Summary of Ecological Risk Assessment Decision Framework Issues
April 7, 2006

On April 3, 2006, EPA and its partners met to discuss the concepts proposed in the Proposed Ecological Risk Assessment Decision Framework (Framework Document) submitted by the Lower Willamette Group (LWG) on March 15, 2006. The statements presented below represent EPA's preliminary response to the ERA framework. The statements provided below are for the purpose of facilitating discussion of the ERA framework document at the upcoming meeting to be held on April 11, 2006 and should not be considered formal comments. At this time it is unclear whether EPA will be commenting formally on the Framework Document.

Aspects of the Framework Document that we like and/or agree with:

- The LWG has made a good effort to put forth a framework that is largely based on existing EPA guidance for conducting ecological risk assessments.
- We agree with the LWG that risk to ecological receptors should be based on exposure scales that are ecologically relevant (e.g., mobility and home range). Additional discussion is needed to determine how, exactly, we define "ecologically relevant scales."
- The decision framework does a good job of presenting, in general, (1) LWG's proposed approach for this site, (2) the components of the framework and how LWG proposes to apply the various lines of evidence to determine risk for a number of receptors of concern, and (3) the ways in which the various models are proposed to be utilized as LOEs in assessing risk.

Primary questions that must be addressed:

In general, the Framework Document highlights two key areas that must be addressed: Lines of evidence (LOE) for the ecological risk assessment (ERA) and spatial scale of the receptors.

<u>Lines of Evidence</u>: The document describes the various lines of evidence that will be used to assess risk to ecological receptors at the site. Although EPA agrees conceptually with the LOE approach, EPA has identified a number of questions that must be addressed to ensure that the LOE approach is appropriately applied. From this standpoint, the LOE approach must incorporate direction from EPA/partners in the December 2, 2005 Identification of Round 3 Data Gaps memo and the February 17, 2006 Round 3 Scope of Work.

- *Empirical data must be the primary LOE for the benthic community*
  EPA is evaluating the benthic predictive approach now, and we are not sure of its utility in assessing risk. However, it is unlikely that the benthic approach will answer all of our questions about risk to the benthic community, and depending on our evaluation, we may find that it is not suitable to answer many or any of our questions. Thus, we may need to rely more heavily on empirical data and other LOEs for assessing risk to the benthic community.

- *Plan for other approaches to reduce uncertainty in modeling efforts*
  The ERA Decision Framework relies to varying extents on modeling for most LOEs. EPA/partners have a significant amount of uncertainty about the ability of these models to accurately predict results (and the LWG references this uncertainty in their acknowledgement of guiding assumptions). This is certainly the case with the benthic predictive model, the food web

model, and the BSAF model. Pending review and approval of these models, we need to plan for the use of other approaches (e.g., logistic regression, mean ERM quotients, other food web modeling efforts, additional benthic toxicity sampling) to reduce uncertainty. LOEs based on models with high levels of uncertainty will be given a low weight, or may not be used at all if they fail to meet minimum standards for the modeling effort.

- *Measurement endpoints should be weighted using criteria that evaluate the relevance to the assessment endpoints for use in the ecological risk assessment*
  It appears that the LOEs in Table 1 are weighed toward relevance of media (e.g., sediment) proposed to be the focus of the feasibility study. Instead, LOEs (or measurement endpoints) need to be weighted relative to each other for each assessment endpoint for the purposes of evaluating different lines of evidence for the risk assessment. This may vary depending on the properties of the chemical class under consideration. For some measurement endpoints, water (surface and/or transition zone) comparisons to AWQC or other threshold levels should be the primary LOE for assessing risk, and risk from water exposures will be evaluated for those receptors as appropriate. At the April 11, 2006 meeting, EPA intends to present an example matrix that shows how different measurement endpoints should be considered in the risk assessment taking into account assessment endpoint, receptor, each COPC group (e.g., metals, PAHs, bioaccumulative chemicals), and each exposure pathway. This approach should be considered to weigh LOEs for all receptors of concern. Criteria for the weighing evaluation must also be discussed.

- *Separating the use of LOEs for the risk assessment and feasibility study*
  The LWG needs to clarify how LOEs will be used for the risk assessment, separate from the feasibility study and/or future monitoring. For example, Table 1 of the Framework document contains FS-related uses (e.g., the document states that primary LOEs will be used to develop cleanup numbers while secondary LOEs will not, and implies that risk to the benthic community from water exposures will not be assessed, focusing only on sediment). EPA recognizes that LOEs may be weighted differently for the risk assessment and the FS.

<u>Spatial Scale</u>: The framework document proposed three different general types of spatial scales for the ecological risk assessment (ERA):

- ***Location-specific*** (individual sediment sampling locations or points)
- ***Area-specific*** (receptor home range and/or habitat)
- ***Site-wide*** (entire ISA)

EPA agrees that it is useful to consider the question of scale for the purposes of the ERA. Additional evaluation to determine the appropriate scales for assessing risk to ecological receptors at the site is required. Questions regarding scale must be resolved as soon as possible to (1) inform our development of Round 3 Field Sampling Plans and (2) determine whether we have adequate data to conduct the risk assessments.

- *All areas of the site will be considered potential habitat for ecological receptors*
  EPA/partners are concerned that areas of unexpected habitat (e.g., seawalls, scoured areas) could be excluded from the risk assessment. All areas of the site should be considered potential habitat for ecological receptors of concern; the ecological risk assessment should not be limited to only certain parts of the site. Following the risk assessment, differences in habitat areas will be addressed as part of the risk management process. In addition, it appears that LWG is

defining scale based on habitat, rather than home range. EPA is considering how home range should be used in determining the appropriate risk assessment scale for some receptors, acknowledging that the use of home range instead of habitat area could change the LWG's definition of scale significantly for some receptors.

- *Defining how exposure data will be selected and used in risk calculations*
  The ERA Decision Framework lacks detailed discussion of exactly how exposure data will be selected and used in risk calculations. The general scale approach seems valid, but different exposure pathways/LOEs (especially dietary vs. tissue) will require different kinds and numbers of calculations for each receptor. Site data should be evaluated through trial exposure point concentration (EPC) calculations to evaluate the implications of different exposure scale choices. Main concerns include:
  - How will habitat and/or home range be used to select specific exposure areas and, hence, data used for calculating EPCs? Proposals were made in LWG's 2004 Comprehensive Ecological Risk Assessment Technical Memorandum, but they were conservative, covered most of the ISA for most fish receptors and are probably not realistic.
  - Given the resolution of the first concern, how many HQs will be calculated for each receptor, and if more than one HQ is calculated for a given receptor (e.g., for small-scale receptors), how will final risk calculations be performed and interpreted?
  - How will dietary vs. tissue vs. water pathways be handled? The Framework Document primarily focused on the tissue LOE for most receptors. However, other LOEs (e.g., dietary pathway LOE) will require different sets of exposure calculations and scales.
  - What calculation statistics will be used to derive EPCs? Although proposals were made in LWG's 2004 Comprehensive Ecological Risk Assessment Technical Memorandum, further evaluation of the implication of various EPC calculation approaches is required.

Other Points:

- It is unclear whether the Framework Document will be the vehicle for reaching agreement on how the ERA will be completed. EPA recommends that the Portland Harbor Managers group identify next steps for the Framework Document the vehicle will be for documenting the ERA approach.
- EPA does not expect to resolve detailed technical issues at the April 11, 2006 meeting. ERA topics which will likely require further technical discussion include:
  - EPCs – Identification of the appropriate techniques for calculating exposure point concentrations.
  - LOEs – Identification of the appropriate LOE on a receptor, contaminant and exposure pathway basis.
  - TRVs – Identification of TRVs for use in the baseline ERA.
  - BSAFs – Identification of the appropriate approaches for developing site specific BSAFs.
- The Framework Document focuses almost exclusively on the ERA. However, the issue of scale and application of models also applies to the human health risk assessment (HHRA). Further discussion of these topics relative to the HHRA is also required.