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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
WATER AND WATERSHEDS

December 6, 2012

MEMORANDUM

SUBJECT: Formal Dispute on the EPA Notice of Non-Compliance and Directed Revisions to the Portland Harbor Draft Final Baseline Human Health Risk Assessment (BHHRA) and Request for Dispute Resolution; Administrative Settlement Agreement and Order on Consent for Remedial Investigation/Feasibility Study, USEPA Docket No. CERCLA-10-2001-0240 – **Final Resolution**

FROM: Daniel D. Opalski, Director
Office of Water & Watersheds

TO: File

By addressing explicitly the first and second "Issues for Resolution" identified by the Lower Willamette Group in its September 21, 2012 "Opening Submission" and incorporating by reference the Partial Resolution of October 25, 2012, this memorandum serves as the Final Resolution of the above-referenced dispute under the Administrative Settlement Agreement and Order on Consent for Remedial Investigation/Feasibility Study, USEPA Docket No. CERCLA-10-2001-0240 (hereafter "Order on Consent").

A. The first issue, as summarized on page 5 of the "Opening Submission," is as follows:

> "The May 2011 draft final BHHRA was consistent with agreed resolutions of EPA comments and did not violate the Consent Order."

In expanding upon this assertion, the Lower Willamette Group presents a number of arguments, including the following: 1) that the May 2011 BHHRA is, in fact, consistent with agreed resolutions of prior EPA comments; 2) that EPA inappropriately considered both "directed" and "non-directed" comments when evaluating whether the Lower Willamette Group was in compliance with the Order on Consent; and 3) that to the extent EPA's determinations identified deficiencies, the number and/or type of issues identified by EPA as the basis for a determination of noncompliance are "trivial" individually and together in comparison to the overall effort. The Lower Willamette Group urges that these arguments together lead to the conclusion that EPA's finding of noncompliance with respect to the BHHRA was in error. Below, I evaluate each of these assertions in detail.

1) Consistency with Agreed Resolutions

As an initial matter, I have reviewed, in particular, EPA's Exhibit 6, the Lower Willamette Group's "Opening Submission," and pages 7 and 8 of the Lower Willamette Group's October 24, 2012 "Reply." I find sufficient ambiguity in EPA's direction and/or the adequacy of the Lower Willamette Group's

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addressing of the comment to warrant withdrawing Items 1, 12, and 17 from Exhibit 6 as part of EPA's basis for its determination of noncompliance. Specifically, with respect to Item 1, I find that the back and forth communications subsequent to EPA's initial comments appeared to muddle rather than clarify what EPA expected of the Lower Willamette Group for an adequate incorporation of the comment. Regarding Item 12, although the Lower Willamette Group's approach to addressing the comment seemed to miss the mark, in its rewrite EPA did not do a demonstrably better job addressing its own comment and, unlike in the case of several other comments, did not make compensating adjustments elsewhere in the text. This has the effect of calling into question the intent of the original comment. Finally, had EPA provided clear, blanket direction to delete/modify any language similar to "same rate every day of every year for 70 years" as referred to in Item 17, it would have been appropriate to hold the Lower Willamette Group to finding and modifying each instance of such language. It was not unreasonable to expect the Lower Willamette Group to be more thorough in identifying similar language without the need for such blanket direction, but I believe that EPA's failure to state explicitly its expectation warrants the removal of Item 17 from Exhibit 6.

Having removed these three Items (and Item 11, which was withdrawn previously by EPA), however, I find that EPA otherwise has carried its burden of demonstrating deficiencies by the Lower Willamette Group in addressing thirteen prior EPA comments. I make this finding based on my review of the original EPA comments, the language of the May 2, 2012 version of the BHHRA, and representations of the parties' intervening communication about the comments.

2) Directed Versus Non-directed Comments

The Lower Willamette Group argues for a distinction in the significance of "directed" and "non-directed" comments, an argument of potentially greater significance because only one "directed comment" remains as part of the basis for a noncompliance determination. From my review of the comments identified in EPA's Exhibit 6, it is clear that despite how the comments may be labeled, each of the non-directed comments includes directive language that cannot reasonably be read other than to create an expectation that Respondents make a change or modification to address the comment.[1] It seems entirely appropriate and most accurate; therefore, to consider these comments part of "EPA's directions for changes," consistent with the language in Section IX, Paragraph 4 of the Order on Consent, which the Lower Willamette Group argues sets a different enforcement bar. Further, in the Lower Willamette Group's Tab 12, in this instance EPA explicitly communicated that resolving its comments would be achieved by "...addressing all directed and non-directed comments consistent with previous directions and agreements..." This language is unambiguous; it sets forward EPA's expectation that all comments be addressed. This tracks the requirement of Section IX, Paragraph 1 of the Order on Consent: "At EPA's discretion, Respondents must fully correct all deficiencies and incorporate and integrate all information and comments supplied by EPA either in subsequent or resubmitted deliverables within a time frame specified by EPA."

[1] I note that in some cases the non-directed comments are less specific in identifying the changes to be made, but they are nonetheless sufficiently clear in identifying the issue or issues that need to be addressed. In these instances, the quality of a revision turns not on direction regarding specific language, per se, but on whether the issue identified is addressed adequately in the revised language chosen by the Respondents. As a corollary, the nature of "agreed resolutions" of comments that don't direct specific language modifications can also be non-specific, i.e. the commitment is to make changes consistent with the comment without indication of the wording that will be used to meet this commitment. Under this circumstance, assessment of adequacy of a change or resolution has to track back to the initial comment, not the apparent "agreed resolution."

The Lower Willamette Group also cites EPA's practice on the project of delineating between directed and non-directed comments when providing input to the Lower Willamette Group. It is plausible that this approach could have led to a belief that non-directed comments would be considered differently in an enforcement context. However, the Order on Consent does not make this distinction, as EPA points out in its "Response." Nor has the Lower Willamette Group presented any evidence that EPA ever relinquished its rights or remedies under the Order on Consent with respect to the addressing of EPA comments. That EPA has not previously made a finding of noncompliance based on non-directed comments does not bind how the agency may proceed under the Order on Consent. The Lower Willamette Group's perception that EPA has fundamentally changed its approach with this action without appropriate communication has been raised energetically by them, and consistent with the Partial Resolution, further communication on this issue between the parties is warranted. This does not, however, change the basic legal analysis of EPA's discretion to proceed under the Order on Consent.

I believe the Lower Willamette Group has over-read the significance of the distinction between directed and non-directed comments. To the extent a non-directed comment clearly communicates a need for a modification and provides sufficient clarity on what that modification needs to address – as is the case with the comments provided in Exhibit 6 – I find that that Respondents' treatment of both directed and non-directed comments can provide the basis for an EPA determination of Respondents' noncompliance with the Order on Consent.

3) Significance of the Number and Type of Deficiencies

Although the Lower Willamette Group does not agree with EPA's determination of noncompliance, the Lower Willamette Group (essentially) emphasizes that even if EPA believed there were some deficiencies, it was more appropriate in this case for EPA to exercise its enforcement discretion by withdrawing the noncompliance determination. The Lower Willamette Group highlights that in its basis for a determination of noncompliance, EPA identified continued concern with how only 16 of its original 223 comments were addressed in the May 2, 2012 BHHRA. They also state that even for the majority of these 16 comments, EPA's own redraft of the BHHRA does not adopt the revision EPA called for, suggesting relative unimportance of the comments.

In response to a question during oral presentations pursuant to this dispute, the Lower Willamette Group asserted that a finding of noncompliance by EPA should be reserved for when there are egregious deficiencies, restating a position they put forth in their written submissions. This proposed compliance gradation is neither particularly objective nor, more importantly, present in the Order on Consent. As a matter of the numbers, after EPA's withdrawal of Item 11, the comments identified as the basis for EPA's determination of noncompliance represent just over seven percent of the total number of original comments. With further reductions of the list as provided herein, this figure is now less than six percent. This represents substantial progress, as recognized by EPA. On the other hand, the BHHRA has been in the works for a number of years, and during that period there have been numerous oral discussions and written exchanges between the parties regarding comments and issues. In fact, many elements of the BHHRA have been in active discussion from the earliest days of the remedial investigation/feasibility study process at the site, long before the drafting of the BHHRA. So it is reasonable for EPA to expect a very high level of resolution at this point in the process. Part of the rationale for an "all comments addressed" standard is that in any particular instance, the significance of potential deficiencies may be

much less about the number of those deficiencies and much more about the substance to which those deficiencies relate. In this context, though EPA unquestionably has some discretion, EPA's "Response" is correct in asserting that even a single comment being addressed inadequately can be the basis for a determination of noncompliance.

I do not disagree with the Lower Willamette Group's contention that the part of EPA's exercise of its discretion can include consideration of the significance of the substance of a given deficiency/comment. On this point, the Lower Willamette Group alleges that EPA's decision not to incorporate its own previous direction into its June 22, 2012, draft of the BHHRA gave a clear indication of the insignificance of the comments in question. EPA argued that in its substantial rewriting of the BHHRA, it had in several cases made changes in the wording and/or organization of the document that effectively satisfied the original comment without following through with the revision initially envisioned. In other cases, where EPA's initial comments asked for a rationale or explanation to justify certain language included in the draft BHHRA, EPA decided to drop the language altogether rather than struggling to come up with a justification for Lower Willamette Group language EPA was questioning in the first place. These two approaches suggest not that the deficiencies were insignificant, but that there were multiple approaches to resolving them. But more generally, the Lower Willamette Group seems to argue that the comments were not significant enough to provide the basis for a noncompliance determination. However, taken as a whole, nearly all of the deficiencies pointed to a tendency in the original draft toward language that downplays risk or overemphasizes the conservativeness of the risk assessment, a subject about which EPA has provided feedback at both the staff and management levels for several years. This is an area of substantial importance in the assessment, characterization and communication of risks posed by the site. On these bases, I do not find compelling the Lower Willamette Group's argument that EPA's comments lack significance or substance.

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In conclusion, therefore, I affirm that the May 2, 2012, BHHRA failed to address EPA comments, and that this failure was sufficient to justify a finding of noncompliance with the Order on Consent. I do not find sufficient reasons to justify overturning EPA's determination of noncompliance as a matter of enforcement discretion. I leave it to the Director and Associate Director of the Office of Environmental Cleanup to consider as they deem appropriate the discretion available in Section XIX of the Order on Consent with respect to imposition of stipulated penalties.

B. The second issue, as summarized on page 10 of the "Opening Submission," is as follows:

> "Certain of EPA's directed revisions to the May 2011 BHHRA are inconsistent with EPA Guidance."

With respect to this issue, I have the benefit of the progress made by the parties in prior stages of the dispute. As an initial matter, the parties both request that the September 17, 2012, revision of the BHHRA should be adopted, with any changes resulting from this decision to be made to this version to create the final BHHRA. The Lower Willamette Group goes further in requesting adoption of its issue resolution tables (Tables 1 and 2), but there is no agreement between the parties on the specific information in these tables. Regarding Tables 1 and 2, I agree with EPA that the adoption of the Tables

along with the September 17, 2012, version of the BHHRA would be inconsistent given that the Tables were not updated to reflect the latest status of the document. Therefore, I am directing adoption of the September 17, 2012, version of the BHHRA, but not of Tables 1 and 2. What then remains of this dispute are three relatively specific issues, the resolution of which should frame the path to the final BHHRA. I will take these up in the order of their presentation in the Lower Willamette Group's "Opening Submission."

1) "EPA's direction on what constitutes a reasonable maximum exposure is inconsistent with guidance, inconsistent with national policy, and arbitrary and capricious."

The fish consumption exposure scenarios are at the heart of the Lower Willamette Group's contention that EPA's revisions to the May 2011 version of the BHHRA were inconsistent with guidance. Although the Lower Willamette Group takes issue with specific aspects of the scenarios, their fundamental contention is that, by its selection of combinations of key exposure factors, EPA defined reasonable maximum exposure (RME) scenarios that cannot be reasonably expected to occur in the context of the Portland Harbor site. Both parties make fair arguments regarding choices for the key exposure factors, but the uncertainties—acknowledged by both parties but given different weight or merit by them—make it difficult to land too definitively on one answer. Indeed, as correctly pointed out by the Lower Willamette Group, EPA's regulations and guidance do not prescribe a specific RME, but rather provide that the RME must fit within the range of plausible exposures, albeit as a more "conservative" case within this range to insure protectiveness. In this context, the Lower Willamette Group has not provided a convincing case that EPA's RME scenarios are inconsistent with guidance. Regardless, as described in detail below, this final resolution establishes revised RME scenarios that are consistent with EPA regulation, guidance, and national policy.

I also note that the written submissions and the oral presentations in this dispute provide adequate basis for me to conclude that direction regarding the RME scenarios was not arbitrary and capricious, as alleged by the Lower Willamette Group. I have addressed the alleged inconsistency with guidance, and the record otherwise reflects a deliberate and clear rationale for EPA's direction, including consideration of perspectives presented by the Lower Willamette Group.

Given that this has already been a lengthy process, I believe it advisable for me to make decisions regarding fish consumption scenarios rather than allowing more time for the parties to work toward resolution. Although the exact RME scenarios may be relatively new as concrete proposals, the building block information has been available for quite some time and there has been ample opportunity for input and information exchange. Therefore, working from the exchanges of proposals during the informal dispute period and the Lower Willamette Group's November 13, 2012, response to my questions following on the oral presentations, I will focus separately on the recreational and subsistence fisher scenarios. There is some interplay in the selection of values for the various factors that are combined to create the overall exposure scenario, but at this point the ranges of differences are such that I can focus on areas of remaining differences only and be assured that the scenarios are consistent with guidance. The agreed 30-year duration of exposure and assumption of no effects from preparation/cooking methods will be applied for both the Recreational and Subsistence Fisher scenarios.

A) Recreational Fishers

Consumption Rate: The 17.5 g/day rate, considered in the guidance as an average rate for sport fishers, represents a good fit for the central tendency (CT) scenario. However, particularly because the 17.5 g/day rate comes from a survey of both consumers and non-consumers, this rate doesn't fit logically in the design of an RME. EPA has relied upon the Columbia Slough creel survey in proposing a 73 g/day consumption rate, using the assumption of 75 percent of the body weight of the fish. Because the survey results support the notion that some fishers near Portland Harbor sometimes consume more than just the fillet (estimated at 30 percent of the body weight), using a consumption value higher than that for fillet alone seems reasonable as part of an RME to account for this variation in the portion of the fish consumed. As EPA acknowledges in its "Response," information from numerous other fish surveys suggest sport fishers primarily consume fillets. Taking this collection of inputs into account, I turn to the Columbia Slough survey results' presentation of rates for consumption at a midpoint, where 50 percent body weight consumption is assumed. From this information I direct the use of a consumption rate of 48.9 g/day, which equates to approximately 6.5 meals per month. I note that this rate may, in fact, underestimate the rate for some recreational fishers based upon the survey, but this midpoint value strikes a reasonable balance given the limitations of the creel survey.

Tissue Type: In commenting on EPA's proposed RME fish consumption rate, and specifically in proposing a rate of 29 g/day, the Lower Willamette Group suggests that if one relies upon the Columbia Slough survey, the consumption rate value should be aligned with the assumption of the tissue type. Seeing the logic of this comment, I am inclined to require the use of an explicit "mixed diet" as part of the scenario, e.g. 2 meals per month whole body and 4.5 meals per month fillet, to arrive at the "effective" consumption of 50 percent body weight on average. However, so as not to further complicate things, I direct instead the use of fillet with skin (as agreed by the parties), with the assumption that using the 50 percent body weight value compensates some for the tissue type consumption variability. The text should explain in a quantitative or semi-quantitative way how the risks of fishers who consume more than just the fillet would be different as the mix of their diets varied.

Species Consumed: Although some recreational fishers pursue only particular fish, the Columbia Slough survey supports the notion that in the area of Portland Harbor, there are fishers who are not so discriminating. Therefore, a multi-species diet is more appropriate for an RME scenario. This assumption also seems to be better aligned with the mid-range consumption rate selected above, i.e. sustaining the rate is more plausible using multiple species than a single species. Based on the rationale presented by EPA, the smallmouth bass shall be used as the surrogate for the multi-species diet on a river-mile scale. The rationale needs to be clearly presented in the text for the benefit of readers who typically pursue and/or keep certain types of fish.

Exposure Area: The Lower Willamette Group expresses concern about the viability of the consumption rates when the exposure area is small. They also argue that fishers are likely to move beyond a one-mile reach. At the same time, in its proposal, the Lower Willamette Group puts forth a single river-mile exposure area for smallmouth bass. Given the concerns otherwise raised by the Lower Willamette Group, it makes sense to add the harbor-wide scale to provide a comparison and to capture both those fishers that may concentrate in one area and those that range more broadly. Therefore, the scenario shall include both river-mile and harbor-wide calculations.

So, in summary, with respect to the key exposure factors presented as part of the dispute, I direct the following for the Recreational Fisher scenarios:

CT:

- 30-year exposure duration
- No effect from preparation/cooking method
- Consumption rate of 17.5 g/day
- Fillet tissue with skin
- Multi-species diet; smallmouth bass as surrogate for river-mile scale
- River-mile as well as harbor-wide scale

RME:

- 30-year exposure duration
- No effect from preparation/cooking
- Consumption rate of 48.9 g/day
- Fillet tissue with skin
- Multi-species diet; smallmouth bass as surrogate for river-mile scale
- River-mile as well as harbor-wide scale.

B) Subsistence Fishers

First, the Recreational Fisher RME scenario summarized above shall suffice as a mid-point scenario, so no additional Subsistence Fisher CT scenario will need to be developed or used.[2] As to the Subsistence Fisher RME scenario, in addition to the agreed factors identified above, the parties agreed during the informal dispute on all of the key factors except tissue type. Again, the information from the Columbia Slough survey supports a scenario that incorporates consumption of more than just fillets, including whole body (or nearly whole body) use in soup. To the extent the Lower Willamette Group has asserted that the survey is more representative of a survey of Subsistence Fishers, the assumption of consumption of more than just fillets aligns even better with a Subsistence Fisher RME scenario. I disagree with the Lower Willamette Group's contention that the fish consumption rate offsets the assumption that only fillets are eaten, but I would agree that it is unnecessary to assume whole body consumption. Therefore, as with the Recreational Fisher scenario, the Subsistence Fisher RME scenario shall be based upon fillet with skin consumption, but the text shall reflect the local information that supports more than fillet consumption. Specifically, both the exposure assessment and risk characterization text should note that although the Subsistence Fisher RME scenario does not explicitly include other than fillet with skin consumption, it is expected that some fishers consume more than just fillets, and that some may do so to a significant degree. The text in the risk characterization discussion also shall describe quantitatively, using calculations based upon available whole-body data, the impact on risks to Subsistence Fishers who incorporate more than just fillet consumption into their diet.

In summary, the Subsistence Fisher scenarios shall be as follows:

CT:

- No separate scenario developed

[2] While the consumption rate for the Recreational Fisher for the RME scenario is now lower, the rate is still high enough that, as had been agreed to previously by EPA, no separate Subsistence Fisher CT scenario is necessary.

RME

- 30-year exposure duration
- No effect from preparation/cooking
- Consumption rate of 142 g/day
- Fillet tissue with skin
- Multi-species diet
- Harbor-wide scale

2) "EPA's June 2012 directed redline fails to comply with EPA guidance stating that a BHHRA must provide an adequate description of the actual risks relating to exposure to contamination."

Though titled more broadly, this issue really centers on the scenarios of the Willamette River as a domestic water source and the consumption of clams (especially Asian clams). Rather than attempt to resolve the merits of the Lower Willamette's Group's contention regarding EPA's June 2012 version of the BHHRA, I begin by noting that, as both parties acknowledge, the September 17, 2012, version of the BHHRA includes all or nearly all of the language requested by the Lower Willamette Group with respect to both domestic water use of the Willamette River and clam consumption. To the extent that not all of the Lower Willamette Group's desired language is included, I find that the language that *is* included sufficiently makes their point about the legal/regulatory context of these scenarios, and the implied (or more than implied) likelihood of the exposures they represent.

What are really in dispute is where various portions of the language should go and possibly how many times it should be repeated. For the benefit of the reader of the BHHRA, I find that the most effective presentation would bring all information (whether "uncertainty" or "context") about these two topics presented as red-lined text in Sections 6.2.2.3 and 6.2.3 forward into appropriate locations in Section 3 (specifically 3.2 and 3.3.6, respectively). In this way, the reader will have the benefit of closely related discussions in one continuous section rather than reading half the story in one location and the other half in another. Section 6 should not repeat any of the information presented in the Section 3 subsections, and there should instead be appropriate cross references from Section 6 to the appropriate subsections of Section 3. Because neither of these matters relates to a primary risk at the site, the current summary section appropriately does not repeat any of this information. Consideration of treatment in the executive summary can be taken up during its drafting, but for the same reason it seems unlikely these scenarios would warrant much, if any, discussion there, either.

3) "EPA's decision to not include a table of contents, executive summary, or conclusion in the BHHRA is inconsistent with EPA policy and guidance and significantly impairs public review and input."

As is now clear from their submissions, there was a misunderstanding between the parties about the intent of EPA's redlining, not a bona fide dispute as to whether the final BHHRA should have a table of contents and executive summary. Both of these elements of the document should be developed after other revisions to the document are completed. With respect to a conclusion section, I do not find the Lower Willamette Group's description of an intended conclusion section distinguishes it sufficiently from the summary section to warrant the inclusion of a separate conclusion section. There are or will be sufficient presentations (including summaries that include significant findings and conclusions) of the

information elsewhere in the BHHRA and in the broader RI/FS. EPA guidance and policy do not require a conclusion section in the BHHRA, and the Lower Willamette Group has not presented a convincing case that the absence of the proposed conclusion section will "significantly impair" the public's review and comment.

Finalizing the BHHRA

As a final matter, I will now address how the parties shall incorporate this Final Resolution into the BHHRA.

The parties have expressed similar expectations in terms of the time needed to finalize the BHHRA moving forward from this point (approximately forty-five days plus final review). I hereby adopt EPA's attachment to its November 13, 2012, response referred to as "List of Tasks to complete BHHRA 11-07-2012.pdf" by file name, and alternatively entitled on its face as "Basis for time to complete BHHRA," with the following modifications:

1) Consistent with my request, EPA included its assumptions, of which there are eight. My resolution does not fully track with either scenario described in the first assumption. Given the magnitude of the changes called for in my resolution, however, I do not believe incorporating these changes should require more than one additional day. I assign this task to EPA to complete concurrent with its work on Tasks 1 and 3, with the same process for Lower Willamette Group review and EPA finalization (i.e., ten days for Lower Willamette Group review and comment; one day for EPA to consider comments and finalize).
2) As a clarification to EPA's sixth assumption, the Lower Willamette Group shall have the right to dispute EPA final decisions on text on the basis that the disputed text is inconsistent with this Final Resolution.
3) In consideration of the date of this Final Resolution, the Lower Willamette Group shall be afforded sixty days rather than forty-five days to complete Tasks 2 & 4 through 22; incorporate Tasks 1 & 3 and Modification 1, above, from EPA; and submit a revised version of the BHHRA to EPA.

Attachment: Administrative Record Summary

Formal Dispute on the EPA Notice of Non-Compliance and Directed Revisions to the Portland Harbor Draft Final Baseline Human Health Risk Assessment and Request for Dispute Resolution; Administrative Settlement Agreement and Order on Consent for Remedial Investigation/Feasibility Study, USEPA Docket No. CERCLA-10-2001-0240 – **Final Resolution**

Administrative Record Summary

1. Lower Willamette Group Opening Submission – Formal Dispute on EPA Notice of Non-Compliance and Directed Revisions to the Portland Harbor Draft Final Baseline Human Health Risk Assessment and request for Dispute Resolution, Lower Willamette River, Portland Harbor Superfund Site, USEPA Docket no: CERCLA-10-2001-0240, including Exhibit 1, Tables 1 -5, and Supporting Documentation CD, September 21, 2012
2. EPA Response to Lower Willamette Group Opening Submission, including Supporting Documentation CD, October 12, 2012
3. Lower Willamette Group Reply to EPA Submission, Formal Dispute on EPA Notice of Non-Compliance and Directed Revisions to the Portland Harbor Draft Final Baseline Human Health Risk Assessment and Request for Dispute Resolution, including Tables 5 and 6 and Supporting Documentation CD, October 24, 2012
4. Oral presentations and discussion among the parties, November 1, 2012
5. Lower Willamette Group Response to Follow-up Request for Information, November 13, 2012
6. EPA Response to Dan Opalski's November 6 Questions (Email transmittal from Lori Cora via Chip Humphrey), with attached "2012-11-09 EPA Assessment of Respondents Tables 1 & 2" and "List of Tasks to complete BHHRA 11-07-2012," November 13, 2012