

# Response to Comments

## Draft Human Health Risk Assessment Guidance

DEQ received several comments its draft *Human Health Risk Assessment Guidance* in a June 11, 2010 letter from the consulting and engineering firm CDM. Additional comments listed below came from a May 26, 2010 public meeting and informally within DEQ. Based these on comments, DEQ revised its human health risk assessment guidance document as discussed in its responses below.



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### Comments from CDM

**1. Page 7, Section 2.6 Screening Procedures, 2nd paragraph:** The 2007 ProUCL program was listed. We suggest that the most recent version of the EPA ProUCL program, currently Version 4.00.04 released in 2009, be used.

**Response:** The current version of ProUCL is now referenced.

**2. Pages 8 to 10, Examples 1A to 1D:** It is difficult to tell which chemical is retained as a chemical of potential concern (COPC) following the screening steps in the examples. We recommend that an additional column be added to the right of each table indicating whether a chemical is retained as a COPC.

**Response:** DEQ added an additional column to the examples for clarity.

**3. Page 10, Example 1D:** Analytical data may be collected for several environmental media at a site, such as soil, groundwater, surface water, sediment, and soil gas. We recommend that ODEQ provide guidance on how and when to group exposure media together for the multiple media screen. It is reasonable to conduct a multiple media screen for those media that people are likely to come into contact under the same exposure scenario. For example, a worker engaging in excavation activities may come into contact with soil and groundwater in an excavation trench. Likewise, people visiting a surface water body may come into contact with surface water and sediment, but not soil or groundwater. Therefore, it will be overly conservative to include all five media in the multiple media screen.

**Response:** DEQ added text to clarify that reasonable scenarios presented in the conceptual site model should be used for screening chemicals in multiple environmental media.

**4. Page 12, Section 3.2.1 Exposure Point Concentrations:** The draft guidance states "To represent reasonable maximum exposure (RME), this means using the 90 percent upper confidence limit (90%UCL) on the arithmetic mean for environmental concentrations..." We suggest that 95 percent UCL (95%UCL), rather than the 90%UCL, be used as the environmental concentration in the risk assessment since 95%UCL has been commonly and widely accepted. In general, 95%UCL is more conservative than 90%UCL. Additionally, the recommendation for a UCL by the ProUCL program is 95%UCL. However, if ODEQ chooses to use 90%UCL, then a clarification is needed as to which statistical method for the 90%UCL will be selected, since ProUCL only provides recommendation for a 95%UCL and not a 90%percent UCL.

**Response:** DEQ rules specify using the 90 percent UCL for exposure point concentrations for reasonable maximum exposure estimates [OAR 340-122-

0084(1)(f)], not the 95 percent UCL. DEQ added text to clarify its suggestions for using the recommendations in ProUCL.

#### 5. Page 13, Section 3.3.1 Sources of Toxicity Values:

a. The draft HHRA guidance places HEAST at the top of hierarchy among the Tier 3 sources. HEAST values were published in 1997 and have not been updated. HEAST does not reflect the most current EPA methodologies that became available in the recent decade. We suggest that HEAST to be placed at the bottom of hierarchy of the Tier 3 sources.

b. We suggest that the California Environmental Protection Agency (Cal/EPA), which is one of the Tier 3 sources listed by EPA 2003 Human Health Toxicity Values in Superfund Risk Assessments, OSWER Directive 9285.7-53, be added as one of the Tier 3 sources.

c. EPA National Center for Environmental Assessment (NCEA) is listed as the second among the Tier 3 sources. NCEA values are generally provided as draft values. As discussed in the EPA OSWER Directive 9285.7-53, draft toxicity assessment is generally not appropriate for use until it has been through peer review. The peer review comments have been addressed in a revised draft and the revised draft is publicly available.

**Response:** DEQ's hierarchy for toxicity values is based on rule [OAR 340-122-0084(1)(c)(A)], and was originally consistent with EPA's hierarchy. EPA has since added provisional peer reviewed toxicity values (PPRTVs) to their hierarchy. DEQ added PPRTVs to its hierarchy in guidance, considering them part of "other U.S. EPA documents or databases" presented in rule.

6. Page 14, Section 3.3.2 Assessment of Carcinogens: The statement ".....oral SFs are derived from drinking water unit risks by assuming a 70-kg body weight and a water ingestion rate of 2 liters per day (L/day)" is not accurate. In general, cancer slope factors (CSFs) are derived from toxicity studies using dose-response models and linear extrapolations. Unit Risk in drinking water is then estimated from the CSF as follows:

$$\text{Unit Risk } (\mu\text{g/L})^{-1} = \frac{\text{CSF } (\text{mg/kg-day})^{-1} \times 0.001 \text{ mg}/\mu\text{g} \times 2 \text{ L/day}}{70 \text{ kg}}$$

**Response:** DEQ removed this section because it was confusing and no longer relevant.

#### 7. Page 15, Section 3.3.3 Assessment of Noncarcinogens:

a. The draft HHRA guidance states "The uncertainty in these estimates may span an order of magnitude". Please note that the overall uncertainty factors for RfDs could span from 100 to 3,000. We suggest the phrase "an order of magnitude" be revised.

b. The equation presented in the draft HHRA guidance for oral RfD is incorrect. The "water unit risk" is not a term in the derivation of oral RfDs. Oral RfDs are derived from no-observed-adverse-effect levels or the lowest-observed adverse-effect levels. Please clarify.

**Response:**

a) DEQ revised the text to quote EPA that overall uncertainty for RfDs could span “an order of magnitude or greater.”

b) Similar to the slope factor conversion, DEQ removed the conversion of water unit risk values to slope factors.

**8. Page 15, Section 3.3.4 Oral-to-Dermal Extrapolation, 2nd Paragraph:** It states “An absorption rate of 50 percent means that the observed toxic response was due to the half of the dose that was absorbed. Therefore, the toxicity of the absorbed dose is twice that of the administered dose”. Please note that the EPA RAGS Part E Supplemental Guidance for Dermal Risk Assessment (2004) recommends an adjustment in oral toxicity factors if the gastrointestinal (GI) absorption of the chemical is less than 50%. When GI adsorption is 50%, no adjustment is necessary.

**Response:** For clarity, DEQ revised its statement regarding EPA’s recommendation for adjusting oral toxicity factors for dermal toxicity.

**9. Page 19, Section 3.4.1.3 Calculation of Cumulative Risk:** There is a discrepancy between the methodology for calculating noncarcinogenic hazard index (HI) under the Risk-Based Decision Making (RBDM) approach and that proposed under the Standard Risk Characterization approach. As mentioned in Section 3.4.2.2 (page 21), hazard quotients for individual chemicals with similar toxicological effects (i.e., the same target organs or tissues) may be summed to yield an effect-specific HI. We suggest that the same methodology be used in the RBDM approach.

**Response:** DEQ believes the approaches for risk-based decision making and standard risk characterization to be the same for evaluating cumulative risk. DEQ revised the text to clarify this.

**10. Page 20, Section 3.4.2.1 Cancer Risk:** Please note that the equation for calculating potential excess lifetime cancer risk is incomplete. The equation only covers ingestion and dermal contact exposures but not inhalation. We recommend that an additional equation be provided for calculating cancer risk from inhalation exposure.

**Response:** DEQ has now included equations for inhalation risk which were inadvertently omitted.

**11. Page 21, Section 3.4.2.2 Noncancer Effects:**

a. Chronic daily intake (CDI) applies only to chronic exposure. Please note that acute and subchronic exposures are recommended by EPA in the RAGS, Part F, Inhalation Risk Assessment Guidance (EPA 2009). It is suggested that these new guidelines from EPA to be incorporated in the draft HHRA guidance.

b. RfC is expressed in units of mg chemical per cubic meter of air (mg/m<sup>3</sup>), not in µg/m<sup>3</sup>. Please correct.

**Response:**

a) DEQ revised the text to explicitly mention subchronic exposure.

b) RfC units were changed to mg/m<sup>3</sup>.

**12. Page 21, Section 3.4.2.3 Human Milk Ingestion:** As noted by the ODEQ, the inclusion of the breastfeeding pathway will affect cleanup decisions. It is anticipated that virtually any detection of PCBs, dioxins/furans, and total DDT will fail the COPC screen once risk-based concentrations for the breastfeeding pathway are developed by ODEQ. PCBs, dioxins/furans, and total DDT could be released to the environment through anthropogenic activities, such as urban runoff, agriculture runoff, transport in air and subsequent deposit, and natural forest fires, that are not site-related. Therefore, it is important to establish background levels for these bioaccumulative compounds to avoid costly and unnecessary cleanups. We recommend that ODEQ develop a common systematic approach to determine how and when to incorporate background levels into risk assessment for these bioaccumulative compounds.

**Response:** DEQ recognizes that acceptable concentrations for bioaccumulating chemicals will be very low, often below regional anthropogenic levels and/or detection limits. This is an important project issue, but it is not an element of human health risk assessments under Oregon rules. DEQ discussed this issue in its *Guidance for Assessing Bioaccumulative Chemicals of Concern in Sediment* (2007). DEQ continues to evaluate this issue.

**13. Page 35, Figure 2 Example Conceptual Site Model (CSM):**

a. The CSM in the current format is difficult to follow. We suggest that the three exposure routes, ingestion, inhalation, and dermal contact, be presented together, if applicable, in the CSM for each exposure medium.

b. The CSM uses UST as an example for primary sources. Since UST is located in subsurface, it seems unrealistic that it may leak and impact surface soil. We suggest that a primary surface source, such as aboveground storage tanks, rather than USTs, be added to the CSM.

c. There are two rows of “Groundwater” under “Tertiary Sources”. We recommend combining them to avoid redundancy.

**Response:** DEQ revised the example conceptual site model in response to these comments.

**14. Page A-15, Table A-1:** We recommend that the EPA 2008 Child-Specific Exposure Factors Handbook be used as one of the references for children. This guidance is designed specifically for assessing exposures for children less than 21 years old.

**Response:** EPA’s 2008 child-specific guidance was inadvertently omitted as a reference, and has now been included.

**Additional Informal Comments**

**15.** The screening of essential nutrients is not discussed in the guidance document.

**Response:** DEQ follows EPA guidance about including essential nutrients in human health risk assessments. DEQ added this approach to Section 2.6.

**16.** The use of J- and EMPC- qualified data in risk assessments is not discussed in the guidance.

**Response:** DEQ follows EPA guidance regarding the inclusion of qualified data in human health risk assessments. J- and EMPC- qualified data should be used in risk assessments. DEQ added a discussion of qualified data to Section 2.6.

17. Some risk assessors may wish to explicitly evaluate exposure factors and toxicity factors that are combined in the infant risk adjustment factor (IRAF).

**Response:** DEQ developed IRAF values to provide the simplest method for calculating potential risks to infants. To be more explicit about the derivation of infant risk adjustment factors, DEQ now provides information in Table 4, Table D-3 and associated Appendix D text about the role of exposure and toxicity.

#### **Alternative formats**

Alternative formats (Braille, large type) of this document can be made available. Contact DEQ's Office of Communications & Outreach, Portland, at (503) 229-5696, or toll-free in Oregon at 1-800-452-4011, ext. 5696.