

Overview of Screening, Risk Ration, & Toxicological Evaluation Procedures for Northern Division Human Health Risk Assessments

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Introduction

The purpose of human health risk assessments is to identify and characterize potential risks associated with human exposure to site-related chemicals of potential concern (COPC) in order to support (1) informed decision-making and (2) remedial response activities resulting in regulatory compliance decisions. At sites where there is a known or suspected release, a formal human health risk assessment may not always be necessary. Rather, a risk ratio/toxicological evaluation (RR/TE) method can be employed at these sites to determine whether further investigation, or a more conventional evaluation of risk would be beneficial for the decision-making process. In essence, this procedure allows for a preliminary indication of potential risk to humans once COPCs in the various media have been identified before performing a more rigorous assessment, if deemed appropriate. This process consists of a preliminary risk-based screening, a risk-ratio comparison, and a toxicological evaluation, if warranted.

Risk Based Screening

The first step in the process of COPC selection is the evaluation of validated analytical data on the basis of qualifiers and the frequency of detection. Inclusion or exclusion of data on the basis of qualifiers should be in accordance with USEPA guidance.

Selection of chemicals for inclusion in, or exclusion from, the human health risk ratio/ toxicological evaluation is a multifactorial process and involves some or all of the following steps:

1. Screening the maximum detected concentration (MDC) of each compound in each medium of concern against its risk-based screening concentration (RBC) for cancer effects, or one-tenth its RBC for noncancer effects for that medium (i.e., soil, ground water), based on site-specific scenarios.
2. Screening the MDC of each compound against its maximum detected background reference concentration (or other agreed upon background reference value).
3. Screening the MDC of each compound against other criteria, including action levels, and, if appropriate, recalculated RBCs based on site-specific reuse scenarios (e.g., calculating industrial RBCs for ground water using parameters for industrial exposures).
4. Chemicals of potential concern (COPCs) can be eliminated from consideration if they are detected in fewer than 5 percent of the samples in a particular medium. This evaluation requires at least 20 samples.
5. Essential nutrients such as potassium, calcium, iron, sodium, and magnesium are removed from the COPC list during screening, and are not considered further in the assessment.

Risk Ratio Analysis

The next step in the screening process is determining the risk ratios for carcinogens and noncarcinogens. For carcinogenic chemicals, the risk associated with exposure to an individual COPC is then estimated by multiplying the risk upon which the RBC is based (1×10^{-6}) by the simple ratio of the MDC to the RBC. For example, if the MDC for benzo(a)pyrene is 3.0 mg/kg and the RBC is 7.84×10^{-1} , the risk ratio is $3.0/0.784 \times 10^{-6}$ or 3.83×10^{-6} . COPC-specific risks are then summed to determine whether the estimated cumulative cancer risk for the assessed exposure route exceeds the benchmark of 5×10^{-5} . Typically, action is initiated at a site when the cumulative cancer risk for all pathways and routes of exposure surpasses 1×10^{-4} . For screening purposes however, a benchmark of 5×10^{-5} is established to account for potential risks posed by pathways and routes not considered by the risk ratio/toxicological evaluation process.

Similarly, the MDC for noncarcinogens is compared to the RBC and the potential risk estimated by multiplying the hazard index at the RBC (1.0) by the ratio of the MDC to the RBC. COPC-specific risks are then summed to determine whether the estimated cumulative non-cancer risk for the assessed exposure route exceeds the benchmark of 0.5. Action is typically initiated at a site when the cumulative non-cancer risk for all pathways and routes of exposure surpasses the benchmark of 1.0. For the purposes of screening, a benchmark of 0.5 is instituted to account for potential risks posed by pathways and routes not considered by this process.

For chemicals that have both cancer and noncancer effects, in general, the RBC is based on cancer risk, and therefore only the cancer risk associated with that COPC is included in the risk ratio sum.

As a preliminary assessment, the risk-ratio comparison is regarded as a reasonable approach for determining the need for a more detailed and site-specific evaluation. If the cancer and noncancer benchmarks are not exceeded, no additional human health risk assessment is required. If either of the risk-ratio screening benchmarks (5×10^{-5} for excess lifetime cancer risk, 0.5 for noncancer) is exceeded, then a site-specific quantitative assessment of risk should be undertaken.

Toxicological Evaluation and Risk Characterization

Typically (but not in every case), risks are driven by the ingestion route of exposure. Therefore, for the purposes of the toxicological evaluation, it is generally the only pathway considered in the characterization of risk in Region III when using the RR/TE method. If the risk estimates are close to the action level benchmarks, this is an indication to proceed to the more traditional method of risk assessment. Other routes of exposure, such as dermal and inhalation pathways, if appropriate, should then be included, and risks across those pathways should be added to the ingestion risk to quantify the total risk estimate.

In general, exposure parameters are selected to reflect only reasonable maximum exposure (RME) conditions, rather than considering both central tendency and RME measures, as is the usual case with the standard approach to risk assessment. One reason for this is to calculate the more conservative estimate of risk and, at the same time, compensate for examining risks through the ingestion pathway only. Site-specific parameters are utilized when available.

Current use (as well as reasonable future reuse of the site) dictates which exposure scenarios to consider in a toxicological evaluation in the same manner as in a formal risk assessment.

Exposure point concentrations are determined either by calculating the 95th percentile upper confidence limit on the mean or by taking the MDC, depending on statistical characteristics of the dataset such as the sample size and distribution.

Once the exposure parameters and the EPC for each COPC have been determined, characterizing the risk associated with the site through the ingestion pathway is fairly straightforward and is identical to the method used in a formal risk assessment. The average daily intake (ADI) is the product of the COPC EPC, ingestion rate, fraction ingested, exposure duration, exposure frequency, and a conversion factor to

balance the units, divided by body weight and averaging time. The ADI is then multiplied by the COPC cancer slope factor to calculate the cancer risk, or is divided by the COPC noncancer reference dose to calculate the noncancer hazard.

Cancer risks and noncancer hazards are each summed across COPCs to determine the total risk estimates for carcinogens and noncarcinogens for each exposure scenario. For constituents that have both cancer and noncancer effects, both cancer risk and noncancer hazard are calculated and included in the sum total estimates. For noncarcinogens, target organ analysis is appropriate prior to summing hazards, to avoid summing across COPCs with different target organs. As with the more conventional methods of risk assessment, cancer risks within or below the range of 10^{-4} and 10^{-6} are considered to be acceptable, and noncancer hazards below 1.0 are likewise considered to be acceptable.

Summary

The risk ratio/toxicological evaluation approach to characterizing risks is a valid and efficacious method of screening and eliminating both COPCs and sites from further assessment of risk involving detailed and formal risk assessment methods. This approach is effective as it ensures health protection while saving both significant cost and time that are associated with more formal risk assessment methods. It is an acceptable alternative in USEPA Region III and has facilitated site closeout in many instances.