NITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION II
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NEW YORK, NEW YORK 10007 -1866

June 19, 2015

BY ELECTRONIC MAIL

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

Re: Lower Passaic River Study Area, 17-Mile RI/FS
CPG letters dated June 12, 2015 regarding EPA comments on the draft BERA and BHHRA

Dear Dr. Law:

On May 1, 2015 the U.S. Environmental Protection Agency (EPA) provided comments on the draft Baseline Ecological Risk Assessment (BERA) submitted by the Cooperating Parties Group (CPG), and on June 5, 2015 EPA provided comments on the draft Baseline Human Health Risk Assessment submitted by the CPG. The CPG submitted both documents to EPA as part of the Remedial Investigation/Feasibility Study (RI/FS) process for the 17-Mile Lower Passaic River Study Area (LPRSA), which the CPG is performing under EPA oversight. The draft BERA and BHHRA are lengthy documents that are critical to the remedial decision-making process. In total, EPA submitted nearly 500 individual comments on these documents covering over 80 pages of text.

Since May 1, EPA and the CPG have had what EPA considers to be five highly productive, conference calls with representatives of the CPG technical team to work through questions or concerns related to the comments. To summarize, a very small number of the comments were found to be either inaccurate or inconsistent with previously approved approaches, and EPA readily agreed that the CPG could disregard those. Several comments required clarification on the part of EPA or the CPG, and again, these issues were quickly resolved. Most of the time the calls focused on technical areas of disagreement between EPA and the CPG that required or still require further discussion to be resolved.

In EPA's view, the technical teams have resolved a number of the issues and concerns raised by the CPG and continue to work productively to address the remaining issues. Despite this progress, the CPG has submitted four letters related to the draft BERA and BHHRA comments, which were highly combative and negative in tone and characterize the EPA oversight process as "unfair". While EPA can only surmise the reasons for this disconnect, we are concerned that it could undermine the progress our technical teams are making and thus further delay a timely completion of the project.

EPA understands that the CPG is awaiting some additional technical information from EPA that the CPG needs in order to finalize the revised BERA and BHHRA. As EPA has indicated during our recent conference calls, given this situation, EPA agrees to an appropriate extension of the 60-day deadline to resubmit revised documents.

EPA has demonstrated a willingness to discuss any and all concerns the CPG has with our comments or directions and will continue to do so; we think this is the most productive path forward. However, the continued submittal of negative written critiques that do not reflect the progress being made at the technical level does not help to advance the RI/FS process. If, for its own reasons, it is the CPG's preference to continue the review process in writing rather than through discussion augmented by written memorialization, as necessary, please let EPA know so we can consider how best to proceed.

Attached hereto are specific responses to many of the questions or concerns that have been raised thus far on the draft risk assessment comments since May 1, 2015.

Please let me know if you have any questions.

Sincerely,

Stephanie Vaughn, Project Manager
LPRSA 17-Mile RI/FS

cc: W. Mugdan, EPA
R. Basso, EPA
S. Flanagan, EPA

Attachments

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Attachment 1
Response to May 15, May 29 and June 12, 2015 Letters from CPG to EPA

Response to May 15, 2015 letter from Robert Law, on behalf of CPG, to Stephanie Vaughn, EPA

1. General Comment 2 – the approach directed by EPA is not inconsistent with the Focused Feasibility Study (FFS). The FFS evaluated only two exposure points: the full lower 8 miles and mudflats. This decision was based on the finding that median surface sediment concentrations do not change significantly within the lower 8 miles. However, this is not the case above River Mile (RM) 8.3. As such, evaluating the river as a single exposure unit for the majority of receptors and exposure pathways is not appropriate for the full 17-mile LPRSA. Additionally, this approach is consistent with the October 2013 Draft Risk Analysis and Risk Characterization Plan (RARC).

2. General Comment 3 (as well as Comments 147, 204 and any other relevant comments) – A significant number of carp were collected from the LPRSA, and an adequate number were collected for tissue analysis and evaluation in all but two reaches of the river. This is the most complete tissue data set that is available for freshwater fish. As such, carp should be evaluated in the BERA so that one representative species can be evaluated for the majority of the river, which aids in understanding potential risks to other omnivorous benthic fish that were not captured in specific sections of the river. In addition, carp are consumed by other fish and terrestrial predators, such as the Great Blue Heron. The CPG argues that carp should not be protected, but this is not what EPA is asking for.

   During our 5/14/2015 technical call, the CPG asked EPA to pull together information about natural predators and other sites where carp were evaluated in the risk assessment. On 5/21/2015, EPA submitted via email pictures of heron eating carp as well as a list of other sites that evaluated carp in their risk assessment process, including the Fox River, Tittabawassee River, Portland Harbor and Kalamazoo River.

3. General Comments 6 and 71 – Attachment 2 provides the additional technical information related to these comments (see Reference Data Selection Process and Sediment Quality Triad Methodology).

4. General Comment 11 – During our 5/7/2015 conference call, we came to the conclusion that non-detect values probably were being handled correctly, but that the draft BERA report did not clearly explain this. EPA recommends that a subsection called "Treatment of Non-Detects" be added to Section 4.3. Language from Section 5.3 of the May 15, 2014 draft final version of the Data Usability Plan can be used.

5. General Comment 13 – During our 5/14/2015 conference call, EPA told the CPG they could use 16 Polycyclic Aromatic Hydrocarbons rather than 34, but that the effects of this should be discussed in the uncertainty section.

6. Comment 44 – This comment was editorial in nature, and simply stated that there was some inconsistent wording used within Table 3-2 of the draft BERA. It was not asking for meaningful changes to the risk questions posed. To maintain consistency with the

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wording used in the Problem Formulation Document (PFD), no changes to the table are required by this comment.

7. Comment 64 – The RARC calls for a comparison of toxicity data to control samples results first and then to reference data in the risk characterization portion of the BERA. Table 3-2 of the draft BERA states that this will be done. In addition, Section 2.5.1.2 addresses this issue. Any inconsistency with the Newark Bay Study Area (NBSA) approach is irrelevant here, and may be appropriate given that the LPRSA and NBSA are significantly different water bodies.

8. Comment 78 – EPA's notes do not indicate that this comment was raised as an issue during any of our conference calls. Further discussion is recommended.

9. Comments 153 and 155 (and other Screening Level Ecological Risk Assessment (SLERA)-related comments) – These comments were discussed during 5/14/2015 teleconference and the CPG indicated verbally that they had re-read the SLERA and understood our concerns. On 5/21/2015 EPA sent the following response to the CPG via email:

    i. Comments 153 and 155 – In general, the PFD lists assessment endpoints for the BERA, not the SLERA. The endpoints for the SLERA should be more generic, similar to the receptors presented in the Conceptual Site Model. To address these comments specifically, please remove Table 1-1, combine Tables 1-2 and 1-3, and remove references to the BERA in this new combined table.

    ii. Comment 156d -- The point of this comment was that in the SLERA, the most conservative value for sediment should be used, regardless of the receptor for which it is related. As long as the most conservative value is used for both plants and other receptor groups for sediment, it is okay to have multiple sediment screening in the SLERA.

    iii. Comment 162 – An "x" is required in the sediment chemistry column for benthic omnivorous fish, invertivorous fish, piscivorous fish, sediment-probing invertivorous birds, piscivorous mammals and amphibians/reptiles. This is consistent with Figures 5-1 through 5-3 of the PFD

    iv. Comment 209 – see response above to 156d.

10. Comment 172 – Appendix A of the October 2013 RARC specifies the Chemicals of Potential Ecological Concern (COPEC) selection process for the BERA, but Comment 172 relates to the SLERA. As we have discussed, the SLERA should take a much more inclusive/conservative approach than the BERA and thus the requested modifications to the screening process are appropriate for the SLERA. At a minimum, frequency of detection should not be used as a criterion for eliminating contaminants in the SLERA.

11. Comment 219 – As was stated during our 5/7/2015 conference call, this comment was forwarded in error and can be disregarded.

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Response to May 29, 2015 letter from Robert Law, on behalf of CPG, to Stephanie Vaughn, EPA

12. Introduction – The introduction to the letter states that EPA requested "that the CPG submit a letter documenting the resolution and resolution language (if applicable) for each of the comments." To be clear, in order to streamline the review process, EPA did state that we would review draft responses and/or language to be used in the revised BERA to clarify certain issues prior to issuance of the response to comments. EPA did not necessarily request a formal letter.

13. Comment 11 – See Response 4, above.

14. Comment 13a – It was not clear in the BERA that the sum of PCDD/PCDF/PCB TEQs were used in the evaluation of total TEQs. To help clarify the document, and as is noted in the letter, the CPG agreed to present the totals at the bottom of relevant tables. In addition, a clarifying sentence or two should be added, where appropriate.

15. Comment 13b – See Response 5, above.

16. Comment 51 – The CPG states that the rules used in the BERA for determining which values to use when multiple values are available are consistent with those outlined in the Data Usability Plan. EPA asked that the process used be explicitly spelled out in the BERA, so it can act as a standalone document.

17. Comment 52 – The CPG states that the rules used in the BERA for evaluating field duplicates and laboratory replicates are consistent with those outlined in the Data Usability Plan. EPA asked that the process used be explicitly spelled out in the BERA, so it can act as a standalone document.

Response to June 12, 2015 letter from Robert Law, on behalf of CPG, to Stephanie Vaughn, EPA Related to the BERA

18. In this letter, the CPG outlines a process for moving the BERA forward. The additional information related to Comment 6 and Comment 71 is being transmitted with this document, 49 days after submission of the majority of the comments. As such, EPA is hereby extending the date for resubmission of a revised draft BERA by 49 days, until August 5, 2015. This should allow time for submission of a RTC for review prior to the document. EPA thinks this is a reasonable timeline, but is willing to discuss the details with the CPG.

Response to June 12, 2015 letter from Robert Law, on behalf of CPG, to Stephanie Vaughn, EPA Related to the HHRA

19. The cover email transmitting EPA comments on the draft BHHRA did not indicate that the document was deficient. It said that if the next draft of the document were found to be deficient, then additional actions could be taken.

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20. General Comment 4 – As discussed during our conference call on 6/15/2015, the Reasonable Maximum Exposure (RME) is, by definition, a single value for any particular exposure scenario, consistent with the following definition (Page 6-5 of RAGs Part A):

    > Actions at Superfund sites should be based on an estimate of the reasonable maximum exposure (RME) expected to occur under both current and future land-use conditions. The reasonable maximum exposure is defined here as the highest exposure that is reasonably expected to occur at a site. RMEs are estimated for individual pathways. If a population is exposed via more than one pathway, the combination of exposures across pathways also must represent an RME.

    In addition, EPA has stated repeatedly that carp must be included in the mixed fish diet, and the RARC states clearly that muscle-only and hepatopancreas-only tissues will be evaluated in the uncertainty analysis only.

    As is stated in the comments, discussion of a diet consisting of individual fish species can be included in the uncertainty section.

21. Comment 64 – EPA is willing to disregard this comment.

22. General Comment 8 – The term Contaminant of Concern (COC) is actually first used in the Executive Summary, not Section 6.4. It is also used in other places prior to Section 6.4. As discussed during our 6/15/2015 conference call, the term "Potential COCs" should be defined in the report as "those chemicals with risks above the NCP risk range of 10-4 or the non-cancer health hazard of 1." The use of the term COC should be replaced throughout the report with the term "Potential COC" and any use of the term Potential COC prior to Section 6.4 of the report should be reviewed for appropriateness.

23. General Comment 10 – The text of the report should state explicitly, where appropriate, that Superfund decisions are based on the RME individual, as per RAGS Part A, not just in Section 4.3. Comment 23d also relates to this issue.

    EPA is still reviewing the second part of this comment (related to the use of the term population) and will provide further direction shortly. The direction provided will not result in any substantive changes to the risk assessment.

24. General Comment 11 – Upon review, the CPG is correct that the term "more realistic" is used only in Section 7. However, this term should still be deleted from the document. CTE scenarios or alternative exposure factors are not more realistic, they are simply different.

25. General Comment 14 and Specific Comments 29, 64, 68, 69, 71 and 123 – As discussed during our 6/15/2015 conference call, all RAGS Part D tables will be updated to reflect current guidance. The CPG will provide draft versions of these tables to EPA for review prior to finalizing the revised document.

26. Comment 46 -- As discussed during our 6/15/2015 conference call, EPA will review this comment and get back to the CPG with clarifying information. Note that some

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information, such as that related to co-eluting PCBs, is not included in the Appendix A tables, so it is not the case that the Region had "all of the necessary information" to perform its review, as asserted by the CPG in questioning the "efficacy of the Region's review.".

27. Comment 209 – The information referred to in this comment is being transmitted with this letter. As with the BERA, the additional information related to Comment 209 is being transmitted 14 days after submission of majority of the comments. As such, EPA is hereby extending the date for resubmission of a revised draft BERA by 14 days, until on or about August 19, 2015. This should allow time for submission of a RTC for review prior to the document. Again, EPA thinks this is a reasonable timeline, but is willing to discuss the details with the CPG.

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