### 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 #15



# Risk Assessment-Application & The Screening Process

#### **DESCRIPTION:**

This TAB provides a brief insight into the application of Risk Assessment Principles and Screening Processes as they apply to contaminated sites.

#### 2. RISK ASSESSMENT CONTEXT

Risk assessment is the process of estimating the likelihood of undesired effects on human and ecological health resulting from exposure to a chemical or a contaminant source. The primary purpose of a risk assessment of a contaminated site is to provide the risk manager with information to determine if remedial action is warranted where chemical concentrations or risk estimates exceed decision criteria, and if so, to provide the necessary information to select an appropriate course of action. Therefore, risk assessment is the part of the integrated risk management process that provides the scientific information used in making risk management decisions. An integrated view of the risk management process is shown in Figure 1. The risk management process is discussed in **TAB** # 17

#### 2. REGULATORY CONTEXT

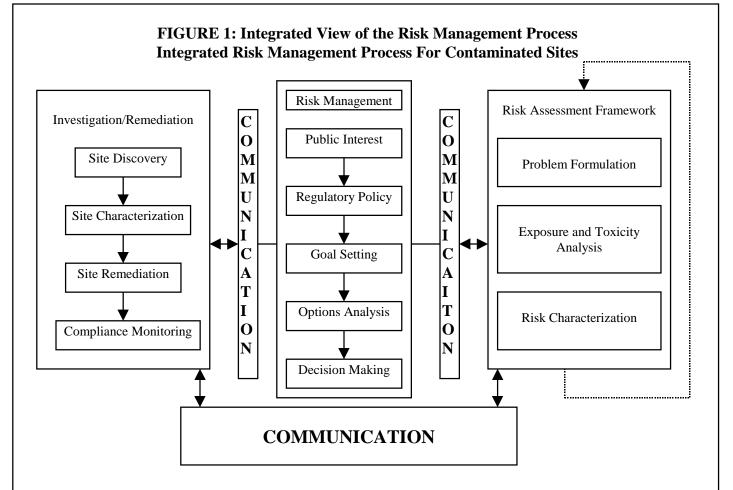
Guidance for conducting risk assessments has been provided by both federal and provincial regulatory agencies. Federal agencies involved with risk assessments include both Health Canada (responsible for the protection of human health) and Environment Canada (responsible for the protection of the environment and ecological receptors). Provincial regulatory agencies are

generally the Provincial Ministry of the Environment and/or the Provincial Ministry of Health. Regulation of each site should be clarified at the initiation of the risk assessment action to identify the regulators that will be involved in the process.

#### 3. PURPOSE

The risk assessment process is intended to:

- Provide focus, during project planning and site investigation, of "potential receptors", the chemicals that they may be exposed to, and the "pathways of concern". The process enables the "screening-out" of chemicals which make little or no contribution to human and ecological health risk.
- Provide a consistent approach for assessment and reporting health risks due to exposures to chemicals from contaminated sites.
- Allow for estimation of site-specific clean-up objectives that would reduce potential risk to a publicly acceptable level and adequately protect human and ecological health.



#### 4. APPLICATIONS OF RISK ASSESSMENT

Risk assessments are used to develop risk-based clean up criteria at contaminated sites for a variety of reasons, including:

- 1. When contamination is difficult, or technologically not feasible to clean up (e.g. contaminants in fractured bedrock).
- 2. When the cost of remediation to generic criteria levels is prohibitive.
- 3. When site-specific factors suggest that generic criteria don't apply (e.g. unusual land use, really hard water, unusual receptors).
- 4. When national/provincial criteria do not exist for a contaminant.
- 5. When there is a high public concern.

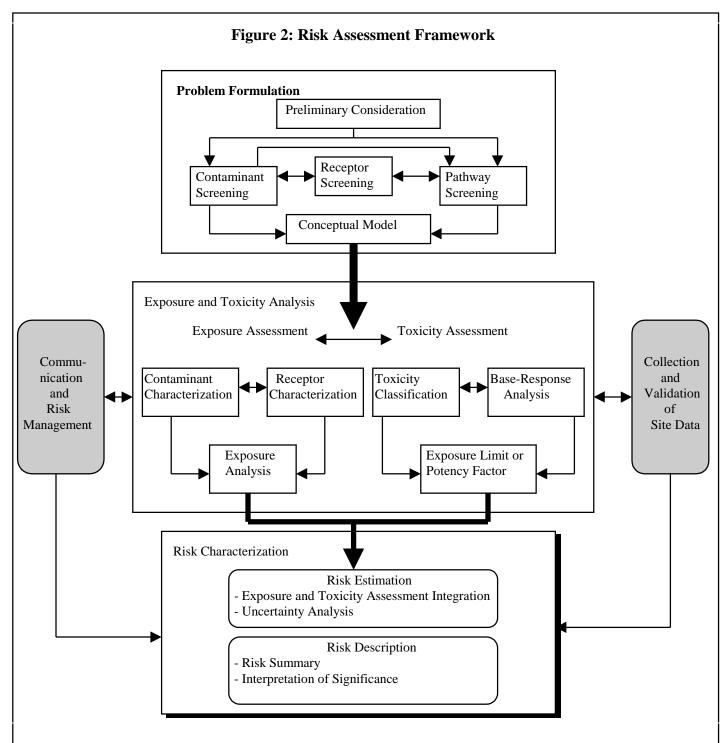
#### 5. FRAMEWORK

The human and ecological health framework described in this TAB is consistent with the Health Canada approach and consists of three phases:

i. Problem Formulation.

- ii. Exposure and Toxicity Analysis.
- iii. Risk Characterization.

These three components (**Figure 2**) are consistent with frameworks developed by other regulatory agencies that may use somewhat different terminology. The objective of the first phase, problem formulation, is to use risk assessment techniques to assist in developing and documenting a site-specific conceptual model to be used in the exposure and toxicity analysis phase. During the final phase, risk characterization, the results of the exposure and toxicity assessment are integrated and interpreted to yield estimates of health risk. During the course of these 3 phases, new information may become available which improves both the qualitative and quantitative phases, and in this respect, risk assessment can be an iterative process. Risk estimates are communicated between the risk manager, regulator, client, site investigator and the public. The risk estimates are used to determine if risk management procedures are required at a contaminated site.



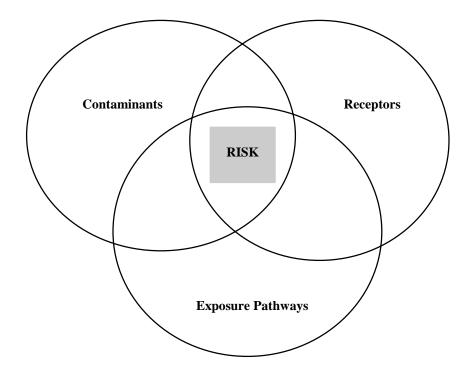
#### 6. PROBLEM FORMULATION

Problem formulation is the first step in the risk assessment process. It is a screening tool used to focus subsequent steps of risk assessment. In the problem formulation phase, the three components of risk: chemicals, receptors and exposure pathways, are systematically screened in such a way, that the remainder of the risk assessment phase deals only with the combinations of chemicals, receptors and pathways that have the potential to cause adverse effects.

It is important to note that all three components must be present for risk to occur (**Figure 3**). If, for example, chemicals are present in high concentrations, but there are no receptors to come into contact with the chemicals, then a health risk cannot occur.

Problem formulation is primarily a qualitative phase in the risk assessment process, where all pathways, chemicals and receptors are

**FIGURE 3: Risk Components** 



methodically characterized, screened and either eliminated or retained for further consideration. A conceptual understanding of the health risks associated with the site is developed during the problem formulation phase.

#### 6.1 Problem Formulation Components

#### Preliminary Considerations

Preliminary Considerations include baseline information such as goals, regulatory issues and scope and complexity of risk assessment. Contaminated site management can be influenced by regulatory and societal issues, and thus it is important that such perspectives be considered when conducting a problem formulation study, so that the results are not only scientifically valid but also address the concerns of stakeholders.

#### The Screening Processes of Problem Formulation

The chemicals, exposure pathways, and receptors of potential concern are identified and screened in order to focus the risk assessment and subsequent site investigations. These three components form the basis of the site's conceptual model which schematically illustrates the locations, types, and concentrations of the chemicals of concern, their

release mechanism, their associated transport media, the exposure routes, and likely receptors.

#### **Chemical Screening Process**

Chemical screening involves identifying chemical substances in different environmental media (air, water, soil, or sediments) that present an ecological or human health concern. These include the following:

- 1. Chemicals with concentrations that exceed established regulatory guidelines (e.g. CCME or provincial guidelines).
- 2. Chemicals that may cause adverse health effects with prolonged or repeated exposure.
- 3. Chemicals with concentrations that substantially exceed natural background levels.

Consideration must be given to the physical and chemical properties (e.g. volatility, solubility, reactivity, and the potential to bio-accumulate) of the substances identified as contaminants. The fate of chemicals in the environment will provide clues as to where the chemicals will migrate and what receptors are likely to be affected.

#### **Receptor Screening**

TAB #15

Receptors can be human, animals or habitats, and are used in risk assessment to determine safe chemical concentrations for a particular site. The objective of screening receptors is to identify the animal and human receptors that are most likely to experience the greatest exposure to contaminants of potential concern. Other criteria used to select ecological receptors of concern include:

- 1. Rare/endangered species/habitats.
- 2. Species occupying critical niches in the ecosystem.
- 3. Species of value to humans.

Consideration should also be given to human and ecological receptors located off-site. While on-site receptors may be intuitively obvious, off-site receptors may not be as apparent, but may experience equal or more significant exposure to contaminants of concern. For example, off-site receptors may include individuals who receive exposure via consumption of drinking water which is obtained from a location down gradient of the chemical source; via inhalation of fugitive dust and/or air emissions carried off-site or by ingestion of contaminated produce or dairy products. In cases where persistent bio-accumulative chemicals are contaminants of concern, food chain effects may implicate additional receptors of concern. This is particularly important where, for example, ethnically distinct sub-populations characterized by high fish consumption or consumption of liver tissue are more likely to receive high exposures through aquatic food chain effects.

#### Exposure Pathway Screening

During the problem formulation phase, the objective of exposure pathway screening is to identify the manner in which receptors may be exposed to contaminants of concerns. For risk assessment purposes, an exposure pathway consists of a contaminant source, release mechanism, transport and residency media, exposure route and receptor. The exposure route has toxicological meaning, and refers to the path by which a chemical makes physical contact with the body and is absorbed via ingestion, inhalation, or trans-dermal adsorption.

A chemical that is not screened out (e.g. one that is retained as a contaminant of potential concern) is a contributor to health risk only if a pathway to a receptor exists, or is likely to exist, and the pathway

results in the receptor being exposed to an unacceptable dose or concentration of contaminants.

#### **SOURCES**

BCE (1993). Quantitative Human Health Risk Assessment: Phase 2 - Review of Methods and Framework Recommendations. British Columbia Ministry of Environment, Lands, and Parks.

Health Canada (1996). *Human Health Risk Assessment of Chemicals from Contaminated Sites.* 

Ontario Ministry of the Environment (1996). Guidance on Site Specific Risk Assessment for Use at Contaminated Sites in Ontario. Standards Development Branch, MOE.

US EPA (1991). Framework for Ecological Risk Assessment.

For further information please contact:

Environment Canada
Ontario Region - Environmental Protection Branch
Environmental Contaminants &
Nuclear Programs Division
4905 Dufferin Street
Downsview, ON M3H 5T4
Telephone: (416) 739-4826
Fax: (416) 739-4405

Our TABs can be found on the Internet at: <a href="http://www.on.ec.gc.ca/pollution/ecnpd/">http://www.on.ec.gc.ca/pollution/ecnpd/</a>