**Response to EPA's January 5, 2017 Responses on Revised Draft BHHRA (December 2015)**

| # | EPA's General Comment (8/25/16) | CPG Response (9/26/16) | EPA Response (1/5/17) | CPG Response (3/1/17) |
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| 1 | The document will require revisions to address EPA comments that were not appropriately addressed from previous comments on the June 2014 draft BHHRA. EPA's comments must be incorporated appropriately; if they are not, the document will not be approvable and EPA will proceed as per Paragraph 44 of the Agreement. If the next draft of the BHHRA is deficient, EPA may elect to modify the document itself pursuant to Paragraph 44 of the Agreement, and, as per Paragraph 47 of the Agreement, the CPG would be required to accept the findings of the modified report (subject to dispute resolution). | The CPG disagrees with the Region's contention that December 2015 version of the BHHRA did not appropriately address the Region's previous comments. As the CPG has previously documented, the Region's comments have had no significant or substantive effect on the risk calculations presented in the June 2014 or December 2015 versions of the 17-mile BHHRA both of which present risk estimates that are comparable to the Region's 8- mile FFS HHRA. The Region's comments are largely based on its unique interpretation of USEPA policy and guidance and its unwillingness to consider a realistic presentation of uncertainties associated with risk assessment. Nonetheless, the CPG will endeavor to address the Region's latest comments that will not result in any demonstrable change in risk characterization for the 17-mile LPRSA.<br><br>The CPG considers this a partial and preliminary response to the Region's comments provided in good faith for further discussions. As such, the CPG reserves its right under the May 2007 AOC in revising and completing this and other deliverables related to the17-mile RI/FS. | The December 2015 version did fall short of addressing all previous comments adequately. While numeric risk estimates are not in question at this point, the discussion presented in the text, if left unrevised, may obscure key risk assessment conclusions.<br><br>The response indicating that CPG will endeavor to address the comments is accepted pending review of the revised text. | The CPG continues to disagree that the December 2015 BHHRA obscured key risk assessment conclusions, namely that risks to human health in excess of the NCP cancer risk range and goal of a protection of a hazard index of one are related primarily to fish and crab tissue containing PCDDs/PCDFs and PCBs.<br><br>However, the CPG has complied with the Region 2's directives stated in these comments and further clarified in conference calls and email communications between the Region and CPG in January and February 2017. The CPG believes it has revised the BHHRA in accordance with Region 2's direction, and as such, requests that the Region approve the BHHRA. |

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| 2 | Consistent with the Dispute Resolution (EPA letter 2/6/12, see page 3693 of the BHHRA Appendices pdf), all instances where it states "At the direction of USEPA Region 2" or "USEPA Region 2 directed the CPG to use" shall also include the phrase "and consistent with guidance and policies."<br><br>Specific examples are provided below.<br><br>• Page ES-5. "USEPA Region 2 has directed the CPG to use [footnote], and…"<br>• Page ES-6. "At the direction of USEPA Region 2, the…"<br>• Page 4-9. "… those that USEPA Region 2 directed the CPG to use …"<br>• Page 4-10. "…those directed by USEPA for use…"<br>• Page 7-7. "USEPA Region 2's directed exposure parameter…"<br>• Page 7-10. "…fish consumption rates were directed by USEPA Region 2 (USEPA 2012b), and were…"<br>• Pages 8-2 to 8-3. "…those that Region 2 directed the CPG to use…" | The February 6, 2012 Dispute Resolution on the RARC Plan does not state that the phrase "and consistent with guidance and policies" was to be added in every instance where the BHHRA states "At the direction of USEPA Region 2" or "USEPA Region 2 directed the CPG to use". The Dispute Resolution directed the addition of the following sentence after the statement that the exposure parameters are those that EPA directed the CPG to use in the BHHRA for the LPRSA: "All of EPA's directions are consistent with EPA guidance, practices, and policies for conducting risk assessments." As per EPA's direction, this statement was added to the RARC Plan (Section 3.4.4) dated April 12, 2012.<br><br>CPG is also not aware of specific EPA guidance or policy stipulating the following:<br><br>• Page ES-6: EPA's directive that anglers always consume both the crab muscle and hepatopancreas, and for both the RME and CTE scenarios<br>• Page 4-15: EPA's directive that a fraction ingested of 100% (all fish/crab comes from the Site) be used for fish and crab consumption, and for both the RME and CTE scenarios<br>• Page 4-16: EPA's directive that cooking loss for fish and crab consumption be zero for the RME scenario<br>• Page 7-32: EPA's directive that the Tier 3 CSF of 150,000 per mg/kg-day be used for TCDD<br><br>While it may be the case that EPA's directions may be found within the range of possibilities allowed by guidance or can be found in other risk assessments, that does not equate with the directed values being appropriate for use in a site-specific LPRSA risk assessment. As CPG has previously stated, EPA has imposed numerous unrealistic assumptions that do not reflect site-specific conditions or comport with the intent of Reasonable Maximum Exposure (RME). However, CPG has performed the BHHRA in accordance with the EPA's directives.<br><br>Nevertheless, to address EPA's comment, instances where the text states "at the direction of USEPA Region 2" or "USEPA Region 2 directed the CPG to use" will be removed from the document. | EPA disagrees with the CPG's assertion regarding whether the assumptions in the risk assessment comport with the intent of Reasonable Maximum Exposure (RME). The selection of parameters is consistent with OSWER Directive 9200.1-120 and Risk Assessment Guidance for Superfund (RAGS) Part A page 3-1.<br><br>The response on removing instances where the text states "at the direction of USEPA Region 2" or "USEPA Region 2 directed the CPG to use" is accepted pending review of the revised text. | The use of the statements stating "at the direction of" or "directed the CPG" have been eliminated except for the first reference to exposure parameter assumptions and accompanying explanatory footnote at the beginning of Section 4.3 (Receptor and Chemical-Specific Exposure Parameters) (see response to comment #9), and the reference to the TCDD cancer slope factor in Section 7.3.2.1, which is agreed-upon text. |
| 3 | The text still uses the term "NCP threshold" which suggests a bright line for decisions at Superfund sites. The Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions, April 22, 1991 clearly states that the risk range is not a bright line. As indicated in previous comments, the presentation of risk should be presented as below the risk range, above the risk range or within the risk range, or above or below or equal to the goal of protection of a non-cancer HQ/HI of 1. | The term will be changed as described. | The response is accepted pending review of the revised text. | Completed. |

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| 4/5 | The Superfund Technical Support Center (STSC) letters of November 12 and 24, 2015 regarding surrogates for cis-nonachlor, oxychlordane, and trans-nonachlor were provided in EPA's December 4, 2015 letter, but were not incorporated in the revised draft because of time limitations in submitting the report. Specific comments provided below address adding the information to Section 5, Section 7, and Tables 5-1 and 5-2. Changes to these toxicity values will also impact risk calculation tables; noncancer hazards will increase slightly for the nonachlors and cancer risks will decrease for all three COPCs. Cis-nonachlor and oxychlordane will no longer be considered potential COCs for the LPRSA with the updated instructions for the relative potency factors. | In its June 5, 2015 comments on the June 2014 draft BHHRA, Region 2 included surrogate recommendations for chlordane isomers. In a teleconference on June 15, 2015, the CPG requested additional information regarding the appropriate surrogate for cis and trans- nonachlor, and Region 2 indicated that they would ask for clarification from STSC.<br><br>In its October 16, 2015 response to CPG, Region 2 included STSC's response. The STSC provided multiple relative potency factors for cis and trans-nonachlor and oxychlordane based on noncancer studies. STSC did not provide specific guidance on which values to apply, nor whether the values applied to cancer effects. CPG requested clarification on this issue during the October 22, 2015 teleconference between Region 2 and CPG representatives, and written request in the CPG's letter to Region 2 dated November 11, 2015.<br><br>On December 4, 2015, Region 2 provided STSC's response, nearly six months after CPG's request for clarification. However, in order to meet the December 18, 2015 deadline for the Revised BHHRA, AECOM had already completed the calculations using professional judgment regarding the application of the relative potency factors. The differences between the STSC approach and the approach taken for the Revised Draft BHHRA are summarized in an email from Robert Law (dmi) to Stephanie Vaughn and Jennifer LaPoma (EPA) on December 10, 2015. As the email and its attached summary indicate, the differences between the approaches are minimal and would not result in changes to the conclusions of the BHHRA. Jennifer LaPoma responded on December 14, 2015 that the CPG should submit the Revised BHHRA in its current form.<br><br>As the differences in risk and hazard estimates are negligible and have no impact on the conclusions of the BHHRA, the CPG proposes to include a statement to that effect in the text rather than populate the minimal change in risks/hazards through the RAGS D Tables and text tables. | The response is partially acceptable.<br><br>While the differences in risk and hazard estimates are very small, they do lead to cancer risk estimates dropping below $10^{-6}$ and therefore off the COC summary tables.<br><br>It is acceptable to include a statement in the text and not update all the RAGS D Tables as noted in the response. However the final COC summary tables in the text must be consistent with the correct toxicity values.<br><br>Please include a footer to all relevant RAGS D Tables that states the following:<br><br>Following completion of the RAGS Part D Tables, the Superfund Technical Support Center provided updated toxicity values (add in the dates) for (add in chemicals). As a result of these updates, there are slight changes in the calculated cancer risks for (add in chemicals) and non-cancer hazards (add in chemicals). The COC summary tables and text have been updated to remove the following chemicals which no longer exceed either the goal of protection of 10-6 or an HI = 1 based on the updated toxicity information. | CPG and Region 2 further discussed the implementation of this update during a conference call on 1/19/2017. During that call, CPG agreed to:<br><br>• Update Appendix J (COPC Percent Contribution Tables) for the Angler to reflect the revised risk and hazard estimates calculated using the chlordane isomer toxicity update<br><br>• Update Appendix K (RAGS Part D Table 10s) for the Angler to reflect the updated COC list and the revised risk and hazard estimates based on the chlordane isomer toxicity update<br><br>• Provide proposed language for the footnotes to be added to the RAGS Part D Table 7s and Table 9s in Appendices H and I.<br><br>CPG provided suggested language for the footnotes on 2/12/17, and Region 2 verbally approved them on 2/14/17. In addition, a new Appendix O was added to the BHHRA to summarize the toxicity value changes and their impacts on the BHHRA. The new appendix is also referenced in a footnote in Section 6.3 of the BHHRA. |
| 6 | For estimation of background risks associated with direct contact with sediment, the BHHRA only discussed cancer risks for comparison to site risks. For this exposure pathway, noncancer hazards were more of an issue for the site than cancer risks (i.e., cancer risks were less than $1 \times 10^{-4}$ but HI was greater than 1), and background noncancer hazards should also be discussed in the text. (The noncancer hazards for background sediment were presented in a table in Appendix L, but not included in the evaluation in Section 6.5.2.) | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |

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| 7 | The Uncertainty Evaluation section is very long (48 pages) and inclusive of potentially valid but secondary information. A meaningful uncertainty section is expected to be a balanced appraisal of major uncertainties that will significantly affect the site-specific numerical risks as they relate to the selection of remedies. There are uncertainty issues that do not need to be included and other uncertainties that should be reduced in size to a paragraph. Per EPA General Comment 12 on the Draft BHHRA (comments dated October 16, 2015), "the text requires revisions to concentrate on the main risk drivers with less emphasis on exposure parameters that are not significant drivers." The discussion of uncertainty needs to concentrate on risks above the NCP risk range and an HI = 1. Similarly, the Executive Summary should concentrate on the main risk drivers consistent with this recommendation.<br><br>The Uncertainty Evaluation continues to discuss uncertainties in some assumptions without linking them to an impact on the site risk estimates. Examples:<br><br>• Critique of default dermal absorption fractions for three sets of chemicals (pp. 7-26 to 7-29) when dermal contact with sediment was a very minor contributor to cumulative risks/hazards for the LPRSA. Indeed, for one of the chemical groups (i.e., PCBs), estimated cancer risks never exceeded $10^{-6}$ and noncancer hazards were well below an HI of 1.<br><br>• Critique of default approach for estimating TCE cancer risks to non-adult receptors (p. 7-39) when TCE cancer risks never exceeded $10^{-6}$.<br><br>Detailed discussions of exposure parameters or chemicals that are not significant drivers distract the reader from issues that are key to interpreting the primary site risks and should be limited to a summary statement or removed from the report. | The CPG maintains that the Uncertainty Evaluation in the Revised Draft BHHRA provides a comprehensive and meaningful discussion of uncertainties relevant to the LPRSA risk calculations. To address Region 2's concern about length and inclusion of potentially secondary information, the discussions of some issues have been condensed or removed from the Uncertainty Evaluation section. See responses to Specific Comments 70, 78, 84, 85, 86, 87, 88, 89, 90, and 97. | The response is accepted pending review of the revised text. | Completed. |
| 8 | Summary sections of the report should include the magnitude of risk/hazard estimates (missing from ES.3 Conclusions and 8.2 Conclusions). Summary sections also should identify key target organs/effects potentially associated with the noncancer hazards (missing from ES.1 Summary of Key Findings, ES.3 Conclusions, and 8.2 Conclusions). | Sections ES.1 Summary of Key Findings, ES.2.4 Risk Characterization Results, and 8.1.4 Risk Characterization Results, all present the magnitude of the risk/hazard estimates.<br><br>Tables ES.1 – ES.4 and the text tables in 8.1.4 also present the risks/hazard estimates by receptor, with the target organs/effects identified in the text tables in 8.1.4. Per Attachment A of EPA's comments, the maximum risk/hazard and target organs/effects will be added to the Conclusions in ES.3 and 8.2. | The response is accepted pending review of the revised text.<br><br>Per CPG response to Comment 11, EPA notes that identification of key target organs/effects will also be added to Section ES.1. | Completed. |

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| 9 | Multiple descriptions of correspondence and calls leading up to final assumptions applied in the risk assessment do not add value to the HHRA report and should be removed. Technical basis for values used should be provided in the main text and uncertainties in those values are discussed in the uncertainty section (Section 7). All correspondence between EPA and the CPG regarding the risk assessment between September 2010 and December 2015 are provided in Appendix M of the BHHRA. It is acceptable to provide the list of correspondence about exposure assumptions once (i.e., footnote 27 on page 4-10), but subsequent descriptions of communications should be removed:<br>• Page 4-13, footnote 28<br>• Page 4-16, footnote 30<br>• Page 4-18, footnote 31<br>• Page 4-21, footnote 32<br>• Page 7-7, second complete paragraph | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 10 | With regard to the Creel Angler Survey (CAS), the document details the attributes of the study, but fails to discuss potential issues with the representativeness of the CAS study. The document does, however, go into a substantial amount of detail questioning the default parameters and other surveys used as the basis of EPA's recommended exposure parameters (see section 7.2.1.2 for example). Discussion of the CAS study in the document should also include identification of potential issues of the CAS study.<br>On page 7-12, last paragraph, the discussion about the fish consumption rates in the range of 1 meal/month to 2 meals/month are supported by the CPG's CAS. As per EPA's previous comments on the BHHRA including EPA's October 30, 2015 email from Stephanie Vaughn to Rob Law, this quantification is inconsistent with the direction provided by EPA and all references to the CAS should clearly state that the data represents current conditions, in the presence of a consumption advisory. | The discussion of the CAS study will note potential issues.<br>The CPG has followed EPA Regions 2's prior direction on this issue; the two sentences immediately following the 1 to 2 meals/month discussion states that the survey was conducted without EPA oversight/review and the data represents current conditions, in the presence of a consumption advisory. | The first part of the response is accepted pending review of the revised text.<br>The second part of the response is unacceptable. With regard to quantifying fish consumption rates on page 7-12 from the CAS, the October 20, 2015 email states "references to the survey can be made anecdotally, not quantitatively." The point regarding potential risks associated with one meal per month can be made without trying to tie it back to the CAS, or to anglers in Washington state (another part of the paragraph), as follows:<br>Shorten the final paragraph on page 7-12 to the following sentence: "Assuming a fish consumption rate of one half- pound fish meal per month (7.5 g/day), keeping all other exposure parameters at their RME values, the risk/hazard for the LPRSA adult angler consuming the mixed fish diet decreases by about four- fold to a cancer risk of $7 \times 10^{-4}$ and an HI of 27. | CPG and Region 2 further discussed this comment during a conference call on 1/19/17, and it was agreed that the final paragraph on Page 7-12 would be retained except for the parenthetical reference to grams per day fish ingestion, as follows:<br>"Fish consumption rates in the range of one meal per month to two meals per month are supported by the CPG's CAS (AECOM 2014a,d). As previously noted, the CPG's survey was completed without USEPA Region 2 oversight or review, and the findings have not been confirmed by Region 2. The results represent current conditions in the presence of a consumption advisory. Assuming a fish consumption rate of one half-pound fish meal per month and keeping all other exposure parameters at their RME values, the risk/hazard for the LPRSA adult angler consuming the RME mixed fish diet decreases by about four-fold to a cancer risk of 7 x 10-4 and an HI of 27." |

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| 11 | Pages ES-1 and ES-2, Section ES.1 Summary of Key Findings | The text regarding the primary purpose of the risk assessment needs to be expanded to "inform the public regarding risks" in addition to the risk manager.<br>The use of the term "threshold" is inconsistent with OSWER Directive 9355.0-30. Consistent with the Directive, a more appropriate term is "exceed the risk range".<br>The discussion regarding the "dominant risk contributor" for the fish consumption pathway highlights TCDD toxicity equivalency and PCBs as the main risk drivers. The only other chemical with an HI > 1 is mercury. The discussion needs to clarify that the other contaminants e.g., pesticides, arsenic, BAP, are below the upper end of the risk range and below an HI = 1. | The requested changes will be made. | The response is accepted pending review of the revised text. | Completed. |
| 12 | Page ES-2, Section ES.1 Summary of Key Findings | Bullets identifying noncancer health hazard estimates with a Hazard Index (HI) greater than 1 should also identify potential health effects (i.e., target organ effects) associated with that hazard estimate. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 13 | Page ES-3, Section ES.1 Summary of Key Findings, Last bullet | The discussion of background should clarify that excluding TCDD-TEQ still results in a cancer risk greater than the risk range and a non-cancer HI > 1. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 14 | Page ES-4, Section ES.2.1 Data Evaluation and Hazard Identification | **Paragraph 1.** Recommend removing statement "as agreed with USEPA Region 2" and "CPG's RI/FS" programs requires consideration since this language suggests that this is not an EPA document.<br>**Paragraph 2.** Change sentence "Because of the conservative screening process that was used …" to "The screening process used to identify COPCs is designed to assure that chemicals not identified as COPCs are minor contributors to the overall risks and hazards from the site."'<br>**Paragraph 3**. Remove the first sentence beginning "Many of the chemicals identified as COPCs…" as it is broad and conclusory. | The requested changes will be made. | The response is accepted pending review of the revised text. | Completed. |
| 15 | Page ES-5, Section ES.2.2 Exposure Assessment | Remove term "conservative." The more appropriate term is "health protective" and should be used throughout the document. | The term "conservative" is used extensively in EPA's Risk Assessment Guidance for Superfund (RAGS), Exposure Factors Handbook, and other risk assessment guidance to describe assumptions and approaches intended to be above average or upper-bound. The use of "conservative" as applied to the description of RME in ES.2.2 (fourth paragraph) is consistent with language from RAGS (Section 6.1.2), which states: "The intent of the RME is to estimate a conservative exposure case (i.e., well above the average case) that is still within the range of possible exposures." Replacement of "conservative" with "health-protective" throughout the document is not appropriate and CPG does not agree to this wholesale change. However, the use of the word conservative will be reviewed and, if appropriate, removed or replaced with health-protective on a case-by case basis. | The response is accepted pending review of the revised text. | Completed. The use of the term "conservative" has been substantially decreased in the revised document. |

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| 16 | Page ES-6, Section ES.2.2, Exposure Assessment | First full paragraph: Insert the following at the end of the first sentence "because even if the consumer does not eat the hepatopancreas, exposure to the chemical may still occur if the crab is cooked before the hepatopancreas is removed." | The requested change will be made.<br>As CPG has previously noted, Zabik et al. (1992) found the percent loss of PCBs from crab muscle tissue boiled with and without the hepatopancreas to be similar (approximately 25% to 35%), indicating that chemicals present in the hepatopancreas do not end up in muscle tissue when the crab is cooked whole. This study indicates that for crab consumers who eat the muscle tissue but not the hepatopancreas, the route of exposure to chemicals in the hepatopancreas would be via consumption of the crab cooking juices. | The response is accepted pending review of the revised text, as long as the second paragraph from the response is not added to the HHRA. | Completed. |
| 17 | Page ES-7, Table ES-1 | Add USEPA 2014 to footnote d. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 18 | Page ES-11 | *Fish Consumption*.<br>The discussion of the cancer risks should clarify whether the other risk contributors e.g., about 4% were above the risk range or not.<br>*Fish Consumption and Crab Consumption*<br>Here, and throughout the document, remove the term "target endpoint" and use the term "target organ effect" consistent with terminology used in RAGS Part A (EPA 1989).<br>*Direct Contact with Sediment and Surface Water*<br>Remove the term "thresholds" and replace with "range or noncancer HI = 1". | The requested changes will be made. | The response is accepted pending review of the revised text. | Completed. |
| 19 | Page ES-12, Section ES.2.5 Identification of Potential Chemicals of Concern | Remove the term "thresholds" and replace with "range or noncancer HI = 1".<br>Replace the text before the table with: "The following table summarizes potential COCs with individual pathway cancer risks greater than $10^{-4}$, and/or an individual pathway noncancer hazard quotient (HQ) greater than 1." Remove chemicals with a cancer risk $<10^{-4}$ and noncancer HI<1 from the summary table and revise the footnotes accordingly (i.e., delete footnotes c and d). Please revise this section to indicate that details regarding other chemicals within the risk range and below a HI=1 are provided in Section 6.4.<br>Replace the text after the table with: "These potential COCs are also present in upstream and regional background media. The levels of these COCs in background fish and/or crab tissue were found to pose consumption risks/hazards above the NCP risk range or noncancer HI=1. For methyl mercury, the background concentrations in fish tissue and the corresponding hazards are comparable to or greater than in fish collected in the LPRSA." | The requested changes will be made. | The response is accepted pending review of the revised text. | Completed. |

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| 20 | Pages ES-12 to ES-15, Section ES.3 Conclusions | Replace Section ES.3 with the revised text provided in Attachment A. Note that comments to this section of the Executive Summary also apply to Section 8.2 Conclusions (pages 8-8 through 8-10), which has text that almost exactly matches, and should also be replaced.<br>Issues with the Conclusions section:<br>The conclusions of the Executive Summary should specifically identify the calculated risk and HI values and not just note that values are above NCP risk/hazard thresholds (e.g., first bullet) or some degree lower than an alternate approach (e.g., fifth bullet). In addition, the text concentrates on the percentage contributions of the chemicals, but should also clarify which chemicals are above the risk range or HQ = 1. EPA notes that the last bullet on pages ES-14 and 8-10, does identify risk and hazard values for background levels. Text in the conclusions summarizing the site risks should be equally transparent.<br><br>The section should briefly identify potential health effects (i.e., target organ effects) associated with the noncancer hazards exceeding an HI = 1.<br><br>Since the PCB toxicity approach has a minimal impact on cumulative risks/hazards, the summary of this topic in the conclusions should be removed.<br><br>The final paragraph of the section includes a phrase that does not make sense as written (i.e., "pose risks that contribute significantly to LPRSA risks"). Risks estimated for receptors in one area do not contribute to risks to receptors in another area. The sentence in Attachment A has been revised to "Upstream and regional levels of several potential COCs, including PCBs, pesticides, PAHs, and mercury, are elevated and may contribute to levels observed in the LPRSA and to risks estimated for LPRSA receptors." | EPA's replacement text for ES.3 and the Conclusions section is acceptable with minor proposed revisions, as shown in EPA's Attachment A in redline strikeout. | The response is accepted, including the CPG's proposed revisions shown in Attachment A. | Completed. |

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| 21 | Page 1-1, Section 1.0 Introduction, Second Paragraph | The second sentence of this paragraph, starting with "Using the data…," should be removed. Change last sentence to: USEPA (2014a) provides standard default exposure assumptions (e.g., parameters for age-specific body weight, skin surface area, dermal absorption, etc.) that can be used at sites based on the Exposure Factors Handbook (2011) in the absence of site-specific information. | The second sentence (and associated paragraph) is nearly identical to the second paragraph in the Introduction to the RARC Plan (Windward/AECOM [in prep]).<br>The last sentence in the paragraph is directive language from the Dispute Resolution. CPG proposes to add EPA's updated default exposure guidance (USEPA 2014a) to the guidance referenced in the sentence.<br>Besides the addition of (USEPA 2014a) to the guidance reference in the last sentence, CPG does not agree that changes to this paragraph are needed. | The response is unacceptable. Remove the second sentence of this paragraph and revise the last sentence as indicated.<br>EPA disagrees with the second sentence characterizing "data and information from recent site-specific studies in the LPRSA" as a "key component" of assessing current/future risks or making risk management decisions at this site.<br>In addition, the last sentence of the paragraph was directive language from the 2012 Dispute Resolution for text in Section 3.3 of the RARC Plan, and in a different context from this use on the first page of the HHRA report. The revised sentence provided in the comment is a more accurate reflection of the 2014 guidance (i.e., it provides standard default exposure assumptions). | Per Region 2's verbal approval provided in a 2/14/2017 conference call with CPG, the text was revised as follows:<br><br>"Consistent with USEPA guidance (2002a, 2005a), an evaluation of contaminated sediment sites should utilize a risk-based framework that is iterative and as site-specific as possible given the available data. Using site-specific data and information that characterize the LPRSA is a key component in defining the human health conceptual site model and for assessing the potential risks for selected receptors, thus providing sound information upon which risk management decisions can be made. The use of site-specific information is consistent with principles articulated by the National Academy of Sciences (NRC 2001) and USEPA (2002a, 2005a) guidance concerning risk management decisions at contaminated sediment sites. USEPA (2014a) provides standard default exposure assumptions that can be used at sites in the absence of site-specific information." |
| 22 | Page 2-2, Section 2.1.1 Site Background, Second Complete Paragraph | In addressing EPA Specific Comment 32 on the Draft HHRA (10/16/15), text was added about the removal action at RM 10.9. In the revised text, the final sentence of the paragraph states that sediments at RM10.9 were removed "to address high concentrations of dioxins and other contaminants found at the surface of sediments in this area." This implies that the high concentrations were just at the surface and have been addressed. However, as part of the removal action, the area has a cap overlying the remaining contaminated sediment. For completeness, please add the following statement to the end of this paragraph: "In addition, as part of the removal action a cap was placed over remaining contaminated sediments in this area." | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 23 | Page 2-2, Section 2.1.1 Site Background, Last Paragraph in Section | Per response to EPA Specific Comment 33c (10/16/15) on the Draft HHRA, add a reference to the RI report in the final sentence about regional conditions. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 24 | Page 2-6, Section 2.3 River Use | As discussed in EPA Comment 39 (10/16/15) on the Draft HHRA, the discussion of fishing should also recognize the potential for exposures under future conditions. Reference to NJDHSS requires update to the New Jersey Department of Health (now NJDOH). | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |

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| 25 | Page 2-7, Footnote 10 | Add the following to the end of footnote 10: ", but did include five results from Newark." | The northwestern quadrant of Newark Bay lies within the municipal boundary of Newark. The fact that five of the 267 intercepts for the Newark Bay Complex survey (Burger 2002) identify Newark as the location where the intercept was conducted is not relevant to the fact that the 1999 survey did not include locations on the LPR. CPG does not agree that the addition of this information to footnote 10 is necessary or appropriate. | The response is partially acceptable. The footnote may remain unchanged, but the text should provide some information about the survey locations included in the Burger study area and not just the statement that it "did not include locations on the LPR." The definition of Newark Bay Complex provided in Comment 31 (for Section 4) should be added to this page:<br>Insert "The Newark Bay Complex study area from Burger (2002) included Newark Bay and tidal portions of the Hackensack River, Arthur Kill, and Kill van Kull.[10]" after the first sentence in the first full bullet on page 2-7. | CPG and Region 2 further discussed this comment during a conference call on 1/19/17, and it was agreed that Region 2 would verify whether the Hackensack River was included in the study.<br>In an email dated 2/16/17 from Jennifer LaPoma (EPA) to Rob Law (de maximis), EPA summarized their position that the Hackensack River should be included in the list of water bodies in Newark Bay Complex that were included in Burger's 1999 survey (Burger 2002). The BHHRA text has been revised accordingly, although the CPG questions the speculative statements made in EPA's 2/16 email and believes that confirmation should be obtained directly from Dr. Burger.<br>Figure 1 of Burger (2002), which EPA cites as one basis for its position because it identifies the Hackensack River, also identifies water bodies that were not part of the 1999 survey, including Passaic River and New York Harbor. |
| 26 | Page 2-8, Footnote 11 | Change the wording to: USEPA Region 2 did not provide input … | The requested change will be made. However, CPG wishes to remind EPA they were invited to participate in the development of the CAS, review the peer review charge, and were provided with a copy of the work plan. | The response is accepted pending review of the revised text. | Completed. |
| 27 | Page 2-9, Section 2.3.1.1 | Last sentence: Add the following after the last sentence of this section "Results of this study have not been published in the peer-reviewed literature." | The results of the CAS have been presented at technical conferences (SETAC, AEHS) and published in the journal *Environmental Toxicology and Chemistry* as part of a peer-reviewed focus article on fish consumption as a driver in risk management decisions (Judd et al. 2015, ET&C, 34(11):2427-<br>36). The addition of this sentence is not appropriate. | The response is accepted. The sentence does not need to be added.<br><br>However, EPA notes that the published paper presents an overview of several different fish consumption studies (including the CAS), and is not a critical review of the study itself. EPA would also caveat the opinion expressed in the paper about the value of the CAS for use in an HHRA. Angling data collected in the presence of "eat none" fish advisories and public awareness of chemical contamination of a waterway may under-predict angling/consumption patterns for those anglers currently unaware of the fish advisories, and for future anglers who consider a waterway to be fixed at the completion of a site remedy. | Noted. |
| 28 | Page 3-1, Section 3.1 Data Evaluation | The discussion in the last paragraph regarding the Cal EPA Air Resources sampling method needs clarification. Need to clarify whether the data was QA/QCed and if Edison had any concerns about this method. | The text will be revised as follows; added text underlined:<br>"It should be noted that some chemicals (e.g., certain metals, PAHs) were analyzed using modified analytical methods. For example, PAHs were analyzed in sediment on some sampling events by Method 429M and on other sampling events by Method ID-0016. Both are isotope dilution <u>gas chromatography/mass spectrometry</u> methods based on California EPA Air Resources Board Method 429 (CARB 1997), and yield results of comparable sensitivity and precision. <u>These modified methods were submitted to EPA for review and approval as part of the project QAPPs. All data generated using these methods were validated per the</u> approved QAPPs." | The response is accepted pending review of the revised text. | Completed. |

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| 29 | Page 4-4, Section 4.1 Human Health Conceptual Site Model | In the third full paragraph on page 4-4, regarding the inhalation pathway, change "30 years" to "26 years." | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 30 | Page 4-9, Section 4.3 | Replace the beginning of last sentence of second paragraph with the following: "While risk management decisions are based on the RME, the purpose of evaluating both an RME and a CTE…" | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 31 | Page 4-13, Section 4.3.6.1 | Remove footnote 28. Add ", included in Appendix M of this BHHRA" to the reference at the end of the first sentence of Section 4.3.6.1. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 32 | Page 4-14, Section 4.3.6.1 Fish Ingestion Rate, Second Bullet | Define Newark Bay Complex either in the bullet or in a footnote on this page, "The Newark Bay Complex study area from Burger (2002) included Newark Bay and tidal portions of the Hackensack River, Arthur Kill, and Kill van Kull." | The requested change will be made. | The response is accepted pending review of the revised text. | Completed; see response to Comment 25. |
| 33 | Page 4-16, Section 4.3.6.3, Cooking Loss for Fish | Remove footnote 30. The technical information is provided in the text of Section 4.3.6.3, and all correspondence is provided in Appendix M of the BHHRA. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 34 | Page 4-17, Section 4.3.6.5, Cooking Loss for Crab | The 2013 document citing NJDHSS, should indicate that NJDHSS is now NJDOH. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 35 | Page 4-18, Section 4.3.6.5, Cooking Loss for Crab | Remove footnote 31. The technical information is provided in the text of Section 4.3.6.5, and all correspondence is provided in Appendix M of the BHHRA. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 36 | Pages 4-19 and 4-20, Section 4.3.7.3 Body Surface Areas in Contact with Sediment and Surface Water | Skin surface areas for adults were based on means rather than 50$^{th}$ percentiles as accurately identified in the tables; the description in the text should be corrected. Replace "50$^{th}$ percentile" with "mean values" in the third, fifth, and sixth paragraphs of this section. | The requested changes will be made. | The response is accepted pending review of the revised text. | Completed. |
| 37 | Page 4-21, Section 4.3.7.4, Sediment to Skin Adherence Factors | Remove footnote 32. The technical information is provided in the text of Section 4.3.7.4, and all correspondence is provided in Appendix M of the BHHRA. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 38 | Page 4-26, Section 4.3.9 Body Weight | The revised body weight for young children was not based on a standard default, but derived from values in the 2011 Exposure Factors Handbook as shown in Appendix N. The description in the text should be corrected as follows:<br>Second sentence, remove phrase "and 17 kg for young children"<br>Third sentence, change "Body weights for adolescent age groups…" to "Body weights for young children and adolescent age groups…"<br>Fourth sentence, add "17 kg for the 1 to <7 year old young child," to the list. | The requested changes will be made. | The response is accepted pending review of the revised text. | Completed. |
| 39 | Page 4-27, Section 4.3.10.2, Oral Absorption Adjustment Factors | Second paragraph: Change "The assumption of 100% RBA results in an overestimate of risk…" to "The assumption of 100% RBA would result in an overestimate of risk…" | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 40 | Pages 4-31 to 4-32, Section 4.4.4.1 EPCs for 2,3,7,8-TCDD in Surface Water | Add the following footnote to the end of the second sentence: A split sample of 11A-CE04- TTR1 was also collected and analyzed separately, and did not confirm the elevated concentration. The split sample result was 81 times lower. | The requested footnote will be added. | The response is accepted pending review of the revised text. | Completed. |

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| 41 | Pages 5-2 to 5-3,<br>Section 5.1 | The fifth paragraph of this section (last paragraph on page 5-2 and top of page 5-3) should be removed because it does not reflect the current IRIS process that was noted in the second paragraph. IRIS is not updated on a monthly basis and the Verification Workgroup was disbanded 20 years ago. | The CPG recommends retention of the first sentence in the paragraph, which points out that most of the toxicity values in the BHHRA are Tier 1 values, selected in accordance with EPA's hierarchy of toxicity values for Superfund risk assessment. The remainder of the paragraph will be removed. | The response is accepted pending review of the revised text. | Completed. |
| 42 | Page 5-3, Section 5.1 Sources of Toxicity Data | The discussion of HEAST is not necessary. HEAST is clearly identified as a Tier 3 Toxicity value so it is not necessary to restate the reasoning for identifying this chemical as a Tier 3.<br><br>The discussion of the toxicity value for Thallium needs to clarify that value is based on Thallium Soluble Salts. Also, this is an Appendix value indicating limitations on its use. The text on page 5-6 regarding these values should be referenced for this chemical. | CPG disagrees that the discussion of HEAST is not necessary. The discussion provides useful information regarding the uncertainties with the toxicity values listed in HEAST, particularly given that HEAST was last published nearly 20 years ago.<br><br>The discussion regarding thallium will be updated as requested. | Unacceptable. HEAST is already identified as a Tier 3 source of toxicity values. The paragraph either belabors points that were already made in describing the tiered system, or may be misleading:<br>"values provided may not represent the most current values available" is misleading in that if more current values were available from a higher- tier source they would have been used;<br>value "has had some form of agency review, but does not appear on IRIS" is a given because IRIS is a Tier 1 source and would have been used if available; and<br>values "should be used only if no dose-response value is available from IRIS or NCEA" is also a given because IRIS and NCEA are Tier 1 and Tier 2 sources.<br>HEAST's last publication date was not actually noted in the paragraph, but again, if more current values were available from a higher-tier source they would have been used.<br>In addition, the only two chemicals in the HHRA with toxicity values from HEAST are TCDD-TEQ/PCB-TEQ and copper. The HEAST paragraph raised the questions that values from HEAST "may not represent the most current values available" and "may not have been generated through the Agency Work Group process", but did not answer those questions in regard to the two chemicals for which HEAST was used. Uncertainties associated with the specific Tier 3 toxicity values used in the HHRA (including these two chemicals) are discussed in Section<br>7.3.6 of the report, and that discussion is more useful than the description here of HEAST. Remove the paragraph on page 5-3 regarding HEAST. | Per Region 2's verbal approval provided in a 2/14/2017 conference call with CPG, the text was revised as follows:<br><br>"HEAST formerly was published annually by the USEPA, with the last publication in 1997; because HEAST is no longer updated regularly, the dose-response values provided may not represent the most current values available. HEAST values used in this BHHRA include the cancer slope factor for TCDD-TEQ and the reference dose for copper; see Section 7.3.6 for additional information regarding these Tier 3 dose-response values." |

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| 43 | Page 5-4, Section 5.1 Sources of Toxicity Data, First Full Paragraph and Table | Per response to EPA Specific Comment 87c (10/16/15) on the Draft HHRA and included in December 4, 2015, letter to CPG, two additional STSC references for surrogate values should be included in the last sentence of the paragraph. These should also be added to Section 9.0 References.<br>USEPA 2015: Letter from Superfund Technical Support Center to Marian Olsen dated November 12, 2015. Clarification on the use of male or female relative potency factors to derive surrogate points of departure.<br>USEPA 2015: Letter from Superfund Technical Support Center to Marian Olsen dated November 24, 2015. Inquiry as to whether the cancer risks of chlordane should be evaluated and if relative potency factors can be applied on the finding of hypertrophy for nonachlor.<br>In addition, based on these letters, chlordane relative potency factors should apply only to the noncancer assessment. In the table on page 5-4, change "Chlordane (IRIS) with RPF" to "Chlordane (IRIS)" in the CSF column for cis-Nonachlor, Oxychlordane, and trans- Nonachlor.<br><br>As noted in the CPG's December 10, 2015 email, updating these toxicity values has minimal impact on final noncancer hazard estimates, but more significant impact on cancer risk estimates. Cis-nonachlor and oxychlordane will no longer be considered potential COCs for the LPSRA with the updated instructions for the relative potency factors. | See response to General Comment 4. The references and a discussion of the changes will be included in the revised BHHRA. As the differences in risk and hazard estimates are negligible and have no impact on the conclusions of the BHHRA, the CPG proposes to include a statement to that effect in the text of the uncertainty evaluation, rather than populate the minimal change in risks/hazards through the RAGS D Tables. | The response is partially acceptable. See response to General Comment 4.<br><br>While the differences in risk and hazard estimates are very small, they do lead to cancer risk estimates dropping below $10^{-6}$ and therefore off the COC summary tables. Include a statement in the text as noted in the response and update the COC summary tables consistent with the correct toxicity values. | Completed. |
| 44 | Page 5-4, Section 5.1 Sources of Toxicity Data, Paragraph after Table | The statements regarding the quality of toxicity values is inaccurate and should be removed. The hierarchy provides adequate information regarding toxicity values and further discussion is not needed. Specifically, ATSDR values are externally peer-reviewed and EPA coordinates with ATSDR. This text should be dropped. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 45 | Page 5-4, Section 5.2 Noncarcinogenic Toxicity Assessment | Replace the term "true threshold" with "threshold." | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 46 | Page 5-5, Section 5.2 Noncarcinogenic Toxicity Assessment, Second paragraph | Not clear why the term "In regulatory toxicity assessment" is used. Remove this phrase. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 47 | Page 5-6, Section 5.2 Noncarcinogenic Toxicity Assessment | The text regarding C9-C18 requires clarification that this value is a surrogate value for initial evaluation and needs to be updated with information provided by NCEA. | The text describing the provisional, screening nature of the noncancer toxicity value for C9-C18 TPH will be revised to further clarify that it is surrogate value for initial evaluation. The text already quotes the PPRTV chemical file regarding the uncertainty associated with the screening value and refers the reader to the PPRTV chemical file for more information. If there is specific additional NCEA information of importance, CPG requests that EPA provide this clarification. | The response is accepted pending review of the revised text and no clarification from EPA is needed. | Completed. |
| 48 | Page 5-6, Section 5.3 Carcinogenic Toxicity Assessment | The text regarding the classifications of carcinogens based on the 1986 Cancer Guidelines needs to clarify that these classifications are being used until the chemicals are reassessed under the IRIS program based on the 2005 Cancer Guidelines. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |

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| 49 | Page 5-7, Section 5.3 Carcinogenic Toxicity Assessment | With regard to "narrative descriptions" in the second full paragraph on this page, replace the phrase "has not generally been implemented for chemicals" with "has not yet been implemented for many chemicals." As discussed above, inclusion of narratives requires a re- evaluation of the chemical as part of the IRIS program. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 50 | Page 5-8, Section 5.3 Carcinogenic Toxicity Assessment | Paragraph 2: Third sentence, remove the phrase "as that is the value used in the RSL tables (USEPA 2015b)." Third sentence should read "… a value meeting Tier 3 criteria developed by NJDEP…" Fifth sentence, remove the phrase "As noted in the user's guide for the RSLs (USEPA, 2015b)," | The requested changes will be made. | The response is accepted pending review of the revised text. | Completed. |
| 51 | Page 5-11, Section 5.5.1, Dioxins and Furans | Include reference to U.S. EPA 1996 regarding the CSF for dioxin of 150,000. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 52 | Page 5-15 | Remove mention of RSLs as a source of toxicity values. The hierarchy should be used. Reference EPA's 1993 Relative Potency Evaluation for PAHS as the source of the carcinogenic PAH toxicity values. | The reference for the CSF for BaP in the table on this page is a typographical error, and should be USEPA 2015a (IRIS). The 1993 RPF guidance is already referenced in the paragraph above the table as well as in the table header. | The response is partially acceptable. In addition to correcting the noted typographical error, remove the second sentence below the table: "The USEPA RSLs for carcinogenic PAHs were derived based on carcinogenic potential only." | Completed. |
| 53 | Page 6-1, Footnote 40 | Add the following to the end of the footnote "However, ORD/NCEA is re-considering the appropriateness of updating this factor for purposes of calculating lifetime average daily dose, and the standard default exposure assumption for lifetime remains 70 years (USEPA 2014a)." | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |

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| 54 | Page 6-1, Section 6.1 Carcinogenic Risk Characterization | Remove the discussion regarding background cancer risk levels based on the American Cancer Society. | The excess lifetime cancer risk (ELCR) is the likelihood, over and above the "background cancer rate" that an individual will develop cancer in his or her lifetime. The discussion provides relevant context for understanding the magnitude of background cancer incidence in the U.S. In other comments, EPA has directed that the magnitude of potential risks needs to be transparently discussed. Furthermore, this discussion was included in the previous version of the BHHRA, with no comment on the first draft. The CPG does not agree that the discussion of background cancer incidence in the U.S. should be removed. | EPA mistakenly left out a comment on the previous version of the BHHRA requesting that the statement in the HHRA regarding background levels of cancer in the U.S. population (Page 6-1, Section 6.1. Carcinogenic Risk Characterization) be deleted. EPA Region 2 does not include this information in other site-specific risk assessments since this statement does not capture the complexity of evaluating contributors to cancer risks (e.g., voluntary risks such as smoking, diet, or sun exposure vs involuntary risks such as chemical exposures), nor does it provide adequate information for the reader regarding the risks from various environmental exposures so that the reader can place the information in context. This type of information is not identified in the summary statement presented in this section of the HHRA the HHRA is not the place for this discussion.<br><br>Conversely, it is entirely appropriate that the magnitude of potential risks associated with exposure to CERCLA chemicals at this site be transparently discussed in this CERCLA risk assessment. Further, by law (40CFR300.430), EPA is required to consider site risks in the following context, rather than the context of the general cancer incidence in the U.S.: "For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between $10^{-4}$ and $10^{-6}$ using information on the relationship between dose and response. The $10^{-6}$ risk level shall be used as the point of departure for determining remediation goals for alternatives when ARARs are not available or are not sufficiently protective because of the presence of multiple contaminants at a site or multiple pathways of exposure."<br>Remove the discussion regarding background cancer risk levels based on the American Cancer Society. | The CPG maintains that referencing the overall U.S. cancer incidence rates for males and females provides context for understanding the additional incidences of cancer associated with exposure to site-related contaminants. However, per EPA's directive in the 1/25/2017 email from Jennifer LaPoma (EPA) to Rob Law (de maximis), the reference to U.S. cancer risk levels based on the American Cancer Society has been struck. The first paragraph in Section 6.1 reads as follows:<br><br>"The purpose of carcinogenic risk characterization is to estimate the upper-bound likelihood that a receptor will develop cancer in his or her lifetime as a result of exposure to a chemical in environmental media. This likelihood is a function of the dose or concentration of a chemical (described in the Exposure Assessment, Section 5.0) and the toxicity values, the CSF (described in the Toxicity Assessment, Section 4.0) for that chemical. The Excess Lifetime Cancer Risk (ELCR) is the incremental likelihood of contracting cancer due to exposure to site-related chemicals. The terms "excess" and "incremental" imply the risk is due to environmental chemical exposure above that experienced by a population in the course of daily life." |
| 55 | Page 6-3, Section 6.2 Noncarcinogenic Risk Characterization | Change from "noncarcinogenic risks" to "noncarcinogenic hazards." Change title to Noncarcinogenic Hazard Characterization.<br>Please remove "NCP" before goal of protection in the last paragraph of Section 6.2. The NCP specifically addresses the risk range and not the noncancer hazard. Please also make this same change to the second bullet on page 6-25 and anywhere else in the document this phrase has been used. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 56 | Page 6-3 and 6-4,<br>Section 6.2.1 Risk Characterization for Lead | Page 6-3, Second sentence of Section 6.2.1: Change "target blood lead level" to "USEPA's blood lead level of concern."<br>Page 6-3 to 6-4, Third sentence of Section 6.2.1: change "USEPA regulatory target" to "USEPA risk reduction goal."<br>Footnote 41: Change "Centers for Disease Control (CDC)" to "Centers for Disease Control and Prevention (CDC)" | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 57 | Page 6-4, Section 6.3 Risk Characterization Results | Please revise the first sentence of the first paragraph to read as follows: The results of the risk characterization are presented below by receptor, highlighting risks exceeding $10^{-4}$ and/or a non-cancer HI greater than 1. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |

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| 58 | Page 6-4, Section 6.3.1 Recreational Angler | The discussion of crab consumption needs to acknowledge that Burger did identify crab consumption in the survey that was used to derive the consumption rate. Add the following to the end of the first paragraph: "Crab consumption rates assumed in this evaluation are based on anglers who catch and consume crabs from the Newark Bay Complex, which includes tidal portions of rivers (Burger 2002)." | The requested change will be made with the specification that the tidal portions of the Hackensack River, Arthur Kill, and Kill van Kull were included, consistent with comment 31. | The response is accepted pending review of the revised text. | Completed; see response to Comment 25. |
| 59 | Page 6-5, Section 6.3.1.1 Recreational Angler – Young Child | Remove "applicable NCP benchmarks". Please replace the "NCP risk range and the goal of protection of an HI=1" | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 60 | Page 6-24, Section 6.3.6 Lead Risk Characterization | The adult lead methodology available at: https://www.epa.gov/superfund/lead-superfund- sites-frequent-questions-risk-assessors-adult-lead-methodology should be cited in place of the reference to Bowers et al. (1994). The Adult Lead Methodology documents are the basis for the evaluation of lead exposures to adults. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 61 | Page 6-24, Section 6.3.7 Risk Characterization Summary | The Risk Characterization Summary should specifically identify the risks exceeding the risk range and goal of protection for non-cancer and the associated chemicals. The reader should not be referred to a Table to find the results of the assessment. At a minimum the key risk pathways should be identified before the discussion of the relative percent contributions of the individual chemicals to the total risk or hazard. | The risk/hazard estimates are presented in the sections immediately preceding the summary section. To minimize repetition, the ranges of risk/hazard estimates will be added to the Summary section. | The response is accepted pending review of the revised text. | Completed. |
| 62 | Page 6-30, Section 6.4 Potential COC Identification | Remove term "target endpoint" and replace with "target organ effect." | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 63 | Page 6-31, Potential COC Identification, Unnumbered Table | The third paragraph on page 6-30 indicates that for each medium and exposure route, potentially carcinogenic potential COCs are presented in these potential COC summary tables according to the following cancer risk range categories: greater than 10-4, greater than 10-5 and less than 10-4, greater than 10-6 and less than 10-5. And an HI greater than 1 and an HI greater than 0.1 and less than 1. However, the unnumbered table on page 6-31 is not a clear presentation of the potential COCs and the media of concern that exceed the risk range and the noncancer goal of protection of an HI=1.<br>In order to address this, please replace the summary table on page 6-32 with a table that includes chemicals by media greater than $10^{-4}$, greater than $10^{-5}$ and less than or equal to $10^{-4}$, greater than $10^{-6}$ and less than or equal to $10^{-5}$. And an HI greater than 1 and an HI greater than 0.1 and less than 1 in this section. | The text table on page 6-31 will be replaced with a summary table that specifies potential COCs by risk/hazard category. | The response is accepted pending review of the revised text/table.<br>Note that with regard to the chemicals discussed in General Comment 4, this summary table should reflect risks/hazards using the corrected toxicity values (i.e., if the updated cancer risk is less than $10^{-6}$, the chemical should not be listed here as a potential COC). | Completed. |
| 64 | Page 6-32, Section 6.4 Potential COC Identification | The last paragraph of Section 6.4 on page 6-32 includes information not necessary for the risk characterization section of the BHHRA. EPA has provided language to replace this paragraph below:<br>Please revise the last paragraph of Section 6.4 to read as follows:<br>Additional factors considered in the identification of potential COCs include contributions from background sources described below. Section 6.5 provides details regarding this evaluation.<br>In addition, overall uncertainties associated with the four steps of the risk assessment process that may also be considered in the evaluation of potential COCs are provided in Chapter 7 of the BHHRA. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |

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| 65 | Page 6-33, Section 6.5 Background Evaluation | Remove term "target endpoint" and replace with "target organ effect." | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 66 | Page 6-34, Section 6.5.1 Summary of Regional Background Data Sets, Table | Correct the number of accessible surface sediment samples from the 2008 LRC Program from "6 samples" to "2 samples", consistent with the number of data points from this program used in Appendix L. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 67 | Page 6-34, Section 6.5.2 Regional Background Risk Evaluation, Third Bullet and Footnote 43 | For estimation of background risks associated with direct contact with sediment, the BHHRA only discusses cancer risks for comparison to the LPRSA. For this exposure pathway, noncancer hazards were more of an issue for the LPRSA than cancer risks (i.e., cancer risks were less than 1 x $10^{-4}$ but HI was greater than 1), and should also be included in the comparison to background. Change the end of the third bullet from "cancer[43]" to "cancer and noncancer" and remove footnote 43. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 68 | Pages 6-39 to 6-40, Section 6.5.2.4 Regional Background Risks for Direct Contact with Surface Sediment | Add a noncancer assessment to this section.<br>Remove the last sentence of the paragraph just before the sediment risk tableon page 6-39.<br>Add a subsection for noncancer sediment hazards on page 6-40. | The requested changes will be made. Please note that Table L-28 already includes the noncancer hazard calculation. | The response is accepted pending review of the revised text. | Completed. |
| 69 | Page 6-40, Section 6.5.2.5 Summary of Regional Background Risks | Remove the phrase "risks posed by" from the first sentence. It should state that "the levels of potential COCs … pose cancer risks…" not that "… the risks posed by the levels of potential COCs … pose cancer risks…"<br>Change the discussion in the second paragraph to include consideration of noncancer hazards from direct contact with sediment rather than just cancer risks. | The requested changes will be made. | The response is accepted pending review of the revised text. | Completed. |
| 70 | Page 7-1 | Replace "due to lack of absolute scientific knowledge" with "due to both variability and uncertainty in exposure patterns of human receptors and toxicity of chemicals."<br>Remove the term "regulatory" from "regulatory risk assessment." | The requested changes will be made, with the following modification: "due to both variability and uncertainty in risk assessment parameters, such as exposure patterns of human receptors and toxicity of chemicals." | The response is accepted pending review of the revised text. | Completed. |
| 71 | Page 7-7, Exposure Scenario Assumptions | Second complete paragraph: Consistent with General Comment 8, remove the first two sentences of this paragraph, from "USEPA Region 2's directive…" through "…(USEPA 2014a)." | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 72 | Page 7-7, Section 7.2.1.1 Sediment and Surface Water Exposures | Add the following sentences after the first paragraph: "As noted in Section 6, direct contact with sediment and surface water are minor contributors to total cancer risks, posing sitewide and segment-specific risks within or below the NCP risk range. Similarly, direct contact with these media are minor contributors to cumulative noncancer hazard, posing sitewide and segment-specific HIs below 1, with the exception of RM 6-9 and RM 6-9 East Bank in particular." | The requested sentence will be added. | The response is accepted pending review of the revised text. | Completed. |
| 73 | Page 7-9, Section 7.2.1.1 Sediment and Surface Water Exposures | Remove "NCP benchmarks". Use term "NCP risk range" and for non-cancer refer to exceeding the goal of protection of a HI=1. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 74 | Page 7-9, Section 7.2.1.2 Fish and Crab Consumption Exposures, First Paragraph | Per response to EPA Specific Comment 124 (10/16/15) on the Draft HHRA, add text here stating that urban populations often have less opportunity to travel to more desirable locations for recreation. | Ability to travel was added to the first paragraph in 7.2.1.1, which presents a general discussion of factors that may affect recreational activities and site choices. The requested change will be made to the first paragraph in 7.2.1.2, replacing the speculative term "often" with "may". | The response is accepted pending review of the revised text. | Completed. |

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| 75 | Pages 7-10 through 7-13, Section 7.2.1.2 fish and Crab Consumption Exposures | Per response to EPA Specific Comment 127a (10/16/15) on the Draft HHRA, the text needs additional clarification that the Burger survey was for the Newark Bay Complex and not Newark Bay alone. These pages still mention "Newark Bay trips," "Newark Bay fish consumption," and "Newark Bay anglers." Locations surveyed by Burger (i.e., the Newark Bay Complex) also included tidal portions of waterways adjacent to Newark Bay. | The first sentence under "Fish Consumption Rate" states that the Burger survey was based on the Newark Bay Complex. The 4th sentence in the 2nd paragraph also states that the anglers were intercepted in the Newark Bay Complex, as does the first line in the last bullet on page 7-10. To provide additional clarity, "Complex" will be added to the remaining instances of "Newark Bay" on the referenced pages. | The response is accepted pending review of the revised text. | Completed. |
| 76 | Page 7-10, Fish Consumption Rate, Second Paragraph, Fourth Sentence | Change "A total of 61 consuming anglers in the Newark Bay Complex were intercepted once…" to "A total of 65 consuming anglers in the Newark Bay Complex were intercepted and interviewed once…" A total of 65 anglers were interviewed and the number dropped to 61 anglers only after USEPA removed 4 outliers. Add a footnote after the edited phrase: "Burger (2002) noted that they saw the same people at the survey locations from time to time but each person was interviewed only once for the study." | The requested changes will be made. | The response is accepted pending review of the revised text. | Completed. |
| 77 | Page 7-10, Fish Consumption Rate, First Bullet | The mean portion size noted here of 11.7 ounces was reported in Burger (2002), but does not reflect the mean portion size in the data used to estimate the fish consumption rate after outliers were removed.<br>The second sentence should be revised to "… mean portion size reported by consumers *in Burger (2002)* of 11.7 ounces…" (text italicized here to indicate addition).<br>In addition, add the following text after the second sentence: "USEPA's analysis of the raw Burger (2002) data identified and excluded four records because the respondents estimated a serving size greater than 30 ounces per meal. The mean portion size was 7.45 ounces for the 61 respondents from the Burger (2002) raw data that were used to estimate the fish consumption rates in this report; this portion size is consistent with the other surveys mentioned above." | The requested changes will be made. | The response is accepted pending review of the revised text. | Completed. |
| 78 | Page 7-12, Table | Per response to EPA Specific Comment 127b (10/16/15) on the Draft BHHRA, a table of fish ingestion rates used in other Region 2 HHRAs has been added to the report. However, this table is limited to just four recent sites and presents an incomplete picture. Figure 3 from the Fish and Crab Consumption Rates memo (USEPA 2012; page 3709 in the Appendices pdf file) has a more complete listing, showing values for 15 sites in Region 2 going back to 1990. Refer the reader to the figure for additional information. In addition, add a footnote below the table:<br>Ingestion rates of 25 and 26 g/day in the table were based on a recommended default fish ingestion rate from USEPA 1997 that is no longer recommended as a default in USEPA 2011. | The requested changes will be made. | The response is accepted pending review of the revised text. | Completed. |

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| 79 | Page 7-12, Fish Consumption Rate, Last Paragraph, Fourth Sentence | This sentence references the BHHRA for the Lower Duwamish River. However, the consumption rate assumed for a site in Washington State (Lower Duwamish River) is not directly relevant to a site in the northeast region of the United States. As stated in the Exposure Factors Handbook (USEPA 2011) with regard to fish intake,<br>"…available data are limited to certain geographic areas and cannot be readily generalized to the U.S. population of freshwater recreational anglers as a whole… For example, factors associated with water body, climate, fishing regulations, availability of alternate fishable water bodies, and water body productivity may affect recreational fish intake rates."<br>Remove the sentence (fourth sentence of paragraph). | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 80 | Page 7-13, Crab Consumption Rate | First paragraph, last sentence, replace with "There is uncertainty in this ingestion rate."<br><br>In addition, as previously noted, references to the area of the Burger (2002) study should state "Newark Bay Complex" and not just "Newark Bay." | The requested change will be made. However, CPG continues to assert there is considerable uncertainty in the appropriateness of the crab consumption rate for the LPRSA both now and in the foreseeable future.<br>The references to Newark Bay will be updated to include "Complex" as requested. | The response is accepted pending review of the revised text. | Completed. |
| 81 | Page 7-14, Crab Tissue Type Consumed | This subsection just mentions how risks are expected to change with assumptions about crab tissue type consumed, but these risks are actually quantified later in the report. Move the second paragraph from page 7-17 (starts with "Many anglers consume only the crab muscle…") to this section. Also, identify the HI values that exceed 1 in the moved text. | The requested changes will be made. | The response is accepted pending review of the revised text. | Completed. |
| 82 | Page 7-15, Section 7.2.1.2 Fish and Crab Consumption Exposures, Cooking Loss | Paragraph following table. In the sixth sentence, beginning with "Despite the variability…" change "…cooking loss factor in the assessment…" to "…cooking loss factor in the CTE assessment…" | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 83 | Page 7-18, Section 7.2.1.4, Consumption of Other Biota | In Paragraph 1, please add the following sentence after the first sentence on this page. "Some of these biota, such as ducks and turtles, are fattier than fish or crabs and therefore may carry heavier burdens of PCBs/TCDD." | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 84 | Page 7-22, Section 7.2.2.2 Uncertainty in Sediment EPCs | The discussion of the sediment EPCs based on a one mile segment requires further clarification. Please note "in Three-Mile Segment" in the final column of the table. Add the following to the text just before the final sentence of this section: "Similar results for one-mile segments are expected for the other receptors with sediment direct contact exposure (e.g., adolescent waders and swimmers, young child waders)." | The requested changes will be made. | The response is accepted pending review of the revised text. | Completed. |

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| 85 | Pages 7-25 to 7-30,<br>Section 7.2.3 Estimation of Exposure Dose | The text should also indicate EPA's process and guidance that allows the evaluation of relative bioavailability of chemicals; however, data on bioavailability for the COPCs was not available to allow the modifications in bioavailability as was done for arsenic. In the first sentence, insert "where data are available," before "…absorption adjustment factors…"<br><br>This whole section, including subsections 7.2.3.1 and 7.2.3.2, focuses on issues of uncertainty in bioavailability from sediments (both dermal and oral), without putting those issues in the context of site risk estimates: direct human contact with sediment, whether through dermal contact or incidental ingestion, is a relatively minor contributor to total risk for the LPRSA . For sediment exposures, cancer risks did not exceed the NCP risk range and noncancer hazard estimates only exceeded the goal of protection of an HI of 1 in a limited section of the river (i.e., RM 6-9, with maximum HI of 5), primarily due to TCDD-TEQ. The introduction to this section should provide this context. EPA would accept editing this section as indicated in these comments or removing it completely because it does not have bearing on the most significant risks for the LPRSA. | Text will be added to the end of the first paragraph of 7.2.3 as follows: " USEPA guidance allows for the site-specific evaluation of relative bioavailability of metals and TCDD (USEPA 2007, 2010e, 2015m); however, site-specific data were not available to support quantitative modification of default bioavailability factors. Therefore, the uncertainty associated with default estimates of bioavailability and dermal absorption is discussed qualitatively."<br>USEPA. 2007. Guidance for Evaluating the Oral Bioavailability of Metals in Soils for Use in Human Health Risk Assessment. OSWER 9285.7-80.<br>USEPA. 2015m. Soil Dioxin Relative Bioavailability Assay Evaluation Framework.<br>The change to the first sentence of the section will be made.<br>The changes to subsections 7.2.3.1 and 7.2.3.2 are discussed below in responses to Specific Comments 85 and 86, respectively. | The response is accepted pending review of the revised text. | Completed. |

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| 86 | Pages 7-26 to 7-29,<br>Section 7.2.3.1 Default Dermal Absorption Fractions | This section should discuss this topic in the context of the risks/hazards for the LPRSA.<br><br>Make the following edits to this section:<br>Change the second sentence in this section (page 7-26) to "The default DAF for PAHs may be overestimated and a lower DAF could be used for TCDD-TEQ for areas with high foc."<br>Insert the following after the second sentence: "Using the default DAFs, no dermal exposures to LPRSA sediment contributed significantly to estimated cancer risks or noncancer hazards. Cancer risks from sediment exposures were all below $10^{-4}$, and primarily from incidental ingestion. Noncancer hazards from sediment exposure only exceeded an HI of 1 in RM 6-9 and RM 6-9 East (HI of up to 5), again primarily from incidental ingestion. Even in these areas, dermal HIs were less than or equal to 1. Estimated cancer risks and noncancer hazards from dermal exposure to sediment could be even lower in non-default DAFs are considered.<br>Remove the phrase "and oral absorption" from the next sentence (previously the third sentence) because this section focuses on dermal absorption factors.<br>TCDD-TEQ – Add the following text after the table on page 7-27: "While a lower DAF may be applicable if accessible areas with sediment foc > 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."<br>PCBs – Remove this subsection from pages 7-27 to 7-28. Cancer risks from dermal contact with PCBs in sediment never exceeded $10^{-6}$ and noncancer hazards were well below an HI of 1.<br>PAHs – Add the following text at the end of this subsection on page 7-28: "However, it is important to note that estimated cancer risks and noncancer hazards from dermal exposures to PAHs in sediment are already within the NCP risk range and below the goal of protection of an HI of 1." | 1. CPG proposes to retain PCBs in the second sentence and note that the subsequent discussion focuses on PAHs and TCDD as sediment dermal contact risks/hazards for PCBs were below $10^{-6}$ and an HI of 1. The discussion of alternative dermal absorption factors for PCBs will be removed.<br>The revised change will be made ("in" will be changed to "if" in the last sentence).<br>The requested change will be made.<br>Per CPG response (b) above, this statement has already been added to the beginning of this section; CPG believes the addition of this statement again (one paragraph later) is unnecessarily redundant.<br>Per CPG response (a) above, this subsection will be removed.<br>Per CPG response (b) above, this statement has already been added to the beginning of this section; CPG believes the addition of this statement again is unnecessarily redundant. | Acceptable.<br>Acceptable.<br>Acceptable.<br>**U**nacceptable. This statement, specifying the risk/hazard associated with TCDD-TEQ in sediment, is not included in (b) at the beginning of the section, and should be added to the TCDD-TEQ subsection.<br>Acceptable.<br>Unacceptable. This statement, specifying the risk/hazard associated with PAHs in sediment, is not included in (b) at the beginning of the section, and should be added to the PAH subsection. | Completed. |
| 87 | Page 7-29, Section<br>7.2.3.2 Oral Bioavailability | As noted in Comment 146 (10/16/15) on the Draft BHHRA, EPA continues to be concerned with presentation of scientific studies that have not been reviewed by the agency to support oral bioavailability factors for chemicals other than arsenic, especially for chemicals that are not even identified in the BHHRA as potential COCs for direct contact with sediment (i.e., PCBs and arsenic).<br><br>See Attachment B for revised text for this section that is to be incorporated in the revised draft BHHRA. | As noted in CPG's prior response to EPA Specific Comment 146 on the Draft HHRA, CPG disagrees with EPA's contention that uncertainty evaluations should not reference values and/or scientific studies that have not been reviewed by the agency. This view is contrary to agency guidance (USEPA 1995b, 2000, 2005b) which supports full and transparent discussion of uncertainties, including data gaps in knowledge and alternative views.<br>Dioxin is identified as a COC for direct contact with sediment, as the HI exceeded 1 for the RM 6-9 East Bank area due to TCDD-TEQ, primarily from ingestion exposure. CPG proposes to focus the oral bioavailability discussion on dioxin and remove the discussions of alternative bioavailability values for other COPCs. EPA's replacement text for 7.2.3.2 is acceptable with minor proposed revisions, as shown in EPA's Attachment B in redline strikeout. | The proposed revisions to 7.2.3.2 as shown in Attachment B in redline strikeout are accepted, with the following minor edit:<br><br>Change<br>"However, the available studies suggest there is strong evidence that oral absorption is less than 100% (USEPA 2010e, 2015m)."<br>to<br>"However, the available studies suggest there is evidence that the relative bioavailability from soil or sediment is less than 100% (USEPA 2010e, 2015m)." | Completed. |

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| 88 | Pages 7-30 through 7-39, Section 7.3 Toxicity Assessment through Section 7.3.3 | EPA's previous comments highlighted that the text should reference the Cancer Guidelines and the non-cancer RfD/RfC Guidance. Changes are recommended based on the Cancer Guidelines and RfD/RfC guidance and the updates to the IRIS agenda regarding the reassessment of cancer toxicity of dioxin. The issue is that although the revised text quoted the documents it also included information that is contradictory to what is said in the EPA Guidance/Guidelines. At this point, as the document is going final, the text should be consistent with EPA's Guidance/Guidelines.<br>See Attachment C for revised text for this section that is to be incorporated in the revised draft BHHRA. Additional comments regarding some of the revisions to text within this section are provided below. | CPG does not agree that the text in the Revised Draft BHHRA was inconsistent with EPA's guidance/guidelines. Please see CPG's responses to specific comments below.<br>EPA's replacement text for Sections 7.3.1 and 7.3.2 is acceptable with minor proposed revisions, as shown in EPA's Attachment C in redline strikeout | The proposed revisions to 7.3.1 and 7.3.2 as shown in Attachment C in redline strikeout are accepted. | Completed. |
| 89 | Page 7-30, Section 7.3 Toxicity Assessment, Paragraph 1 | In Paragraph 1, the statement regarding the Cancer Guidelines indicates the evaluation of the cancer slope factor only. The text needs to also indicate the evaluation of the Weight of Evidence for Carcinogenicity as part of the process and as noted in the Cancer Guidelines. The text indicates "and effects assumed to be without a threshold (potentially carcinogenic), although there is increasing scientific evidence that many carcinogens also act via a threshold mechanism." The term "threshold" is inaccurate. Footnote #3 of the Cancer Guidelines indicates the term "linear" is used consistent with the Guidelines in place of the term "threshold". The Guidelines text also indicates that "Estimating thresholds can be problematic; for example, a response that is not statistically significant can be consistent with a small risk that falls below an experiment's power of detection." The Cancer Guidelines do not support the conclusions presented in the LPRSA revised draft BHHRA (December 2015) that "there is scientific evidence that many carcinogens also act via a threshold mechanism." Further the guidelines indicate: "The Agency's more current guidelines for these effects (U.S. EPA 1996a, 1998b), however, do not use this assumption, citing the difficulty of empirically distinguishing a true threshold from a dose-response curve that is nonlinear at low doses."<br>It is recommended that the text indicate: "The Cancer Guidelines highlight the "difficulty of empirically distinguishing a true threshold from a dose-response that is non-linear at low doses". Alternatively, this text can be dropped since we do not have non-linear toxicity values in the LPRSA assessment – the only mention is chloroform, later in this section, which is not a potential COC. The sentence regarding overestimates of risks is inconsistent with the Cancer Guidelines. Specifically, the Guidelines state: "The use of upper bounds generally is considered to be a health-protective approach for covering the risk to susceptible individuals, although the calculation of upper bounds is not based on susceptibility data.<br>Similarly, exposure during some lifestages can contribute more or less to the total lifetime risk than do similar exposures at other times. The dose-response assessment characterizes, to the extent possible, the extent of these variations."<br>Revisions to Paragraph 1 of Section 7.3 based on the Cancer Guidelines are provided in Attachment C. | Use of the term "threshold" is not inaccurate. Footnote #3 of the 2005 Cancer Guidelines explicitly states that "the term "nonlinear" refers to threshold models (which show no response over a range of low doses that include zero).<br>The reference to "more current guidelines for these effects (USEPA 1996a, 1998b)" refers to USEPA's guidelines for reproductive toxicity and neurotoxicity not cancer risk assessment.<br><br>The Cancer Guidelines acknowledge that the approaches used are intended to be "health protective" to address uncertainty in the absence of complete information. More often than not, the outcome of health-protective approaches is risk estimates that are more likely to over than underestimate any actual risk.<br><br>EPA's replacement text for the first paragraph of Section 7.3 is acceptable with minor proposed revisions, as shown in EPA's Attachment C in redline strikeout | The proposed revision to the first paragraph of Section 7.3 as shown in Attachment C in redline strikeout is accepted. | Completed. |

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| 90 | Pages 7-30 to 7-31,<br>Section 7.3 Toxicity Assessment, Paragraphs 2 through 4 | These paragraphs were in Section 5.1 in the June 2014 Draft BHHRA and moved to the uncertainty section, per response to Comment 84 (10/16/15). However some edits and additional information should be provided based on the relevant guidance mentioned in that comment/response.<br>**Paragraph 2**: This paragraph focuses on limitations in the application of animal study results to predicting human dose-response relationships. The Cancer Guidelines (USEPA 2005b) provide additional insights into how animal study information is weighed by EPA, and some points from the guidelines should be added here.<br>**Paragraph 3**: Change from term conservative to "health protective." Remove reference to "Sections 5.3 and 5.4 below" which is artifact from the text's earlier location in the report.<br>**Paragraph 4**: The text refers to a 1989 guidance and needs to be updated to reflect the current guidelines/guidance.<br>See Attachment C for revised text for this section that is to be incorporated in the revised draft BHHRA. | EPA's replacement text for paragraphs 2 through 4 of Section 7.3 are acceptable with minor proposed revisions, as shown in EPA's Attachment C in redline strikeout | The proposed revisions to paragraphs 2 through 4 of Section 7.3 as shown in Attachment C in redline strikeout are accepted. | Completed. |
| 91 | Pages 7-34 through 7-39, Section 7.3.3 Uncertainty in TEF Approach | Nearly 5 pages of the uncertainty section are devoted to discussing the TCDD TEQ Approach (USEPA 2010) as applied to dioxin and PCB data for this project. It is agreed that areas of uncertainty exist within the TCDD TEQ Approach. However, missing from the text is the acknowledgement that this approach, since first introduced in the 1980's:<br>Has been the focus of intensive scientific scrutiny<br>Has been improved and strengthened over the years by incorporating newer scientific studies as they became available and through World Health Organization (WHO) consensus regarding congener-TEF assignments provided by leading experts regarding toxicity of dioxin and dioxin-like compounds (DLCs)<br>In current form, is considered standard practice nationally and internationally for use in risk assessments involving dioxin and DLCs<br>In short, the TCDD TEQ Approach has substantial scientific standing and is considered the best tool available for assessment of dioxins and DLCs in CERCLA risk assessments.<br>Section 7.3.3 must affirmatively acknowledge the validity and applicability of the TCDD TEQ Approach for use in the subject BHHRA.<br>See Attachment C for revised text for this section that is to be incorporated in the revised draft BHHRA. | The uncertainty section devotes several pages to this topic because dioxin is the principal risk driver at the LPRSA. PCBs are also discussed because some of the congeners are presumed to also have dioxin-like effects. While the TCDD TEQ approach may be considered standard practice for risk assessment of dioxin- like compounds, there are key uncertainties that should be acknowledged to present a transparent and complete assessment of the TEQ risk. The text has focused on presenting a full and clear discussion of issues related to this important area of uncertainty.<br>EPA's replacement text for Section 7.3.3 is acceptable with minor proposed revisions, as shown in EPA's Attachment C in redline strikeout. This includes re- instating in two places relevant important information on TEF uncertainties that was presented in the Revised Draft BHHRA. | The proposed revisions to 7.3.3 as shown in Attachment C in redline strikeout are accepted, with the following minor edits:<br>Change<br>"The WHO 2005 TEFs were developed using a consensus process of scientific expert panels…"<br>To<br>"The WHO 2005 TEFs were developed using consensus judgement of scientific expert panels…"<br>Change<br>"…spanning a range of at least an order of magnitude…"<br>To<br>"…spanning a range of an order of magnitude…" | Completed. |

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| 92 | Page 7-39 to 7-40,<br>Section 7.3.4 Potential Contribution from Early- life Exposures to Lifetime Risk | Paragraph 1, First Sentence: Remove phrase "and infant (0-1 yr)" from the first sentence because the ADAF approach includes an infant of 0 to <2 years.<br><br>Paragraph 1, after first sentence: The rest of the first paragraph criticizes the default approach for estimating TCE toxicity to non-adult receptors, without putting this uncertainty into context for this LPRSA. Estimated cancer risks from exposure to TCE at the LPRSA never exceeded $10^{-6}$. Remove all of this paragraph after the second sentence.<br><br>Paragraph 2, Final Sentence: The following text requires revisions. "While there is uncertainty in the extent of early life exposures, the available data suggest that in utero and infant exposures to bioaccumulative COPCs via the mother's consumption of LPRSA fish and crab are not contributing appreciably to lifetime risk." Replace the sentence with the following: "The extent to which women of childbearing age are consuming or will consume LPRSA fish and crabs is uncertain." | Paragraph 1, First Sentence: The phrase "and infant (0-1 yr)" was included because the young child receptor evaluated in the BHHRA is a child aged 1 to <7. To clarify, the CPG proposes the following revision:<br><br>Through the use of ADAFs, this BHHRA addresses the few COPCs that are assumed to exert carcinogenic effects via MMOA (i.e., potentially carcinogenic PAH, hexavalent chromium, and TCE), such that all age groups except pre-conception, in utero and infant (0-1 yr) are quantitatively addressed by this BHHRA. Note that the USEPA's ADAF approach does include an infant aged 0 to <2 years; however, this BHHRA evaluates a young child aged 1 to <7, such that the 0 to <1 year infant is not explicitly included.<br>Paragraph 1, after first sentence:<br>The text was not intended as a critique on the USEPA approach, but rather to highlight that the approach taken in the BHHRA is health-protective. The USEPA RSL equations for TCE do in fact differentiate between the mutagenic effects for kidney cancer and the non- mutagenic effects for non-Hodgkin's lymphoma and liver cancer through the use of adjustment factors to the cancer slope factor and inhalation unit risk factor (See Section 5.1.8 of the May 2016 RSL User's Guide (https://www.epa.gov/risk/regional-screening-levels-rsls-users-guide-may- 2016)). Using the approach taken by USEPA for RSL derivation, the potential risks for TCE would be lower than those predicted by the BHHRA. However, since TCE is not a risk-driver, the discussion about TCE will be removed.<br>Paragraph 2, Final Sentence: The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 93 | Page 7-40, Section<br>7.3.5 Use of Surrogate Values | The following sentence needs revision: "The COPCs that required surrogates generally consist of chemicals/groups where the assignment of surrogates is generally accepted, including PAH compounds, DDx isomers, chlordane isomers, endosulfan isomers, butyltins, and TPH ranges."<br>Within this sentence, replace the phrase "where the assignment of surrogates is generally accepted" with the phrase "that have been reviewed by the STSC, and for which the STSC has developed specific surrogate recommendations." | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 94 | Page 7-40, Section<br>7.3.6 Tier 3 Toxicity Values | Replace the text in this section prior to the table with the following:<br><br>"There is uncertainty associated with the toxicity values based on Tier 3 sources due to the variable nature of peer-review and consensus among scientists on the best estimate of toxicity. While most COPCs have Tier 1 or 2 toxicity values, it was necessary to identify Tier 3 toxicity values for six COPCs: organic arsenic, copper, thallium, TPH C9-C18, hexavalent chromium, and TCDD-TEQ. The following table summarizes the relevant exposure and toxicity information for these six compounds; their contribution to the risk results is discussed below." | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 95 | Page 7-43, Section 7.4 Risk Characterization | In Paragraph 1, change "…upper-bound exposure estimates…" to "…upper-bound and average exposure estimates…" | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |

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| 96 | Page 7-43, Section 7.4.1 Risk from Multiple Chemicals | In Paragraph 2, cancer slope factors are mischaracterized as "upper 95th percentile estimates on a COPC's carcinogenic potency" and "upper 95th percentiles of probability distributions." Correct the description to "upper bound estimates of a COPC carcinogenic potency" throughout Paragraph 2. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 97 | Page 7-44, Section 7.4.1, table | Remove arsenic from this table as an example since it is associated with other types of tumors including liver, etc. | The referenced table presents noncancer endpoints. It is not clear why arsenic should be removed. | The response is accepted. No change is needed to the table on page 7-44. | No change. |
| 98 | Pages 7-44 to 7-45, Section 7.4.2 | Change the language in the first sentence to: Generally, the goal of a risk assessment is to estimate risk to the RME individual.<br>Third sentence: Change "extremely conservative (health-protective)" to "health protective, and the majority of people will have a lower level of potential risk."<br>Remove the rest of the paragraph, starting with "For example, …" The example would only be accurate if all the input variables have the same variability and shape, which is rarely the case in actual situations as discussed in EPA's 2004 Office of the Science Advisor Staff Paper on Risk Assessment Principles & Practices (EPA/100/B-04/001). Factors with greater variability (e.g., chemical concentrations, which can vary at the LPRSA by more than 2 orders of magnitude), influence the resulting percentile position much more than factors with more limited variability (e.g., loss of chemicals due to cooking). The staff paper notes that "selecting the mean value for the concentration input value and 95th percentile values for the others will result in a calculated exposure that is much closer to the mean of the resulting distribution than the 95th percentile (or higher), because the resulting distribution is heavily influenced by the concentration input." This statement also holds true when using the 95% UCL on the mean of the concentrations for a robust data set.<br><br>Add the following to the end of the first sentence at the top of page 7-45: "consistent with guidance (USEPA 1989, 1990, 2014). Consequently, the resulting risk estimates are expected to be on the high end of the range of risks but within the range of plausible outcomes."<br>Add the following bullet to the list on page 7-45:<br>95 percent upper confidence limit on the arithmetic mean concentrations of chemicals in fish and crab tissue<br>Revise the bullet regarding cancer slope factors from "95th percentile cancer slope factors" to Upper bound cancer slope factors<br>Add to end of the section:<br>"As stated in the Cancer Guidelines and other guidance documents, within a population a portion will be at the high end of the distribution while risks to the average individual represented by the 50th percentile will be lower. This risk assessment found that the risks to the average individual (i.e., CTE scenarios) still remained above the risk range and/or the goal of protection of an HI = 1."<br>Based on the above comment, Attachment D provides the revised Section 7.4.2 to be incorporated in the revised draft BHHRA | The CPG does not agree that the combined effect of the directive assumptions and approaches used in the BHHRA resulted in risks that are "within the range of plausible outcomes."<br>With regard to the compounding conservatism discussion, it is important to note that most of the key exposure parameters, including concentration, ingestion rate, exposure duration, are lognormal in shape and have similar variability such that the combination of upper-bound assumptions leads to risks that exceed the 95th percentile (Cullen 1994, Burmaster and Harris 1993).<br>Other "baseline" assumptions and approaches that also contribute to the overall pattern of compounding conservatism include the use of an FI of 1, assuming no change in exposure concentrations due to natural attenuation or biodegradation in the future, and the use of upper-bound toxicity values. The very conservative nature of the risk assessment process and resulting risk estimates is generally not recognized.<br><br>EPA's replacement text for Section 7.4.2 is acceptable with minor proposed revisions, as shown in EPA's Attachment D in redline strikeout. | The CPG's response still fails to recognize that the concentrations used in the HHRA are estimates of the mean concentrations, and not upper-bound values. In addition, the response is mistaken in stating that concentrations, varying by more than 2 orders magnitude, have a similar variability to other exposure parameters.<br>The proposed revisions to 7.4.2 as shown in Attachment D in redline strikeout are acceptable, except for removing the phrase "but within the range of plausible outcomes." The phrase must be retained. | Completed.<br><br>Per the 2/15/2017 email from Jennifer LaPoma (EPA) to Rob Law (de maximis), the phrase "within the range of plausible outcomes" was not included in the second sentence of the second paragraph of Section 7.4.2.<br><br>The CPG's request for Region 2's re-analysis of the Connelly et al. (1992) data set is still outstanding. |

| # | Page No. | EPA Specific Comment (8/25/16) | CPG Response (9/26/16) | EPA Response (1/5/17) | CPG Response (3/1/17) |
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| 99 | Page 7-45, Section 7.4.3 Risks to Sensitive Populations | In the last sentence, change "through the use conservative assumptions" to "through the use of health protective assumptions." | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 100 | Page 7-48, Section 7.5 Summary of Uncertainty in BHHRA for the LPRSA | Change the statement "very conservative" to "health protective". | The text will be revised to remove "very" and the phrase "and provide a high degree of health-protectiveness" will be added to the end of the sentence. | The response is partially accepted pending review of the revised text: Change the end of the sentence from "very conservative" to "conservative and health-protective." | Completed. |
| 101 | Pages 8-2 to 8-3, Section 8.1.2 Exposure Assessment | The discussion regarding EPA Region 2 needs to clarify that the values provided to the CPG are consistent with guidance. Also clarify that the RME is the basis for decisions at Superfund sites. | See response to General Comment 2. The text will be clarified to note the RME is the basis for decisions at Superfund sites. | The response is accepted pending review of the revised text. | Completed. |
| 102 | Page 8-3, Section 8.1.3 Toxicity Assessment | Remove the reference to Bowers et al. for the lead exposure. The appropriate references are the IEUBK and Lead Methodology which may incorporate the Bowers work. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 103 | Pages 8-4 through 8-6, Section 8.1.4 tables | Highlight the exceedance of the risk range for individual chemicals on the tables in Sections 8.1.4.1 and 8.1.4.2. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 104 | Page 8-8, Section 8.2 Conclusions | Indicate that the RME is the basis for the decision in appropriate bullets. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 105 | Page 8-10, Section 8.2 Conclusions | Last paragraph, second sentence: Change "conservative" to "health protective." Last paragraph, third sentence: Clarify that the evaluation of risks in the absence of background is consistent with guidance. | The requested changes will be made. | The response is accepted pending review of the revised text. | Completed. |
| 106 | Pages 8-8 through 8-10, Section 8.2 Conclusions | Revise this section per comments provided on the Executive Summary (Section E.3 Conclusions). | See response to Specific Comment 19. | The response is accepted, including the CPG's proposed revisions shown in Attachment A. | Completed. |
| 107 | Table 3-12 | The report is missing Table 3-12, which is listed in the Table of Contents as "Analysis of Tissue COPCs Not Identified as Surface Water or Sediment COPCs." | The table was inadvertently omitted and will be included in the revised BHHRA. | The response is accepted pending review of the revised text. | Completed. |
| 108 | Table 5-1, chemicals using Chlordane as surrogate | Per final response to Comment 87c on the Draft BHHRA (provided in December 4, 2015 letter),<br>Change the RfD for cis-Nonachlor from 1.72E-04 mg/kg-day to 1.04E-04 mg/kg-day. Change the relative potency factor (RPF) in footnote g from 2.9 to 4.8.<br>Change the RfD for trans-Nonachlor from 2.51E-05 mg/kg-day to 1.55E-05 mg/kg- day. Change the RPF in footnote g from 19.9 to 32.2.<br>Footnote g should be updated to include the November 12 and November 24, 2015, letters from STSC to Marian Olsen. | See responses to General Comment 4 and Specific Comment 42. | The response is partially acceptable. See responses to General Comment 4 and Specific Comment 42. | Completed.<br>A reference to STSC's 11/12/2015 letter (which pertains to noncancer) has been added to Table 5-1 footnote (g).<br>A reference to STSC's 11/24/2015 letter (which pertains to cancer) has been added to Table 5-2 footnote (g). |
| 109 | Table 5-2, PCBs | As noted on page 5-12 of the text, the "lowest risk and persistence" CSFs for PCBs were not used in this BHHRA. Remove these two rows from the table, or add a footnote to the table indicating the values were not used in the BHHRA. | The requested change will be made. | The response is accepted pending review of the revised text. | The requested footnote has been added to Table 5-2. |

| # | Page No. | EPA Specific Comment (8/25/16) | CPG Response (9/26/16) | EPA Response (1/5/17) | CPG Response (3/1/17) |
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| 110 | Table 5-2, chemicals using Chlordane as surrogate | Per final response to Comment 87c on the Draft BHHRA (provided in December 4, 2015 letter), chlordane RPFs should apply only to the noncancer assessment and should be removed from this table.<br>Change the cancer slope factor for cis-Nonachlor from 1.02E+00 (mg/kg-day)$^{-1}$ to 3.50E-01 (mg/kg-day)$^{-1}$.<br>Change the cancer slope factor for Oxychlordane from 1.96E+00 (mg/kg-day)$^{-1}$ to 3.50E-01 (mg/kg-day)$^{-1}$.<br>Change the cancer slope factor for trans-Nonachlor from 6.97E+00 (mg/kg-day)$^{-1}$ to 3.50E-01 (mg/kg-day)$^{-1}$.<br>Change footnote g to "Value for chlordane is used as a surrogate based on structural similarity. Letters from Superfund Technical Support Center toMarian Olsen dated August 5, November 12, and November 24, 2015." | See responses to General Comment 4 and Specific Comment 42. | The response is partially acceptable. See responses to General Comment 4 and Specific Comment 42. | Completed. |
| 111 | Tables 6-15 through 6-21, Identification of Potential COCs | Remove cis-Nonachlor, Oxychlordane, and/or trans-Nonachlor from these tables as necessary based on revised risks using the updated toxicity values. Also, add Dieldrin as a potential COC in Tables 6-15, 6-17, and 6-19 for Angler (Adult)/Crab Muscle & Hepatopancreas. | See responses to General Comment 4 and Specific Comment 42. Dieldrin will be added as a potential COC for Adult Angler Crab Muscle and Hepatopancreas in Tables 6-15, 6-17<br>and 6-19. | The response is unacceptable.<br>See responses to General Comment 4 and Specific Comment 42. Chemicals that would not be potential COCs if the correct toxicity values were applied should be removed from the tables summarizing potential COCs. | Completed. Note that trans-nonachlor remains a COC for the RME mixed fish diet for noncancer. |
| 112 | Table 6-21, Summary of Potential COCs By Medium and Scenario | Add an "X" to the table for PCBs (non-DLC) for RME Crab Muscle and Hepatopancreas (based on information in Table 10.7). Add gamma-Chlordane to the table with an "X" for RME Mixed Fish Diet (based on information in Table 10.7) | The "X"s for these constituents were inadvertently left out, and the table will be revised as requested. | The response is accepted pending review of the revised text. | Completed. |
| 113 | Appendix L, pages 1-1 to 1-2, Fourth Paragraph, Second Sentence | Change "The approach used for establishing background concentrations…" to "The approach used for evaluating background concentrations…" | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |
| 114 | Appendix L, Section 3.1 Outlier Identification, Footnote 2 and Final Paragraph of Section | The footnote on page 3-1 states that BaP in surface water is not evaluated further in the background appendix. However, on page 3-3, the final paragraph in Section 3.1 is about BaP in surface water and refers to summary statistics in Table L-10. Either remove the paragraph and Table L-10, or move footnote 2 to follow this paragraph. | The footnote will be moved as requested. | The response is accepted pending review of the revised text. | The footnote has been struck because benzo(a)pyrene is no longer a COC. |
| 115 | Appendix L, page 4-1, Section 4.0 Exposure Point Concentrations for Background Risk and Tables L-15 through L-19 and L-21 through L-24 | Per response to Comment 218 (10/16/15) on the Draft BHHRA, the text should clarify which statistic was used as the EPC.<br>At the end of the first paragraph on page 4-1, insert the sentence "The EPC is the lower of the UCL and maximum detected concentration for data sets with at least 5 detected samples; for data sets with fewer than 5 samples or 5 detects, the EPC is the maximum concentration."<br>In Tables L-15 through L-19 and L-21 through L-24, copy footnote f from Table L-25 and insert the footnote after "Exposure Point Concentrations" in the title. | The requested change will be made. | The response is accepted pending review of the revised text. | Completed. |

| No. | Page No. | Specific Editorial Comments (8/25/16) | CPG Response (9/26/16) | EPA Response -1/5/17 | CPG Response (3/1/17) |
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| 116 | Page 5-2, Section 5.1, Third Bullet | Change the reference for HEAST from USEPA 1997c to USEPA 1997b. | The requested change will be made. | Acceptable. | Completed. |
| 117 | Page 6-35, First Full Paragraph | Change "Appendix J" to "Appendix L" where the background data were checked for outliers. | The requested change will be made. | Acceptable. | Completed. |
| 118 | Page 7-18, Section 7.2.2, Third Paragraph, Third Sentence | Currently reads "Results are provided in Appendix F American eel…" Insert the word "for" after "Appendix F." | The requested change will be made. | Acceptable. | Completed. |
| 119 | Page 7-24, Section 7.2.2.4, Second Paragraph, Last Sentence | Remove the phrase "…surface water, sediment, and…" because Table 7-1 just presents data for tissue. | The requested change will be made. | Acceptable. | Completed. |
| 120 | Page 7-34, Section 7.3.2.3, Second Paragraph, Last Sentence | Change the reference at the end of the sentence from USEPA 2013a to USEPA 2015a. | The requested change will be made. | Acceptable. | Completed. |
| 121 | Page 9-17, References | For USEPA, 2014a, add the following to the end of the citation: "FAQs updated September 14, 2015." | The requested change will be made. | Acceptable. | Completed. |
| 122 | Table 3-11a | The text for locations of maximum concentrations in blue crab tissue were cut off throughout the table. Please revise the row height/width accordingly. | The requested change will be made. | Acceptable. | Completed. |
| 123 | Table 6-2 | Values in this table should match the sitewide values presented in Table 6-8 (for RME) and Table 6-12 (for CTE), but occasionally differ because of the number of decimal places presented (e.g., 0.1 shown rather than 0.09). Please make information in these tables consistent. | The requested change will be made. | Acceptable. | Completed. |
| 124 | Appendix A, List of Tables and Attachments | In the titles for Tables A-1, A-10, and A-19, change "Butylins" to "Butyltins"<br>Add the two new attachments for data usability worksheets to this TOC list | The requested change will be made. | Acceptable. | Completed. |
| 125 | Appendix A, Table A-19 | In the title, change "Butylins" to "Butyltins" | The requested change will be made. | Acceptable. | Completed. |
| 126 | Appendix L, page 2-1,<br>Table L-1 | Correct the number of fish tissue samples from above Dundee Dam. Change "50 fillet samples" to "47 fillet samples" based on the information in later tables (e.g., Table L-4). | The requested change will be made. Additionally, Table L-5 will be revised to remove repeated samples for smallmouth bass and to add a missing sample for northern pike. | Acceptable. | Completed. |
| 127 | Appendix L, Table L-5 | There should only be 3 samples listed for Smallmouth Bass. Remove the repeated samples.<br>Insert the missing Northern Pike sample. | The requested change will be made. | Acceptable. | Completed. |
| 128 | Appendix L, Table L-9 | Footnote j (about "Blue crab – muscle only") is missing. Please add. | The requested change will be made. | Acceptable. | Completed. |
| 129 | Appendix L, Table L-18 | Correct the FOD for Hexachlorobenzene from 3:6 to 3:3. | Hexachlorobenzene was analyzed via two methods, E1699M and SW8270D, such that there are six results.(two for each sample). The results for the SW8270D method were not detected and will be eliminated from the summary statistics and the FOD will be updated to 3:3. Because the minimum, maximum, and mean detected statistics do not include non-detects, and a UCL was not calculated, no other changes are necessary. | Acceptable. | Completed. |
| 130 | Appendix L, Table L-20 | Remove "Largemouth &" from column header for Smallmouth Bass. Correct information in footnotes a through e as follows:<br>American eel EPC selected in Table L-16 (not L-13)<br>Channel catfish EPC selected in Table L-17 (not L-14)<br>Common carp EPC selected in Table L-19 (not L-16)<br>Smallmouth bass EPC selected in Table L-18 (not L-15, and remove Largemouth bass from footnote)<br>White perch EPC selected in Table L-15 (not L-12) | The requested changes will be made. | Acceptable. | Completed. |