6.3.5 Uncertainty Assessment

Because risk characterization is a bridge between risk assessment and risk management, it is important that the major assumptions, professional judgments, and estimates of uncertainties be described in the risk assessment. According to EPA guidance (1989), evaluations of uncertainty should be presented in tables that indicate whether each assumption used in the analysis is likely to overestimate or underestimate risk or whether the effect of uncertainty on the risk estimates is unknown. The potential magnitude of the effect of each source of uncertainty should be assessed and expressed as low, moderate, or high. The following

paragraphs describe some of the areas of uncertainty that are inherent in risk assessment methodology.

Some uncertainties expected to be associated with the selection of COCs include:

- Risks associated with chemicals intentionally excluded from the risk assessment
- Risks associated with chemicals unintentionally excluded from the risk assessment

Some uncertainties associated with the exposure assessment that may influence the risk evaluations include, but are not limited to:

- Assumptions used in developing exposure point concentrations
- Difficulties in accurately characterizing current land use
- Risks associated with pathways excluded from the risk assessment
- Data limitations and data gaps

When uncertainties cause overestimation of exposure, the risks predicted from such exposures also likely will be overestimated. The degree of uncertainty associated with such estimates will depend, in part, on the extent and quality of available data, other information, and modeling efforts.

Uncertainties associated with the toxicity assessment include:

- The quality of studies as the basis for toxicity factors
- Potential differences in toxicity and absorption efficiency between humans and laboratory animals

- The applicability of studies conducted on experimental animals dosed at high levels to human exposures at lower concentrations

- The validity of the crucial underlying assumption in the dose-response model for carcinogens (linearized multistage model) that there is no threshold for carcinogenesis (that is, there is no dose of a carcinogen that is not associated with a risk of cancer)

The confidence of the calculated estimate of risk depends on the underlying uncertainties in each step of the risk assessment process. In addition, aspects of the risk characterization process itself introduce uncertainties, including those associated with adding risks or HQs for multiple chemicals and compounding of upper bound estimates in the exposure assessment.

A discussion of the major assumptions, professional judgments, and estimates of uncertainty must be described in the ecological risk assessment. As in the human health assessment, evaluations of uncertainty should be presented in tables that indicate whether each assumption made in the analysis is likely to overestimate or underestimate risk, or whether the effect of uncertainty on the risk estimates is unknown (EPA 1989). Because of the level of effort required for each type of assessment, with the screening assessment having a higher degree of uncertainty, the screening and detailed evaluations will differ with regard to uncertainty. Some sources of uncertainty in a screening level ecological risk assessment are (EPA 1996):

- The use in the exposure analysis of maximum contaminant concentrations detected in environmental media as exposure concentrations for potential ecological receptors

- The assumption that an exposure area use factor for potential ecological receptors is 100 percent (i.e., 100 percent of the diet and home range lies within the exposure area)

- The ecological effects analysis applies Toxicity Reference Values (TRV) and NOAELs that are estimates of potential adverse effects derived from laboratory studies and extrapolated to site conditions

- The assumption that 100 percent of the chemicals are bioavailable

- The potential that adverse effects on ecological receptors will differ during different life stages.

Screening Level Risk Evaluation

Discussions of uncertainty in screening level assessments should be comprehensive enough to describe all important sources of uncertainty, conservativism, and variability in the results, but generally should not include quantitative analyses of uncertainty. All assumptions must be documented. According to EPA guidance (EPA 1989), "it is important to fully specify the assumptions and uncertainties inherent in the risk assessment to place the risk estimates in proper perspective. Another use of uncertainty characterization can be to identify areas where a moderate amount of additional data collection might significantly improve the basis for selection of a remedial alternative." In the case of a permit application, discussions of uncertainty may identify areas in which additional data could improve the risk analysis significantly, if a screening evaluation indicates unacceptable risks.

The guidance identifies several sources of uncertainty that should be addressed "in risk assessments in general, and in the exposure assessment in particular" (EPA 1989):

- The definition of the physical setting

- The applicability of the model and its assumptions

- The transport, fate, and exposure parameters

- The tracking of uncertainty or how uncertainties are magnified through the various steps of the assessment

At a minimum, the permit applicants should address these four sources of uncertainty qualitatively. The potential magnitude of the effect of each source of uncertainty also should be assessed and expressed as low, moderate, or high.

Detailed Risk Evaluation

The evaluation of uncertainty for a detailed risk evaluation should include all of the points described above for screening level evaluations. The description of uncertainty in a detailed risk evaluation is likely to be more in-depth than that for a screening level evaluation, because more site-specific information is used and more modeling may be conducted. In addition, the permit applicant may elect to conduct a quantitative analysis of uncertainty. One method for quantitatively assessing risk is Monte Carlo simulation. Monte Carlo simulation is a statistical technique that can be used to simulate the effects of natural variability and informational uncertainty that often accompany "real-world" situations. It is an effective tool for quantitative evaluation of uncertainty associated with point estimates. It is a process whereby an outcome is calculated repeatedly for many "what if" scenarios, using in each iteration randomly selected values for each of the variable or uncertain parameters from a predetermined probability density function that describes distribution of the variable.

EPA has not developed national guidance on performing Monte Carlo analyses, but regional EPA offices have developed regional guidance documents that can be consulted for input variables. EPA Regions 3 and 8 have instituted guidance for Monte Carlo simulations. Because of the complex nature of the assessments, a statistician and risk assessor should review the results.

In reviewing risk assessments to evaluate their treatment of uncertainty, the permit writer may wish to focus on the last four points covered in the

discussion of the screening level assessment as a way to structure comments in the NOD. Without adequate discussion of those points, neither the screening level assessment nor the detailed risk assessment will provide the level of information about uncertainty that is required. Typically, a screening level assessment that includes a discussion of those points also will include an adequate discussion of uncertainty in general, while a discussion that does not include those points will be inadequate.