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Mr John Sands
U.S. Department of Energy
Richland Operations
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Dear Mr. Sands:

Oregon appreciates the opportunity to participate in your workshop held January 10-11, 2008, to discuss stakeholder concerns and to hear DOE's plans for revision of the draft A Risk Assessment for the 100 and 300 Areas of the Hanford Site. We were pleased to hear that DOE and its contractor for the project, Washington Closure Hanford (WCH), are proposing extensive changes in response to the many comments received from regulators and stakeholders. We concur with the general intent of many of the changes discussed during the workshop, but take this opportunity to raise several questions and concerns stimulated by presentations and discussion at the workshop.

We support the plan to thoroughly reorganize and rewrite the document to improve readability and understanding. We trust that the redrafted report will be better structured and easier to understand than was the case for the draft A report. We are also pleased that DOE plans to include groundwater and to look at future risks in the revised reports; we believe the assessments will benefit from this more inclusive evaluation of risk in the river corridor. We concur generally with the planned approach to develop two stand-alone report volumes separating information for human health and ecological risk assessments, but we urge careful consideration of options for preparing the sampling and data analysis summaries that will support the two volumes. In side discussions with WCH staff during breaks in the workshop, it seems that you may be undecided how to package descriptions of sampling and data analysis, even to the point of one (perhaps facetious) suggestion of preparing a third "data" volume. If the two volumes are to be truly stand-alone, a complete sampling and analysis section must be provided as part of each report. Moreover, because some of the sampling activities and much of the data manipulation are different for the two assessments, it seems to make sense to provide separate descriptions for the two assessments. We encourage you to maintain information in a common data base, but to make sampling and data analysis descriptions as straightforward as possible in support of the risk assessment presentations.

On the first morning of the workshop, Randy Ryti (Neptune, Inc., a subcontractor for WCH), presented and discussed a flow chart (Slide 11 of the presentation package) intended to explain proposed refinement of the process for identifying contaminants of potential concern (COPCs)

among the analytes included in the project database. We were told that DOE and WCH are preparing a "white paper" that will discuss in detail the revised procedure summarized in the flow chart and that will be used for COPC identification in the next draft of the river corridor risk assessment. We recommend the white paper address a number of questions about this process as listed below. We recognize the need to refine the selection process to exclude non-Hanford contaminants and likewise to exclude potential contaminants for which there is a negligible actual risk, but we have several concerns about the process as represented by this diagram.

- The process shown does not actually identify any COPCs. One pathway leads to a "narrative analysis" in which potential COPCs will be retained or excluded from further consideration and analysis, but the flow chart provides no insight into that selection process. There are no questions, no logical decision paths, nothing that delineates an objective process for a final decision whether an analyte will be retained as a COPC in the risk assessment.
- What happens to chemicals identified as "uncertain COPCs" in the risk assessment? Are they in or out of quantitative risk analyses; what factors will be considered in making that decision? Will there be any narrative discussion in the revised report describing the potential implications of including or excluding each of these analytes from the assessment?
- The first box on the flow chart excludes "essential nutrients" from consideration as COPCs. The oral presentation indicated that the list of chemical species excluded at this decision point would be limited to a few macronutrients (e.g., iron, calcium, potassium), but this must be explained in detail, with a complete list of chemicals that will be excluded by this decision. Many elements that are essential micronutrients are toxic at high concentrations, and it is inappropriate to exclude them.
- What is meant by "> background or reference" at the third decision point? Must a concentration be statistically higher than the background/reference concentration to be retained at this step? What if the putative background concentrations are toxic? We are concerned that true COPCs might be dropped at this decision point, given the continued debate about the adequacy and representativeness of background or reference concentrations used in the draft risk assessment, together with the high heterogeneity of background and operational area samples in many locations.
- What is meant by "toxic" in the fourth box, and how would a teratagen or mutagen be classified? We presume that the term "toxic" is being used here in the broadest sense to include any substance that is known or suspected of being harmful to humans and other organisms. How will the "toxic" metric be applied; will a threshold concentration be applied in making this assessment (i.e., would a contaminant be excluded unless it is found above a threshold concentration at which harmful effects have been reported in humans or other organisms)? If so, how are threshold concentrations selected?
- Finally, we are concerned with the decision logic for undetected contaminants. The flow chart indicates that if the analytical process for an undetected contaminant met the target detection limit, that contaminant will be excluded from further consideration as a COPC. The logic as stated is flawed and is not acceptable. If the detection limit for a COPC is too high, such that exposure at a concentration equal to the detection limit poses a substantive risk to human health and/or the environment, the decision logic presented here could exclude a substance that poses an unacceptably high risk. We suggest adding an additional decision point relating the detection limit to risk threshold; if the detection limit is well below a concentration that might pose a significant risk, that substance can be excluded. However, if exposure at the detection limit might cause risk, then the substance must be retained or at least classified as an "uncertain COPC."

A second focus of Randy's presentation (slides 13-21) was on defining "representative concentrations" of contaminants in the risk assessment calculations. DOE and WCH indicated that they plan to prepare a second "white paper" to discuss their approach for defining representative concentrations of contaminants in the data used for the quantitative risk assessment. We have a number of questions and concerns arising from handout materials and oral presentation made on January 11, and ask that these be addressed in the second white paper.

- The overview (slide 14) notes that the approach was applied "across all data sets and analytes" including data that "had not been collected with the intention of supporting UCL calculations." What is the intended meaning of this statement, and what are the implications of using data collected for a different purpose? What is wrong with the data referenced by this statement? If sample sizes were too small, additional samples should have been collected. If samples were not representative, additional samples should have been collected, and/or the data should not have been used. If sampling/analytical methods were insensitive, imprecise, or inconsistent, the data should not have been used. Regardless, project managers should have carefully evaluated the nature and quality of existing data to meet the needs of this assessment, prior to sampling for the risk assessment, to insure that an adequate number of representative samples were collected to support reliable risk analyses.
- The subsequent bullet on the same slide describes the methodology used to compute upper confidence limits (UCLs) as an estimator for reasonable maximum exposure (RME) for the risk assessment and notes that "some UCL values were much higher that the maximum value." Why should this be a surprise? Given the small sample sizes and heterogeneous (and typically skewed, often log-normal) distributions of sample concentrations for many contaminants, we would be surprised if this were not the case. Is the issue here the validity of the approach used to calculate UCLs, or that the estimated values of those UCLs were often very high?
- The process outlined for estimating central tendency exposure (CTE) and RME on slides 19 and 20 raise a number of concerns:
    - Based on numbers of detects in the data base used in the draft A risk assessment, how many instances are there for number of detects to be equal to zero, one, two, three, four, five or more? What are the broad implications of the proposed approach, especially for generating estimates of RME? What percent of risk estimates will not have an estimate of RME, and therefore will not have any way of bounding the upper limits of risk? How will such missing risk estimates be factored into overall analyses of risk?
    - Slide 19 indicates that for sample sizes of three or four, the maximum detected value will be used as estimator of RME. From a statistical standpoint, this does not seem to make any sense. Why not calculate a 95% UCL and use that value? The slide also notes that RME values estimated in this way will be flagged in tables and explained in text, but how will those flags be propagated through the risk assessment; specifically how will they be incorporated into summary tables and graph and into narrative statements about aggregate risk?
    - Also for sample sizes of three or four, the slide indicates the mean will be used as the CTE. Do you intend to use the arithmetic mean of the raw values, log-transformed values, or something else? This same question applies for larger sample sizes also.
    - The approach for sample sizes of five or more identifies Student's t as one approach for estimating RME. Will these statistics be done assuming a normal distribution,

will data be log-transformed, or what? What will be the basis for assumptions about data distributions?

- The default assumption used in the draft A assessment (i.e., a lognormal distribution of contaminant concentrations) was presumably based on experience with contaminant data from Hanford and other contaminated sites. As WCH and its subcontractors begin using ProUCL for estimating RMEs, what will be the basis for discarding that assumption and using an alternate data distribution (e.g., gamma)? Given the small sample sizes of many data subsets used to estimate RMEs, it's unclear whether there will be any objective basis for choosing among normal, log-normal, or other distributions based on statistical evaluations as described in ProUCL. We recommend that DOE and its contractors develop an *a priori* set of rules for defining the statistical distribution of data and to consistently follow those rules in data analyses.

Finally, as discussed in the workshop on Friday morning, we strongly encourage DOE and WCH to include within the revised assessment report a thorough characterization and discussion of the uncertainties in data, models, and risk estimates. Risk estimates in the draft report were typically reported as sets of specific values, without any meaningful expression of the uncertainty that surrounds them. Uncertainty in a complex project like this derives from many sources, and it is important that presentation and subsequent discussion of risk estimates fully describe and acknowledge (and quantify where possible) potential sources and magnitude of uncertainty, and discuss resulting uncertainty associated with final risk estimates.

Oregon has been consistently engaged in development of risk assessments for the Columbia River corridor at Hanford. We appreciate the open communication that has been a hallmark of this project, and we look forward to continuing to work with you and your contractors during revision of the draft A assessment. If you have any questions or want to discuss any of our comments, please call me at 503-378-4456.

Sincerely,

Paul W. Shaffer
Ecologist

cc: Larry Gadbois, U.S. EPA
John Price, Washington Department of Ecology
Hanford Natural Resource Trustee Council

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