UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
OREGON OPERATIONS OFFICE
805 SW Broadway, Suite 500
Portland, Oregon 97205

December 23, 2009

Mr. Robert Wyatt
Northwest Natural & Chairman, Lower Willamette Group
220 Northwest Second Avenue
Portland, Oregon 97209

Re: Portland Harbor Superfund Site; Administrative Order on Consent for Remedial Investigation and Feasibility Study; Docket No. CERCLA-10-2001-0240 – Preliminary Comments on the Baseline Human Health and Ecological Risk Assessments

Dear Mr. Wyatt:

EPA has completed its initial review of the draft Baseline Ecological Risk and Human Health Risk Assessments. These documents were submitted to EPA by the Lower Willamette Group (LWG) on September 2, 2009 and September 23, 2009 respectively. These comments are targeted on elements of the baseline human health and ecological risk assessments (BHHRA and BERA) considered critical to the identification of chemicals of concern (COCs) and development of preliminary remediation goals (PRGs).

The attached comments include general comments and detailed comments regarding the identification of COCs and development of PRGs. The final section of the comments include a specific set of 10 modifications to the BHHRA and BERA that must be made prior to the development, screening and detailed evaluation of remedial action alternatives in the draft feasibility study for the Portland Harbor site. EPA expects these changes to be incorporated prior to our expected April check-in on the remedial action alternatives development and screening step.

If you have any questions regarding this matter, please contact Chip Humphrey at (503) 326-2678 or Eric Blischke (503) 326-4006. All legal inquiries should be directed to Lori Cora at (206) 553-1115.

Sincerely,

Chip Humphrey
Eric Blischke
Remedial Project Managers

cc: Greg Ulirsch, ATSDR
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PRELIMINARY EPA COMMENTS ON THE BASELINE HUMAN HEALTH AND ECOLOGICAL RISK ASSESSMENTS.
DECEMBER 23, 2009

EPA has completed its initial review of the draft Baseline Ecological Risk and Human Health Risk Assessments. These documents were submitted to EPA by the Lower Willamette Group (LWG) on September 2, 2009 and September 23, 2009 respectively. EPA is providing these preliminary comments to expedite the development and completion of the Portland Harbor Feasibility Study (FS). These comments are targeted on elements of the baseline human health and ecological risk assessments (BHHRA and BERA) considered critical to the identification of chemicals of concern (COCs) and development of preliminary remediation goals (PRGs). EPA expects to provide a more detailed set of comments on the BHHRA and BERA in early 2010.

Overall, most of the procedures followed in the BHHRA and BERA are consistent with and followed the procedures agreed upon by EPA and the LWG for completing the baseline risk assessments. There are also a number of instances where procedures in the BERA go beyond or are in addition to the procedures agreed upon or directed for use in the BERA. While additional risk assessment procedures and analyses are appropriate, indeed are encouraged, what is inappropriate according to EPA guidance and policy for both BHHRA and BERA is the making of risk management decisions within risk assessments.

The risk assessments tend to minimize the risks to human health and the environment. For human health, the BHHRA improperly overstates the conservative nature of the human health risk assessment, overstates the uncertainties in the HHRA, and pre-maturely identifies "risk drivers" as a subset of the COCs. The BERA eliminates lines of evidence, such as comparison of bulk sediment chemical concentrations to published sediment quality guidelines that were directed by EPA to be used in the BERA. The BERA also prematurely makes risk management decisions by eliminating COCs and lines of evidence (LOEs) in the risk characterization sections of the BERA. The following general comments are intended to provide the LWG an overview of EPA's concerns regarding the BHRRA and BERA:

General Comments:

<u>Inappropriate Risk Management Decisions in the BERA</u>

Numerous instances exist where identified unacceptable risks are dropped out of the BERA prior to completion of the risk characterization sections of the BERA. EPA requires quantification and tabulation of all identified unacceptable risks in the risk characterization sections of the document. This includes unacceptable risks of any magnitude for all chemicals, receptor groups and exposure pathways, including unacceptable risks found only in localized areas of the site. To not carry such risks through the end of the risk characterization provides an incomplete description of unacceptable risks and limits the identification of COCs and the development of PRGs to be carried forward into the draft FS. The decisions to drop certain unacceptable risks from the risk characterization are risk management decisions that are inappropriate to be included in the draft BERA. EPA requires the BERA to identify, quantify and tabulate all

unacceptable risks in the risk characterization conclusions, not just those that the LWG believes are sufficiently reliable to form the basis of site remediation.

The first bullet on page ES-2 is the first of many instances in the draft BERA where inappropriate risk management decisions are described and made in the BERA. The statement that "the majority of COCs identified in the draft BERA were determined to pose no unacceptable risks to ecological populations or communities" is incorrect. As stated above, all identified COCs with a hazard quotient (HQ) $\geq$ 1.0 potentially pose unacceptable risks to ecological receptors. Whether these risks rise to a level requiring remediation is a risk management decision to be made by EPA. The primary goal of the BERA is to describe all unacceptable risks and their associated uncertainties, not to make judgments regarding the acceptability of identified risks.

The 7th bullet on page ES-2 is another example of an inappropriate risk management decision in the BERA. While EPA in this instance agrees with the LWG that mercury contamination is a greater Willamette River issue requiring watershed-scale risk management, this conclusion is a risk management decision, not a risk assessment conclusion, and is inappropriate to discuss in the BERA. The risk assessment conclusions for mercury in the BERA should be limited to the unacceptable risks presented in, for example, Tables 11-1 and 11-2.

All chemicals that exceed unacceptable risk should be carried forward into the draft Feasibility Study (FS). Information regarding the magnitude of the risk, the distribution of the risk and the strength of the measurement endpoint may be incorporated into the draft FS for the purpose of focusing remedial action decisions. However, it is important that the draft FS develop remedial action alternatives that meet the remedial action objectives for all chemicals that present an unacceptable risk to human health or the environment.

Evaluation of Localized Risk in the BERA

The risk characterization and conclusions should not be based on the spatial distribution or frequency of HQ $\geq$ 1.0. The COC list in the BERA is to be based solely on the magnitude of risk. It is entirely appropriate for the BERA to describe the identified ecological risks in terms of the spatial pattern and limitations of identified risks, as well as to describe whether COCs represent site-wide risks to multiple receptors, represent risks to only one receptor or represent risks in a limited area or section of the site, or something in between these extremes. This information may be used by EPA to identify a subset of the entire COC list that will require development of PRGs. However, it is not acceptable for the BERA to eliminate chemicals from the final COC list for the BERA for which the magnitude of risk is small (i.e. a hazard quotient only slightly greater than one), or which pose unacceptable risks in only a limited area of the site.

The difference between identification of unacceptable risks in the BERA, and how those unacceptable risks may be used by EPA risk managers in making response or remedial decisions is given in an EPA Office of Solid Waste and Emergency Response (OSWER) directive. OSWER Directive 9285.7-28 P (Issuance of Final Guidance: Ecological Risk Assessment and Risk Management Principles for Superfund Sites, October 7, 1999) is explicit in its Principle number 4 regarding characterization of site risks, and is repeated here to make clear to LWG

what EPA requires for a risk assessment. "When evaluating ecological risks and the potential for response alternatives to achieve acceptable levels of protection, Superfund risk managers should characterize site risks in terms of: 1) magnitude; i.e., the degree of the observed or predicted responses of receptors to the range of contaminant levels, 2) severity: i.e., how many and to what extent the receptors may be affected, 3) distribution; i.e., areal extent and duration over which the effects may occur, and 4) the potential for recovery of the affected receptors. It is important to recognize, however, that a small area of effect is not necessarily associated with low risk; the ecological function of that area may be more important than its size."

The failure to carry through to the completion of the BERA all chemicals identified as posing unacceptable risks to one or more ecological receptors, all lines of evidence directed to be used in the BERA by EPA and compounded by the subsequent development of PRGs for only a subset of chemicals posing unacceptable ecological risks in a document separate from the BERA, demonstrates the shortcomings of the BERA to provide the information needed by EPA risk managers to make remedial decisions at the Portland Harbor site. EPA should not have to review the details of a BERA with 18 attachments to identify those chemicals identified somewhere in the BERA as posing unacceptable risks. They should all be identified in both the executive summary and conclusion sections of the BERA. The penultimate BERA conclusion that only five chemicals (PCBs, dioxins/furans, mercury, PAHs, DDx compounds) are COCs is not consistent with LWG's own determinations throughout the BERA, and is unacceptable to EPA.

Statements Regarding Population Level Effects

The BERA makes numerous statements regarding the risks associated with population level effects (e.g., page 3 of the executive summary and text boxes on pages 253, 292 and 510 of the main BERA text). EPA acknowledges that remedial action alternatives are generally based on population or community level effects as stated in OSWER Directive 9285.7-28P (Issuance of Final Guidance: Ecological Risk Assessment and Risk Management Principles for Superfund Sites, October 7, 2009): "Superfund remedial actions generally should not be designed to protect organisms on an individual basis (the exception being designated protected status resources, such as listed or candidate threatened and endangered species or treaty-protected species that could be exposed to site releases), but to protect local populations and communities of biota." However, the OSWER Directive goes on to state: "Levels that are expected to protect local populations and communities can be estimated by extrapolating from effects on individuals and groups of individuals using a lines-of evidence approach." EPA believes that the approach used to consider population level effects based on measurement endpoints in the BERA are appropriate and consistent with EPA guidance.

Inappropriate Statements Regarding Fish Ingestion Rates

The BHHRA makes numerous statements throughout the document that question the fish consumption rates used to evaluate the risks to human health. For example, the three main rates are referred to as high (17.5 g/day), higher (73 g/day), and highest (142 g/day). EPA disagrees with this characterization. The EPA rate of 17.5 g/day (two 8-oz meals per month) is based on the 90th percentile of the general population, which includes non-consumers of fish. The 90th

percentile for fish consumers is much higher (200 g/day). EPA uses the 17.5 g/day rate to approximate a fish-consuming population that does not include tribal or subsistence fishers. It is not an unreasonable rate, and should not be referred to as a "high" ingestion rate, but rather as a "low" ingestion rate.

The rate of 142 g/day used as the highest rate for non-tribal fishers in this risk assessment is the 99th percentile for consumers and non-consumers from the same USDA study; the consumption rate for consumers only from this study is 506 g/day. The ingestion rate of 142 g/day was used by EPA in developing its Ambient Water Quality Criteria for consumers who obtain much of their daily protein from fish; therefore, it is appropriate to use this value as a "high" ingestion rate for this risk assessment. It should be kept in mind that the rate of 142 g/day does not truly describe subsistence consumption as a "subsistence" fish consumer would obtain almost all of their protein from fish. The more appropriate rate for subsistence fishers may be closer to the 506 g/day value which is the 99th percentile value for consumers only in the USDA study. This is supported by the fish consumption study of the Suquamish Tribe in Puget Sound whose 90% biota consumption rate is over 500 g/day. The consumption rate of 142 g/person/day was used to represent high frequency non-tribal fishers in this risk assessment. For subsistence fish consumers, who could represent an important population in PH, using 506 g/day as an approximate subsistence value, only about 28% (142 g/day divided by 506 g/day) of total fish consumption would have to come from the LWR in order for a consumption rate of 142 g/person/day and the upper range risks estimated in the HHRA to apply.

For the third non-tribal adult fish consumption rate used in this risk assessment, 73 g/day, data from the Columbia Slough Study was used. The possible uncertainties in this study and in the consumption rates derived from it rate are appropriately discussed in the BHHRA. The BHHRA discussion and the data from the USDA study support use of a fish consumption value of 74 g/day as "medium" consumption rate, not a "higher" consumption rate.

The arguments concerning uncertainties in fish ingestion rates provided in the HHRA are not compelling. Further, EPA believes that the body of information available regarding fish consumption rates both nationally and locally makes it clear that the fish ingestion rates used in the BHHRA appropriately address a range of exposures that might occur for consumers of locally caught fish. Text throughout the document should be revised to indicate the nature of these risk estimates, as indicated above, and appropriate text substituted to acknowledge the need to protect high consuming fish populations and discuss fish ingestion rates in that context.

Shellfish consumption

Although the extent of shellfish consumption in the lower Willamette River is not known, certain information regarding the consumption of shellfish in the lower Willamette River is available. The Oregon Office of Environmental Public Health, Department of Health Services (DHS) had previously received information from ODFW indicating that an average of 4300 lbs of crayfish were commercially harvested from the portion of the Willamette River within Multnomah County each of the 5 years from 1997-2001. Most of this catch was sold to the Pacific Seafood Company of Oregon. DHS also has information from local commercial crayfish harvesters indicating that Europe is a major portion of their market. Furthermore, as part of the McCormick

and Baxter assessment in 1991, Ken Kauffman at DHS talked with the wife of a licensed commercial crayfish harvester who served (at that time) as the secretary-treasurer of the Oregon Crayfish Association. She indicated that the area around McCormick and Baxter was a very productive Cray fishery and that she and her husband had harvested there prior to the advisory on many occasions.

In addition to this historical commercial crayfish harvesting information in the Lower Willamette, DHS also occasionally receives calls from citizens interested in harvesting crayfish from local waters who are interested in fish advisory information. Between 2001 and 2007, DHS fielded 8 calls from citizens who reported catching and eating crayfish from Portland-area waters (only one was specifically from the Study Area). DHS has no way of knowing what percent of individuals who catch and eat crayfish contact their office first to ask for fish advisory information. They estimate, however, that for each person who contacts them regarding the safety of consuming crayfish from the Lower Willamette, there are many more that catch and consume the animals without contacting their office.

Further, the fact that collection of Corbicula is illegal is relevant but not particularly important for the pathway in general. There are indications that Corbicula are being collected and consumed (e.g., from the Linnton Community Center's discussion with transients). It is reasonable to assume that bivalve consumption is a current and potential future exposure pathway and that future biomass would increase. Therefore, the low clam mass (e.g., see page 123 in the BHHRA) that may limit current bivalve consumption does not apply to future exposure.

Risk Characterization for Non-Cancer Effects

In the draft BHHRA, the calculation of a chronic hazard index (HI) for each exposure pathway is not presented in the risk characterization tables (i.e., in the Section 5 tables in the draft HHRA). EPA's Risk Assessment Guidance (Risk Assessment Guidance for Superfund Volume I, Human Health Evaluation Manual (Part A) provides the following guidance on the evaluation of noncarcinogenic effects:

Noncarcinogenic effects, chronic exposures – For each chronic exposure pathway calculate a separate chronic hazard index (HI) from the ratios of the chronic daily intake (CDI) to the chronic reference dose (RfD) (i.e., the HQ) for individual chemicals as described in the box below.

Chronic Hazard Index = CDI_1 /RfD1 + CDI2 /RfD2 + ... + CDIii /RfDii
where:
CDI = chronic daily intake for the ii th toxicant in mg/kg-day, and

RfD = chronic reference dose for the ii th toxicant in mg/kg-day.

If the HI is greater than unity as a consequence of summing several hazard quotients of similar value, it would be appropriate to segregate the compounds by effect and by mechanism of action and to derive separate hazard indices for each group.

Per EPA risk assessment guidance, the chronic HI for each exposure pathway should be added to these Risk Characterization tables in the final HHRA. In addition, only those exposure pathways which have a chronic HI greater than 1 should be included in tables that show the calculation of the End-Point Specific HIs. Unnecessary tables totaling hundreds of pages that are now included in the draft HHRA can and should be eliminated when this is done.

Inappropriate Statements Regarding Compounding Conservatism and the Range of Uncertainties

There are numerous statements in the draft HHRA regarding the compounding of conservative risk assumptions which resulted in the LWG concluding that the final risk characterization results are unreasonable. This issue is also highlighted in the LWGs October 8, 2009 letter. EPA disagrees with this characterization. The approach used in this HHRA follows standard EPA guidance on risk assessments and is similar to risk assessment approaches used on other Superfund sites. Overall, EPA believes the risk assessment for Portland Harbor is consistent with the application of reasonable maximum exposure assumptions and is not overly conservative.

EPA also has concerns with the language and ranges used in discussing uncertainties in the BHHRA. For example, in the presentation of uncertainty, the range of variation in hazard index values is greatly overstated. This is because each toxic endpoint in an exposure scenario is considered independently. Instead, each scenario should be evaluated based on the chemical(s)/endpoint combination resulting in the greatest hazard index. For example, in Table 5-186, the HI range for tribal fisher direct exposure to in-water sediment across all half-mile segments is listed as 0.00000008 to 1. This range is developed using the very lowest chemical/endpoint combination (naphthalene causing whole body effects) to the highest chemical/endpoint combination (arsenic causing skin effects). The lowest HI for a scenario is irrelevant for decision making; decisions are based on the highest calculated HI at each location. The correct range for tribal fisher sediment exposure should be developed using the highest chemical/endpoint combination at each location (Table 5-36). This range is 0.002 (arsenic, skin effects) to 1 (dioxin TEQ, reproductive effects). In this example, the HI range in Table 5-186 is overstated by a factor of 25,000. This overstatement of HI uncertainty is typical of many other scenarios. However, if as described above, end-point specific HIs are calculated according to EPA guidance for only for those exposure pathways with a chronic HI greater than 1, all of the end-point specific HIs presented in Table 5-36 would be deleted from the BHHRA (an elimination of 49 pages for this one receptor/exposure media/exposure route) as none of the exposure pathways have an HI greater than 1. This conclusion can be found on page 78 of the draft BHHRA where it states, *"The tribal fisher scenario for in-water sediment results in no HIs greater than 1."* The correct evaluation will need to be performed before the agencies have an appropriate view of uncertainty associated with non-cancer risks.

One of the major uncertainties that was not discussed in the draft HHRA is that relating to the calculation of end-point specific HIs. In deriving these endpoint specific HIs, only one health endpoint is used for each chemical, even though most chemical have a myriad of health effects as exposures increase. By considering these effects individually, certain noncarcinogenic risks may be under estimated. For example, a majority of the non-cancer impacts from the site for

many biota are from PCBs and total TEQ. The end-point used for deriving the RfD for PCBs is immunotoxicity (based upon immunological effects seen in a monkey study at a dose of 0.005 mg/kg/day and a 300 fold Uncertainty Factor) and the end-point used for deriving the RfD for dioxin/furan TEQ and PCB TEQs is reproduction. However, if the reproductive endpoint for PCBs based upon the LOAEL of 0.02 mg/kg/day is used with the same Uncertainty Factor as the immunological endpoint to derive an RfD for a reproduction end-point for PCBs, the RfD for reproductive effects will be 4 times the RfD for immunological effects. For the chemicals that have the largest non-cancer contribution in the HHRA, the Uncertainty Section should discuss the possibility of under predicting non-cancer health impacts by using only one endpoint per chemical.

Inappropriate Comparison to Regional Risk Levels

There are several inappropriate discussions relating to background and "regional" risk levels, especially for biota. EPA and the LWG agreed that the biota data collected upstream of the Portland Harbor site by the LWG would not be used in the BHHRA. Therefore, there is no background data set for biota for Portland Harbor that can be used and/or evaluated in the BHHRA. Therefore, any reference to "background" in relation to biota in the BHHRA should be deleted. EPA acknowledges our agreement to use upstream tissue data for information purposes in the remedial investigation report.

Comparisons are also made to risks from biota consumption in other "regional" risk studies (e.g., the EPA *Columbia River Basin Fish Contaminant Survey*, and the ODEQ mid-Willamette Basin study). Comparison to these studies, which were initiated because of known or suspected concern with contamination in the particular areas in which they were done, should not be included in the BHHRA. EPA's risk assessment guidance is clear that for a BHHRA, risks from contaminants at the site are to be characterized. Following this risk characterization, comparisons to background risk can be discussed in the risk assessment if such data are available (they are not for Portland Harbor). Comparisons to risks from other contaminant surveys are irrelevant and have no purpose in the BHHRA as they provide no useful information on the Portland Harbor Site risks or background risks.

Inappropriate Evaluations of Surface Water and Transition Zone Water

In EPA's more detailed comments on the BHHRA which will follow in early 2010, comments will be provided on the changes needed on the data selected and methods used to evaluate surface water and groundwater. For example, although EPA agreed that "integrated data" could be used to select COPCs and develop exposure point concentrations for surface water as a drinking water source, it was assumed that surface water data from throughout the Portland Harbor site would be used and that this data would be integrated as appropriate (e.g., near bottom and near surface samples would be combined in an area). Instead only surface water data from the river transects, Willamette Cove, Cathedral Park and the Shipyard were used. However, water could be withdrawn from the river at any point for use as drinking water. Another example is the screening of TZW for the biota consumption exposure pathway. To perform this screening, only shallow TZW data within a 100-foot radius of a shellfish sampling station were used and, within this subset of TZW data, only chemicals in biota that that were above 10^{-6} or an HI of 1 for consumption of shellfish were selected. This results in the screening of an

unacceptably small subset of TZW data and does not allow for an evaluation of TZW contaminants that are of concern for bioaccumulation.

Inappropriate Discussions of "Risk Drivers"

Section 8.2, Risk Drivers, should be deleted from the BHHRA. The role of the BHHRA is to identify Contaminants of Concern (COCs) based upon the risk calculated from the RME. For the Portland Harbor BHRRA, COCs are defined both by:

- EPA's target risk range of 10^{-6} to 10^{-4} and point of departure of 10^{-6} for cancer and a Hazard Index (HI) of 1 for non-cancer effects, and;

- ODEQ's acceptable risk levels of less than or equal to 1 x 10^{-6} for individual carcinogens and less than or equal to 1 X 10^{-5} for cumulative excess cancer risks for multiple carcinogens; and a HI of less than or equal to 1 for non-cancer effects.

It is not the role of the BHHRA to focus on a subset of the COCs based upon the "considerations" listed on pages 142 and 143. These "considerations" include such things as the relative percentage of each chemical's contribution to the total human health risk, uncertainties associated with exposures, frequency of detection (localized and study-area wide), comparisons of Portland Harbor site risk to risks in "regional" studies, and the magnitude of risk exceedance above 10^{-4} to 10^{-6}. These "considerations" are risk management issues and should be dealt with outside of the BHHRA (e.g., in the FS). Therefore, Section 8.2 should be deleted and Section 9, conclusions, should summarize the COCs and exposure scenarios as defined by the two bullets above.

Infant Exposure to Human Milk

EPA and the LWG agreed that the human milk pathway for infants (i.e., previously referred to as "breastfeeding") would not be included in the draft HHRA, but would be included in the final HHRA. EPA has been collaborating with ODEQ, OR DHS, ATSDR, and two university researchers to ensure that the method to be used for the risk characterization for this pathway is appropriate and defensible. This collaboration compared two physiologically-based pharmacokinetic (PBPK) models for infant exposure to human milk (the Haddad model, an 8-compartment physiologically-based pharmacokinetic (PBPK) model that has been validated by comparing estimated milk concentrations against concentrations measured in a Canadian Inuit population, and the Yang model, a 3-compartment PBPK model) to an EPA model which is a single compartment, first-order kinetic model described in EPA's *Human Health Risk Assessment Protocol for Hazard Waste Combustion Facilities*[i] (Combustion Guidance). The result of this comparison has shown that the EPA model is accurate and protective and should be used for the risk characterization for infant exposure to human milk in the Portland Harbor BHHRA as well as in other risk assessments done in Region 10. EPA will be providing this methodology, including the appropriate parameters to be used, to the LWG by the end of February. The risk characterization results from this pathway will impact the non-cancer evaluations primarily for PCBs for both biota consumption and other pathways. This should also

be reflected in the CSM for the site such that in Figure 3.1 all of the receptors should be shown as potentially complete for infant exposure to human milk)

PRG and COC specific Comments:

BERA Comments

Elimination of the Logistic Regression Model as a Line of Evidence

EPA does not agree with the elimination of the Logistic Regression Model as a line of evidence for evaluating benthic risk. However, EPA is still in the process of reviewing the benthic risk evaluation received on November 13, 2009.

Elimination of transition zone water as a Line of Evidence

The draft BERA states that "TZW was evaluated but was not used to identify COCs and is therefore not discussed further in the conclusions." This is an inappropriate elimination of a valuable line of evidence (LOE) deviates from the procedures outlined in the February 15, 2008 BERA problem formulation. Table 6-28 identifies 63 chemicals (15 metals, 16 PAHs, 3 SVOCs, 6 insecticides, 16 VOCs, 5 petroleum fractions, cyanide and perchlorate) that exceed TZW TRVs in one or more samples at one or more of the 10 facilities where TZW samples are available. All 63 of these chemicals must be identified as posing unacceptable ecological risks in the risk characterization for TZW. They form a possible basis for making remedial decisions both in the in-water and upland (source control) portions of the Portland Harbor site.

Elimination of generic SQGs as a line of evidence for evaluating benthic risk from the BERA

The draft BERA states that "None of the generic SQGs could reliably predict toxicity in Portland Harbor sediments (Attachment 7); therefore, the generic SQGs were not used in risk characterization for the BERA." There is not basis in the February 15, 2008 BERA problem formulation for the elimination any TRVs in any line of evidence based on an assessment of TRV reliability. Further, published reliability criteria for generic SQGs such as probable effect concentrations (PECs, MacDonald et al. 2000) largely meet LWG's proposed reliability criteria, meaning the PECs, at least, should have been used in risk characterization of bulk sediment chemistry given LWG's own reliability criteria.

Level 2 Risks to the Benthic Community

The BERA determined that only Level 3 effects (empirical toxicity tests and site specific sediment quality guidelines developed through benthic toxicity predictive models) represent a risk to the benthic community. EPA believes that Level 2 effects (empirical or predicted) represent a risk to the benthic community and should be used for PRG development.

Elimination of certain chemicals as COCs

Table 11-2 of the BERA identified a number of chemicals as not posing unacceptable risk. In particular, certain measurement endpoints have been inappropriately identified as not presenting unacceptable risk. These include the assessment of surface water exposures, the assessment of localized risks to sandpiper based on a comparison to dietary TRVs, the assessment of risks to bald eagle based on comparison to estimated bird egg TRVs, the assessment of risk to the benthic community through a comparison to sediment quality guidelines, the assessment of dietary exposures to fish and wildlife through a comparison to dietary dose TRVs, the assessment of risk to fish and invertebrates based on a comparison to tissue residue TRVs, and the assessment of benthic risk through consideration of both level 2 and level 3 effects.

In some cases, the omissions eliminate some key COC-Receptor Group pairs such as the potential risks to osprey and eagles from 4,4'-DDE based on modeled egg tissue concentrations and the failure to consider localized risks associated with specific sources (e.g., potential risks to the benthic community from tributyl tin based on predicted tissue concentrations in Swan Island Lagoon, potential risks to fish from PAHs based on surface water exceedances in the vicinity of RM 6 and potential risks to shorebirds from pesticides at beaches B-16 and B-22).

As stated in the general comments above, determination that certain chemicals did not pose an unacceptable risk to ecological receptors based on factors such low hazard quotients, the distribution of hazard quotient exceedance and the perceived strength of the measurement endpoint is inappropriate in the risk characterization portion of the BERA. As a result, all chemicals identified in Table 11-2 should be carried forward into the draft FS as COCs. Information regarding the magnitude of the risk, the distribution of the risk and the strength of the measurement endpoint may be incorporated into the draft FS for the purpose of focusing remedial action decisions. However, it is important that the draft FS develop remedial action alternatives that meet the remedial action objectives for all chemicals that present an unacceptable risk to human health or the environment.

<u>Technical errors in the calculation of risk to fish and wildlife from the ingestion of contaminated diets</u>:

There appear to be two technical errors in the calculation of risks to fish and wildlife from ingestion of contaminated diets:

1. Calculating dietary risks by adding together the two hazard quotients for risks from ingestion of contaminated prey and risks from ingestion of contaminated sediment. Total risks from all components of the diet should be calculated by summing the ingested doses from sediment and contaminated prey ingestion, then calculating a single hazard quotient combining risks from the two dietary fractions. The equation for this was given as Equation 1 on page 40 of the February 15, 2008 BERA problem formulation. It appears that the hazard quotients from the two dietary fractions were summed to obtain total risk, rather than the correct approach of summing the two ingested dose estimates, then calculating a single hazard quotient. EPA does not object to quantifying risks separately from sediment ingestion and contaminated prey ingestion, as this provides useful information. However, the total dietary risk calculations should be corrected as described earlier in this comment.

2. In the situation where only one of the two dietary fractions (either sediment or prey) has a hazard quotient > 1, the BERA shows the final HQ as only the HQ from the pathway with HQ > 1, not the sum of both HQs. This is not correct, total risk is that from the sum of ingested doses from sediment and prey. The LWG approach underestimates total dietary risks. Another problem with the BERA approach is the situation where both sediment and prey ingestion HQs are between 0.5 and 1.0, in which case the BERA drops both dietary fractions and concludes that chemical does not pose a risk. Could have a situation where prey HQ = 0.7 and sediment HQ = 0.7, for example, yielding a total HQ of 1.4 and a chemical of concern. The BERA approach would not identify such a chemical as a COC at all. Dietary ingested doses must be summed before calculating the total dietary HQ, even when both individual components of the diet (i.e. sediment and prey) have individual HQs < 1.

The water TRV for dioxin continues to be mistakenly listed as 0.0001 ug/l. The correct water TRV for dioxin is number is 0.00001 µg/l. The correct value can be found on page B-10 of the EPA water quality criterion document for dioxin which can be found at the following website:

http://www.epa.gov/waterscience/criteria/library/dioxincriteria.pdf

The same value is also provided in the summary table of all aquatic life table of the 1986 Gold Book (Quality Criteria for Water 1986).

BHHRA Comments

As discussed above, all of the COCs selected for human health, based upon both EPA and ODEQ acceptable cancer and non-cancer risk levels, should be carried through into the FS and PRGs should be developed for these COCs if possible. Before submittal of EPA's final comments on the BHHRA, EPA will fully review the COCs selected by the BHHRA (listed in Table 8-1) to ensure that we are in agreement with this list and will review the latest list of PRGs sent to EPA by the LWG on December 10, 2009.

Given that there is risk to human health from exposure to water (surface and ground) and sediment, response action is warranted at the Portland Harbor Superfund Site. Given that response action is warranted, and to the extent that "any hazardous substance, pollutant or contaminant will remain onsite" then any applicable or relevant and appropriate requirements under the circumstances of the release or threatened release of hazardous substances under federal or state law must be achieved at the completion of the remedial action. As a result, surface water and transition zone water should be evaluated against relevant human health water quality criteria (i.e., SDWA MCLs and CWA AWQCs). These chemicals should be carried forward into the Portland Harbor FS and used for the development of PRGs.

Risk Assessment Modifications to be Incorporated into the Draft Feasibility Study:

Although EPA is still in the process of reviewing the draft BHHRA and BERA for the Portland Harbor site, EPA has developed the following modifications to the risk assessment process for

the identification of COCs and development of PRGs to bee used in the draft FS for the Portland Harbor site:

1. Use the Logistic Regression Model for the development of site specific SQGs. These SQGs should be used in conjunction with generic SQGs and SQGs generated based on the logistic regression model to identify areas of sediment contamination for evaluation in the draft FS.
2. Retain the Transition Zone Water LOE as a measure of benthic risk. This information may be used in the assessment of groundwater upwelling and the evaluation of CDFs, CADs and sediment caps in the draft FS.
3. Benthic risks should be determined based on both level 2 and level 3 effects identified from the sediment toxicity tests performed at the site. This information should be used to identify areas of sediment contamination for evaluation in the draft FS.
4. All COCs with hazard quotients greater than or equal to 1 must be identified as potentially posing unacceptable risk. This information will be used to identify areas of sediment contamination for evaluation in the draft FS.
5. Generic SQGs that meet the reliability analysis requirements must be included in the assessment of benthic risk. This information will be used to identify areas of sediment contamination for evaluation in the draft FS.
6. All chemicals presented in Table 11-2 should be included as COCs. PRGs should be developed for these chemicals unless it is not possible to relate the measurement endpoint to a sediment concentration.
7. All chemicals identified as posing unacceptable risks from lines of evidence EPA directed LWG to use, but which were eliminated by inappropriate LWG risk management decisions prior to the completion of risk characterization, must also be incorporated in Table 11-2 of the BERA.
8. Table 11-2 must either amended, or split into multiple tables, so that it provides information on both which lines of evidence any given chemical poses unacceptable risks, and the magnitude of the identified risks. As currently structured, Table 11-2 provides little more than an incomplete list of chemicals identified as posing unacceptable risks to one or more receptors, and provides no information on the magnitude of risks.
9. The dietary risk evaluation must be recalculated and the COCs and PRGs adjusted accordingly for use in the draft FS.
10. Chemicals present in surface water and transition zone water evaluated above the relevant a human health water quality criteria (i.e., SDWA MCLs and CWA AWQCs) should be carried forward into the Portland Harbor FS and used for the development of PRGs.

[i] U. S. EPA. *Human Health Risk Assessment Protocol for Hazard Waste Combustion Facilities.* (EPA 530-R-05-006, September 2005.