6.3.4 Risk Characterization

Risk characterization combines exposure estimates and toxicity values to calculate numerical estimates of risk and hazards to human health. Risk characterization comprises the following steps:

- Review toxicity and exposure assessment results
- Quantify risks for individual contaminants in each medium
- Quantify risks from exposure to multiple contaminants for each pathway
- Combine risks from the various exposure pathways, when appropriate, to quantify total risk for each exposure scenario
- Evaluate and present uncertainties that underlie risk estimates

For both the human health and the ecological risk characterizations, the permit writer should decide whether the correct toxicity values have been used for each receptor and exposure pathway, whether risks and HIs have been summed for all exposure pathways for each receptor, and whether total risks and HIs also have been presented for each COC.

The method described in EPA 1989 should be used to calculate the ILCR for carcinogens. Quantifying total excess cancer risk requires calculation of risks associated with exposure to individual carcinogens and summing risks associated with simultaneous exposure to several carcinogens for the same human receptor. Risks associated with exposures to single carcinogens should be calculated as follows:

Risk = CDI x CSF

where:

Risk = A unitless probability of an individual developing cancer over a 70-year lifetime
CDI = Chronic daily intake of the contaminant averaged, over 70 years (mg/kg-day)
CSF = Carcinogenic slope factor expressed in $(mg/kg\text{-}day)^{-1}$

The ILCR for an individual will be calculated by summing chemical-specific risks across all appropriate pathways. The exposure pathways and chemicals that pose the greatest risk should be identified.

Unlike carcinogenic effects, noncarcinogenic effects are not expressed as a probability. Instead, adverse effects caused by noncarcinogens are expressed as the ratio of the CDI to the RfD (or RfC), when both values are based on similar exposure periods. The ratio is termed a hazard quotient and is calculated as follows:

Hazard Quotient = CDI/RfD

where:

CDI = Estimated exposure level (or intake)
RfD = Reference dose

The CDI and RfD are expressed in the same units and are based on the same exposure period. If the CDI exceeds the RfD, the hazard quotient will be greater than one, indicating that a potential health hazard may exist.

Noncarcinogenic risks should be aggregated for each exposure pathway into a noncarcinogenic hazard index as follows:

$$HI = CDI_1/RfD_1 + CDI_2/RfD_2 + \ldots + CDI_i/RfD_i$$

where:

CDI_i = Exposure level or intake for the i^{th} toxicant

RfD_i = Reference dose for the i^{th} toxicant

Risk characterization also is a concern in an ecological risk evaluation. Because of the complex nature of ecological assessments, the risk characterization often is conducted through a weight-of-evidence approach, under which different types of data are evaluated together (EPA 1994). For example, the screening risk calculation is repeated in the detailed risk assessment, with site-specific intakes calculated for the exposure assessment and toxicity values from the literature both used. Hazard quotients (HQ) are summed for all chemicals and pathways, if appropriate. In addition to the risk calculation, conclusions should be drawn from studies or tests conducted for additional site investigations to establish links between assessment endpoints and measurement endpoints (EPA 1994). In the risk characterization, all available information should be reviewed and conclusions presented.

For all complete exposure pathways, ecotoxicity values compiled from a literature search should be compared with the calculated exposure estimates, using the HQ method. As stated previously, the ecotoxicity threshold value should be based on the documented and best conservatively estimated chemical-specific NOAEL for the screening level and detailed risk calculations (EPA 1994). An HQ for a direct exposure assessment is a ratio of the maximum environmental concentration (mg/kg) to an ecological benchmark (for example, EPA water quality criteria). An HQ for an indirect exposure assessment is the estimated chemical intake (mg/kg-day) to an ecotoxicity screening value (for example, a NOAEL). HQs should be calculated as follows:

$$HQ = EEC_1/TRV_1 + EEC_2/TRV_2 + \ldots + EEC_i/TRV_i$$

or

$$CDI_1/NOAEL_1 + CDI_2/NOAEL_2 + \ldots + CDI_i/NOAEL_i$$

where:

HQ	=	Hazard quotient for a given chemical, potentially complete exposure pathway, and selected ecological receptor
EEC_i	=	Expected environmental concentration (mg/kg or mg/L)
TRV_i	=	Toxicity reference value for a given chemical and ecological receptor (mg/kg or mg/L)
CDI_i	=	Estimated chemical intake (mg/kg-day)
$NOAEL_i$	=	No-observed-adverse-effect-level (mg/kg-day)

According to EPA guidance (1994), it is necessary to sum the HQs to account for simultaneous exposure. If the resulting hazard index (HI), which is equal to the sum of the HQs, is less than 1.0 in the screening level risk assessment, it is concluded that there is little or no ecological threat at the site. However, if the resulting HIs exceed 1.0, adverse ecological effects are likely to occur, and a detailed ecological risk assessment should be conducted.