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Via Electronic Delivery

Re: Lower Passaic River Study Area (LPRSA) Draft Baseline Ecological Risk Assessment (BERA) – USEPA Region 2 May 1, 2015 Comments – Data Use Comment Resolution

Dear Ms. Vaughn:

This letter was prepared in response to discussions between USEPA Region 2 (Region 2) and the Cooperating Parties Group (CPG) regarding resolution of specific data use comments provided by Region 2 in its May 1, 2015 comments on the CPG's draft BERA dated June 13, 2014. Specifically, during the May 7, 14, and 21, 2015 EPA-CPG teleconferences, comments 11, 13a, 13b, 51, and 52 were raised by the CPG, because these comments were inconsistent with previous agreements, documents and/or direction from Region 2. In response, Region 2 requested during the May 21 teleconference that the CPG submit a letter documenting the resolution and resolution language (if applicable) for each of the comments. The following describes the comment and the resolution reached between Region 2 and the CPG on these comments.

Region 2 Comment 11 – *"Setting non-detect values to zero rather than using EPA-approved statistical software (e.g., ProUCL) requires justification beyond just a discussion in the uncertainty sections. It is unclear why a standardized approach is not used throughout the draft BERA. Setting non-detect values to zero may underestimate risks where reporting limits are high. The same approach for addressing non-detect values should be used in both the BERA and the HHRA."*

CPG Response to Comment 11 - The treatment of non-detects (NDs) in the BERA and the Baseline Human Health Risk Assessment (BHHRA) followed the rules described in Sections 4.1 and 5.3 of the Data Usability and Data Evaluation Plan (Data Usability Plan; Windward and AECOM in prep). The Data Usability Plan has been reviewed and commented on by Region 2 multiple times. The most recent version of the Data Usability Plan was submitted to Region 2 on May 15, 2014, and addressed the presumed final two comments provided by Region 2 on April 10, 2014[1].

[1] The Data Usability and Data Evaluation Plan was submitted to Region 2 on February 26, 2010, a revised draft was submitted on April 13, 2012, and a final revised draft on May15, 2014. Region 2 commented on the 2010 and 2012 drafts; comments were received on April 1, 2010 and April 10, 2014, respectively. Region 2 has not provided final approval or additional comments on the CPG's May 15, 2014 draft document.

Applicable sections of the Data Usability Plan and BERA are included as an attachment to this letter.

Consistent with Section 5.3 of the Data Usability Plan, the ProUCL recommended detection limit substitution method was used in generating upper confidence limits (UCLs) for both baseline risk assessments. Section 4.3.7 of the BERA states:

> *"Because ProUCL has an option for handling non-detect data (USEPA 2013b), all data (detected and non-detected) were used."*

Section 4.4.1 of the BHHRA states:

> *"Reporting limits for non-detected data were entered into ProUCL at the full reporting limit. ProUCL identifies the appropriate method with which to estimate the concentrations of the undetected data rather than simply substituting a value such as the detection limit or one-half the detection limit."*

Consistent with Section 4.1 of the Data Usability Plan, for COPCs where sums are used (e.g., Total PCBs, Dioxin TEQs), the sum is calculated as the sum of the detected congeners. If none of the individual congeners were detected, the total concentration was flagged as non-detected (U qualified) with a reporting limit equal to the maximum reporting limit of the individual congeners. The maximum reporting limit was then included in the derivation of the UCL for the total in ProUCL, and ProUCL determined the appropriate detection limit substitution method.

A discussion of the impacts to exposure concentrations and risk estimates based on treatment of NDs in sums (as zero (i.e., the sum of detects only), one-half of the detection limit (DL), and full DLs) is included in the uncertainty sections of both the BERA (Section's 6.5.4.2, 7.1.4.2, 7.3.4.2, 7.4.4.2, 8.1.4.2, 8.2.4.2, 9.1.4.2) and the BHHRA (Section 7.2.2.4). This approach is entirely consistent with Region 2's comment on this matter. As stated in Region 2's Data Usability Memo comments received on April 1, 2010:

> *"EPA is still evaluating how best to handle non-detects for congeners with multiple congeners, and Region 2 has contacted Headquarters for further guidance. As such, additional comments on this section will be made at a later date. In the meantime, however, <u>it may be useful to select some examples from the existing dataset to determine the overall impact of using zero, one-half the detection limit, or the full detection limit on the calculated concentrations</u>."* [emphasis added]

The analyses in both the BERA and the BHHRA demonstrate and document that the impact of alternate methods of treatment of NDs in sums would have a negligible impact on risk estimates. Furthermore, the approach taken in the BERA and BHHRA is fully consistent with the 17-mile LPRSA project-specific plans, USEPA guidance, and other sites.

<u>Resolution to Comment 11</u> - Region 2 asked the CPG to provide text documenting where this information on the treatment of NDs and the evaluations are located in the BERA submitted on

June 13, 2014 and the BHHRA submitted on June 6, 2014. The Data Evaluation and Reduction section (Section 4.3 Data Reduction Rules) of the BERA describes how NDs are treated. In addition, each BERA uncertainty section (uncertainties in risk characterization) discusses the treatment of NDs:

- Benthic Assessment (Section 6; specifically Section 6.5.4.2) – Table 6-30 has an evaluation of treatment of NDs for surface water for invertebrates.
- Fish Assessment (Section 7; specifically Sections 7.1.4.2, 7.3.4.2, and 7.4.4.2) - Table 7-10 has an evaluation of the treatment of NDs for fish tissue. Table 7-26 has an evaluation of the treatment of NDs for surface water for fish. Table 7-30 has an evaluation of the treatment of NDs for fish eggs.
- Bird Assessment (Section 8; specifically Sections 8.1.4.2 and 8.2.4.2) - Table 8-13 has an assessment of the treatment of NDs for bird diet. Table 8-21 has an assessment of the treatment of NDs for the bird egg evaluation.
- Mammal Assessment (Section 9; specifically Section 9.1.4.2) - Table 9-15 has an evaluation of the treatment of NDs for mammalian diet.

Similar sections are provided in the BHHRA:

- Section 3.2.1 (Summary Statistics) describes how total PCBs and dioxin toxic equivalence concentrations were calculated by summing detected congeners.
- Section 4.4.1 (Calculation of Exposure Point Concentrations) describes how full reporting limits were entered into ProUCL, and that ProUCL then identified the appropriate method for estimating concentrations of non-detects.
- Section 7.2.2.4 (Approach for Handling Non-Detect Results in Totals) discusses uncertainties associated with summing only detected congeners for totals and provides comparisons based on using one-half of the reporting limit and the full reporting limit in sums. Table 7-2 presents a comparison of calculated sums for TCDD-TEQ, PCB-TEQ, and total PCBs using three ND treatments (ND = 0, ND=1/2 RL, and ND=RL) for fish and crab tissue types.
- Section 7.2.2.4 also presents an evaluation of the impact of using USEPA's Advanced KM TEQ Calculator (provided in EPA's Dioxin Tool Box) on the maximum and mean TCDD-TEQs in sediment, surface water, and tissue. The KM TEQ Calculator provides an alternate method of estimating non-detect congeners based on the Helsel's 2010 work.

No changes will be made in the handling of NDs in the BERA and the BHHRA.

Region 2 Comment 13a – *"The total TEQs should be evaluated by a calculation of the sum of PCDD/PCDF/PCB TEQs together for each individual sample."*

CPG Response to 13a - The CPG notes that these sums were provided in the June 13, 2014 BERA. Section 4 of the BERA, Data Evaluation and Reduction, describes the process for calculating Total TEQs, which are the sum of all TEF-weighted PCDD/PCDF congeners and dioxin-like PCB

congeners on a sample basis, consistent with the methods presented in Table 4-1 and Section 4.1 of the Data Usability Plan. Moreover, the TEQ summation approach used in the BERA is consistent with EPA's 2013 guidance, *Use of Dioxin TEFs in Calculating Dioxin TEQs at CERCLA and RCRA Sites.*

Resolution to Comment 13a – During the May 21 call, Region 2 stated that this was a simple misunderstanding and this issue could be resolved by adding the sums to tables (in addition to the individual constituents). The CPG agreed to present the totals at the bottom of the tables where applicable (e.g., tables of COIs and COPECs in the SLERA).

Region 2 Comment 13b - *"In addition, evaluation of PAHs in sediment should be conducted using EPA's toxic unit approach, calculated for 34 PAHs".*

CPG Response to Comment 13b - The operational definition and summing methods for PAHs (as low molecular weight PAHs, high molecular weight PAHs, and total PAHs [as the sum of 16 PAH compounds]) were presented in Section 4.1 of the Data Usability Plan. The only comment regarding PAH sums was provided by Region 2 in their April 1, 2010 comments on the February 26, 2010 draft Data Usability Plan:

> *"The rationale for inclusion of an alkylated PAH (2-methylnaphthalene) in the PAH totals should be included."*

In response to this comment, CPG removed 2-methylnaphthalene from the PAH sum in the revised draft Plan dated April 13, 2012, and EPA did not comment on PAH sums in their April 10, 2014 comments on the revised draft Data Usability Plan. Further, the PAH sums presented in all of the data summary reports submitted by CPG to Region 2 were calculated using the method presented in Section 4.1 of the Data Usability Plan. Moreover, Region 2 provided no comments regarding the summing of PAHs in these data summary reports:

- 2009 Fish and blue crab tissue chemistry data for the Lower Passaic River Study Area (last submitted September 19, 2011; Windward 2011);
- 2010 Small forage fish tissue chemistry data for the Lower Passaic River Study Area (last submitted July 18, 2012; Windward 2012a);
- 2009 and 2010 Sediment chemistry data for the Lower Passaic River Study Area (last submitted May 23, 2014; Windward 2014c); and
- 2011 Caged bivalve study data for the Lower Passaic River Study Area (last submitted July 18, 2012; Windward 2012b).

Resolution to Comment 13b - Region 2 stated during the May 21 teleconference that this issue has been resolved. The CPG should only evaluate the 16 PAHs agreed to previously. Region 2 asked the CPG to qualitatively discuss 34 PAHs in the uncertainty section of the BERA.

Region 2 Comment 51 – *"A set of rules should not be used to determine what value to use when multiple values are available. Instead of a set of rules, each value that has multiple results should be evaluated and the most appropriate value should be used. High-resolution methods are not superior to the low resolution method. A table listing the samples with their multiple results, along with a column for rationale of which value is chosen should be included."*

CPG Response to Comment 51 - This comment is contrary to the design and intent of the Data Usability Plan that CPG and EPA developed with the express intent of establishing a standard and consistent set of rules to be applied in both baseline risk assessments. The rules for selecting a single value when multiple values are reported are presented in Section 4.2 of the Data Usability Plan as well as the data summary reports submitted to Region 2 (see above list in CPG Response Comment 13b) since 2011, all of which went through multiple rounds of Region 2 comments. Specifically, Section 4.2.1 of the Data Usability Plan discusses the selection of a single result when multiple values are available due to analyte overlap. Region 2 provided no comments regarding data rules for selecting single values when multiple results were reported in either the drafts of the Data Usability Plan or any of the subsequent data summary reports listed above in response to Comment 13a.

Resolution to Comment 51 – Region 2 stated that the CPG should follow the rules as outlined in the Data Usability Plan in both the BERA and the BHHRA, and as previously submitted in the data summary reports.

Region 2 Comment 52 – *"The rules provided for evaluating the field duplicates and laboratory replicates are generally acceptable; however, for values that fall under the first bulleted rule, a table should be created that shows both values to confirm that the results are not vastly different. If the values are vastly different, then additional text should be provided to explain why averaging the results is valid."*

CPG Response to Comment 52 - The rules for evaluating field duplicates and lab replicates were presented the Data Usability Plan and a number of data summary reports, all of which went through multiple rounds of Region 2 review and comment.

In addition to the impracticality of this comment (i.e., the level of detail for data documentation sought by Region 2 would be significant in both the BERA and BHHRA), this comment directs the CPG to take an approach inconsistent with previous agreements and plans. No comments were provided by EPA regarding treatment of field and laboratory replicates presented in Section 4.2.2 of the Data Usability Plan. Further, the same treatment of

laboratory replicates has been applied in the data summary reports prepared by the CPG and submitted to EPA since 2011. It should be noted that the data summary reports submitted by CPG to EPA (listed above in response to comment 13a) present all reported field duplicate results (i.e., sediment field duplicates). In addition, Appendix A of the BHHRA presents all of the analytical data used, including individual results for parent and duplicate samples.

Resolution to Comment 52 – Region 2 stated that the CPG should follow the rules as outlined in the Data Usability Plan in both the BERA and the BHHRA, and as previously submitted in the data summary reports.

The CPG requests the Region to confirm its agreement with the resolution of these comments. The CPG urges the Region to review its 17-mile BHHRA comments currently in preparation and address and revise similar comments.

The CPG requests that Region 2 incorporate this letter and its attachments into the Administrative Record for the 17-mile LPRSA operable unit of the Diamond Alkali Superfund Site.

Please contact Bill Potter or me with any questions or comments.

Very truly yours,
de maximis, inc.

Robert H. Law, PhD
CPG Project Coordinator

cc: Ray Basso, EPA Region 2
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CPG Members
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Attachments