U.S. ENVIRONMENTAL PROTECTION AGENCY, REGION 2

June 01, 2018

BY ELECTRONIC MAIL

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

Re: Re: Lower Passaic River Study Area Draft Remedial Investigation Report – Administrative Settlement Agreement and Order on Consent for Remedial Investigation/Feasibility Study (Agreement) CERCLA Docket No. 02-2007-2009

Dear Dr. Law:

The U.S. Environmental Protection Agency (EPA) has reviewed the Draft Remedial Investigation (RI) Report, Section 8, dated December 2017 prepared by Anchor QEA on behalf of the Cooperating Parties Group (CPG) for the Lower Passaic River Study Area Remedial Investigation/Feasibility Study. The Draft RI containing Section 8 is dated December 2017 and revised tables, for the section were received from the CPG on March 29, 2018. Comments from EPA's partner agencies have been incorporated into the enclosed comments. EPA in providing the enclosed comments on the CPG's revised RI Report with this letter in accordance with Section X, Paragraph 44(d) of the Agreement.

Please proceed with revisions to the draft RI Report within 30 days consistent with the enclosed comments. If there are any questions or clarifications needed, please contact me to discuss.

Sincerely,

Diane Salkie, Remedial Project Manager
Lower Passaic River Study Area RI/FS

Enclosure

Cc: Zizila, F. (EPA)
Sivak, M. (EPA)
Hyatt, B. (CPG)
Otto, W. (CPG)

616159

EPA COMMENTS

Lower Passaic River Study Area Remedial Investigation/Feasibility Study, Remedial Investigation Report Sections 8, dated Dec 2017

No.	Section	General or Specific	Page No.	EPA Comment
1	Section 8	General	N/A	A key goal of the risk assessment is to demonstrate that unacceptable risks associated with a release of hazardous substances are present at the site and thus remedial measures are warranted. The RI report should include a clear summary of the results of the Baseline Human Health Risk Assessment (BHHRA), such that it is clear whether remedial actions are warranted. Section 8 should be revised to clearly present the key findings of the BHHRA. This summary section (Section 8) should follow the July 2017 HHRA's Executive Summary and Section 8.0: Summary and Conclusion of the report and not reiterate issues that were discussed and resolved over the past few years. Rewrite this section using the two HHRA sections noted above as guidance. The identified unacceptable human health cancer risk and noncancer hazards derived through the BHHRA should be listed directly in the text and discussed (as they were in the two referenced HHRA sections). EPA reserves the right to reexamine the Section 8 text after it is revised to draw from the HHRA's Executive Summary and Section 8: Summary and Conclusion and associated tables/figures.
2	Section 8	General	N/A	Revise Section 8 to present and discuss Reasonable Maximum Exposure (RME) risk values identified in the BHHRA to provide the reader with an understanding of the magnitude of the risk estimates. For example, in addition to noting that chemicals and exposure pathways that exceed a noncancer hazard of 1, a range of hazard indices should be included. As currently written, the only specific RME risk/hazard value currently mentioned in Section 8 text is a noncancer hazard of 5 associated with sediment exposure; specific RME risk values associated with fish and crab ingestion must also be presented and discussed in the text.
3	Section 8, second paragraph; 8.1.5, first paragraph; 8.2.1, third	General	20; 22; 24	Section 8 text notes in several places that the BHHRA was performed in accordance with the Revised Risk Analysis and Risk Characterization (RARC) Plan that was never finalized. The series of drafts of the RARC did document decisions for the BHHRA up to 2013. However, additional refinement of methods and procedures for

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	paragraph			the HHRA were subsequently made through two drafts of the BHHRA report (June 2014 and December 2015), comments on those drafts, and additional communications between the CPG and EPA into 2017, as documented in the Final BHHRA itself. A revised version of Section 8 should cite the Final BHHRA report rather than the RARC report as the document presenting the approach for conducting the BHHRA.
4	Section 8	General	26 to 33	Several subsections appear to be mislabeled, starting on page 26. Toxicity assessment, risk characterization, identification of potential chemicals of concern, and uncertainties in the risk assessment are all incorrectly presented as subsections within "8.2 Exposure Assessment". A revised version of Section 8 should be structured to give appropriate weight to the risk assessment components (e.g., 8.3 Toxicity Assessment, 8.4 Risk Characterization, 8.4.1 Risk Characterization Results, 8.4.2 Potential Chemicals of Concern Identification, 8.4.3 Uncertainties in the BHHRA).
5	Section 8, second paragraph and footnote 16	Specific	20	Consistent with the General Comment regarding the RARC, revise the indicated paragraph as follows, and remove the associated footnote 16 ***(emphasis added to identify requested change)***: "The BHHRA was performed in accordance with applicable USEPA risk assessment guidance (USEPA 1989a, 1991a, 1991b, 2001, 2004a, 2004b, 2009a, 2014). ***The BHHRA presents the methods and procedures used*** and reflects USEPA Region 2-CPG agreements and agency directives for conducting baseline risk assessments.
6	8.1.5, first paragraph, first sentence	Specific	22	The COPC screening approach is documented in the Final HHRA report and summarized in this RI subsection. Consistent with the General Comment regarding the RARC, remove the following sentence: "The COPC screening was conducted using the USEPA-approved approach outlined in Appendix A of the RARC Plan (Windward and AECOM [in prep])."

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7	8.2.1, third paragraph, second sentence	Specific	24	Consistent with the General Comment regarding the RARC, revise the text as follows: "Based on the human health CSM, the exposure scenarios…"
8	Section 8.2.2.1	Specific	26	Text regarding the CPG's Creel Angler Survey is inappropriately highlighted. If the paragraph on this topic is kept in Section 8, it should be the last paragraph of Section 8.2.2 and does not warrant a subsection. See Comment #4. The CPG's Creel/Angler Survey of the LPRSA had problematic issues which were highlighted as discussed during the review of the HHRA. The results of this survey were not used as a critical path of information for risk assessment decisions. Therefore, CPG's Creel Angler survey should not be included within the 11-page summary of key findings of the HHRA.
9	8.2.2.1, second paragraph	Specific	26	The subsection entitled "Toxicity Assessment" should be presented as Section 8.3 rather than a portion of Section 8.2.2.1. See Comment #4.
10	8.2.2.1, first paragraph	Specific	27	The subsection entitled "Risk Characterization" should be presented as Section 8.4 rather than a portion of Section 8.2.2.1. See Comment #4.
11	8.2.2.1, second paragraph	Specific	27	Text states: "The potential carcinogenic risks and noncarcinogenic hazards calculated for each receptor scenario are then summed to yield cumulative risks and hazards by receptor. For each receptor, the cumulative potential carcinogenic risks were compared to the NCP risk range of 10^{-4} to 10^{-6}." For the purposes of a BHHRA summary in the RI, an improved general description is needed of what is meant by the NCP acceptable cancer risk ranges and noncancer health hazard levels. For example, it should be described that NCP risk range of 10^{-4} to 10^{-6} refers to a range of cancer risks representing one potential excess cancer incidence per population of 10,000 (i.e., one in ten thousand) to one potential excess cancer incidence per population of 1,000,000 (i.e., one in a million). A similar

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				explanation for what the NCP noncancer hazard level refers to is also needed.
12	8.2.3	Specific	28	The subsection entitled "Risk Characterization Results" should be presented as Section 8.4.1 rather than a portion of Section 8.2 Exposure Assessment. See Comment #4.
13	Section 8.2.3	Specific	28 to 30	As currently presented, those exposure scenarios which fall within acceptable NCP cancer risk ranges and noncancer hazard levels are highlighted. Readers are referred to Tables 8-4 to 8-7 for a full listing of all resulting risk and hazard results derived for the LPRSA. However, as a risk assessment summary section in this RI, the exposure scenarios which fall above the NCP acceptable cancer risk ranges and noncancer health hazard levels are of greatest interest. As in any document/section, the important issues or conclusions pertinent to the next phase must be highlighted. Non-issues (i.e., low risks and hazards) should not be given the same prominence as real issues (i.e., elevated risks and hazards). The second paragraph in this section unacceptably highlights non-issues as opposed to real issues, which are needed to link the RI with the action to be taken in future phases. Therefore, the risk conclusion information, as presented in the July 2017 BHHRA Executive Summary and Conclusions sections must be presented in a concise form in Section 8 of the RI, as well as referenced to the appropriate tables. To address this issue, one of two approaches could be used. First, divide Section 8.2.3 into two subsections; the first subsection would describe and present the exposure scenarios evaluated representing unacceptable NCP risks and hazards. The second subsection would describe and present those exposure scenarios evaluated which fall within acceptable NCP risk ranges and hazard levels. Alternately, amend each paragraph in Section 8.2.3 to highlight where unacceptable risk was found and cite the risk or hazard levels derived. For example, for the

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				existing second paragraph in this section, add the following (or similar) statement: "Cancer risk derived for the combined young child/adult receptor consuming a mixed fish diet was found to be 4 x 10^{-3}, which represents 4 potential excess cancer incidents per a population of 1,000. This risk is outside of the acceptable NCP risk range of 1 x 10^{-4} to 1 x 10^{-6}, as described earlier in this section. Similar statements must be added to the text in Section 8.2.3 to address all risks and hazards which fall outside of NCP acceptable levels. This information could also be accomplished in bullet form, or supplemented through insertion of a concise table within the text. If this section is replaced with something close to the Executive Summary from the HHRA, then the two specific approaches described above may not be needed.
14	8.2.3	Tables 8-8 and 8-9, and associated text	29 to 30	Tables 8-8 and 8-9 and the associated text present a portion of information about two issues contributing to uncertainty in the risk assessment without adequate context. Replace the text for these two paragraphs (i.e., "The BHHRA also showed that composition…variation in risk and hazard based on dietary preference.") with the fourth paragraph from ES.3 Conclusions, Fish and Crab, from the Final BHHRA (pages ES-14 through ES-15). Remove Tables 8-8 and 8-9. If risk and hazard estimate values are to be shown, use figures like those in the HHRA (Figure 7-3 and Figure 7-4), which provide a visual comparison to target risk range and target hazard index, and a comparison of several single-species diets.
15	8.2.4	Tables 8-11 through 8-17, and associated text	30	Information is repeated in the tables and the redundancy compromises the tables' usefulness. Reducing the number of tables will reduce the redundancy and avoid misunderstanding the presented information. Remove Tables 8-11 through 8-16, which repeat information already provided in Tables 8-4 through 8-7 and 8-10. Remove Table 8-17, which repeats information provided in Table 8-10 but in a

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				format that obscures the relative significance of potential COCs. Remove most of the third paragraph of this section, "Tables 8-11 through 8-16 present…potential COCs by medium and scenario." Move the last sentence of this paragraph to the end of the second paragraph.
16	8.2.5, first sentence	Specific	31	The first sentence should be removed. Additionally, see Comment #15 above.
17	Section 8.2.5	Specific	33	Since the goal of Section 8 is to present an overview of the key findings of the BHHRA, the section should end with a conclusion section which summarizes unacceptable risks and hazards. This important information, together with similar information from the BERA, comprise the basis for moving toward a feasibility study and remedial action.

N/A – not applicable