TABS ON CONTAMINATED SITES

Contaminated Sites Program - Federal Sites

This is one in a series of Technical Assistance Bulletins (TABs) prepared by Environment Canada-Ontario Region for Federal Facilities operating in Ontario.

TAB #16

Risk Assessment-Exposure Model, Toxicity Analysis and Evaluation

DESCRIPTION:
The process of quantitatively predicting the likelihood of an adverse response in humans or wildlife due to exposure to one or more chemicals is collectively known as environmental risk assessment.

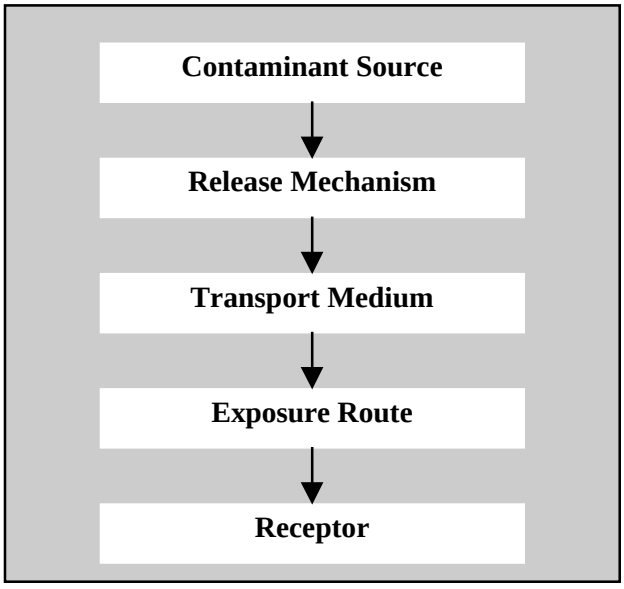
Risk assessment of contaminated sites is used to determine if remediation of the site is warranted to protect human health and the environment, and to provide information to facilitate risk management.

1. DEVELOPMENT OF A CONCEPTUAL EXPOSURE MODEL

An objective in conducting a problem formulation is to clearly illustrate the relationship between the chemicals of concern, the exposure pathways that exist, and the receptors of concern. The conceptual exposure model facilitates this objective by allowing all interested parties (risk manager, regulator, public-interest group, etc.) to see an early "snapshot" of the site, thereby ensuring that all important issues are addressed. Separate Conceptual Exposure Models should be developed for human and ecological receptors to avoid producing complex and confusing schematic diagrams.

A Conceptual Exposure Model is derived by tracing the chemical from its source to the receptors using the elements outlined in **Figure 1**. The principle is to provide a sufficient qualitative description and illustration to foster an understanding of how these elements may ultimately combine or interact to generate health risks to specific receptors.

Figure 1: Conceptual Model Elements Required to Produce Human Health Risk



2. EXPOSURE AND TOXICITY ANALYSIS

If it is determined during the problem formulation phase that there are significant exposure pathways for chemicals of concern to come into contact with receptors of interest, a quantitative risk assessment (QRA) may be warranted. The objective of a QRA is to quantify health risks associated with the chemicals of concern. Exposure and Toxicity Assessments are the first quantitative steps of the QRA, followed by Risk Characterization which provides an overall estimate and explanation of the human or ecological health risk.

Exposure Assessment
Exposure Assessment involves estimating the dose or concentration of the contaminant taken in by human and ecological receptors per unit time (e.g. the quantity of contaminant and the daily intake rate). For aquatic organisms (e.g. fish) the Exposure Assessment often consists of stating the exposure concentration and not the intake rate. Exposure Assessment is conducted for all contaminants, receptors, and exposure pathways identified as being of primary concern by the problem formulation process.

Receptors can be exposed to contaminants through a number of environmental media including air, water, soil, and food. Contamination may occur in one medium, but the contaminant may migrate to others. Therefore, contamination in one medium (e.g. soil) may result in multi-media exposure (e.g. soil, air, water). Although the exposure media of concern are usually *identified* in the problem formulation phase, multimedia exposure is *quantified* in the Exposure Assessment.

For virtually all animals (including humans) the primary routes of contaminant exposure are through inhalation, ingestion, and dermal (or trans-dermal) absorption. In the case of fish, absorption across the gills is often the prime route of uptake, although dietary intake may be important for some species. The relative importance of each of these exposure routes will vary depending on the receptor selected to assess the site.

Depending on the specific characteristics of the site, the following general elements are usually involved in an Exposure Assessment:
a) Characterization of contaminant concentrations.
b) Exposure amortization.
c) Receptor characterization.
d) Bio-availability assessment.
e) Micro-environment analysis.
f) Exposure analysis.

Depending on the particular site characteristics and regulatory requirements, some elements of the exposure assessment may not require detailed consideration.

a) Characterization of Contaminant Concentrations
Risk assessors can use a wide range of investigative and analytical techniques to determine the concentration of the contaminants at the site. For each contaminant of concern, estimates of the concentrations must be defined for each environmental medium of interest (e.g. soil, ground water, surface water, sediment, air, vegetation). Concentrations may be derived from two broad methods:
I. direct monitoring (e.g. sampling and chemical analysis of media at the site coupled with summary statistics); or,
II. environmental modelling (e.g. mathematical modelling to predict contaminant concentrations in various media).

The selection of a representative contaminant concentration to reasonably reflect site conditions, within an environmental medium of interest, is a critical issue in estimating potential health risks. For risk assessments conducted using *deterministic* analysis, contaminant concentrations are expressed as point estimates. A standard approach is to use upper end estimates (e.g. upper 95th percentile estimates, or maximum values) of site concentrations in order to ensure that potential risks from the contaminants are not underestimated. This is often used as a further screening tool prior to conducting more detailed and realistic exposure assessments. If predicted exposures are determined to be acceptable using conservative assumptions, then the actual exposure experienced by receptors at the site are likely to be considerably *less* (e.g. conservative assumptions will overestimate exposure). However, estimates of human and ecological health risks using upper end estimates of contaminant concentrations may result in highly unrealistic risk estimates, especially if the areas or volumes of contaminated materials are small and/or other exposure parameters (e.g. intake rates, exposure frequency, etc.) are also overly conservative. In these circumstances, or when there is a strong need to understand the uncertainty

associated with the assessment, a probabilistic analysis may be employed. In this case, probability distributions for several input parameters including the concentrations of contaminants in various environmental media can be used in an iterative computation (e.g. Monte Carlo method). The validity of the assigned distributions is important to the risk assessment, and should be discussed with regulators and the investigating engineer to confirm that they reasonably reflect site conditions.

b) Exposure Amortization
Exposure amortization generally applies to human exposure to genotoxic carcinogenic substances and is the process of determining a lifetime average daily exposure rate from a less-than-lifetime exposure (e.g., where exposure may only be five years in duration, but the risk of cancer persists after exposure has ceased).

c) Receptor Characterization
Receptor habits and characteristics are major factors in determining exposure. Almost every equation used to estimate exposure has at least two terms which attempt to define a specific receptor's characteristics or parameters. Examples of these receptor characteristics include body weight, volume of air inhaled per unit time, amount of soil consumed inadvertently, and time spent indoors and outdoors for human receptors (e.g. determine frequency of exposure). The values for each of these receptor characteristics vary substantially, and therefore define which receptors receive the greatest exposure from the contamination (e.g. bird versus mouse, or adult versus child).

d) Bio-availability Assessment
Bio-availability is used to estimate the internal dose received by a receptor as a result of exposure to a contaminant. Some contaminants are absorbed poorly by the body such that the internal dose is much less than the exposure dose. A bio-availability factor is important in exposure estimates if:

i. The contaminant matrix is significantly different from the matrix used in the reference toxicity study to derive the safe exposure limit (e.g. contaminant in soil versus in drinking water).
ii. The contaminant form is different from that used in the reference toxicity study to derive the safe exposure limit (e.g. inorganic versus organic).
iii. The bio-availability is significantly different between receptors at the site and the research animal used to derive the safe exposure limit.
iv. The route of exposure for the receptor is different from the route of exposure in the reference toxicity study used to derive the safe exposure limit (e.g. inhalation versus dermal).

e) Micro-environment Analysis
Micro-environments are defined as smaller regions of the site characterized by higher concentrations of contaminants and/or physical features that could affect the exposure of receptors. Analysis of micro-environments may identify areas of the site that are visited more frequently, or specific areas where unacceptable exposure could occur. When warranted, consideration of micro-environments improves the realism of the exposure assessment.

The use of micro-environments may be important under the following conditions:

i. When the concentration of contaminants is not uniformly distributed throughout the entire site;
ii. When the site is not used by receptors in a uniform manner (e.g. some areas of the site are used and others are not).

As a general rule, if either of the above conditions exist at the site, micro-environment analysis will assist in improving the quality of the exposure assessment and consequently the overall risk assessment.

f) Exposure Analysis
Exposure Analysis is simply the process of integrating those elements described in subsections (a) through (e) to quantify exposure to the contaminants of concern for each significant pathway identified in the exposure assessment. Exposure should be expressed as “µg of contaminant/kg body weight/day”.

3. TOXICITY ASSESSMENT

Toxicity Assessment for Human Health Risk Assessment
For human health risk assessment, Toxicity Assessment involves classifying the contaminants in accordance with their potential toxic effects, and estimating the acceptable dose or concentration that can be received by a receptor without experiencing measurable adverse health effects (e.g. exposure limit or toxicity reference value). Toxicity

Assessment is conducted for all contaminants of concern and each exposure route, as dictated by the problem formulation phase.

For human health risk assessment, the risk assessor must determine whether or not the contaminant is considered by appropriate regulatory agencies to be a threshold or non-threshold response contaminant. Briefly, a threshold response contaminant is one that only presents toxicity when the receptor receives a dose beyond a specified limit (e.g. exposure to contaminants below the threshold response dose does not constitute a health risk). A non-threshold response contaminant is one which does not manifest toxicity via such a threshold response mechanism and thus, any exposure could *theoretically* result in an adverse effect (e.g. genotoxic carcinogens are believed to act in this manner).

The toxicity reference value or "reference dose" is expressed in the same units as referenced in the exposure analysis (e.g. “µg of contaminant/kg body weight/day”), and is used for threshold chemicals. For known or suspected human carcinogens, which are non-threshold chemicals, a “slope factor” is used, instead of a reference dose, to express the potency of contaminant toxicity (units are $[\mu g/kg \text{ body weight/day}]^{-1}$).

Toxicity Assessment for Ecological Risk Assessments
The basic principles applied in human health toxicity assessments apply to ecological toxicity assessments; however, carcinogenicity is rarely considered. The selection of appropriate toxicity reference values relates to the desired level of protection that is to be given to ecological receptors at the site. This reference value can be influenced by many factors including regulatory policy. As a result, selection of a toxicity reference value should be conducted in consultation with the appropriate regulatory authorities.

4. RISK CHARACTERIZATION

Risk Characterization is the final step in the quantitative risk process and it involves:

a) a numerical estimation of health risks; and,
b) a description and evaluation of the estimated risks associated with exposure to contaminants of concern.

Risk Characterization follows the Exposure and Toxicity Assessment phases. It is conducted for all contaminants, receptors, and exposure scenarios of concern. Results from Risk Characterization, plus various engineering, economic, and societal factors, are used to develop remediation or risk management options for the site under consideration.

Numerical Estimation of Health Risks
Health risks are estimated by comparing the predicted exposure(s) to the acceptable toxicity reference values. For threshold-acting contaminants, the human and non-human risk estimate is expressed as a Hazard Quotient (HQ), or an exposure ratio, such that,

HQ = (predicted exposure)/(exposure limit)

For human exposure to some carcinogen, a Numerical Cancer Risk (NCR) estimate is calculated by multiplying the predicted exposure by the potency factor or slope factor, such that,

NCR = (predicted exposure) x (potency factor)

Risk estimates for various exposure pathways of concern and for contaminants which act on similar biological systems (e.g. all the chemicals at a site where liver effects are evident) should be added together to provide an estimate of the total risk associated with exposure to a contaminant mixture (e.g. the hazard index, HI). Likewise, total cancer risk can be derived from summation of the cancer risks posed by individual chemicals.

Description and Evaluation of Risk
For a threshold-response contaminant, a Hazard Quotient (or Hazard Index for grouped chemicals) that is less than or equal to one, indicates that the estimated exposure is within the degree of exposure that is considered acceptable. Hazard Quotients or Hazard Indices that are greater than one, suggest that the estimated exposure exceeds the acceptable exposure limit. Hazard Quotients (and Hazard Indices) which are greater than one should be compared against background values, since there are a number of contaminants that will demonstrate risk values greater than one even at ambient (e.g. natural) background conditions. In addition, since conservative factors are often used to derive the toxicity reference values, there is often a considerable margin of safety between the reference value and exposure that can actually produce measurable adverse health effects. Thus, a risk

value greater than one does not necessarily mean that adverse health effects will certainly occur. Nevertheless, a risk estimate that is greater than one represents a health concern that should be closely examined to identify the reason for the elevated health risk, and where necessary, appropriate mitigative action should be taken.

For a non-threshold response chemical, a Numerical Cancer Risk estimate may be compared to a regulatory agency's acceptable cancer risks, if one exists. Target levels of acceptable cancer risk vary, depending on the regulatory agency, and are in the range of 1 in 100,000 to 1 in 1,000,000. Accordingly, cancer risk estimates that are less than an acceptable regulatory level are viewed to be acceptable.

SOURCES

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US EPA (1992). *Framework for Ecological Risk Assessment.*

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GLOSSARY OF TERMS USED IN RISK ASSESSMENT

Absorption -The process involved with the taking up of contaminants by the skin, mucous surfaces, or absorbent vessels.

Background - An area not influenced by those contaminants released from the site under evaluation.

Background assessment - A standard used to compare the effects of receptor exposure to a contaminant originating from a site of concern (e.g. pulp mill, incinerator, etc.), to the effects expected from exposure to the same contaminants at concentrations estimated for the same location (urban or rural) in the absence of the site of concern.

Bio-availability - Fraction of contaminant that enters the general systemic circulation following administration or exposure.

Carcinogen - An agent that is reactive and can act directly to cause cancer.

Chemical (Contaminant) of Potential Concern - A chemical which is not excluded as a result of screening procedures and is retained for further risk assessment.

Conceptual Model - A qualitative model of how site specific health risks may form, based on hypotheses describing contaminant source, release, environmental transport and biological uptake.

Deterministic Analysis - An analytical approach to modeling which employs point estimates of input and output parameters and does not address uncertainty (variability) in the parameters.

Dose rate - Dose per unit time, for example in mg/day, sometimes called dosage. Dose rates are often expressed on a per-unit-body-weight basis, yielding units such as mg/kg/day expressed as averages over some time period, for example a lifetime.

Environmental Medium - One of the major categories of material found in the physical environment that surrounds or contacts organisms (e.g. water, soil, or air) and through which contaminants can move and reach the organisms.

Exposure Limit - The maximum recommended daily exposure to a contaminant, or, for contaminant uptake.

Exposure pathway - The route by which a receptor comes into contact with a contaminant in an environmental medium. Examples of exposure pathways include the ingestion of water, food and soil, the inhalation, of air and dust, and dermal absorption.

Exposure scenario - A set of facts, assumptions, and inferences about how exposure takes place. This information helps the exposure assessor in evaluating, estimating, or quantifying exposures.

Hazard Quotient (HQ) - A term used by some regulators to estimate risks associated with exposures to chemicals with a threshold-type dose-response relationship. Similar to the Exposure Ratio value approach, a Hazard Quotient is calculated by dividing the predicted exposure by the exposure limit, but only for threshold-response contaminants.

Internal Dose - The amount of a contaminant penetrating the absorption barriers (the exchange boundaries) of an organism via either physical or

biological processes. In some cases, this term is synonymous with absorbed dose.

Micro-environments - Relatively smaller areas within a site such as localized areas of high concentrations of contaminants, areas with structures that may attract receptors (e.g. log pile providing cover for animals or attracting children to play on) that can be treated as homogeneous.

Non-Threshold Response Contaminant - A chemical for which, *in theory*, any exposure has the potential to cause adverse effects. For these contaminants (e.g. genotoxic carcinogens) exposure is associated with a risk factor calculated from the q_1^*.

Numerical Cancer Risks (NCR) - A numerical cancer risk estimate that is used by some regulators to estimate risks associated with exposures to non-threshold response contaminants (e.g. genotoxic carcinogens). A numerical cancer risk value is calculated by multiplying the estimated exposure by the potency factor (q_1^*).

Potency factor - see q_1^*

q_1^* - A measurement of carcinogenic potency. This is the slope of the dose-response curve from the linearized multistage model for the estimation of risk following exposure to a carcinogen.

Receptor - The person or organism potentially exposed to contaminants.

Residency Media - The environmental media (e.g. soil, water, air) where, based on its physical/chemical properties, a chemical would tend to exist in greatest concentrations.

Risk-Based Reference Concentration - A site-specific environmental quality concentration developed from basic exposure principles (equations) and the use of a pre-defined target risk estimate. This concentration is used for chemical screening.

Risk Estimation - The integration of the exposure assessment and toxicity assessment to evaluate the likelihood of adverse health effects associated with exposure to an environmental contaminant.

Route of Exposure - The physiological means by which a chemical enters the body. Conventionally taken to mean ingestion, inhalation or trans-dermal uptake.

Probabilistic Approach (Stochastic Approach) - an analytical approach to modeling which employs probability distribution functions to describe input and output parameters and therefore addresses uncertainty (variability).

Threshold Response Contaminant - A contaminant which manifests toxicity via threshold response mechanisms and accordingly has it toxicity expressed as an RFD (Reference Dose), ADI (Acceptable Daily Intake) or TDI (Total Daily Intake). It is not a genotoxic carcinogen.

Toxicity - The production of any type of damage, permanent or temporary, to the structure or functioning of any part of the body. The conditions of exposure under which toxic effects are produced - the size of the dose and the duration of the effective dose may vary greatly among contaminants.

Uptake - The process by which a contaminant crosses an absorption barrier and is absorbed into the body.

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