Kristen Carpenter, CDM Smith*
Scott Kirchner, CDM Smith

Date: *May 30, 2017*

Subject: *Refinements to Lead Models for the LPRSA Human Health Risk Assessment*

At the request of the United States Environmental Protection Agency Region 2 (EPA) and the United States Army Corps of Engineers (USACE), CDM Federal Programs Corporation (CDM Smith) reviewed lead modeling results from the Human Health Risk Assessment (HHRA) report (AECOM 2017) for the Lower Passaic River Study Area (LPRSA) against lower blood lead levels of concern identified in a recent memorandum, "Updated Scientific Considerations for Lead in Soil Cleanups" (USEPA 2016). In addition, CDM Smith refined exposure point concentration assumptions used to estimate lead exposures in the modeling.

Appendix G of the HHRA provides an evaluation of the potential exposures to lead in accessible surface sediment, surface water, and blue crab tissue from the LPRSA. Receptors were evaluated by age group, including young children (1 to <7 years of age), adolescents (7 to <19 years of age), and adults. Potential exposures to lead for young children were quantified using the USEPA Integrated Exposure Uptake Biokinetic (IEUBK) model that correlates lead levels in the environment to blood lead levels in children. For receptors greater than 7 years of age, the USEPA Adult Lead Methodology (ALM) model was used. Predicted blood levels were compared to USEPA's blood lead level of concern of 10 micrograms of lead per deciliter of blood (µg/dL) for all age groups, and to USEPA's risk reduction goal that at least 95% of young children in a population have blood lead levels below 10 µg/dL. Based on the modeling presented in Appendix G of the HHRA, >99% of receptor populations were estimated to have blood lead levels below 10 µg/dL. Therefore, lead was not identified as a potential chemical of concern (COC) for LPRSA.

However, the December 2016 USEPA memorandum, "Updated Scientific Considerations for Lead in Soil Cleanups" (USEPA 2016), notes that current scientific literature provides evidence that adverse health effects are associated with blood lead levels less than 10 µg/dL. Specifically, the memo states that there is "clear evidence of cognitive function decrements… in young children (4 to 11 years old) with mean or group blood Pb levels between 2 and 8 ug/dL" and that another study found sufficient evidence of "adverse effects on academic achievement, IQ, other cognitive measures,

attention-related behaviors, and problem behaviors at BLLs below 5 ug/dL." Although the memo specifically addresses soil, in order to be protective, CDM Smith reran IEUBK and ALM modeling for select sediment receptors from the LPRSA HHRA to determine whether lead might be a potential COC for the site based on lower blood lead levels of concern.

Model Results Using HHRA Assumptions with Lower Blood Lead Levels of Concern

Modeling was performed using the same exposure assumptions used in Appendix G of the HHRA while adjusting the target blood lead level to values lower than 10 µg/dL.

Among young child receptors, predicted blood lead levels in the HHRA were highest for the young child swimmer and young child wader, both with a predicted geometric mean blood lead level of 3 µg/dL. These two receptors were assumed to have the same amount of exposure to sediment. Only 0.5% of these young child receptor populations were predicted to have a blood lead level above 10 µg/dL.

Using the HHRA exposure assumptions, the IEUBK model was run for several different blood lead levels of concern, referred to as "Cutoff" in the model results (presented in Attachment 1). The values of 2, 5, and 8 ug/dL that were mentioned in the memo (EPA 2016) were used. In addition, the model was run iteratively with different cutoffs to identify the blood lead level at the 95th percentile of the exposed population (bolded in the table below).

IEUBK Model Results for Young Child Swimmer or Waders Using HHRA Inputs

Blood Lead Level of Concern	**10 µg/dL**	**8 µg/dL**	**6.5 µg/dL**	**5 µg/dL**	**2 µg/dL**
Predicted Geometric Mean Blood Lead Level (µg/dL)	3.0	3.0	**3.0**	3.0	3.0
% Above	0.5	1.9	**5**	13.9	80.6
% Below	99.5	98.1	**95**	86.1	19.4

As shown in the table above, as the blood lead level of concern decreases below 10 µg/dL, an increasing portion of the population would have blood lead levels exceeding the levels of concern. For young child swimmers or waders, the IEUBK model predicts that 5% of the population would have blood lead levels exceeding 6.5 µg/dL. About 14% of that population would have blood lead levels exceeding 5 µg/dL and about 81% of that population would have blood lead levels exceeding 2 µg/dL.

For an adolescent wader receptor, the predicted blood lead level in the HHRA using the ALM model was 1.2 µg/dL, and the probability that fetal blood lead levels would exceed 10 µg/dL was only 0.008%. The table below presents ALM model results for a range of blood lead levels of concern, referred to as "target PbB level of concern" in the model.

ALM Model Results for Adolescent Waders Using HHRA Inputs

Blood lead level of concern	**10 µg/dL**	**8 µg/dL**	**5 µg/dL**	**2.8 µg/dL**	**2 µg/dL**
Predicted geometric mean blood lead level in adolescent wader (µg/dL)	1.2	1.2	1.2	**1.2**	1.2
Probability that fetal blood lead level exceeds the blood lead level of concern	0.008%	0.03%	0.46%	**5.0%**	14.8%

For adolescent waders, the ALM model predicts that the 95th percentile blood lead level among fetuses of wader receptors would be 2.8 µg/dL. Almost 15% of the population would have fetal blood lead levels exceeding 2 µg/dL. It should be noted that even if there were no lead in sediment (i.e., sediment lead concentration set to 0 mg/kg in the model), the ALM model predicts that 8.7% of the population would have fetal blood lead levels exceeding 2 µg/dL solely due to the default baseline blood lead level of 1 µg/dL used in the model.

IEUBK Model Results Accounting for Intermittent Exposure

Exposure to sediment at the LPRSA is not expected to occur continuously (i.e., 7 days/week), but intermittently: 1 to 3 days/week during the summer months for many of the receptors evaluated in the HHRA. While such intermittent exposure is accounted for in the ALM model, it is not accounted for in the IEUBK model for young children. Blood lead levels modeled in the HHRA for young children basically assumed a consistent exposure to the concentrations of lead in site sediment. If children are exposed to lower concentrations of lead in off-site soil on the 6 days per week when they are not at the river, then the modeling in the HHRA may overestimate blood lead levels.

USEPA guidance (USEPA 2003) recommends using a simple time-weighted average approach to account for exposures at more than one location. The soil and sediment concentrations are weighted based on the estimated fraction of total soil and sediment ingestion that occurs at the site and away from the site (e.g., at a residence). A "separate calculation is made up front (i.e., outside the model) to obtain appropriately weighted average concentrations of soil lead. These average values can then be entered directly into the model as fixed media concentrations." (USEPA 2003)

$$Weighted\ PbC_{medium} = \sum_{i=1}^{n} C_i \times EF_i$$

where:

Weighted PbC_{medium} = Weighted lead concentration in medium (mg/kg)

C_i = Media concentration at location *i* (in this case, *i = LPRSA* or *residential yard*) (mg/kg)

EF_i = Exposure frequency at location *i* (in this case, *i = LPRSA* or *residential yard*) (days/week). The sum of the days/week at the LPRSA and residential yard is 7.

The default soil-lead concentration in the IEUBK model (i.e., 200 mg/kg) was used to represent concentrations in residential yards in the calculation of a time-weighted average concentration. IEUBK guidance (USEPA 1994) states that the natural concentration of lead in soil from weathering of crustal materials is about 10 to 25 mg/kg, and that "a plausible urban background is 75 to 200 mg/kg". The default value of 200 mg/kg is considered "a reasonable, nationally representative soil lead concentration for the continental United States" (USEPA 2017).

As summarized in Appendix G of the HHRA (Table G-1), sediment-lead concentrations at the LPRSA range from 3.94 to 2,050 mg/kg, with a site-wide mean concentration of 234 mg/kg. When the river is divided into 3-mile segments, the highest mean concentration within any segment is 317 mg/kg for River Miles 6-9 East Bank, and this value was used to represent concentrations in LPRSA sediment in the HHRA models and in the calculation of a time-weighted average concentration below.

Young children are assumed to visit the LPRSA once a week for 13 weeks per year (i.e., during summer months) or 13 days/year. As noted in USEPA guidance (USEPA 2003), the time-weighting factor should be based on the smallest time period in which the exposures repeat. Therefore, the time weighting is 1 day/7 days and not 13 days/365 days. The IEUBK predictions are expected to approximate the blood lead concentrations within the seasons when exposures to lead in the environment occur.

Based on the above assumptions, a time-weighted average concentration was calculated as follows:

$$\text{Weighted } PbC_{\text{soil and sediment}} = (200 \text{ mg/kg} \times 6 \text{ days}/7\text{days}) + (317 \text{ mg/kg} \times 1 \text{ day}/7 \text{ days})$$

$$= 171.4 \text{ mg/kg} + 45.3 \text{ mg/kg}$$

$$= 216.7 \text{ mg/kg}$$

The table below presents IEUBK model results using the time-weighted average concentration of 216.7 mg of lead in soil and sediment for young child swimmers.

IEUBK Model Results for Young Child Swimmer Using Time Weighted Average Concentration

Blood Lead Level of Concern	**10 µg/dL**	**8 µg/dL**	**5 µg/dL**	**4.5 µg/dL**	**2 µg/dL**
Geometric Mean BLL (µg/dL)	2.1	2.1	2.1	**2.1**	2.1
% Above	0.04	0.2	3.2	**5.2**	53.9
% Below	99.96	99.8	96.8	**94.8**	46.1

Using a time-weighted average soil/sediment lead concentration of 216.7 mg/kg, the IEUBK model predicts that about 95% of the young child swimmer population would have blood lead levels below 4.5 µg/dL.

Uncertainties

There are uncertainties in the ability of the lead models to predict blood lead levels for the receptors at the LPRSA. In addition to the uncertainties noted in Appendix G of the HHRA, the HHRA exposure scenarios, while considered reasonable maximum exposures (RME), are at the lower limits of the lead model designs. Exposures were assumed to occur one to three times per week over a 13-week period (i.e., 91-day period). The Technical Review Workgroup for Metals and Asbestos (TRW) Lead Committee "recommends that users not apply the IEUBK model or the ALM to assess exposure frequency less than 1 day per week and of duration shorter than 90 consecutive days... The reliability of these models for predicting PbB concentrations for exposure durations less than 90 consecutive days has not been assessed" (USEPA 2016a). The models may overpredict blood lead concentrations for exposures that are less frequent and of shorter duration than the HHRA RME scenarios.

In addition, there is uncertainty in the use of a default soil lead concentration of 200 mg/kg to estimate the time-weighted average. Average urban soil lead concentrations near the LPRSA have not been measured and may be higher or lower than 200 mg/kg. Off-site soil lead concentrations would be associated with sources other than the LPRSA. As noted in USEPA 2016b, Superfund programs do not normally set cleanup levels below natural or anthropogenic background levels. The single measurement of lead in accessible sediment above Dundee Dam, upstream of the LPRSA, was 189 mg/kg. This upstream concentration is just a bit lower than the default soil lead concentration of 200 mg/kg. However, the data is extremely limited and cannot be counted on to characterize background sediment or soil concentrations with any certainty.

Conclusions

Although the December 2016 memo specifically addresses soil, in order to be protective, CDM Smith reran the IEUBK and ALM modeling for select receptors from the LPRSA HHRA who may be exposed to other media (e.g., sediment, surface water). Using the blood lead level of concern of 5 µg/dL identified in the memo shows that the percentage of children below that target is generally in

agreement with the conclusions in Appendix G of the HHRA. Therefore, lead is not considered to be a COC for the LPRSA.

References

AECOM. 2017. Baseline Human Health Risk Assessment for the Lower Passaic River Study Area, Revised Draft Final. Prepared for: Cooperating Parties Group, Newark, NJ. March.

USEPA. 2016. Updated Scientific Considerations for Lead in Soil Cleanups. OLEM Directive 9200.2-167. December 22.

USEPA. 1994. Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children. OERR 9285.7-15-1. EPA/540/R-93/081.

USEPA. 2003. Assessing Intermittent or Variable Exposures at Lead Sites. OSWER 9285.7-76. EPA-540-R-03-008.

USEPA. 2016a. Recommendations for Assessing Short-Term Exposure Scenarios Involving Lead at Superfund Sites. OLEM Directive 9285.6-54. August 2.

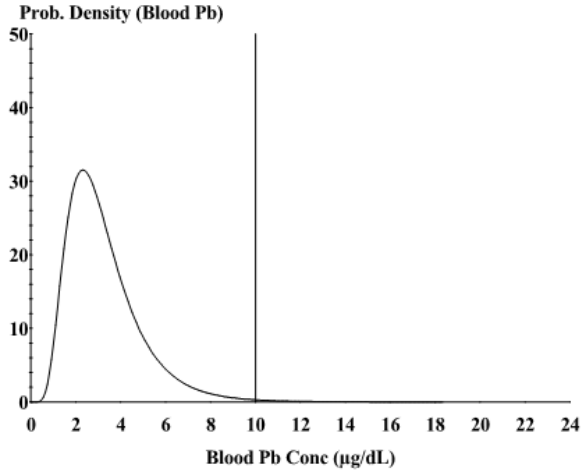
USEPA. 2016b. Updated Scientific Considerations for Lead in Soil Cleanups. OLEM Directive 9200.2-167. December 22.

USEPA. 2017. Lead at Superfund Sites: United States Geological Survey (USGS) Background Soil-Lead Survey. https://www.epa.gov/superfund/lead-superfund-sites-united-states-geological-survey-usgs-background-soil-lead-survey.

cc: Marian Olsen, USEPA Region 2

Attachment 1

IEUBK Output, Young Child Swimmer, HHRA Assumptions, Cutoff = 10 ug/dL

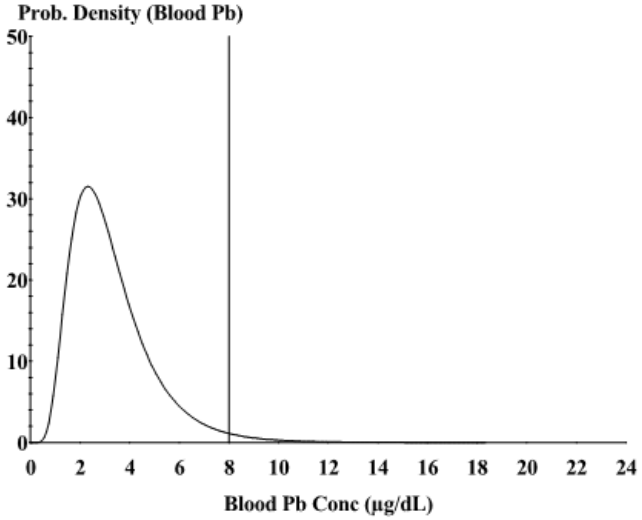


Cutoff = 10.000 µg/dl
Geo Mean = 3.002
GSD = 1.600
% Above = 0.523
% Below = 99.477

Age Range = 12 to 84 months

Run Mode = Research
Comment = Young Child Swimmer, 10 ug/dL

IEUBK Output, Young Child Swimmer, HHRA Assumptions, Cutoff = 8 ug/dL

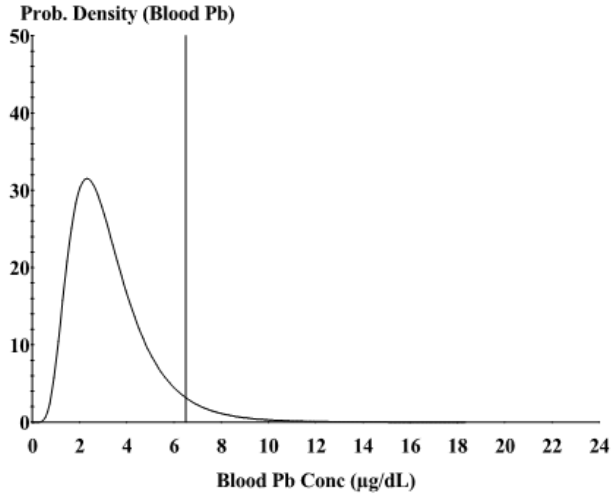


Cutoff = 8.000 µg/dl
Geo Mean = 3.002
GSD = 1.600
% Above = 1.852
% Below = 98.148

Age Range = 12 to 84 months

Run Mode = Research
Comment = Young Child Swimmer, 8 ug/dL

IEUBK Output, Young Child Swimmer, HHRA Assumptions, Cutoff = 6.5 ug/dL

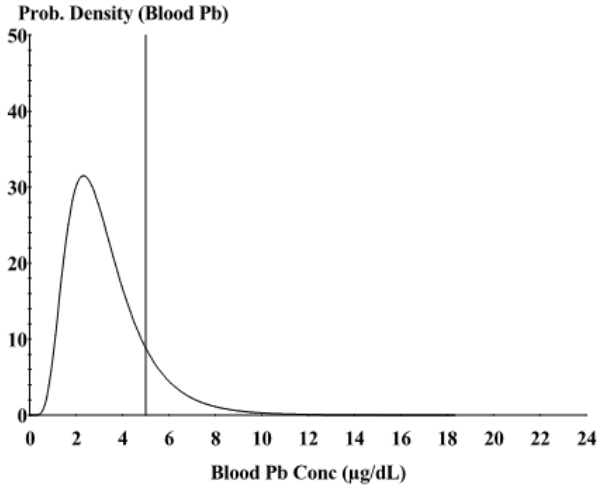


Cutoff = 6.500 µg/dl
Geo Mean = 3.002
GSD = 1.600
% Above = 5.014
% Below = 94.986

Age Range = 12 to 84 months

Run Mode = Research
Comment = Young Child Swimmer, 6.5 ug/dL

IEUBK Output, Young Child Swimmer, HHRA Assumptions, Cutoff = 5 ug/dL

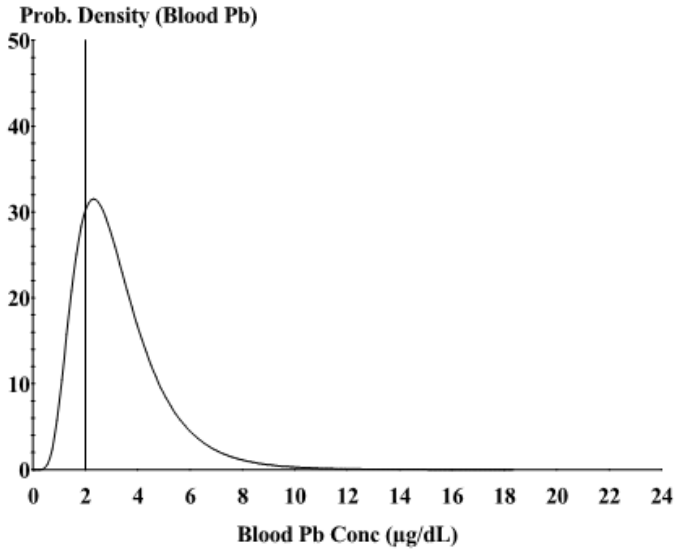


Cutoff = 5.000 µg/dl
Geo Mean = 3.002
GSD = 1.600
% Above = 13.890
% Below = 86.110

Age Range = 12 to 84 months

Run Mode = Research
Comment = Young Child Swimmer, 5 ug/dL

IEUBK Output, Young Child Swimmer, HHRA Assumptions, Cutoff = 2 ug/dL

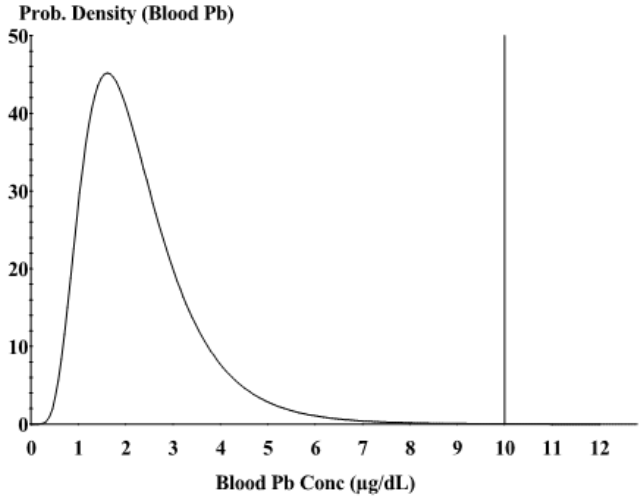


Cutoff = 2.000 µg/dl
Geo Mean = 3.002
GSD = 1.600
% Above = 80.628
% Below = 19.372

Age Range = 12 to 84 months

Run Mode = Research
Comment = Young Child Swimmer, 2 ug/dL

IEUBK Output, Young Child Swimmer, TWA concentration, Cutoff = 10 ug/dL

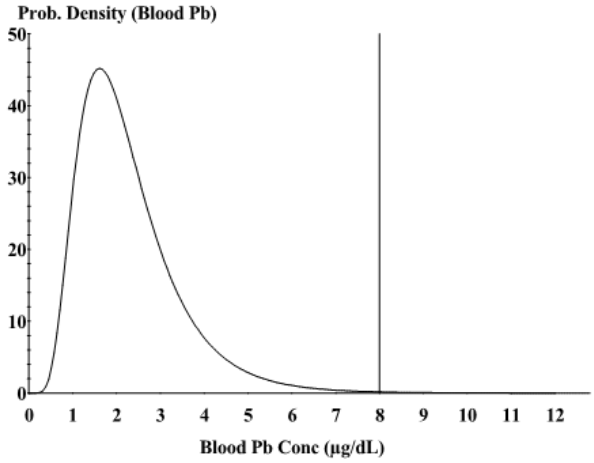


Cutoff = 10.000 µg/dl
Geo Mean = 2.094
GSD = 1.600
% Above = 0.044
% Below = 99.956

Age Range = 12 to 84 months

Run Mode = Research
Comment = Young Child Swimmer, TWA, 10

IEUBK Output, Young Child Swimmer, TWA concentration, Cutoff = 8 ug/dL

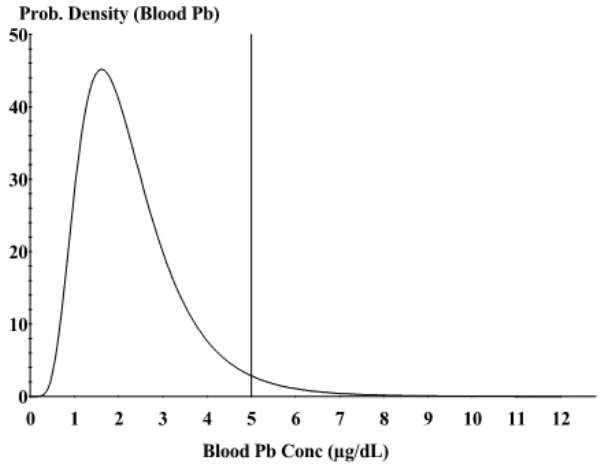


Cutoff = 8.000 µg/dl
Geo Mean = 2.094
GSD = 1.600
% Above = 0.218
% Below = 99.782

Age Range = 12 to 84 months

Run Mode = Research
Comment = Young Child Swimmer, TWA, 8

IEUBK Output, Young Child Swimmer, TWA concentration, Cutoff = 5 ug/dL

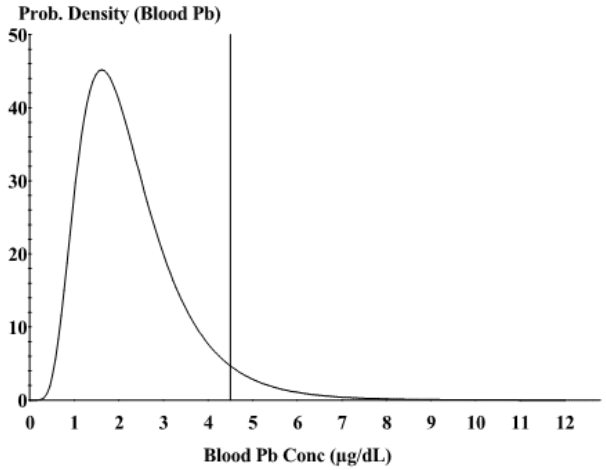


Cutoff = 5.000 µg/dl
Geo Mean = 2.094
GSD = 1.600
% Above = 3.205
% Below = 96.795

Age Range = 12 to 84 months

Run Mode = Research
Comment = Young Child Swimmer, TWA, 5

IEUBK Output, Young Child Swimmer, TWA concentration, Cutoff = 4.5 ug/dL

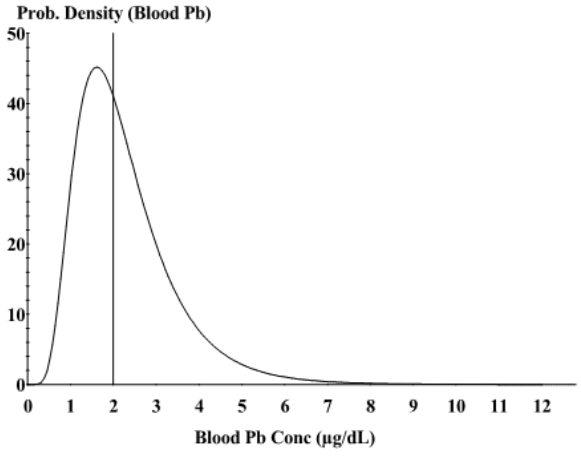


Cutoff = 4.500 µg/dl
Geo Mean = 2.094
GSD = 1.600
% Above = 5.183
% Below = 94.817

Age Range = 12 to 84 months

Run Mode = Research
Comment = Young Child Swimmer, TWA, 4.5

IEUBK Output, Young Child Swimmer, TWA concentration, Cutoff = 2 ug/dL



Cutoff = 2.000 µg/dl
Geo Mean = 2.094
GSD = 1.600
% Above = 53.904
% Below = 46.096

Age Range = 12 to 84 months

Run Mode = Research
Comment = Young Child Swimmer, TWA, 2