# Ecological Risk Assessments of Priority Substances Under the Canadian Environmental Protection Act

## Guidance Manual

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# Chapter 1

# Framework and Overview

The *Canadian Environmental Protection Act* (CEPA) was established in 1988 and has as its focus the cradle-to-grave management of toxic substances. Section 12 of CEPA requires the Ministers of Environment and Health to compile and publish a list of substances known as the Priority Substances List. Substances on this list must undergo a joint environmental and human health assessment within five years to determine whether they are "toxic" as defined in Section 11 of CEPA which states:

> *A substance is toxic if it is entering or may enter the environment in a quantity or a concentration or under conditions that:*
>
> *(a) have or may have an immediate or long-term harmful effect on the environment, or*
>
> *(b) constitutes or may constitute a danger to the environment on which human life depends, or*
>
> *(c) constitutes or may constitute a danger in Canada to human life or health.*

If the assessment concludes that a priority substance is "toxic", the substance enters into the risk management phase where the federal government, with input from the provinces, industry and the Canadian public, determines what controls, if any, will be put in place to mitigate effects.

The first Priority Substances List (PSL) included 44 substances and was published in February, 1989. Substances on this list included organic compounds, metals, mixtures of related chemicals, and effluents and emissions. Assessments of substances on the first PSL were completed and published by February, 1994. An expert advisory panel to the Ministers was convened in December 1994 to determine those substances currently in need of assessment for placement on the second PSL. Following a series of consultations with interested parties, the panel recommended a list of 25 substances to the Ministers for inclusion on the second PSL (Box 1.1).

Ecological risk assessment (ERA) is a key part of the process of assessing and managing substances in Canada (Box 1.2). Substances on the PSL usually undergo both an ERA and a human health risk assessment. The purpose of this manual is to describe the ERA framework for assessments of priority substances in Canada and to

provide specific guidance on each step of the ERA (Box 1.3). A companion document (the "resource document") elaborates on the guidance provided in this manual and describes methods and approaches in much greater detail.

## *1.1 What Are We Trying to Protect?*

The objective of an ecological risk assessment under CEPA is to describe and estimate risks to exposed receptors, whatever their perceived value to society. It is during the risk management phase that societal values become important (Menzie 1995).

Ecological risk assessments are complex. They are concerned about protecting numerous species that may be affected either directly by a substance or indirectly as a result of disruptions to ecosystem structure and function. Given our inadequate understanding of ecosystem structure and function, and the limited information typically available, assessors must be careful in deciding which effects are really ecologically significant. Several factors affecting this judgment are discussed below.

### *Levels of Biological Organization*

Effects to the environment from exposure to chemical substances can occur at various levels of biological organization. Effects at lower levels, such as the biochemical, are not always transmitted to higher levels, such as ecosystems (Allen and Starr 1982; O'Neill *et al.* 1986). Conversely, in cases where effects to higher levels have occurred, lower levels of organization will

***Box 1.1.*** *Second List of Priority Substances*[a]

Acetaldehyde
Acrolein
Acrylonitrile
Aluminum chloride, Aluminum nitrate, Aluminum sulphate
Ammonium in the aquatic environment
1,3-Butadiene
Butylbenzylphthalate (BBP)
Carbon disulfide
Chloramines
Chloroform
N,N-Dimethylformamide (DMF)
Ethylene glycol
Ethylene oxide
Formaldehyde
Hexachlorobutadiene (HCBD)
2-Methoxy ethanol, 2-Ethoxy ethanol, 2-Butoxy ethanol
N-Nitrosodimethylamine (NDMA)
Nonylphenol and its ethoxylates (NPE)
Phenol
Releases from copper smelters and refineries
Releases from zinc smelters and refineries
Releases of radionuclides from nuclear facilities (impacts on non-human species)
Respirable particulate matter $\leq 10\ \mu m$
Road salts
Textile mill effluents

[a] See expert advisory panel report for details on how substances were selected (Government of Canada 1995).

***Box 1.2.*** *Assessing and Managing Toxic Substances in Canada*

The federal and provincial governments rely on a wide range of voluntary, legislative and regulatory instruments to effectively manage toxic substances in the Canadian environment. Of these, the *Canadian Environmental Protection Act* (CEPA) is the most wide-reaching statutory authority. CEPA sets out procedures for the identification and assessment of new and existing substances, and provides for the establishment of regulations controlling the import, manufacture, transport, storage, use and disposal of toxic substances. For new and existing substances deemed to be "toxic" to human health or the environment, regulations or other control measures are developed in consultation with industry, other federal government departments, provincial governments and the public. CEPA complements other federal statutes such as the *Pest Control Products Act*, the *Fisheries Act*, and the *Transportation of Dangerous Goods Act*, and provides the basis for federal-provincial cooperation on environmental protection. In addition to these statutes, the Canadian government recently released the *Toxic Substances Management Policy* that has as its key objectives: the virtual elimination of persistent, bioaccumulative and toxic substances that result predominantly from human activity (*i.e.*, Track 1 substances); and management of other toxic substances throughout their entire life cycles (*i.e.*, Track 2 substances). Finally, Canada is involved with various non-regulatory initiatives to deal with toxic substances, including the Accelerated Reduction and Elimination of Toxics program, region specific action plans, and international efforts to reduce the production and use of harmful substances.

also have been seriously disrupted (Allen and Starr 1982; O'Neill *et al.* 1986). Therefore, effects observed at the community and ecosystem levels are more harmful and are of more concern than those at lower levels.

Few studies have directly tested priority substances for effects at the population, community or ecosystem levels of organization. Most toxicity studies are conducted in the laboratory using relatively small sample sizes relative to population sizes in natural communities. However, many endpoints measured in laboratory and field studies have *implications* for populations, communities and ecosystems. Measurement endpoints such as endocrine disruption, lethality and reproductive impairment provide a strong link to the growth and survival of natural populations. A strong link between measurement endpoints (*e.g.*, reproductive fecundity) and assessment endpoints (*e.g.*, population age-structure) can help build a strong case for finding a substance "toxic" as defined in CEPA. It is impossible to specify a rigid cutoff point where effects are

***Box 1.3.** Scope of Guidance Manual*

The guidance manual is intended to describe the scientific principles and approaches for ecological risk assessments of priority substances in Canada. The manual and the corresponding resource document were prepared by assessors in the Chemicals Evaluation Division of Environment Canada and have been extensively reviewed by staff at Environment Canada, other federal and provincial government departments, industry representatives, experts from a variety of international programs, consultants and academics.

The guidance manual **is** intended to:

- provide guidance to assessors in the Priority Substances Assessment Program,
- improve the quality and consistency of ecological risk assessments of priority substances,
- describe the assessment process, decision points, key assumptions, default positions, and preferred approaches, and
- inform the scientific community, other governments, industry and the public.

The guidance manual **is not** intended to:

- be a cook book with rigid rules for how to conduct an assessment,
- be a text book (extensive background material is, however, provided in the resource document),
- provide guidance on assessing effects to human health, as this has been addressed in a publication by Health Canada (1994), or
- address policy issues regarding management of the program, or describe in detail the risk management process for toxic substances under CEPA.

considered sufficient to declare the substance "toxic". Professional judgment is required. The following examples illustrate how such judgment may be applied.

- Based on an entry characterization and a pathways analysis for chemical A, richness and abundance of grain-eating birds has been selected as the assessment endpoint. No field surveys or tests have been conducted to determine whether community level endpoints have been affected in areas where the chemical has been released. Available information indicates that the chemical is acutely toxic to chickens in laboratory tests and, further, dead birds have been reported following releases of the chemical. While these measurement endpoints are at the individual level, one can reasonably argue

that the evidence suggests a *potential* for adverse effects to the assessment endpoint. This evidence could therefore be used to help build a case that chemical A is "toxic" under CEPA. It is not possible in this case, however, to *prove* that such effects will occur, let alone determine the consequences of such effects. Many factors could enhance or mitigate the translation of effects from the individual to community level of organization. For example, if the birds are under food stress in the field, adverse effects predicted by laboratory studies on well fed birds may considerably underestimate true risk. Conversely, if numbers of birds are regulated by recruitment from uncontaminated populations elsewhere, risks predicted by the laboratory test results alone will overestimate true risk (Underwood 1995).

- The assessment endpoint for chemical B is abundance of salmonids based on evidence that the chemical is released in wastewaters, is water soluble, and is persistent. Chemical B is an estrogen agonist. Laboratory evidence shows that it competitively binds to the estrogen receptor, thus blocking binding by endogenous 17β-estradiol, estrone and estriol; it causes estrogen-inducible *in vitro* responses in fish cells and *in vivo* in rats (example adapted from Kramer and Giesy 1995). Further, levels of the chemical are highest during periods of low steroid biosynthesis in salmonids such as during male embryo development. This increases the relative potency of exogenous chemical B relative to the endogenous estrogens. Finally, there have been anecdotal observations of hermaphroditic fish downstream of wastewater treatment plants. Field studies in areas heavily contaminated by other estrogen agonists show that observed effects at the biochemical and physiological level can be translated into serious adverse effects at the population level due to declines in reproductive success (Fry *et al.* 1987). This evidence could be used to build a case that chemical B is "toxic" as defined under CEPA. As with chemical A, numerous factors can enhance or mitigate the true risks posed by chemical B. For example, if anti-estrogens, such as co-planar PCBs, are also present in wastewaters, risks due to chemical B alone will be partially mitigated (Kramer and Giesy 1995).

- The assessment endpoint for chemical C, which is released periodically in wastewaters, is abundance of salmonids. The chemical is not considered persistent. At levels found downstream from outfalls following its release, induction of cytochrome P450 mRNA and P450 protein in rainbow trout has been observed within 18 hours of the initial exposure. The levels of mRNA in chemical C-treated fish peaked at about two days and decayed by five days; P450 protein levels remained elevated somewhat longer but declined to control levels at about 10 days. Corresponding acute and chronic toxicity studies indicate that trout survival, growth and reproduction were not affected at similar levels of chemical C following a single-dose treatment. Given that chemical C is released only periodically, is not persistent, and its effects at the biochemical

level do not appear to translate to effects at higher levels, the evidence suggests this chemical would not be "toxic" as defined under CEPA.

*Other Considerations*

Should effects to a few, sensitive populations, communities or ecosystems be sufficient cause for a CEPA "toxic" conclusion? Are on-site or mixing zone effects considered in the assessment?

According to Section 3 of CEPA, the "environment" includes, among other things, all living organisms and interacting natural systems. This definition indicates that effects to any population, community or ecosystem can be sufficient justification for a CEPA "toxic" conclusion.

Sections 3 to 24 of CEPA do not exempt on-site or mixing zone effects from inclusion in ecological risk assessments. Evidence of such effects to populations, communities or ecosystems in Canada may be included in the justification for a CEPA "toxic" conclusion. However, when comparing on-site or mixing zone monitoring data to toxicity thresholds for a substance, it must be established that biota in Canada have the potential to be exposed to the observed levels. For example, since aquatic biota do not normally occur in effluent pipes or storage lagoons, environmental concentrations data from these areas should not be used to estimate exposure to aquatic biota. Conversely, since aquatic biota do occur in riverine systems near outfall pipes, concentrations data from these areas could be used to estimate exposure.

## *1.2 Beyond "Toxic"*

Although Section 11 of CEPA legally only requires a determination of whether a substance is "toxic", ecological risk assessments will often need to go further and specify the probabilities and magnitudes of effects to different endpoints at different locations in Canada. Such information is required to determine the priority for risk management actions and to ensure that mitigation measures are cost-effective and directed at the most serious problems. Detailed characterization of a substance's entry to the Canadian environment and, in some cases, assessment of the consequences of alternative risk mitigation measures or products may also be required to ensure sound decision-making at the risk management stage.

Ecological risk assessments of priority substances follow a process of continuous refinement beginning with problem formulation and proceeding through to worst-case assessments and, when appropriate, to probabilistic assessments. As each iteration is completed, a decision must be made whether to continue refining the assessment. This decision requires answers to the following three questions (modified from Hope 1995). First, is there sufficient information to sustain a weight-of-evidence

conclusion that the substance is "toxic"? Second, if the substance is "toxic", is there sufficient information to permit sound decision-making at the risk management stage? Third, if there is a need to further refine the assessment, are there sufficient resources in terms of expertise, time and money to gather and analyze the required information? Risk managers in Environment Canada and interested parties in industry, non-government groups and other government departments will have to be consulted to help answer these questions.

### *1.3 Weight-of-Evidence Approach*

Traditionally, ecological risk assessments of chemicals have relied on the results of a few, relatively simple laboratory bioassays and measured or estimated concentrations in a single medium to predict effects in complex, poorly understood ecosystems (Suter and Loar 1992; Chapman 1995). This approach is fraught with assumptions and uncertainties. Alternate approaches such as using batteries of tests, field observations, ecoepidemiology, and population and ecosystem modeling can be used to estimate risk, but each has its own assumptions and associated uncertainties. Rather than relying on a single approach, assessors must evaluate each separate line of evidence, organize these in some coherent fashion, and then use a weight-of-evidence approach to estimate risk (Suter 1993a).

The following should be considered in evaluating each line of evidence (adapted from U.S. EPA 1992):

- *Relevance of the Evidence to the Exposure Scenario of Interest.* Lines of evidence that are most relevant to exposure scenarios in Canada are given the greatest weight.

- *Relevance of the Evidence (Measurement Endpoint) to the Assessment Endpoint.* Lines of evidence that require a minimum of extrapolation to the assessment endpoint are of greater importance.

- *Confidence in the Evidence or Risk Estimate.* Confidence is a function of the sufficiency and quality of the data and estimation techniques, including adherence to protocols, appropriate experimental designs and associated estimates of power, and theoretical plausibility.

- *Strength of Causality.* Some lines of evidence, such as observed field effects, may include a variety of stressors in addition to the priority substance of interest. In these cases, it is necessary to examine the strength of the causality relationship. Fox (1991) lists seven principles that can guide assessors in objectively assessing the relationship between a priority substance and an adverse environmental effect: time order, strength of association, specificity of

association, consistency of the association, coherence of the association, probability, and predictive performance (see Chapter 6 for more discussion).

By using a weight-of-evidence approach, risk assessment can reduce, but not eliminate, the biases and uncertainties associated with using only one approach to estimate risk. At the same time, it is a useful tool for identifying those areas where research is most needed.

## *1.4 Framework for Ecological Risk Assessment of Priority Substances*

Ecological risk assessment of priority substances involves three major steps: problem formulation, analysis and risk characterization (Figure 1.1; see also U.S. EPA 1992). To ensure that assessments proceed only to the level of refinement required for effective decision-making, a tiered approach has been adopted. Tier 1 is a worst-case analysis, Tier 2 is a probabilistic analysis, and Tier 3 estimates risks due to anthropogenic sources for naturally occurring substances.

Problem formulation focusses on scoping and planning (Chapter 3). Pathways analysis and the identification of sensitive receptors help to determine endpoints that are at high risk of exposure -- *assessment endpoints* (Suter 1993b). Since direct toxicity information is not always available for assessment endpoints, *measurement endpoints* will need to be used to estimate effects to assessment endpoints (Suter 1993b). A *conceptual model* is then prepared that describes the ways in which the substance behaves in the ecosystem and its possible effects (Chapter 3). As with the U.S. EPA framework, the PSL framework involves risk assessors, risk managers and other interested parties during the risk assessment, particularly in the problem formulation stage (see also Moore and Biddinger 1995; Hope 1995). Involving risk managers in the risk assessment process helps to ensure there is sufficient information to develop appropriate management strategies. Involving interested parties such as those from industry, non-government groups and other government departments helps to ensure that all viewpoints are considered. This should lead to improved information exchange, and a better understanding of the issues.

The analysis phase consists of three major parts: entry, exposure and effects characterization. The objective of entry characterization is to determine the major natural and anthropogenic sources, locations and quantities of a substance entering the Canadian environment (Chapter 4). Entry characterization includes all phases of the life cycle of the substance. Information gathered from the characterization of entry may be used to further refine the problem formulation, as input to the characterization of exposure, and in the development of mitigation measures during risk management.

The objective of exposure characterization is to determine an *estimated exposure value* (EEV) for each assessment endpoint (Chapter 5). For a Tier 1 worst-

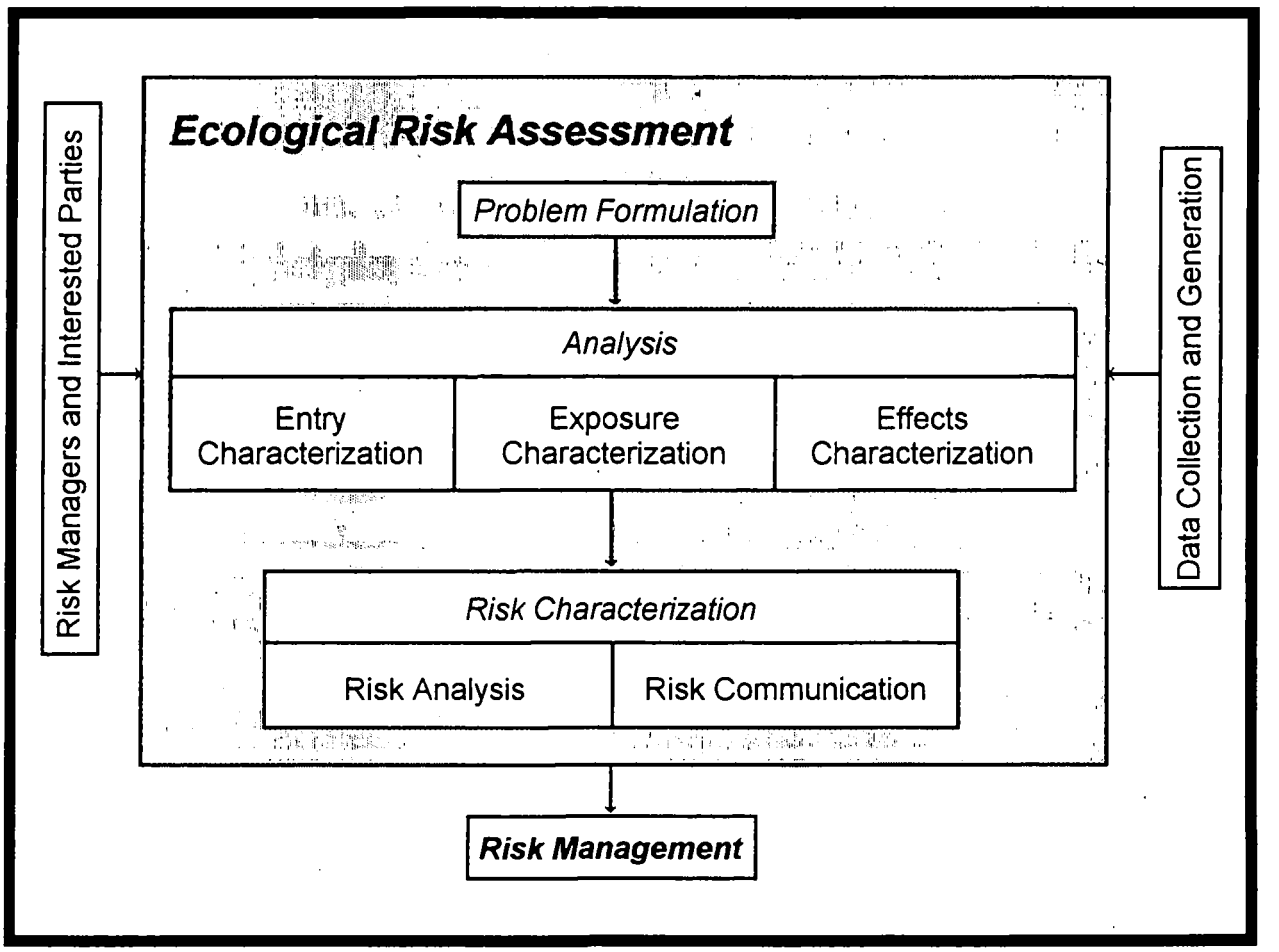


***Figure 1.1.*** Framework for ecological risk assessment of priority substances (modified from U.S. EPA 1992).

case analysis, the EEV may be the maximum concentration measured in Canada. For a Tier 2 analysis, the EEV may be a distribution of concentrations from an area of concern. For estimates of exposure to wildlife, the EEV may be in the form of tissue residues or, more likely, total daily intake. In cases where the risk characterization involves a quantitative uncertainty analysis (a Tier 2 analysis), it is necessary to estimate variance and the shape of the distribution for each exposure parameter. For a Tier 3 analysis, exposure is separated into two components: the natural component ($EEV_n$) and the anthropogenic component ($EEV_a$).

The results of toxicity tests on measurement endpoints are used to determine the *critical toxicity value* (CTV) for each assessment endpoint (Chapter 6). Only in rare instances will estimates based on quantitative structure activity relationships (QSARs) be used exclusively to estimate the CTV. However, QSAR estimates may contribute to the weight-of-evidence and help corroborate toxicity test results or field evidence. For

organisms exposed through soil or sediment, extrapolation techniques, such as equilibrium partitioning, may be used in the absence of empirical data.

Toxicity information must be critically evaluated against accepted practices or protocols for quality assurance and quality control (QA/QC). The results of toxicity studies with proper QA/QC on the most sensitive measurement endpoint with relevance to the assessment endpoint are used to derive the CTV. In order of preference, the CTV may be in the form of an $EC_{10}$ (or lower if the estimate is the result of interpolation) calculated from the dose-response curve; a Lowest Observed Effects Level (LOEL) if the $EC_{10}$ cannot be calculated; or a median effects dose (*e.g.*, $LC_{50}$) if an $EC_{10}$ or LOEL cannot be derived. In cases where the risk characterization involves a Tier 2 quantitative uncertainty analysis, it will be necessary to estimate variance and the shape of the distribution for each effects parameter (*e.g.*, $EC_{10} \pm$ 95% confidence limits).

Several entries on the second PSL are effluents or emissions (*e.g.*, Releases from copper smelters and refineries). Chapter 7 discusses approaches for the characterization of entry, exposure and effects for effluents and emissions, since these approaches differ from those used for single substances.

Risk characterization comprises two stages -- risk analysis (Chapter 8) and risk communication (Chapter 9). In risk analysis, the first tier of the assessment process is to conduct a worst-case analysis using the quotient method. This involves dividing the estimated exposure value (EEV) for a worst-case situation by the estimated no effects value (ENEV). The EEV for the worst-case situation is generally the maximum level observed in the Canadian environment, while the ENEV is calculated by dividing the CTV by an application factor to derive a value with a very low probability of causing adverse effects to the assessment endpoint. If the worst-case quotient is <1 for all assessment endpoints, there is little justification for proceeding to the higher tiers of the assessment process; the substance is not considered "toxic" as defined in Section 11 of CEPA.

If one or more quotients from the worst-case analysis are >1, Tier 2 quantitative uncertainty analyses are recommended to determine the probability of specified adverse effects. Such analyses are only possible if sufficient input data are available and the assumptions of the chosen technique can be met. As a minimum, major sources of uncertainty and variability should be qualitatively identified.

A Tier 3 analysis is required for naturally occurring substances that have the potential to cause harmful effects as determined by the Tier 2 analysis. A Tier 3 analysis requires adjusting the effects characterization to take into account the tolerance of organisms normally found in naturally enriched areas, and partitioning exposure to account for natural and anthropogenic sources separately. If the analysis

indicates that anthropogenic sources can cause harmful effects to organisms normally found in the area of interest, then the substance is declared "toxic".

In some assessments, it may be possible to estimate the ecological consequences of exposure to a substance through the use of field studies, population models or food web models. Generally, such modeling techniques have not been adequately tested and thus should not be used as the sole basis for deciding if a substance is "toxic" as defined in CEPA. Nevertheless, such approaches can be used as part of the weight-of-evidence approach to estimate risk and describe the ecological consequences of continued substance exposure.

Ecological risk assessments help shape the risk management decisions of the federal government in controlling toxic substances. Further, assessments are important for communicating risks to the media and other interested parties. Chapter 9 provides general guidance for better communication.

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# Chapter 2

# Data Collection and Generation

## *2.1 Introduction*

This chapter provides an effective approach to collect and generate data required for ecological risk assessments of priority substances under the Canadian Environmental Protection Act. Chapter 2 of the resource document provides details about information sources available to collect and generate this data.

Data used when conducting assessments of Priority Substances must be of acceptable quality. All key data must be verified by consulting its primary source. Assessors should obtain original references to critically and scientifically evaluate the data. In cases where sources of information are incomplete (*e.g.*, information on detection limits, sample sizes, measured concentrations, etc. are not reported), assessors should contact individual authors to obtain the data necessary to evaluate the study. Also, erroneous data may result from transcription or typographical errors during the process of publication or database development. Since published data varies in quality, assessors should become familiar with issues of data quality. Specific QA/QC issues are addressed where applicable throughout this manual and the accompanying resource document.

The data collection and generation process described below has been designed as a flexible guideline for assessors. While this process is an effective approach for obtaining most types of data required for assessments of priority substances, information gathering may need to be customized on a substance-by-substance basis. As with the problem formulation phase of an assessment, data collection is an iterative process, and many of the following steps may need to be revisited throughout the assessment process as additional key words, data sources or needs are found. Guidance on search strategies is provided in the chapter.

## *2.2 Stage One: Data Gathering Required for Problem Formulation*

The first stage of the data collection and generation process involves gathering data required for problem formulation, from initial scoping through to the development of a conceptual model (Chapter 3). The aim of the first stage is to complete a thorough review of existing sources of information about the substance and to identify as early as possible any data gaps.

At an early stage in the data collection process, assessors should develop a set of key words that will be used to search for information in databases. The chemical name, CAS number and synonyms are a good starting point for single chemicals. Key

words should be continuously refined throughout the data collection process to obtain all available data. Assessors should always conduct a manual search of important references cited in journal articles, reports and databases. A manual search of such references serves not only to verify data, but may also lead assessors to new sources of information. Additional guidance on search strategies for mixtures and effluents is presented in Chapter 7. Data gathered during stage one are then used to develop an initial conceptual model for the assessment.

*Data Provided by the Priority Substances List (PSL) Secretariat*

Scientific dossiers prepared by the PSL Secretariat are made available to assessors. These dossiers include basic information about the substance's chemical identity, physical and chemical properties. They also provide an initial review of toxicological and entry data, international assessments, and the rationale provided to the Ministers' Expert Advisory Panel to recommend the substance for the PSL. For many substances, the information provided by the PSL Secretariat may be sufficient to complete the initial scoping stage of the assessment. These data may not be sufficient to conduct initial scoping of complex substances, thus more extensive data collection may be required for (consult Chapter 7 on mixtures and effluents for additional guidance).

*Existing International Assessments*

The objective of this step is to collect and review ecological assessments that have been conducted by other organizations or countries, such as the United States Environmental Protection Agency, or the Chemicals Program of the Organization for Economic Cooperation and Development (OECD). These assessments may provide valuable scientific data and references. They may also provide assessors with an overall picture of the key issues in the assessment.

*Desk References*

Desk references can provide valuable environmental information. Sources that should be consulted include chemical dictionaries, encyclopedias, guidelines reports, handbooks of physico-chemical properties, texts summarizing environmental fate and exposure data, etc.

*Readily Available Databases/Catalogs*

After reviewing international assessments and desk references, assessors should conduct an extensive literature review with a focus on Canadian data. Assessors should begin with the variety of information sources available at low cost,

including Environment Canada information holdings and databases. This first general search for data should be conducted with the keywords identified previously.

*Commercial Databases*

Assessors should review the data gathered thus far. Once data gaps are identified, key words should be redefined and the search criteria tailored to target missing data. Assessors should use the information presented in Chapter 2 of the resource document to select commercial databases with the appropriate focus and scope for the types of data required. The search strategy for a particular substance may need to be changed depending on the focus of a given database. Retrieving irrelevant or duplicate data can thus be minimized.

*Specialty Resources*

In order to ensure that all existing data have been found to fill data gaps, assessors should conduct a careful search of specialized inventories, databases or reports. Assessors should use their knowledge of the substance to identify groups who likely have specialized published or unpublished data. Industry associations, other federal government departments and provincial governments will be important resources in this process.

*Concluding Stage One*

The data collected are then reviewed focusing on the most recent publications and reviews to build an initial conceptual model that can be discussed with interested parties and refined throughout the assessment. While additional data are collected during stages 2, 3 and 4, assessors can conduct an in-depth analysis of the literature.

## *2.3 Stage Two: Further Characterization with Participation of Interested Parties*

In stage two, interested parties are invited to help refine the conceptual model. As well, assessors identify people and groups whose information and/or expertise could assist with the assessment .

*Consultation with Interested Parties*

Assessors should consult with interested parties including risk managers, Environment Canada regional offices and research institutes, other government departments, provinces and territories, industry associations and representatives, environmental groups and academia. Such consultations provide an opportunity to tap into scientific and technical support and expertise. They also provide a cost-effective

approach to quickly obtain unpublished data. This step also provides a forum to develop partnerships required for research.

## 2.4 Stage Three: Legislative Notices to Fill Data Gaps

Efforts should be made to gather as much data as possible on a voluntary basis. Sections 16 and 18 of CEPA may be used, if necessary, to obtain information that could not be gained with voluntary measures.

### *Section 16 and Section 18 Notices*

Section 16 of CEPA authorizes the gathering of existing data for the *purpose of assessing whether a substance is toxic or capable of becoming toxic.* Assessors can determine whether the required data exist and data gaps critical to the assessment may be filled.

Section 18 of CEPA can be used when the Ministers of Environment Canada and Health Canada have *reason to suspect that a substance is toxic or capable of becoming toxic.* Section 18 provides three methods to gather data about a specified substance. A notice may require that those involved with the substance notify the Minister of their involvement, provide specified information in their possession or to which they can reasonably be expected to have access, or perform toxicological and other tests specified by the Minister and submit the test results once completed.

Data gaps should be identified as early as possible in the problem formulation phase, since preparing and executing notices may take several months. The Use Patterns Section of the Chemicals Control Division of Environment Canada will work in conjunction with assessors to prepare Section 16 and 18 notices. Before notices are sent out, assessors should identify the appropriate companies to which it should be sent and clearly define the types of information required. This ensures that notices are read and acted upon by people knowledgeable in the area and that replies will be useful to the assessment.

## 2.5 Stage Four: Generation of Data Through Research

Research activities will be coordinated from a program perspective by the Chemicals Evaluation Division of Environment Canada to ensure a consistent approach and efficient and cost-effective use of resources.

### *Recommendation of Research Activities*

After data collection and problem formulation, assessors should identify any research activities that are required to complete the assessment. An ecological risk

assessment review group will review the proposed data generation needs and identify overall priorities and the most efficient means of fulfilling those needs (details of this process are explained in the policy document). The lead assessor will be responsible for overseeing the generation of data for their substance. Appropriate partners should be involved in the conduct or sponsorship of this work.

# Chapter 3

# Problem Formulation

## *3.1 Introduction*

*Goals and Objectives*

Problem formulation is the planning phase in ecological risk assessment. Here, the goals and focus of the assessment are established, data gaps are identified, and a strategy for proceeding with the assessment is devised. This phase includes the development of an *initial scoping* and a *pathways analysis*, consideration of *receptor sensitivity*, analysis of the *ecological relevance* of potential receptors, selection of *assessment endpoints* and associated *measurement endpoints*, and the development of a *conceptual model* (Figure 3.1).

In the problem formulation phase, risk assessors begin working with risk managers in Environment Canada and with interested parties in other government agencies, industry and community groups to ensure that the ecological risk assessment will have a firm scientific basis and will ultimately be useful for decision making.

An example of a problem formulation is presented in Section 3.3 of the resource document.

*Relationship With Other Phases*

Information set out in the problem formulation phase is used as the starting point for more in-depth analyses that follow during the characterization of entry, exposure and effects phases. Problem formulation is an iterative process. When little information about a substance is available at the beginning of the process, the initial problem formulation will be general and qualitative. As more information is obtained and analyzed, the problem formulation will take on a sharper focus, will be more explicit in its identification of assessment and measurement endpoints, and will present more quantitative details. As the ecological risk assessment proceeds through the entry, exposure and effects characterization phases, problem formulation should be updated to serve as a running summary of the assessment.

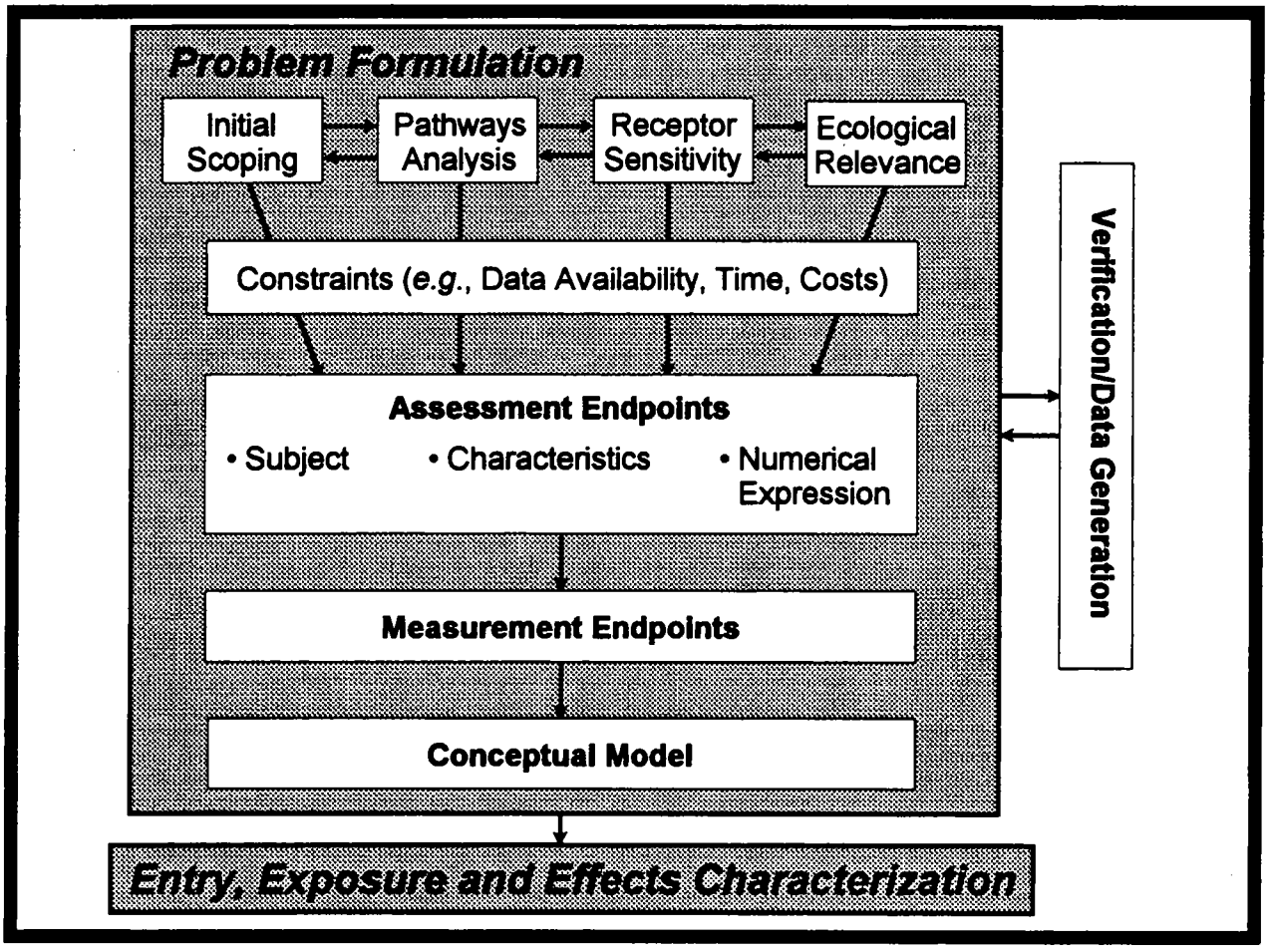


***Figure 3.1.*** The problem formulation phase in ecological risk assessments of priority substances.

## *3.2 Initial Scoping*

Initial scoping begins by considering the rationale the Ministers' Expert Advisory Panel on the Second Priority Substances List (Government of Canada 1995) gave for selecting the substance and the expected focus of the assessment. Additional preliminary information is gathered at this stage (see Section 2.2).

Information about the identity of the substance is presented in the initial scoping stage, including an internationally accepted chemical name, following rules established by the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS), other commonly used synonyms and trade names, and the Chemical Abstracts Service Registry Number, when available. For elements, the relative abundances of isotopes, oxidation states in the environment, and the identities of common environmental forms should also be determined. This information is

needed to permit an efficient literature search and other data-gathering activities. In addition, the molecular structure of organic chemicals should be elucidated for possible use in models or quantitative structure activity relationships (QSARs) for exposure or effects characterization (Chapters 5 and 6).

Physical and chemical properties of the substance should be determined for predicting its environmental fate and potential effects. For organic substances, these usually include molecular weight, molecular volume, water solubility, vapour pressure, partition coefficients and dissociation constants. For inorganic substances, relevant properties vary depending upon the chemical forms (*e.g.*, atoms, compounds or complexes). Important parameters for inorganic substances include atomic or molecular weight, common isotopes and valence states, water solubility, equilibrium constants and vapour pressure. Values chosen for key parameters used in fate or exposure models may significantly affect model predictions. Therefore, values for key parameters should be determined as accurately as possible and any uncertainty clearly presented. Experimental methods of quantification are preferred, but calculated values based on QSARs, for example, may be acceptable at this stage.

## *3.3 Pathways Analysis*

Pathways analysis considers a substance's entry into the environment and its probable environmental partitioning. This analysis is used to predict a substance's geographic distribution and fate in the Canadian environment and potential receptors that may be exposed to it.

Consideration should be given to the potential for environmental releases at any stage of a commercial substance's life-cycle, including:

- manufacturing, processing and formulation,
- storage, distribution and transportation,
- use, and
- disposal.

A substance may also enter the Canadian environment in other ways, for example from natural sources, by transboundary transport, as a transformation product of another substance, or as a component of a mixture.

To characterize environmental releases, information is required on:

- substance production volumes, consumption, imports, exports and uses,

- significant sites of release in Canada from human activities and from natural processes,
- amounts, forms and conditions under which the substance is released into the environment,
- patterns of releases (*e.g.*, continuous, intermittent, seasonal), and
- environmental compartments (*e.g.*, air, water, soil) receiving releases.

The release rates and spatial and temporal release patterns from a source or set of sources should be estimated in order to predict the geographical areas in Canada that could be affected and the extent of exposure in terms of both time and space.

A substance's environmental fate and routes of exposure may be characterized by:

- identifying its probable environmental partitioning to air, soil, surface and ground water, sediment and biota,
- estimating its geographic distribution and concentration ranges in the Canadian environment,
- identifying ecosystems that may be exposed, and
- identifying living or non-living components of the ecosystems that may be affected.

Characterization of environmental partitioning and fate involves analyzing information about a substance's:

- physical and chemical properties,
- quantified release into various compartments of the environment,
- persistence in various compartments of the environment, and
- bioavailability and tendency to bioaccumulate in living tissue.

This information is required for models that may be used to help characterize the environmental fate of a substance and to define sensitive parameters and data gaps when establishing research priorities. The characterization of the environmental fate of a substance is discussed in more detail in Section 5.3.

Information about quantities of a substance released in specific regions within Canada can be used to predict its concentration in various environmental compartments. Models such as the fugacity-based CHEMCAN model (see Chapter 5 of the resource document), may be used to make such predictions. If Canadian data are not available, environmental monitoring data from similar areas, such as the northern United States, may be used to support the plausibility of predicted environmental concentrations. A discussion of the characterization of environmental concentrations is presented in Section 5.6.

From the initial characterization of environmental partitioning and fate, and predicted environmental concentrations, it should be possible to predict, in a general way, ecosystems that are at risk (*e.g.*, aquatic ecosystems). When specific sites of release are known, it is then possible to identify the ecosystems more precisely, for example, a specific stretch of a river. Within ecosystems, particular components may be exposed to the substance under investigation. For example, benthic organisms are likely to be exposed to substances that partition to sediments. When precise ecosystems have been identified, it is then possible to more precisely identify the components of those ecosystems that may be exposed (*e.g.*, salmonid fish in a specific stretch of a river).

Non-living components of the environment upon which human life depends may also be exposed and considered in the environmental assessment. For example, stratospheric ozone may be exposed to persistent substances that reach the stratosphere when released into air.

### *3.4 Receptor Sensitivity*

Consideration of receptor sensitivity involves the analysis of effects data from laboratory and/or field studies in order to determine the concentrations or doses that cause adverse effects and to identify species or larger taxonomic groups from among the potential risk receptors that are likely to be particularly sensitive to the substance. QSARs may also be a used in the initial identification of sensitive organisms. These would have to be confirmed by laboratory or field testing during the effects characterization stage.

### *3.5 Ecological Relevance*

The environmental roles of highly exposed and/or sensitive receptors are analyzed in order to identify the receptors' ecological relevance and to predict possible indirect effects on other ecosystem components, such as predator or prey species. This can be accomplished by considering the receptors' life cycles and by determining any special functions they may have in the environment. For example, microorganisms

may be vitally important in nutrient cycling, while earthworms are important for the aeration and conditioning of soil.

The results of the initial scoping exercise, pathways analysis and consideration of receptor sensitivity and ecological relevance are then used to select assessment and measurement endpoints.

## *3.6 Choosing Assessment Endpoints*

An assessment endpoint is "a quantitative or quantifiable expression of the environmental value considered to be at risk in a risk assessment" (Suter 1993, p. 499). Potential assessment endpoints exist for all ecological levels of organization (ASTM 1994; U.S. EPA 1992a). Possible assessment endpoints at the ecosystem level include primary productivity, energy flow, nutrient cycling and decomposition of organic matter. At the community level, assessment endpoints could include biodiversity, including species richness and evenness, and food-web structure. Possible assessment endpoints at the population[1] level could include reproductive success, population abundance, age and size structure. At the individual level, assessment endpoints could include survival or physiological status, reproductive capacity, growth rate and development, or behaviour.

Assessment endpoints should be selected from as high a level in the ecological hierarchy as possible (*i.e.*, ecosystem > community > population) in order to indicate the significance of potential direct or indirect effects. For example, an adverse effect on microorganisms that are important decomposers may indicate an ecosystem endpoint such as 'the rate of nutrient recycling'. When population-level assessment endpoints are selected, it may still be useful to try to predict the higher-level endpoints that may be affected, recognizing that extrapolating up the ecological hierarchy introduces additional uncertainty at each step.

In many cases, abundance of the most sensitive species in each environmental compartment of concern may be a practical assessment endpoint to consider first. Analysis of environmental fate and modes of action, however, may suggest that other endpoints may be more sensitive and therefore more suitable in some situations. Several assessment endpoints are needed to assess substances that partition to more than one environmental compartment or that occur in the environment in a number of geographical areas. Furthermore, selection of several assessment endpoints ensures that a range of ecosystem values is considered in the assessment.

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[1] A "population" is defined as a collective group of organisms of the same species occupying a particular space and having the potential to interbreed.

### *3.7 Choosing Measurement Endpoints*

A measurement endpoint is "a quantitative summary of the results of a toxicity test, a biological monitoring study, or other activity intended to reveal the effects of a substance" (Suter 1993, p. 499). Each assessment endpoint must have one or more measurement endpoints. Measurement endpoints are needed because assessment endpoints often refer to characteristics of populations and ecosystems defined over fairly large geographic areas and relatively long time periods. These factors make the direct measurement of effects difficult or impossible. Furthermore, assessments should be made *before* environmental harm occurs. The relationships between assessment and measurement endpoints must be clearly described.

If an assessment endpoint is a particular fish population, an appropriate measurement endpoint could be the result of an acute or chronic toxicity test using the same species or a related species. Similarly, if abundance of an endangered raptor were chosen as an assessment endpoint, dietary $LC_{50}$ values from studies with another bird species would be an appropriate measurement endpoint. For the protection of terrestrial plants, necrosis, chlorosis or reduction in growth of legumes or conifer seedlings resulting from soil and/or atmospheric exposure to the substance could be used as measurement endpoints.

Acceptable measurement endpoints for ecosystem-level assessment endpoints include measurements of total biomass, productivity and nutrient dynamics derived from microcosm or mesocosm studies or from field surveys if a cause/effect relationship can be established. Acceptable measurement endpoints for community-level assessment endpoints include number of species, measures of species evenness, community quality indices and changes in community type derived from microcosm studies or field surveys. Acceptable measurement endpoints for population-level assessment endpoints include presence or absence of indicator species, abundance, age and size distributions, reproductive performance, and frequency of mass mortality derived from toxicity test results or field surveys (ASTM 1994). Lethality and reproductive impairment, measured in laboratory toxicity studies, provide a strong link to the effects of the substance on the growth and survival of natural populations.

Often, the identity of particularly sensitive organisms is not known. It is therefore desirable to review effects data from a battery of toxicity tests using organisms from several taxonomic and trophic levels. Such organisms should be representative of biota in the environmental compartment(s) to which the substance of concern is believed to partition.

## 3.8 The Conceptual Model

A conceptual model should be prepared to describe as explicitly as possible a substance's predicted fate, the mechanisms by which it could affect assessment endpoints and the likely ecological consequences of these effects. The level of detail, the information needed, and the methods to be used to complete the assessment, including any research needs, should also be specified at this stage.

Assembling a conceptual model based upon the characterization of the problem and the selection of assessment and measurement endpoints is really a summary of the risk assessment plan. The conceptual model is developed by constructing a series of qualitative exposure scenarios that describe how the priority substance could interact with assessment endpoints. Each scenario defines the assessment and measurement endpoints, their relationship, and spatial, geographical and temporal scales (U.S. EPA 1992b). Each scenario should also describe the methods and analyses that will be used to estimate risk. Since there is no universal method for quantifying ecological risk, several methods should be specified (Suter and Barnthouse 1993). Possible methods include:

- field studies or fate models to estimate exposure,
- statistical regression techniques to estimate effects levels for measurement endpoints,
- the quotient method to estimate risk,
- Monte Carlo analyses to estimate the probabilities of specified effects, and
- population models to estimate, for example, risks of extinction over a given time period.

The rationale for choosing a particular scenario or method should be documented (U.S. EPA 1992b).

Assessors should consult with risk managers at Environment Canada (*e.g.*, Response Assessment Directorate, Commercial Chemicals Evaluation Branch, National Office of Pollution Prevention or Air Pollution Prevention Directorate, depending on the type of substance) to determine if the proposed conceptual model will provide information to support any subsequent risk management decisions. Assessors should also discuss the conceptual model with interested parties and selected experts to exchange information, prepare plans to conduct new studies if necessary, and to refine the proposed conceptual model. Such discussions should continue on a regular basis for the duration of the risk assessment. Once agreement has been reached on

the conceptual model and on the plan to carry out the assessment, the detailed entry, exposure and effects characterization phases of the ecological risk assessment can begin.

An example of a conceptual model is included in Section 3.3 of the resource document.

## *3.9 References*

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**U.S. EPA. 1992b**. Framework for ecological risk assessment. Risk Assessment Forum, Washington, United States Environmental Protection Agency. Washington, D.C. EPA/630/R-92/001. 41 p.

# Chapter 4

# Entry Characterization

## *4.1 Introduction*

*Goals and Objectives*

The entry characterization phase identifies the anthropogenic and natural sources of a substance and estimates the amounts and frequencies of its release into the Canadian environment. This information is then used to assess the relative significance of various sources and help define the spatial and temporal scales for the assessment.

*Relationship with Other Phases*

In the entry characterization phase, the entry portion of the pathways analysis developed during problem formulation is verified and refined. This is achieved by accurately identifying and quantifying the various sources and releases. Entry characterization sets the stage for the characterization of exposure. For example, information about sources and releases are required as inputs to fate and transport models (Chapter 5). For substances declared "toxic" as defined in Section 11 of CEPA, entry characterization provides information essential for developing appropriate risk mitigation measures.

Access to current and accurate information is key to completing an accurate and useful risk assessment. Chapter 2 describes several mechanisms to obtain entry information. This information is often difficult to obtain because it is typically site-specific and is usually not available in the published literature. To overcome these difficulties, it is imperative to establish, as early as possible, a forum for the efficient exchange of information among risk assessors, risk managers and other interested parties.

Figure 4.1 summarizes the main steps involved in entry characterization.

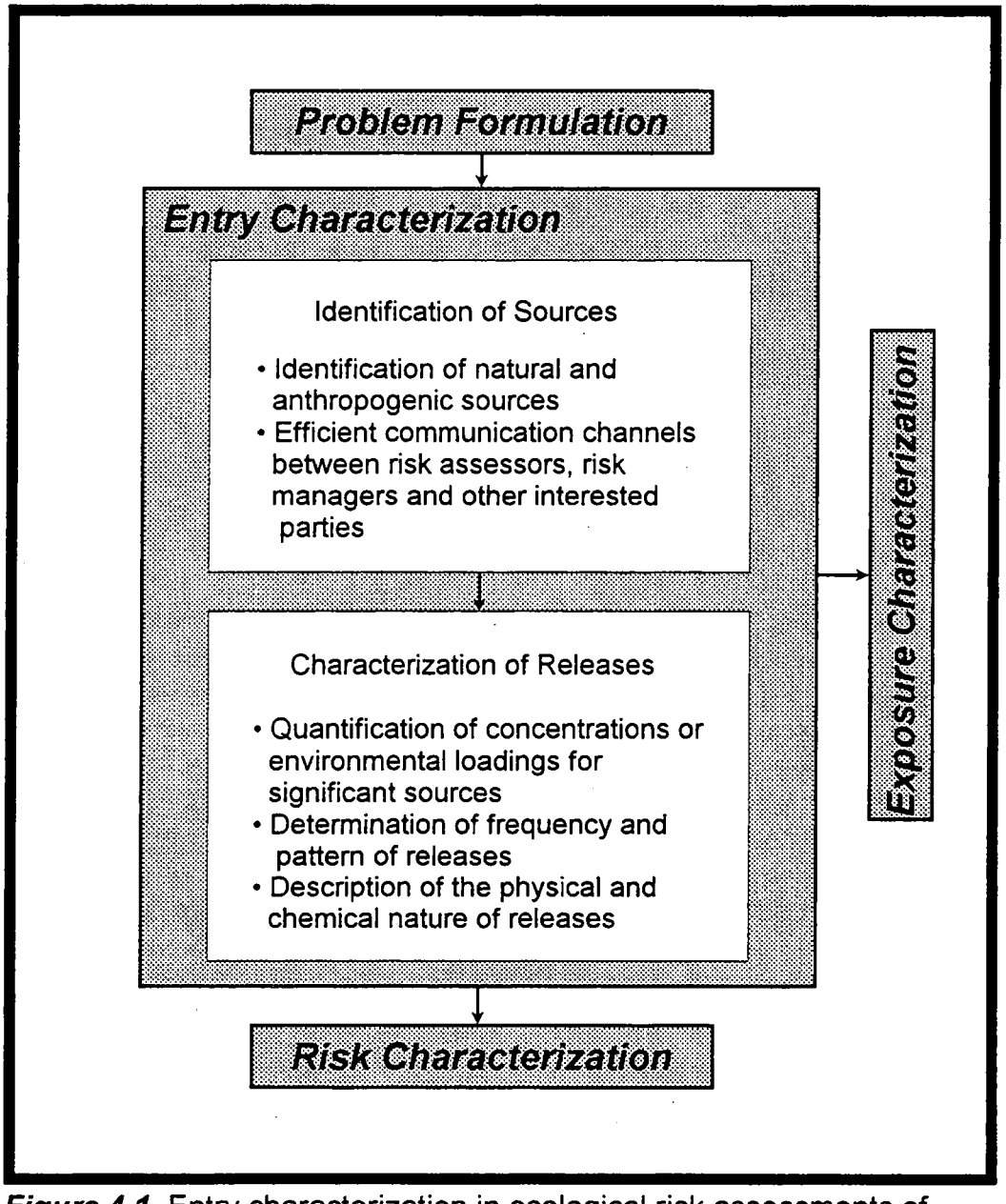


***Figure 4.1.*** Entry characterization in ecological risk assessments of priority substances.

## *4.2 Identification of Sources*

The first step in entry characterization is to identify a substance's sources in Canada. This includes natural and anthropogenic sources and transboundary sources. While major sources should have been identified during the problem formulation stage, some significant sources may have been missed.

Table 4.1 in the resource document presents matrices to summarize and organize entry information and assist in the analysis of source data These matrices are generic tools that should be tailored to the specific needs of each assessment.

*Natural Sources*

Inorganic and organic substances may be produced by a wide variety of natural processes. All processes leading to a substance's release into the Canadian environment should be identified.

Natural sources of inorganic substances to the atmosphere include windblown dusts, sea spray, volcanic emissions, crustal degassing (Rasmussen 1994), volatile exudates from plants, volatile compounds formed by soil microbial activity (Cullen and Reimer 1989), and natural combustion events (Havas and Hutchinson 1983). For soil, bedrock or glacial deposits from which it was derived are the primary natural source. Inputs also occur from natural atmospheric fallout, and from sediment deposits in areas subjected to periodic flooding. Primary natural sources of inputs to aquatic systems are weathering and erosion of geological materials and natural atmospheric fallout.

Many organic substances, including halogen-containing chemicals, may be produced by natural processes. Many types of organisms, including terrestrial plants, fungi, microorganisms and mammals, contain haloperoxidase enzymes that can halogenate organic compounds in the presence of chloride, bromide or iodide (Gribble 1994). In addition, abiotic processes, such as forest fires and volcanic eruptions, can produce a variety of chlorinated organic compounds including dioxins and chloromethane (Sheffield 1985; Gribble 1994).

Matrices such as the one presented in Table 4.1A in the resource document may be used to organize information related to natural sources.

*Anthropogenic Sources*

Many industrial and commercial activities may be responsible for the direct release of potentially harmful substances into the environment. Environmental releases can occur at any time during a substance's life-cycle, including production,

transportation, use and disposal. An information matrix based on this "cradle-to-grave" approach is presented in Table 4.1B in the resource document.

Manufacturing sites, which may include raw material extraction and chemical syntheses, should be identified along with estimates of annual production at each site. Releases at the manufacturing and processing stage may take a variety of forms including liquid effluents, stack gases and accidental or fugitive emissions.

The amount of the substance imported annually into Canada should be determined, along with its destination by province or city.

Expected modes of transportation, distribution and storage should be identified since environmental releases can result from accidents such as pipeline ruptures, train derailments, tank truck collisions and leakage from storage tanks.

The specific uses and applications of the substance in Canada should be determined. When possible, this should include the identity and locations of industrial, commercial and institutional users of the substance. Information about the substance's domestic or household uses should also be obtained.

Required information about the disposal of the substance includes disposal sites and a general description of disposal methods. Different environmental compartments may be affected depending upon the treatment or disposal method employed. For example, incineration can result in significant atmospheric emissions due to incomplete combustion, or reactions of components in stack gases. Landfills that are not adequately sealed can release soluble substances to local soils and groundwaters. Disposal of municipal sewage sludge on agricultural land can result in releases of volatile substances to air and soluble substances to local soils and groundwater (Webber 1990; Webber and Shamess 1987).

*Transboundary Sources*

Substances can enter the Canadian environment through long and short range transport. Transboundary transport is generally recognized for persistent substances. It can also be significant for less persistent substances if an important source is located near the Canadian border. An example is smog and incinerator emissions migrating from Detroit into the Windsor area. Entry of substances into Canada by aquatic transboundary transport has been well documented. An example is the contamination of the Great Lakes and St. Lawrence River from toxic landfill sites in the United States. The matrix presented in Table 4.1C in the resource document can be used to organize such information.

*Indirect Sources*

In addition to the direct releases listed above, some substances can be formed in the environment from other synthetic substances as a result of natural biotic or abiotic transformation processes. Trichlorobenzenes, for example, can be formed in anaerobic sediments by reductive dechlorination of more highly chlorinated benzenes (Hollinger *et al.* 1992). Such processes should be identified, and their contribution to measured ambient exposures taken into account.

## *4.3 Characterization of Releases*

Once the key sources have been identified, entry characterization should focus on a more refined analysis of the specific characteristics of the releases. Data gathered during this step should, to the extent possible, be quantitative. The objectives are to:

- quantify the substance's releases in Canada,
- identify the frequency and patterns of the releases, and
- describe the substance's physical and chemical nature.

Table 4.2 in the resource document presents a generic matrix to help organize this information and assist in the analysis of data associated with the characterization of releases. This matrix may be adapted to the specific needs of each assessment.

*Quantifying Releases*

Releases of a substance can be characterized in several ways. Key quantitative parameters are concentrations of the substance either in effluents, stacks or in the receiving environment, and environmental loadings -- amounts released per unit of time.

In general, site-specific monitoring data provide the most accurate means of estimating substance concentrations and rates of release in stack gases, effluents, spills, etc. (Carpenter *et al.* 1990). However, monitoring data are often unavailable. Even when such data exist, their quality can vary depending on the location of sample stations, the accuracy of monitoring techniques, and the timing of sampling and release events. Also, because of the non-point nature of many natural sources, it is often difficult to obtain accurate empirical estimates of natural release rates. In cases where monitoring data are of insufficient quality or quantity to reliably quantify releases from major sources, release estimates may be based on model calculations or emission factors.

Models used to characterize releases may be simple mass-balance types, requiring information on a few, easily obtained parameters, or complex ones requiring more extensive information on system processes, data from monitoring programs, historical records, or assumptions about probability distributions. Case Study 4.1 in the resource document provides an example of a simple mass-balance model used to quantify releases from municipal waste water treatment plants. This type of model can also be used to quantify releases from natural sources, if steady-state conditions in the receiving compartment are assumed. Case Study 4.2 in the resource document provides an example of the use of a complex model.

Emission factors are usually expressed as the mass of a substance emitted per unit of mass or volume of product, or per unit time during a production process. Factors may be generated using monitoring data, models or professional judgment. Lists of factors for predicting releases of substances from industrial sources have been compiled by various national and international agencies (*e.g.*, CEU 1995). Care must be used when applying such factors to ensure they are based on conditions that are relevant to the industrial processes and emissions control technology currently used in Canada. Release estimates based on emission factors are generally less reliable than those based on monitoring or site-specific models. If an assessment moves beyond a tier 1 evaluation of worst-case quotients (Chapter 8), it may be necessary to confirm release estimates based on emission factors. Case Study 4.3 in the resource document provides an example of how emission factors are used to estimate releases of an organic chemical associated with different commercial applications.

Release data pertaining to leakage from storage facilities or to accidents during transportation are not always available. These data may be of limited use in estimating exposure since the magnitude and locations of such releases are often not adequately reported. For some substances, it may be possible to estimate releases on a regional or national scale by summing releases due to local accidents, or by considering recent trends in the number of accidents and sizes of spills. Material balances showing the volumes of substances being transported, the principal modes of transportation, the physical form of the substance during transport and the locations of shipping and receiving points may be useful in identifying areas that are most at risk of exposure.

*Frequency and Patterns of Releases*

The frequency and patterns of releases from each source should be determined whenever possible. For example, a substance may be released from a site continuously or intermittently. The quantities that are released may vary with the seasons. If releases are intermittent, monitoring periods must be long enough to allow the average and maximum rates of release to be ascertained. Seasonal variations in release rates should be determined since variations can affect total loading estimates,

etc. Furthermore, information about seasonal variations is needed in the exposure characterization phase in order to make meaningful exposure estimates.

The quantity of a substance released into the environment varies depending upon its commercial use. Solvents used for cleaning are highly dispersive; much of the quantities used are released into the environment. Chemical intermediates, on the other hand, are usually consumed in chemical processes and are released in only limited quantities. Estimates of the amounts of a substance used in different applications, combined with dispersivity data can indicate the magnitude of such releases in different areas.

When comparing releases from different sources, it is important to recognize that environmental impacts may differ depending on whether releases are point or non-point. For example, while the absolute magnitude of releases from non-point sources may be large, the environmental impact may be small if releases are spread over wide areas. Conversely, although releases from a point source may be small in absolute terms, they may cause significant harm locally if they are confined within a small area.

*Chemical and Physical Nature of the Substance Released Into the Environment*

An analysis of a substance's physical and chemical properties should be conducted for each significant source. This is used during exposure characterization to gain an understanding about how a substance is likely to partition in the receiving environment.

Assessors should obtain site-specific information about a substance's physical forms and chemical nature. This is especially important for metals and other chemical elements that can be released in a variety of forms each with its own reactivity and mobility properties. For organic substances, the chemical form is usually defined, but physical phase association (*e.g.*, aqueous solution or suspended solid in an effluent) can vary. This may be an important fate determinant. For solids released into air and water, properties of particular importance include density, size and shape (which determine their rates of removal by gravitational settling), and solubility (which determines their persistence in the solid form and ultimately their bioavailability) (Webber 1990; Webber and Shamess 1987).

*Recognition of Trends in Releases*

Changes in release quantities and patterns may occur because of changes in the quantity of a substance produced or used at a facility. They can also occur due to changes in industrial processes or waste treatment technologies. Therefore, it is necessary to note any recent trends in environmental releases, so that possible exposure scenarios may be considered during the exposure characterization phase.

For example, it may take many years for a persistent substance to disappear from the environment even if releases have been stopped or severely reduced. Less persistent chemicals would disappear much more quickly. Similarly, any anticipated increases or decreases in releases or changes in release patterns should be noted for use in the exposure characterization phase.

## *4.4 References*

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# Chapter 5

# Exposure Characterization

## 5.1 Introduction

*Goals and Objectives*

The purpose of this phase of the assessment is to verify and refine the exposure portion of the pathways analysis developed during problem formulation. Its objective is to quantifying contact between a substance[1] that has been released from identified anthropogenic sources and appropriate risk receptors[2]. The primary outputs are Estimated Exposure Values (EEVs), expressed as concentrations or doses, based on empirical data. EEVs are summarized as frequency distributions that reflect both real spatial and/or temporal variability, as well as errors and uncertainties associated with key exposure parameters. If possible, EEVs should be apportioned among identified anthropogenic and natural sources when results of a tier 2 risk analysis (see Chapter 8) indicate that actions to reduce exposure may be required and when contributions from natural sources to tier 2 EEVs may be significant.

*Relationship with Other Phases*

This phase relies on input from problem formulation, and information on amounts and forms of the substance released as determined during entry characterization (Chapter 4). Maximum EEVs are used as numerators in risk quotients during the tier 1 risk analysis; entire EEV distributions are used for tier 2 (Chapter 8). Tier 3 risk analysis uses estimates of the contibutions of natural and anthropogenic sources to measured EEVs (Chapter 8). Figure 5.1 summarizes the principal steps involved in detailed exposure characterization.

## 5.2 Physical and Chemical Properties of the Substance and Receiving Environments

Information on a substance's physical and chemical properties, as determined during problem formulation, should be refined as required. Values chosen for a few key parameters, such as vapour pressure, partition coefficients and aqueous solubility, may significantly affect fate or exposure model outcomes. Values for such parameters, and their associated uncertainties, should be determined as accurately as possible.

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[1] Discussion in this Chapter focuses on single substances or chemically related groups of substances. Exposure characterization for complex mixtures and effluents is described in Chapter 7.

[2] When risk receptors are wildlife species (birds, mammals, amphibians or reptiles), assessors should contact the Canadian Wildlife Service for additional guidance on exposure characterization.

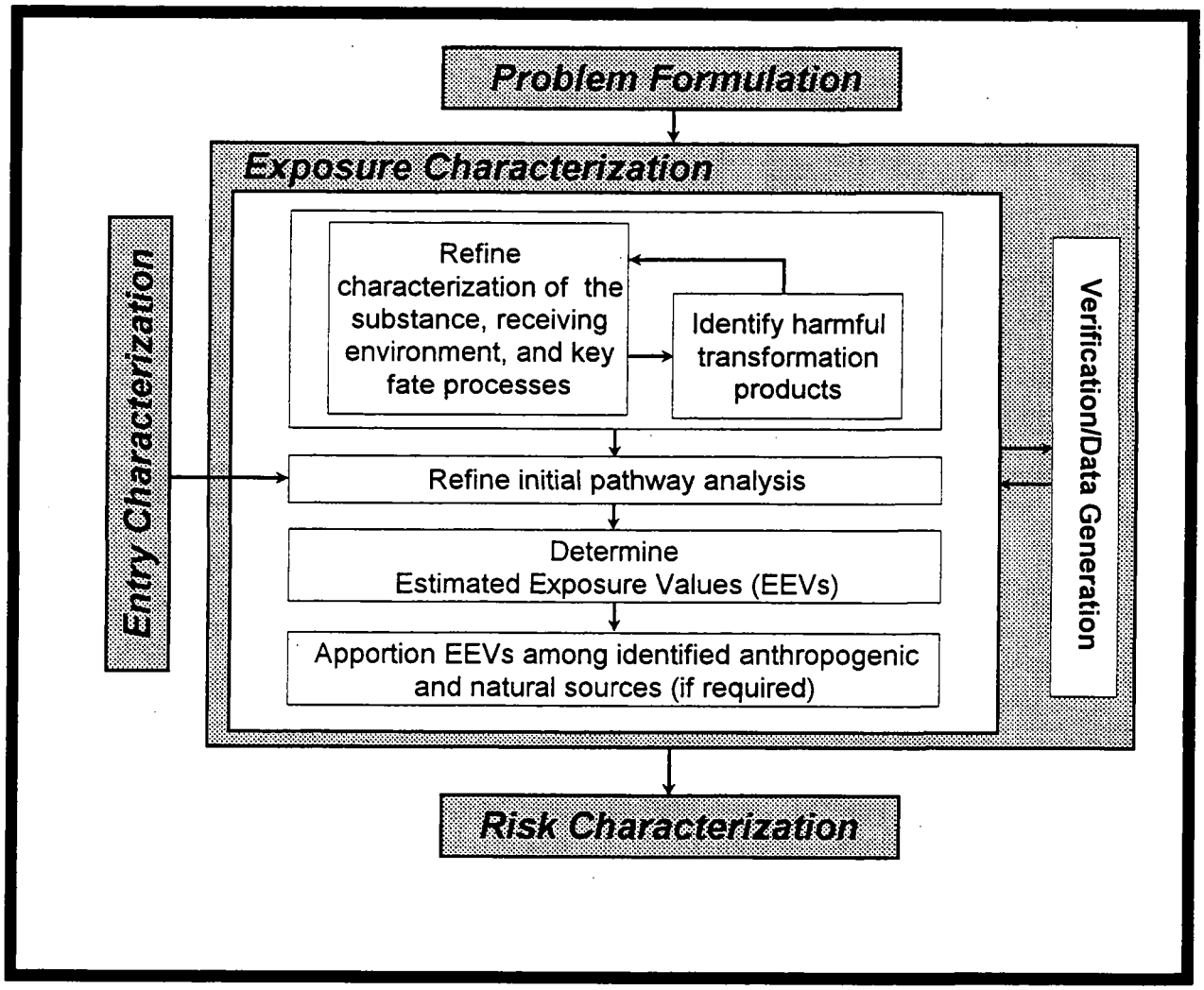


***Figure 5.1.*** Exposure characterization in ecological risk assessments of priority substances.

Experimental methods of quantification using accepted protocols (*e.g.*, OECD 1993a) are preferred, particularly for tier 2 risk analysis. However, values calculated as described by Lyman *et al.* (1990) or OECD (1993b), may be acceptable for less critical parameters, especially in tier 1. An example of the use of QSARs to calculate partition coefficients is provided in the rersource document.

Information on the physical and chemical properties of the receiving media, that influence the behavior, chemical form, and/or environmental concentrations of the substance should also be refined as needed. The information required varies, depending upon the application, the nature of the media, and key fate processes. Parameters of possible importance include light intensity, pH, oxidation potential, temperature, concentrations of other chemical substances, and the nature and

abundance of solid phases (see reseouce document). For fate and exposure modeling, other data may be needed -- intermedia partition coefficients, physical dimensions and bulk densities of environmental compartments, advective and diffusive flow rates. Values for key environmental properties and associated uncertainties used in fate or exposure models for tier 2 should, whenever possible, be based on field data from the area of concern. Tier 1 risk estimates or less critical environmental properties, can be based on empirical data for similar areas or estimates based on professional judgment.

### *5.3 Fate Processes*

Information on the nature and rates of key transport and transformation processes, which affect the environmental persistence and/or bioavailability of the substance, should be refined as required. For example, more accurate estimates of rates of intra- or inter-media, advective or diffusive transport may be needed. Transformation processes of potential importance include, complexation, precipitation and dissolution, sorption and desorption, oxidation and reduction, hydrolysis, volatilization, and photolysis (*e.g.*, Mill 1993; Hamelink *et al.* 1994). Rates of fate processes may be calculated (*e.g.*, OECD 1993b) for tier 1 risk estimates. For tier 2 key rate values and associated uncertainties should be determined empirically using acceptable laboratory and/or field test methods (*e.g.*, Knox *et al.* 1993; OECD 1993a). More detailed information on environmental fate processes is provided in the resource document.

The extent to which the substance accumulates in organisms which serve as food sources for sensitive predators should be determined as bioaccumulation and/or bioconcentration factors (BAFs or BCFs). BAFs calculated from field data are the preferred measure of accumulation potential. Experimental BAFs (or BCFs, when ingestion of food is not an important exposure route) are also acceptable. Test durations should be sufficient to achieve a steady state concentration in the test organism (ASTM 1993; OECD 1993a). For organic substances, BAFs or BCFs, may also be estimated from QSARs and/or $K_{ow}$ values (*e.g.*, OECD 1993b) if the uncertainty associated with such estimates is acceptable.

### *5.4 Transformation Products*

Products of transformation reactions identified during detailed fate characterization should be evaluated for their potential to cause adverse effects, using professional judgment, taking into account a substance's inherent toxicity, environmental persistence and bioaccumulation potential (see resource document). Transformation products that are likely to cause significant adverse effects should undergo a full ecological assessment. When the distribution of the transformation product is linked to its parent priority substance, the product's assessment should be incorporated into that of the parent.

## *5.5 Pathways Analysis*

Detailed pathways analysis should integrate data on releases of the substance from identified anthropogenic[3] sources (Chapter 4), with information on its physical and chemical properties and those of the receiving environment, as well as key transport and transformation processes. The objective is to refine and verify the initial pathways model developed for problem formulation. This involves describing the fate of the substance from its point of release to its accumulation in media where risk receptors are exposed.

Whenever possible, detailed pathway analyses -- particularly tier 2 -- should be based on outputs from numerical fate and exposure models. For example, refined estimates of releases from detailed entry characterization (Chapter 4) could be used in a regional multi-media fugacity model (*e.g.,* Mackay *et al.* 1991; Cowan et al. 1995) to confirm the identity of environmental compartments where organic substances are expected to accumulate. Single-medium models for air, surface water, soil and ground water, such as those described in ECETOC (1992), could also be used to predict environmental fate on more local scales. Guidance on the selection of such models may be found, for example, in U.S. EPA (1987, 1988, and 1991). Experts should normally be consulted when using complex models.

***Box 5.1.*** *Example of Qualitative Pathways Analysis*

A qualitative pathways analysis relating leakage from an above-ground storage tank to exposure of organisms in a nearby stream could take the form of a statement that because,

- the concentration of a persistent substance in an aquifer below a leaking tank, used to store the substance, was observed to decrease with increasing distance from the tank, and
- the groundwater is flowing relatively rapidly towards the stream, and
- the substance was detected in the stream, below (but not above) the expected point of entry of the contaminated groundwater plume,

release of the substance from the tank, and its dispersion in groundwater, has resulted in exposure of organisms in local surface water.

[3] Natural sources may also be targeted for pathways analysis, but this is only essential for tier 3 risk analysis (Chapter 8).

When numerical modeling methods cannot be applied or are not required, because there is abundant field data, for example, pathways analyses may be expressed in conceptual terms (Box 5.1).

Detailed pathways analyses should include verification of environmental media where the substance accumulates, and where it is likely to occur and cause harm. This normally requires measured concentrations for contaminated media in the area of concern. The identity and main routes of exposure of the principal risk receptors should also be verified at this stage. A table listing the primary routes of exposure for different classes of organisms is provided in Section 5.5.3 of the resource document.

## *5.6 Quantifying Exposure*

Generally, exposure should be quantified as a distribution of empirically determined or calculated Estimated Exposure Values (EEVs) for each identified risk receptor in each area of concern.

### *Approaches to Quantification*

EEVs may be based on concentrations of the substance in tissues of exposed organisms, or on various measures of external exposure (Suter 1993). For dermal contact, EEVs may be expressed as concentrations in external media such as water or soil. In cases of exposure by ingestion or inhalation, EEVs should be determined as rates of intake. When more than one medium could contribute significantly to external exposure, EEVs should be calculated as the sum of intakes of all relevant media. A computerized multi-media exposure model developed by the Canadian Wildlife Service (Brownlee *et al.* 1995) should be used to estimate exposures of birds, mammals, amphibians and reptiles. An example of output from this model is illustrated in Table 5.1.

EEVs for complex routes of exposure may be estimated as an internal dose using toxicokinetic models (Suter 1993). As explained in the resource document, while biomarker data may be used as part of the weight-of-evidence for exposure, exposure quantification should normally be based on more conventional concentration data.

### *Use of Field Data*

EEVs, particularly those used in tier 2 risk analyses, should usually be based on results of monitoring studies undertaken in the areas of concern. Methods of sample collection, handling, storage and analysis used in key studies should be carefully evaluated. Methods should follow acceptable protocols such as CCME (1993). When chemical species are determined changes in chemical form should be avoided.

***Table 5.1.*** Estimated maximum total daily intake of hexachlorobenzene for a 1 kg adult mink in the St. Clair River area[a].

| ***Medium*** | ***Maximum Concentration***[b] | ***Intake of Medium*** | ***Maximum Daily Intake ($ng \cdot kg\text{-}bw^{-1} \cdot day^{-1}$)*** |
|---|---|---|---|
| Air | 0.29 $ng \cdot m^{-3}$ | 0.55 $m^3 \cdot day^{-1}$ | 0.16 |
| Water | 87 $ng \cdot L^{-1}$ | 0.1 $L \cdot day^{-1}$ | 8.7 |
| Diet 1: 100% fish | 283 $ng \cdot g^{-1}$ | 215 $g \cdot day^{-1}$ | 60,845 |
| Diet 2: 100% birds or mammals | 30 $ng \cdot g^{-1}$ | 158 $g \cdot day^{-1}$ | 4740 |
| Total Daily Intake - for Air, Water and Diet 1 | | | 60,854 |
| Total Daily Intake - for Air, Water and Diet 2 | | | 4749 |

[a] Bioavailability factor (see below) assumed to be 1.
[b] Concentration data obtained from Health Canada and Environment Canada (1993), assuming that concentrations in birds and mammals are approximately equal.
[c] Methods of estimating intake are described in Moore *et al.* (1996)

Methods should also avoid contamination, or loss of analyte prior to or during analysis. Accuracy, precision or reproducibility, and detection limits of analyses should be documented. To demonstrate accuracy, standard reference samples (*e.g.*, Environment Canada 1995) should be analysed, and the concentrations reported should be within the accepted range. Analytical precision is acceptable if results of replicate analyses of a sample are within 20% of the average, 95% of the time (see Box 5.2)[4]. Less precise data may be acceptable in some circumstances, however. An analytical method is usually adequate if concentrations in most of the samples exceed the detection limits. However, if detection limits are significantly lower than the Estimated No Effect Value, a "not detected" result may be useful. Additional guidance on evaluating the quality of chemical data is provided in Appendix IV of the resource document.

The number and location of sampling stations and when samples were collected should permit the characterization of spatial and temporal variations of exposure in both impacted areas, and in appropriate background or reference locations. In addition, when there is ambiguity about the identity of sources contributing to measured EEVs, sampling and analytical methods should permit apportionment of EEVs among

[4] Precision is sometimes also expressed as a coefficient of variation. The coefficient of variation that corresponds to a precision of 20%, at the 95% confidence level, is 0.1.

possible anthropogenic and natural sources (see below). Ideally, exposure estimates should be based on data that are no more than a few years old. Older data may be acceptable, when releases have not changed significantly over time, and when

- estimating worst-case exposure values for tier 1 exposure characterization,
- estimating levels of a persistent substance in media that remain compositionally stable for relatively long periods, such as soil and sediment, or
- determining background concentrations of a substance.

***Box 5.2.*** *Quantification of Precision (P) at Approximately the 95% Confidence (2S) Level*

Using data from the repeated analysis of a representative sample:

$$P(\%) = 2S \cdot C^{-1} \cdot 100$$

where (C) is the mean measured concentration in the sample, and (S) the standard deviation of the measured values. Multiplication by 100 converts the quotient to a percent. To achieve 95% confidence, the analysis should ideally have been repeated 30 or more times.

The above was adapted from Fletcher (1981).

*Use of Calculated Values*

EEVs may be calculated by applying simple exposure conversion models to empirical exposure data. For example,

- equilibrium models (see Appendix II of the resource document) may be used to calculate concentrations of bioavailable forms of a substance,
- body burden values may be calculated as the product of measured concentrations in an exposure medium and a bioaccumulation factor (BAF), or
- total rate of intake may be calculated as the sum of measured concentrations in food, water and air, multiplied by consumption rates (*e.g.*, Table 5.1).

Monte Carlo or other simulation methods should be used when calculating EEVs by multiplying or dividing distributions of exposure parameters. For example, probability density functions for concentration in food and food intake rate may be multiplied in this way, to obtain a distribution of EEVs for food ingestion (see Chapter 8).

When the quality or quantity of empirical data are limited, outputs from appropriate fate and exposure models (see previous discussion of models -- section 5.5) may also be used as part of a weight-of-evidence approach to quantifying EEVs. Outputs from such models may also be useful for determining whether present releases of persistent CEPA "toxic" substances are likely to cause further environmental harm.

If there is insufficient empirical data of acceptable quality, outputs from exposure models should usually not be used as the sole source of EEVs. Exceptions may occur, however, particularly for tier 1 risk analysis, when exposure models are simple and uncertainties associated with calculated exposure values are small. An example would be a dilution model where a measured concentration in an effluent is divided by a dilution factor.

*Determining Bioavailability*

Generally speaking EEVs should be based on concentrations of bioavailable forms of substances, particularly for tier 2 risk analysis. However, for tier 1, EEVs may be based on total concentrations -- as opposed to the bioavailable fraction -- in exposure media (see Chapter 8).

***Box 5.3.*** *Empirical Relationships Between Uptake of Substances, Exposure Concentrations and Properties of Exposure Media*

Regression methods may be used to relate data on concentrations of a substance in organisms to concentrations of the substance in an exposure medium, as well as physical and/or chemical properties of the medium that determine bioavailability. For example,

- the metal content of plants ($M_{plant}$) may be related to the HCl-extractable metal content of the supporting soil ($M_{soil}$), as well as its pH, clay and organic matter (OM) content as follows:

  $$M_{plant} = a(M_{soil}) + b(pH) + c(\%clay) + d(\%OM) + e$$

  where a,b,c,d and e are empirically derived coefficients, or

- the metal content of molluscs ($M_{mollusc}$) may be related to the $H_2O_2$-extractable metal content ($M_{sed}$) and organic carbon (OC) content of host sediment as follows:

  $$M_{mollusc} = a[M_{sed} \cdot (\%OC)^{-1}]$$

  where a is an empirically derived coefficient.

The above was adapted from Martens (1968) and Tessier *et al.* (1984), respectively.

Body burden data are the preferred measure of exposure to bioavailable forms of substances that are not significantly metabolized, when complementary effects data are available (McCarty *et al.* 1992). Tissue concentrations may be based on analysis of a whole body, or individual organs.[5] Whole-body burdens of hydrophobic substances should generally be normalized to lipid contents (Gobas and Mackay

[5] Data on internal body burdens should not be used when toxic effects result from accumulation of a substance on the surface of organisms (*e.g.*, accumulation of aluminum on the surface of fish gills).

1988). Since whole-body data on the metal content of organisms may not be indicative of potential biological effects (Hare 1992; Cain *et al.* 1995), data on metal levels in cytosol are preferred.

When tissue concentration data are lacking, values may be predicted using empirically derived regression equations (see Box 5.3). These relate concentrations of the substance in organisms to levels in exposure media, and physical and chemical properties of the media such as pH, clay or organic matter content. However, caution should be used when applying such equations to organisms or environmental conditions that differ significantly from those for which the regressions were developed.

When body burden data cannot be used, exposure should ideally be based on levels of dissolved or "soluble" forms of the substance in key exposure media including pore waters of sediments or soils. Bioavailable forms of substances should be determined on a case-by-case basis, depending upon the nature of the substance and the assessment endpoint(s). In the case of organic and metallo-organic compounds, un-ionized[6], freely dissolved forms are primarily available for uptake (Suffet *et al.* 1994). For metals, freely dissolved "aquo ions" (*e.g.*, $Zn(H_2O)_6^{2+}$) are often considered the most bioavailable species (Benson *et al.* 1994). However, oxyanions are also taken up by organisms (Benson *et al.* 1994), and there is evidence that some dissolved organic and inorganic metal complexes are also bioavailable (Campbell 1995).

Methods that can be used to directly measure concentrations of various dissolved forms of both organic and inorganic substances are described in Suffet *et al.* (1994) and Pickering (1995) (see Appendix II of the resource document). When there are no empirical data on specific bioavailable forms, equilibrium models may be used to estimate concentrations of dissolved species (see Appendix II of the resource document). For example, MINEQL$^+$ (Schecher and McAvoy 1991) could be used to calculate concentrations of different dissolved metal species from total concentrations in unfiltered water samples, and data on the nature and amounts of other dissolved and solid phases. Similarly, the equilibrium partitioning model of Di Toro *et al.* (1991) may be used to estimate concentrations of the freely dissolved form of a neutral organic compound in the pore water of a sediment if its concentration and that of organic carbon in the solid phase of the sediment are known[7].

Uptake of metals as aquo ions may be reduced by competition for adsorption sites on the surface of exposed organisms between the aquo ions and hydrogen,

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[6] Ionized forms of organic compounds are not entirely unavailable for uptake by organisms. For example, organic cations can (to some extent) partition to lipid phases, especially for chemicals that have neutral forms which are strongly hydrophobic (Erickson *et al.* 1994).

[7] Alternatively, bulk concentrations in sediment and soil may be normalized to (*i.e.*, divided by) the fraction of organic carbon present in these media.

calcium or magnesium ions (Campbell 1995). For example, a decrease in pH may decrease uptake of zinc or cadmium, when concentrations of bioavaialbe forms of these metals remain constant (Campbell and Stokes 1985). Furthermore, as water hardness increases the toxicity (an effect of uptake) of many metals decreases (Erickson *et al.* 1995). These effects may be addressed by normalizing metal concentrations to concentrations of the competing ions. For example, normalized EEVs could be generated by dividing concentrations of an aquo ion by the total concentration of calcium and magnesium (*i.e.*, hardness) ions in a solution. Alternatively, exposure may be determined as body burdens if, for example, regression equations similar to those in Box 5.3 -- relating metal uptake, pH, hardness and metal concentrations in solution -- can be generated.

Exposure to "soluble" solid forms of metals and metalloids in solid phases can be measured using chemical reagents that remove the more weakly-bound forms of the substance (see Appendix II of the resource document). Reagents should be selected carefully, taking into account the nature of the substance and the conditions of exposure. Box 5.3 presents examples of two such reagents used to estimate the fractions of bioavailable metal in soils and sediments. The bioavailable fraction of metals in ingested and inhaled solids may be estimated by using a weak acid extraction intended to simulate conditions in the gastrointestinal tract, or by using data from absorption studies with laboratory organisms (*e.g.*, Stern 1994). The rate of intake of bioavailable forms of a substance may be estimated by applying a bioavailability factor ranging from 0 to 1 to total intake values (see footnote a, Table 5.1). Unless information indicates otherwise, the bioavailability factor for ingested and inhaled substances is usually assumed to be 1 (U.S. EPA 1992).

*Treatment of Temporal and Spatial Variability*

EEV distributions may reflect both real spatial and/or temporal variability of exposure, as well as uncertainties associated with exposure measurements, and ignorance of true values for key parameters used in calculations (Hoffman and Hammonds 1994). General guidance on treatment of variability in EEVs arising from heterogeneity is presented here. A description of estimation methods for quantitative uncertainty analysis is presented in Chapter 8.

The measured maximum EEV, or the 98th percentile of EEV distributions based on a large number (*e.g.*, $\geq$1000) of values determined by Monte Carlo simulation methods, should be used as numerators in risk quotients for tier 1 risk estimates. For tier 2 risk analyses, the entire distribution of EEVs should be used. Whenever possible, for higher tier EEVs, spatial and temporal variations should be separated. In such instances, EEVs may take the form of frequency distributions that reflect the variability of exposures at the same time but at different location, or at different times at a particular monitoring station. If sample locations were selected at random, and

organisms are assumed to be uniformly distributed within the sampled area, EEV distributions representing spatial variability can be used to estimate the proportion of the population of risk receptors that are exposed at levels above the ENEV. If sampling times were selected appropriately, temporal EEV distributions may likewise be used to estimate the proportion of time that exposure values exceed the ENEV at a particular monitoring station.

For discontinuous exposures, the timing, duration and frequency of exposure are important. Timing may be a key determinant of exposure for mobile organisms with seasonal migration patterns. In such cases, EEVs should be based on data for times when risk receptors are likely to be exposed to the substance, or are particularly sensitive to the substance (*e.g.*, during spawning).

Generally, exposure is characterized by estimating typical exposure values for specified time intervals such as a day or month. The selection of an appropriate period used to determine average exposure depends upon whether exposure is episodic or continuous, and upon the acute or chronic nature of the assessment endpoint. Short exposure integration periods are used when exposure is episodic or assessment endpoints are acute. Longer periods -- those of a month or more -- should be used with chronic endpoints.

If exposure values are based on infrequent sampling of mobile media such as air and river water, variations in intensity of sources, and flow and dilution characteristics must be considered when determining if such data are representative. EEVs based on one-time or short-duration sampling of relatively immobile media, such as soils and sediments, may often be assumed to represent longer exposure periods, if substances are persistent.

If samples were collected frequently relative to the preferred exposure integration period, typical exposure concentrations that are representative of the preferred time interval should be determined. This would apply, for example, if samples were collected monthly, and an integration period of a one year was considered optimal. Because of uncertainties about the shape of data distributions, medians should generally be used to estimate typical exposure values (Garrett 1991)[8]. If required for tier 2 uncertainty analysis, confidence limits may be estimated for medians (*e.g.,* Dixon and Massey 1969).

Tier 2 EEVs are often expressed as frequency distributions intended to reflect the variability of exposure of individuals within an exposed population at a specified time (U.S. EPA 1992). To determine the exposure of individuals when assessment

[8] In situations where the parent distributions are approximately normal, an arithmetic mean may be used. A geometric mean may be used for distributions that approximate lognormality.

endpoints are chronic, spatial variations in exposure values should be integrated (or at least averaged) over areas that correspond to the "home range" of individual organisms. Areas involved could be as small as a few $m^2$ for small immobile organisms, or as large as 100s of $km^2$ for large mammals. In practice, however, such integration is usually not possible because of limited knowledge of the home-range of exposed individuals, and the limited sample densities of most field surveys. Consequently, tier 2 EEV distributions are typically based on "raw" or unaveraged exposure data. When interpreting EEVs based on such "raw" data it should be recognized that there will be a tendency to overestimate the proportion of a population that is exposed at concentrations above a selected effect threshold (Hattis and Burmaster 1994).

## *5.7 Apportioning EEVs Among Identified Sources*

When releases from sources other than those of concern may have contributed significantly to measured EEVs, it is desirable to apportion EEVs among identified sources. This step is required for tier 3 risk analysis, when a tier 2 analysis for a natural substance suggests that actions to reduce exposure are required, and contributions of natural and anthropogenic sources to exposure must be distinguished (see Chapter 8).

Methods used for source apportionment may be simple, such as comparing concentrations of a substance in an exposure medium to distance from a point source (*e.g.*, Freedman and Hutchinson 1980). In other cases, more complex receptor models (*e.g.*, Gordon 1988), or specialized statistical or chemical methods (*e.g.*, Forestner 1983; Maenhaut *et al.* 1989) may be required. These and other methods are described in Appendix III of the resource document. Since there are large uncertainties associated with results of most source apportionment methods, several methods should be applied whenever possible, using a weight-of-evidence approach.

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# Chapter 6

# Effects Characterization

## *6.1 Introduction*

*Goals and Objectives*

The objective of the effects characterization phase is to define a critical toxicity value (CTV) or distribution for each assessment endpoint. A CTV is usually an estimate of low toxic effect, such as LOEL or $EC_{10}$, and may be in the form of a point estimate for tiers 1 and 2, or a distribution for tier 3, such as $EC_{10} \pm 95\%$ confidence limits. Chapter 8 describes the approaches to be used for deriving an estimated no effects value (ENEV) from a CTV.

*Relationship with other Phases*

The effects of a substance on assessment and measurement endpoints identified during problem formulation are determined during the effects characterization stage. It is important that sensitive receptors be identified as assessment endpoints. This is particularly important for uptake models that require input parameters such as ingestion rates or inhalation rates that differ for each receptor. It may become apparent that the assessment and measurement endpoints originally identified are not appropriate. This would be the case, for example, if the results of toxicity studies show that other types of organisms are more sensitive than previously believed or if the results of detailed exposure characterization indicate that the substance partitions to media other than those originally identified during problem formulation. In such cases, problem formulation would have to be revised and different endpoints identified.

Once CTVs for the appropriate assessment endpoints are determined, they are used as inputs to the next phase of the risk assessment, the risk characterization phase.

*Overview of Approach*

Toxicity information should include data from a wide range of trophic levels. These help determine which populations, communities and ecosystem processes may be particularly susceptible to adverse effects as well as the types and magnitude of these effects. Assessors should attempt to locate data pertaining to Canadian species and conditions whenever possible.

Available toxicity studies are critically evaluated, and only studies of acceptable quality are given further consideration (Appendix IV of the resource document). Assessors should consult standard protocols such as OECD (1993a) for guidance on

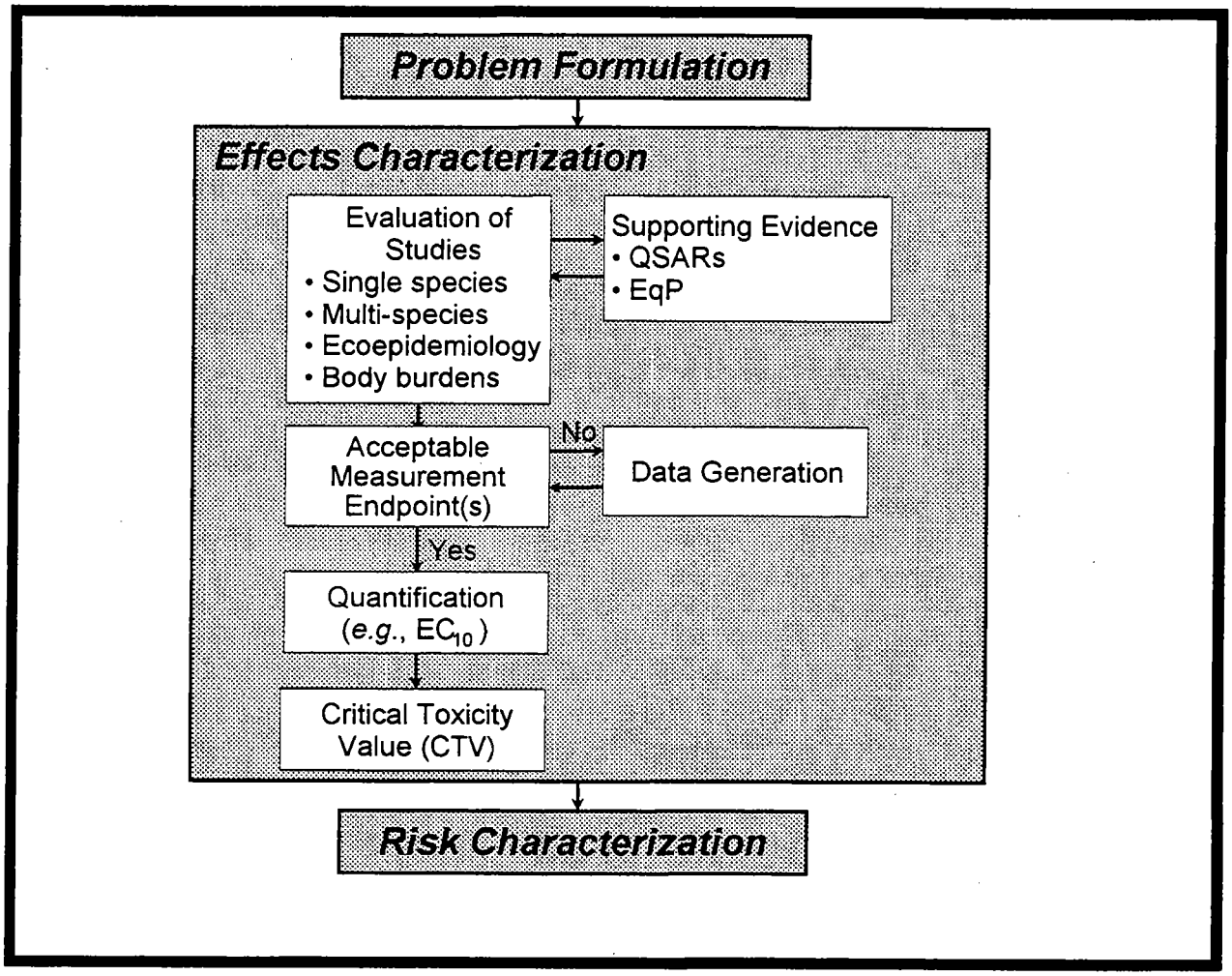


***Figure 6.1.*** Effects characterization in ecological risk assessments of priority substances.

acceptable studies. If no acceptable studies are available, research will be carried out to supply the required information.

Where necessary, the results from acceptable studies are refined to yield the type of experimental endpoint required. In order of preference these are $EC_{10}$, $EC_x$, LOEL, NOEL, $EC_{50}$ or other measure of central tendency.

Assessors should identify sources of uncertainty, both qualitative and quantitative, related to toxicological data. This will be taken into account at the risk characterization phase in selecting the appropriate application factor or in a quantitative uncertainty analysis. Areas of concern include uncertainties regarding the relationship between the substance and assessment endpoint, uncertainties associated with parameters in the studies, and natural variations in relevant media.

## *6.2 Types of Effects Information*

Studies on single species, multispecies, ecoepidemiology, body burdens, quantitative structure activated relationships (QSARs), and the equilibrium partitioning method can all be used to characterize effects on the measurement endpoint(s) of concern. Depending on the substance being assessed, several of these types of studies can be used. The limitations of each, however, should be considered. Acceptable studies contribute to an understanding of a substance's effects and the weight-of-evidence. The most relevant studies contribute toward the determination of CTVs. These studies should use Canadian species or closely related species. They should be from a range of trophic levels and represent a variety of exposure routes.

Full lifecycle studies that determine effects on embryonic development, hatching success, survival of juvenile stages, growth, reproduction, and survival of adults are preferred. In their absence, results may be employed from partial lifecycle studies using the most sensitive stages of the lifecycle (OECD 1993a). If there is only one study, assessors will have to decide on a case-by-case basis whether it provides sufficient information to establish that there are adverse effects on the measurement endpoint.

*Single Species Toxicity Tests*

Single species toxicity tests determine the effects of substances on organisms of a single species under specified test conditions. Such tests are needed to obtain information about the concentrations of substances and durations of exposure that cause changes in survival, reproduction, growth, physiology, biochemistry or behaviour of individuals within particular species (Cairns 1983). Biochemical or physiological perturbations may also have implications for population effects (Section 1.2). Such effects at lower organization levels include endocrine disruption (Colburn *et al.* 1993), genotoxicity (Anderson *et al.* 1994) and immune suppression. Standard measurement endpoints are available for some of these examples (OECD 1993a; Kramer and Giesy 1995).

The usefulness of single species tests for predicting effects depends on the degree to which predictions can be extrapolated to natural systems with confidence, and the tests' replicability and reproducibility (Cairns 1992). Single species toxicity tests make it easier to determine the direct effects of varying individual test conditions. In the case of microcosm or mesocosm tests interactions among species or environmental components may be masked. Standardized test methods yield the greatest degree of confidence (OECD 1993a). Standardized test methods developed by agencies such as Environment Canada, the United States Environmental Protection Agency and the Organisation for Economic Co-operation and Development have

enhanced the likelihood of achieving reproducible results when single species tests are carried out by researchers in different laboratories. Section 6.5.1 of the resource document lists some of the tests developed by these organizations. If other test methods are used, the procedures must be described in sufficient detail so that the reliability of the results can be judged.

When using single species laboratory tests for assessing risk the following points should be kept in mind. Physiological or biochemical variations among species, such as uptake and metabolism, can alter the potential toxicity of a substance. Inbred laboratory strains may be unusually sensitive or resistant to the test substance. Single species tests are often unable to accurately predict effects at higher levels of ecological organization where population dynamics such as age structure and density may have an effect. Ecosystem characteristics such as changes in community function, energy flow, and nutrient cycling cannot be predicted from single species tests (Cairns 1983). Unlike many microcosm and mesocosm tests, single species toxicity tests are not designed to integrate the simultaneous study of toxicity and various chemical transformation and partitioning processes. Behavioral and ecological parameters, such as competition and seasonal changes in temperature, may affect a species sensitivity to a substance. Application factors or quantitative uncertainty analyses may reduce many of these uncertainties (Chapter 8). Ideally, risk assessors should rely on a number of single species *and* multispecies toxicity tests. The two types of tests complement each other and present a more accurate characterization of effects than either type used alone.

*Multispecies Toxicity Tests*

Multispecies toxicity tests, including microcosm, mesocosm and field tests, incorporate ecological components (species, functional groups, or habitat types) that simulate processes as they occur in nature (SETAC 1992). A *microcosm* can range from a small laboratory-scale simulation of a portion of an ecosystem to a large outdoor tank. A *mesocosm* can range from laboratory microcosms to large, complex ecosystems (Grice and Reeve 1982; Odum 1984). Mesocosm tests, generally, performed outdoors, are usually better than microcosms at approximating natural ecosystems (Taub 1985). Field tests, once considered as large mesocosms, normally involve the isolation of terrain or part of a body of water and include within their boundaries the normal flora and fauna found under unperturbed conditions.

There are few examples of protocols for standardized microcosm tests for aquatic and terrestrial systems. Several aquatic mesocosm test protocols have been described in the literature (Touart 1988) and terrestrial mesocosms have been used for several decades (Barrett 1968). Field tests can confirm whether predicted fate, chronic effects, or bioaccumulation actually occur under reasonably realistic field conditions.

They can also reveal secondary effects that result from species interactions (OECD 1995).

Multispecies tests can demonstrate ecosystem recovery processes following a spill or stress (Harrass and Sayre 1989). They may be particularly useful in the ecological assessment of complex mixtures and effluents (Chapter 7). Harrass and Sayre (1989) suggest that acceptable multispecies test data include three key features: *credibility, applicability* and *endpoint interpretability* (Section 6.2.2 of the resource document). Assessors should ensure that these features are included in multispecies test protocols.

Microcosm experiments, like single species tests, are not globally sensitive to all stresses. When microcosms lack appropriate target species for substances with specific modes of action, little effect will be detected (Pratt *et al.* 1993). Toxicity to individuals, as measured by single-species tests, is not always reflected in toxicity to populations, and population interactions tend to dampen responses at the community level (Koojiman 1985). Complex interactions can vary from one system to another so that meaningful differences are often obscured. Assessors should be cautious in making projections to ecosystems based on these tests (Odum 1984). Microcosms require a period of stabilization for component species and are very costly when compared to single species toxicity tests (U.S. EPA 1992a). Natural communities are often difficult to sustain in an artificial arrangement. There may be extinctions and changes in community structure irrespective of substance exposure (Buikema and Voshell 1993).

*Ecoepidemiology*

Ecoepidemiology attempts to determine the causes of observed effects in the field by examining the spatial and temporal relationship between these effects and suspected causal agents (*i.e.*, PSL substances). Effects of concern include diseases in individuals and populations, disturbances in communities, and disruptions of ecological systems. In most risk assessments, laboratory toxicity data are used to predict adverse effects on the environment, whereas ecoepidemiology starts with observed field effects and attempts to identify causes. Epidemiological criteria may be used in conjunction with other laboratory-derived information to determine the potential of substances to cause adverse effects.

Ecoepidemiology may prove especially useful in assessments of complex mixtures where direct cause and effect relationships are difficult to ascertain in the laboratory (Chapter 7). Confidence in causal relationships can be increased by selecting reference sites and evaluating changes along a concentration gradient where differences in other environmental factors are minimized (U.S. EPA 1992b).

Statistical associations derived from well-controlled experimental studies can aid in establishing causal relationships even when the causative agent has not been demonstrated conclusively. Confounding factors that can obscure a substance's effects include differences in habitat quality between areas, natural variations in environmental parameters within areas, the occurrence of undetected stressors, and the movement of organisms into or out of the study area (U.S. EPA 1992b).

Results will often be inconclusive. The best that can be expected is to reach the most reasonable explanation based on the evidence at hand. In ecoepidemiology, most studies are observational, and experiments to confirm cause-effect relationships may be difficult or impossible to carry out.

Ecoepidemiology has the same basic principles as epidemiology. Fox (1991) has adapted criteria to help assess the relationship between a suspect substance and an adverse environmental effect (see resource document for complete listing). While these criteria do not provide proof of a cause and effect relationship, they do provide a process and framework upon which to exercise judgment.

*Critical body burden (CBB)*

Critical body burdens (CBBs) are the minimum tissue concentration that causes an adverse effect on a measurement endpoint, the reproductive potential of *Daphnia*, for example. Traditionally, results from acute and chronic toxicity tests are expressed in terms of the concentration in the external medium in relation to the biological response or measurement endpoint. The CBB method, which is based on whole tissue concentrations or the concentration in a particular target organ, can be an effective surrogate for the target site(s) of action. It can provide a more direct measure of a predicted adverse effect than an external exposure concentration--such as single species testing--since problems associated with estimating bioavailability and accumulation are essentially eliminated.

When appropriate, CBBs should be summarized and compared to tissue residue or body burden data collected in the field. This information may be used as the basis for the risk assessment or to support a weight-of-evidence approach for other analyses such as the external concentration method. While CBBs of organic substances have been linked to acute toxicity of narcotics in aquatic organisms, more research is required before this concept can be generally applied to other modes of toxic action (McCarty and Mackay 1993).

Assessors should use body burden data, and where possible, CBBs, along with more traditional toxicity information in characterizing effects in both the aquatic and terrestrial compartments. If research is required to fill data gaps, CBBs should be

measured during standard toxicity bioassays. This reduces uncertainties in comparing field and laboratory data relating to bioavailability, exposure routes and intake rates.

CBBs may be especially useful for assessing complex mixtures. Narcotic substances are essentially of equal strength on a molar residue basis and, therefore, the toxicity of mixtures of these substances is additive. Based on this additivity theory, acute lethality occurs if the sum of the chemical concentrations in the organism reaches the threshold level (McCarty and Mackay 1993).

*Quantitative Structure Activity Relationships (QSARs)*

In the absence of empirical data, quantitative structure activity relationships (QSARs) may be used to predict effects of chemical substances. QSARs may also be used to determine the physical and chemical properties of a substance. QSARs are developed for groups of substances that are differentiated by mode of action, which varies with the structure and physical-chemical properties of the substances or by chemical class[1]. QSARs are *only* applicable to substances within that group.

QSARs can be used to make preliminary estimates of toxicity in problem formulation, to corroborate empirical data, and to determine the need for additional testing. QSARs are used as supporting lines of evidence for estimating CTVs and not the primary source of evidence.

Two QSAR programs, ECOSAR and TOPKAT, are widely used for health and environmental assessments. The CEU (1995) also uses QSARs for aquatic toxicity tests (Section 6.2.5 of the resource document).

ECOSAR, developed by the U.S. EPA, uses over 100 QSARs for 40 chemical classes to predict acute and chronic toxicity to fish, *Daphnia*, green algae, and a 14-day $LC_{50}$ for earthworms in artificial soil (U.S. EPA 1994a). Approximately 50% of the QSARs are for neutral organic chemicals. The remainder are for ionizable organic chemicals such as esters, amines, phenols, anilines or aldehydes.

TOPKAT, developed by Health Designs, Inc. (HDI 1990), uses structure-activity relationships and statistical techniques to estimate various effects, including *Daphnia magna* $EC_{50}$ and fathead minnow $LC_{50}$.

Other QSAR programs could also be used for assessment purposes. The OECD (1992) recommends the following:

[1]Chlorinated phenols, nonionic surfactants, phosphate esters.

- The substance under investigation and those used in the QSAR should be similar in terms of structure and mode of action.
- Only QSARs that have been verified in terms of range of application and predictive capability should be used.
- A detailed description of the domain of the QSAR should be provided. This includes the structural rules defining the group of substances and the ranges of the parameters for which the QSAR is valid.
- The data used to develop the QSAR should be described or referenced.

QSARs that fail to meet these criteria may still be useful, but they should be applied with particular caution. When the need for QSARs is identified, assessors should consult with experts to verify the predicted effects of these models.

*Equilibrium Partitioning* (EqP)

The Equilibrium Partitioning (EqP) method estimates effect levels for benthic, soil-dwelling and groundwater organisms exposed to hydrophobic, nonpolar, non-ionic organic substances (DiToro *et al.* 1991; van de Plassche and Bockting 1993). It assumes a chemical equilibrium among porewater, organic carbon in solid phases, and resident biota. It also assumes that water-column organisms and those in the contaminated medium are equally sensitive to the substance. The advantage of this method is that effect values can be calculated quickly using effect data for water column organisms if the $K_{ow}$ of the substance and the organic carbon content of the solid medium are known. However, the uncertainties associated with this method's basic assumptions can often limit its usefulness (Chapman 1989). Effect values derived from this method may be used as screening values for problem formulation. Such data can also contribute to a weight-of-evidence approach for selecting a particular CTV for tier 2 risk analysis.

## *6.3 Deriving Critical Toxicity Values (CTVs)*

The dose-response curve describes the response of individuals, populations or other biological systems to a range of concentrations or doses of a substance. For most priority substances, dose-response relationships will be available for a variety of endpoints and experimental conditions. Other sections in this chapter describe how to select these studies to conduct an effects characterization for a particular assessment endpoint. The next step is to derive the CTV. A CTV is usually an estimate of low toxic effect (*e.g.*, $EC_{10}$, LOEL) and may be in the form of a point estimate for tiers 1 and 2, or a distribution for tier 3 (*e.g.*, $EC_{10} \pm 95\%$ confidence limits). In stating the CTV, assessors should indicate the type of result, the organism involved and the duration of

the test (*e.g.*, the CTV is 5 mg/kg from a 14-day $LC_{50}$ for earthworms in soil). Chapter 8 describes the approaches to be used to derive an estimated no effects value (ENEV) from a CTV. This section describes the preferred approaches and methods for quantifying CTVs.

Analysis of variance (ANOVA) is the most common method for estimating the LOEL (LOEC) or NOEL (NOEC). The ANOVA method involves the transformation of the data to produce a normal distribution and statistically compares the treated and control groups. Assessors can refer to the resource document or statistical texts for an explanation of ANOVA methodology (Snedecor and Cochran 1980; Sokal and Rohlf 1981). The use of ANOVA to derive estimates of low toxic effect has been severely criticized (*e.g.*, Stephan and Roger 1985; Pack 1993; Suter 1996):

- NOELs and LOELs are test concentrations or doses that do not correspond to consistent effects levels from one test to the next. LOELs, for example, may vary from 5 to >50% effect.

- Poor experimental design will mistakenly indicate that a substance is less toxic than it really is.

- Most information in the dose-response curve is not used (*e.g.*, the slope, confidence limits).

- Hypothesis testing leads to conclusions (*i.e.*, toxic or not) rather than descriptions (*e.g.*, level causing 10% mortality). Descriptive tools are more useful in ecological risk assessment.

$EC_x$ point estimation is more descriptive. This approach generally requires five or more treatments, and involves specifying a model--logistic, probit or multistage--and estimating its parameters through regression analysis. The desired $EC_x$ estimate (*e.g.*, $EC_5$) is then determined by interpolation. The $EC_x$ approach is the preferred method for all tiers and has the following advantages:

- It is a well-defined procedure for interpolation of effect to untested concentrations or doses.

- Poor experimental design will be reflected in the breadth of the confidence limits, but will not affect the $EC_x$ point estimate.

- All of the available information in the dose-response curve is used in the analysis.

The points listed below provide guidance on how to derive a CTV. For any given approach or method, assessors must ensure that assumptions have been met and limitations understood. A discussion of the methods and rationale behind any of these points is in Section 6.3 of the resource document.

- Assessors should examine the graph of the dose-response curve. This is the simplest means of showing the relationship between dose and response. By including replicates, the degree of scatter may be examined and outliers identified. This information may then be used to choose an appropriate statistical analysis or to judge the analysis reported by the author.

- For toxicity studies used to derive the CTV, dose-response curves with confidence limits should be estimated. This is generally done with the sigmoid-shaped probit or logistic model as the default models. Other models may be required if the dose-response curve has an unusual shape (*e.g.*, for nutritionally essential elements). An $EC_x$ statistical package is available in the Chemicals Evaluation Division (Moore and Caux 1996). The package includes three models in the logistic family, and the probit and Weibull models. It also includes goodness-of-fit statistics and automatically calculates $EC_x$ values from 0.1 to 99.9%. The co-authors of the package can assist assessors with analyses of dose-response curves. Other statistical packages may be used if desired (*e.g.*, SAS).

- The $x$ in the $EC_x$ from the estimated dose-response curve should be no lower than 10, unless it is being estimated by interpolation (Moore and Caux 1996).

- Generally, a non-linear regression analysis is preferred over a weighted linear regression analysis. Concentrations or doses should be $\log_{10}$ transformed, unless there is a compelling reason not to do so. With continuous data, it is not advisable to standardize the data to controls. This introduces dependencies among treatment replicates, thus violating the assumption of independence. With this type of data, controls should be treated as a separate model parameter. Model adequacy must be tested with a goodness-of-fit statistic and, if the model fit is inadequate ($p < 0.05$), the results should not be used. For replicated tests, deviations from model estimates are due to within-treatment variance and lack of model fit. Only the latter is of concern. Deviations due to within-treatment variance should not be included in estimates of goodness-of-fit. An *F*-test can easily separate deviations due to within-treatment variance and lack of model fit (Neter *et al.* 1983). Tier 3 CTVs require 95% confidence limits for use in the uncertainty analysis.

- If a LOEL or NOEL is used as the CTV, the following information should be provided: number of replicates, test variance, $\alpha$, $\beta$, and test dose intervals. This

is critical since conventional hypothesis testing will usually determine a NOEL and LOEL, even with poor dose-response data (Stephan and Rogers 1985; Suter *et al.* 1987; Barnthouse *et al.* 1987). Generally, LOELs are preferred to NOELs, and MATCs are not used to derive a CTV.

## *6.4 Aquatic Effects Characterization*

*Pelagic Biota*[2]

The results of single species or multispecies toxicity tests have often been used to estimate no effects concentrations or to derive water quality objectives or guidelines for substances. For the surface water compartment, results from long-term toxicity tests for organisms from different trophic levels can help determine which populations, communities and ecosystem processes may be particularly susceptible to adverse effects and to determine the types and magnitude of these effects. From the set of acceptable studies, the test result indicating the lowest toxic effect (*e.g.*, the lowest derived $EC_{10}$) should be used as the CTV for pelagic biota.

For most substances, results from single species toxicity tests will probably be the most abundant source of effects data on pelagic biota. However, results from multispecies tests and ecoepidemiology studies can be extremely useful in characterizing direct and indirect effects under natural or near-natural conditions. Field test results are particularly valuable when characterizing the effects of complex mixtures and effluents on pelagic biota. The CBB approach is particularly relevant when it is be difficult to determine the concentration of bioavailable forms of a substance in the environment (Section 6.2).

*Benthic Biota*

Sediments are an important component of aquatic ecosystems. They provide habitat to organisms such as aquatic plants, worms, insects, amphipods, and molluscs that spend a major portion of their lifecycle living on or in aquatic sediments. Sediments act as sinks, and subsequently, as sources of substances that have entered the aquatic environment. Substances found in sediments may adversely affect benthic species and/or bioaccumulate in benthos and to higher trophic levels.

The Water Quality Institute (Denmark) and RIVM (1995) provide a compendium of available standardized test methods. Environment Canada has also produced a number of sediment toxicity methods (Environment Canada 1994a,b). These toxicity tests, however, don't pertain to the toxicity testing component of the procedure but

[2]Pelagic biota are free-swimming or free-floating aquatic organisms that inhabit the water column.

rather to sediment handling[3]. In addition to toxicity tests, Lee *et al.* (1989) and U.S. EPA (1994b) have developed methods for estimating bioaccumulation in sediment organisms (Section 5.6). Some benthic organisms have been routinely used in water column tests. However, only a limited number of these spiked sediment toxicity tests have been standardized to examine an organism's exposure to sediment-associated substances such as whole sediment, pore waters or elutriates. Despite the paucity of standardized tests, a number of approaches have been developed to evaluate the toxicological significance of substances in freshwater, marine and estuarine sediments. Overall, assessors should be flexible. They will need to evaluate potentially relevant benthic toxicity information by applying sound scientific principles and basic QA/QC considerations.[4] Due to the complexities of interpreting data in the sediment compartment, assessors are advised to consult with sediment specialists when applying the following approaches.

Assessors should locate all acceptable sediment toxicological data on Canadian marine and freshwater species. These data should cover a range of feeding behaviours, substrate preferences, locomotion, and degree of association with bottom sediments. Sediment toxicity tests must use the appropriate sediment phase since benthic organisms may be exposed to some or all of these phases during their lifecycle. Qualitative and quantitative sources of uncertainty with the toxicological data should be documented. These uncertainties will be taken into account in selecting application factors or in conducting uncertainty analysis during risk characterization.

Spiked-sediment toxicity tests establish cause-and-effect relationships between exposed organisms and spiked concentrations of individual substances or mixtures (Water Quality Institute (Denmark) and RIVM 1995). A spiked sediment toxicity test is directly analogous to a water column test except the substance and test species are added to solid-phase sediments, not water. Researchers can use a standard clean sediment to provide inter-laboratory comparability. Artificially prepared sediments may also be used over field sediments thereby avoiding concerns that the sediments may have been contaminated with other substances. Assessors should be aware about concerns regarding the viability of organisms in artificial sediments. Data interpretation still relies on expert judgment. For example, sediment spiking may be strongly influenced by the methodology and this may affect the comparability of results.

As with pelagic biota, single species toxicity tests may be used to determine CTVs for sediment-dwelling biota. Toxicity tests may be short-term acute or longer-term chronic.

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[3]How sediments are spiked or how long the substances is allowed to equilibrate.

[4]See Important Considerations in Section 6.4.2 and Appendix IV, respectively, of the resource document.

Often no suitable spiked sediment toxicity tests will be available from the literature. When this is the case, a weight-of-evidence approach should be used to establish associations between a substance's concentrations in sediments and observed adverse biological effects. These associations can be based on data from laboratory tests conducted on field-collected sediments that contain mixtures of substances. These are referred to as co-occurrence data. Field data in the literature, should be evaluated on a case-by-case basis to determine their usefulness.

CCME (1995) provides a further discussion of the co-occurrence approach based on work by Long (1992), Long and Morgan (1990), and Long and MacDonald (1992). Other types of co-occurrence approaches include the apparent effects threshold (AET), sediment quality triad and informal evaluations of chemistry and biological responses (U.S. EPA 1992c). Sediment specialists should be consulted when applying a co-occurrence approach.

The benthic community structure assessment is another weight-of-evidence approach that may be used to compare a community living at a reference station with a community living in a contaminated area. This allows assessors to determine if effects have occurred on infaunal species and to identify spatial and temporal trends in sediment.[5] This information can be used to determine if a mixture of substances has affected community dynamics downstream of an industry, for example. This weight-of-evidence approach is that it is a recognized *in situ* method for determining sediment quality. It can be applied to a wide variety of aquatic ecosystems and to a wide variety of chemical groups. However, this approach does not identify substances found in the mixture.

The EqP approach (Section 6.2) may be used when the sediment solid phase contains more than 0.2 percent organic carbon.

Sediment quality guidelines and standards from various jurisdictions should also be reviewed for possible information on priority substances (*e.g.*, CCME 1995).

*Groundwater Biota*

Groundwater occupies pores and crevices in rock and soil in the phreatic or saturated zone. Traditionally, it has been a resource for drinking water, agriculture, and industry. However, recent investigations have shown that a rich, biologically diverse ecosystem exists within groundwater. The groundwater ecosystem provides habitat, food, and nutrient cycling for microbes such as bacteria and protozoa and micro- and macro-invertebrates especially copepods and amphipods (Botosaneanu

[5]Examples of this approach are given by Diaz 1992; La Point and Fairchild 1992; Persaud *et al.* 1992; Reynoldson and Zarull 1993; Reynoldson *et al.* 1995.

1986; Danielopol 1992; Marmonier *et al.* 1993). These organisms improve groundwater quality by biodegrading potentially toxic substances, support surface water food chain ecosystems and may improve the water quality of rivers, streams, wetlands and estuaries (Simons pers. comm.; Perciasepe 1994). There is now increasing research into groundwater ecosystem dynamics and functioning, the identification and distribution of groundwater organisms and the effects of contaminants on groundwater organisms.

While there are many approaches to evaluate the effects of priority substances in surface water, research to determine the effects of substances on natural populations of groundwater ecosystems is an emerging field. No standard toxicity test protocols exist for groundwater organisms and only effects on bacteria mineralization and acute toxicity tests with groundwater invertebrates are described in the literature (Notenboom *et al.* 1994). Assessors should use all available data as long as good general QA/QC practices and sound scientific principles are followed. In addition, all available data from the approaches described below should be included in a weight-of-evidence approach. Due to the difficulty in interpreting effects data for groundwater and surrogate organisms, assessors are advised to consult with groundwater ecology experts.

Substances with low $K_{ow}$ and $K_{oc}$ values are of the most concern to groundwater biota because they travel the furthest distance and may create the largest plume (Lesage pers. comm.). However, substances with high $K_{ow}$ may also be of concern as they tend to adsorb to organic matter in the saturated zone, desorb slowly and therefore may be a source of contamination for a long time. The assessor should be aware of the physical and chemical properties of the substance and the material through which it is being transported.

Simple exposure screening strategies and laboratory toxicity tests are recommended for evaluating effects on groundwater organisms. Test organisms should be representative of Canadian species and representative of groundwater biota in terms of function, trophic level and route of exposure. When reviewing toxicity studies, assessors should be aware of the influence of pH, oxygen content, temperature and other parameters that can influence the bioavailability of the substance and hence the toxicity of organic and inorganic substances. For more discussion, see Important Considerations in Section 6.5.3 of the resource document.

If groundwater toxicity data are unavailable and groundwater biota have been identified as being exposed to elevated levels of a substance, surrogate species such as surface water crustaceans may be used to determine the CTV for functionally similar species (Notenboom *et al.* 1994). It is also possible that effects threshold data for groundwater organisms could be estimated from toxicity results from soil-dwelling organisms such as earthworms (van den Berg and Roels 1991).

Assessors should identify areas of qualitative and quantitative uncertainty in the toxicological data. These may include uncertainties regarding the relationship between the substance and the groundwater ecosystem, the parameters of the study, and natural variations in groundwater systems.

The CTV is obtained from a weight-of-evidence approach that examines all appropriate data. Chronic, full lifecycle studies measuring nonlethal effects such as growth and reproduction are preferred. The EqP method (Section 6.2) may also contribute to the weight-of-evidence approach. If only acute toxicity data are available or are more sensitive than the chronic information, the CTV may be based on an $LC_{50}$, $EC_{50}$, or other significant $EC_x$.

An additional weight-of-evidence approach involves measuring effects to macroinvertebrates (*e.g.*, stonefly larvae) in the groundwater/surface water interaction zone. The disadvantage of this method is that volatilization and dilution may affect the concentrations of the substance in the groundwater and direct testing of groundwater organisms is not currently possible (Simons pers. comm.).

## *6.5 Terrestrial Effects Characterization*

*Soil Biota*

Substances found in soils may exist as distinct solid or liquid phases, or may be dissolved in the soil water, vaporized in the soil air, or adsorbed or absorbed to mineral or organic particles. Soil properties play a key role in determining the bioavailability of a substance to soil organisms. These properties include soil particle size distribution (percentage of sand, silt and clay), moisture content, pH, total organic carbon content and redox potential (Section 5.6).

For assessment purposes, soil biota are organisms that live at least part of their lifecycle in the soil. They may live above ground, in the litter layer, in the mineral soil or in soil pore water. Soil biota include microorganisms, invertebrates and plants. Mammals, birds, reptiles and amphibians are assessed separately as wildlife (see below).

There are a variety of approaches to assess the effects of priority substances on soil-dwelling biota, including single species and multispecies toxicity tests and field studies. Toxicity test protocols have been developed to assess effects on earthworms and terrestrial plants (OECD 1993a; U.S. EPA 1985). However, the only internationally harmonized soil toxicity test using invertebrates is the acute earthworm toxicity test (OECD 1984). See the resource document Section 6.6.1 for a description of this test and other tests currently undergoing research to standardize lethal and sublethal toxicity tests for a wider range of soil-dwelling organisms.

Data should be evaluated based on good general QA/QC practices and sound scientific principles. Toxicity information should ideally include data from a wide range of trophic levels and from both above ground and soil-dwelling biota. Soil organisms can be exposed to substances in soil via three routes: (1) oral uptake of food, soil particles or pore water, (2) dermal uptake from contact with pore water and/or soil particles, and (3) inhalation of soil air (see Table 5.5 of the resource document). Assessors should therefore consider the partitioning of the substance within soil compartments and the life habits of the soil biota to determine the relevance of toxicity test data. Toxicity studies considered in assessments should use test organisms and soil with properties that are representative of the areas of concern in Canadian environment.

For terrestrial toxicity testing, important trophic levels and functions are decomposition (microorganisms and detrivores), primary production (plants), and invertebrate fauna (herbivores and saprovores). To compare these tests, standardized soil that has similar textural composition, pH, organic matter content, water content and density, should be used (van Leeuven and Hermens 1995).

If toxicity information on soil biota is unavailable, acute and chronic toxicity data for aquatic species may be used to estimate effects on soil organisms that are exposed primarily to a substance via soil pore water. Aquatic species that can be used as surrogates for related terrestrial organisms include crustaceans, insect larvae, annelids, plants and algae (VKI 1994). Two modifying factors must be considered, namely soil organic carbon content ($f_{oc}$) and soil water content ($f_w$) such that:

$$CTV_s = ((f_{oc} \bullet K_{oc}) + f_w) \bullet CTV_d$$

where,

$CTV_s$ = CTV for soil biota
$f_{oc}$ = mass fraction of organic carbon in the solid phase
$K_{oc}$ = organic carbon partitioning coefficient (where $K_{oc} \approx K_{ow}$, the octanol-water partition coefficient)
$f_w$ = mass fraction of water content in soil
$CTV_d$ = CTV of the dissolved substance on an aquatic organism (modified from VKI 1994).

Predictive approaches such as the equilibrium partitioning approach and QSARs can provide supporting information as part of the weight-of-evidence, but should not be used alone to derive the CTV. These approaches involve considerable uncertainty. Assessors should consult Section 6.2.6 and 6.2.5, respectively, of the resource document for information on the EqP method and QSARs.

*Wildlife*

For assessment purposes, wildlife refers to wild mammals, birds, amphibians, and reptiles. Because of the complexities in predicting the effects of substances on wildlife, assessors should consult with the Canadian Wildlife Service when wildlife are the assessment endpoint.

Wildlife may be exposed to substances through: inhalation of and dermal contact with soil, sediment, water or air; oral intake of aquatic or terrestrial prey, or; accidental ingestion of soil or sediment or by cleaning feathers or fur. Receptors identified as assessment and measurement endpoints should, therefore, have similar exposure routes. For a volatile substance that partitions to the air, an inhalation study is preferred. For a hydrophobic substance that partitions to biota, an oral ingestion study is preferred. A model that estimates a substance's daily intake rates for wildlife has been developed for estimating multimedia exposure (Appendix III of the resource document). All of the major routes of substance exposure identified in this model should be assessed.

Wildlife testing protocols have been reviewed recently by Hoffman (1995). Avian protocols include acute oral ($LC_{50}$), short-term dietary ($LD_{50}$), chronic reproduction, embryo toxicity/teratogenicity, behavioural and field toxicity tests. Mammalian wildlife assessments rely heavily on laboratory data (Hodgson 1987) generated for human assessments, although U.S. EPA protocols are available for the mink (*Mustela vison*) and European ferret (*Mustela putorius furo*). There are no protocols for amphibians. However, the aquatic life stages appear to be the most sensitive.

The range of sensitivity to environmental substances depends on taxonomic class, age, size and life history characteristics. For example, birds are generally considered more sensitive than mammals, amphibians or reptiles. Smaller species consume more substance per unit body weight. These generalizations should be applied with caution since there are always exceptions (Tucker and Leitzke 1979). Due to differences in wildlife physiology and sensitivity between classes, interclass extrapolations of quantitative data are not recommended. However, when physiological similarities between classes and the mechanism of action are known, data may be discussed qualitatively in relation to another class to provide supporting evidence for the assessment.

For wildlife, measurement endpoints such as reproductive and developmental toxicity[6] and reduced survival are preferred since they can be directly related to

[6]Includes effects on spermatogenesis, fertility, pregnancy rate, number of live embryos, neonatal mortality, egg-shell thinning, egg production, hatchability, and offspring survival.

potential population level effects. A substance may also have an impact on wildlife populations through behavioural alterations, decreased food supply or habitat degradation. Chronic studies on organ-specific effects may be used if the effect can potentially reduce survival in wildlife. Biochemical or physiological perturbations such as endocrine disruption, genotoxicity and immune suppression may also have serious repercussions for wildlife population effects. The Canadian Wildlife Service has established a working group to address this issue. However, there are no standard measurement endpoints for identifying population level effects for some of these examples.

Field studies are preferred when cause and effects relationships can be clearly established to derive a CTV for wildlife. They can integrate many environmental factors that cannot be replicated in a laboratory study. When field studies are unavailable, laboratory studies may be used, with preference given to wildlife species. CBB studies (Section 6.2) and other body burden studies may also be relevant, particularly for metals.

## 6.6 Effects Mediated Through the Atmosphere

Substances identified during problem formulation that are likely to partition to the atmosphere may be assessed under either Section 11(a) or 11(b) of CEPA. Their behaviour should be compared to substances known to cause either stratospheric ozone depletion, ground level ozone formation, or global warming using one or more of the methods outlined below.

Under Section 11(b), "toxic" determinations should be limited to stratospheric ozone depletion only. Other atmospheric effects, such as global warming and ground level ozone formation are assessed under Section 11(a) of CEPA since they are either considered to cause direct adverse effects on the environment or because there is no clearly defined link to specific human health effects. "Toxic" determinations for global warming and ground level ozone formation under 11(a) of CEPA may not be straight forward due to the complexities in predicting potential atmospheric effects. However, assessors should consult with experts in the Atmospheric Environment Service or elsewhere for assistance on substances that may be implicated under Section 11(a).

The following sections summarize the methods available for estimating a first approximation of the various potentials of atmospheric effects.

*Stratospheric Ozone Depletion*

Ozone-depleting potential (ODP) is the ratio of calculated ozone column change for each mass unit of a gas emitted into the atmosphere relative to the depletion

calculated for an equal mass of reference gas, CFC-11 (ODP=1). In a first approximation, the ODP value can be calculated using the formula:

$$ODP = (T_S/T_{CFC\text{-}11})(M_{CFC\text{-}11}/M_S)([n_{Cl}+\alpha n_{Br}]/3)$$

where $T_s$ = atmospheric lifetime of substance S
$T_{CFC\text{-}11}$ = atmospheric lifetime is 60 y
$M_{CFC\text{-}11}$ = molecular mass of CFC-11 is 137.5 g·mole$^{-1}$
$M_S$ = molecular mass of substance S
$n_{Cl}$ and $n_{Br}$ = the number of Cl and Br atoms per molecule
$\alpha$ = a measure for the effectiveness of Br in ozone depletion with respect to Cl, a reasonable parameter is $\alpha$ = 30.

In general, ODP values approach zero for species with atmospheric lifetimes less than one year. In accord with the Montreal Protocol on Ozone Depleting Substances, a substance with an ODP greater than zero may be considered "toxic" under Section 11(b) of CEPA.

*Ground Level Ozone Formation*

Substances that contribute to ground level ozone formation are volatile, reactive hydrocarbon gases (VOCs) at ambient tropospheric temperatures. Such substances possess a wide range of ozone producing potentials.

The photochemical ozone creation potential (POCP) index measures the relative effect on ozone of a unit mass of any organic compound compared to that caused by an equivalent mass of ethene (CEU 1995). Ethene has a POCP value of 100. A first indication of episodic ozone formation can be obtained from a reactivity scale based on the rate constant for the (OH-hydrocarbon)-reaction and molecular weight of the substance, "S", compared to ethene.

$$\text{OH-scale} = (k_s/M_s)(M_{ethene}/k_{ethene}) \times 100$$

where k = rate constant at T = 298 K for the reaction with OH-radicals
$k_s$ = rate constant for the reaction with OH-radicals for substance S
$k_{ethene} = 8.5 \times 10^{-12}$ cm$^3$·mol$^{-1}$·sec$^{-1}$
$M_s$ = molecular mass of substance S
$M_{ethene}$ = 28 g·mole$^{-1}$

There is too much uncertainty associated with this methodology to assign an ozone forming potential threshold above which a VOC could be considered "toxic" under Section 11(b). However, with technical assistance it may be possible to generate more accurate ozone forming potentials.

Computer simulations can be used by appropriate experts to arrive at more precise estimates of the ozone creation potential for individual organic compounds (Carter 1994). These simulations produce reactivity scales that take into account kinetic and mechanistic reactivity. In general, reactivity scales numerically rank each VOC providing a measure of how its emissions affect ozone formation.

Two sets of reactivity factors have been calculated: the maximum incremental reactivity (MIR) scale and the maximum ozone incremental reactivity (MOIR) scale. Many substances already have published values for their reactivity or they can be generated, if necessary (Dann 1995).

With more precision it may be easier to determine the extent of the contribution of any given VOC to ground level ozone formation. However, the problem of defining a threshold for that contribution to be "toxic " under Section 11(a) remains.

Consequently, until a consensus about what constitutes a "toxic" determination under Section 11(a) for ground level ozone formation, and the magnitude of the associated threshold, evidence of ozone formation should only be used as part of a weight-of-evidence approach for Section 11(a) "toxic".

*Global Warming*

Global warming potential (GWP) is the ratio of warming for each unit of mass of a gas emitted into the atmosphere relative to the warming for a mass unit of the reference gas CFC-11. Assessors will be able to estimate the GWP of a substance "S", using the following formula.

$$GWP = (T_S/T_{CFC\text{-}11})(M_{CFC\text{-}11}/M_s)(S_S/S_{CFC\text{-}11})$$

where $T_S$ = atmospheric lifetime of substance S
$T_{CFC\text{-}11}$ = atmospheric lifetime of CFC-11 is 60 y
$M_S$ = molecular mass of substance S
$M_{CFC\text{-}11}$= molecular mass of CFC-11 is 137.5 g/Mol
$S_S$ = IR absorption strength in the interval 800-1200 $cm^{-1}$
$S_{CFC\text{-}11}$ = IR absorption strength of CFC-11 is 2389 $cm^{-2}\cdot atm^{-1}$

Methods for deriving absorption strengths ($S_s$) are described by Rogers and Stephens (1988), Kagann *et al.* (1983) and CEU (1995). Using this calculation, substances with an estimated GWP of 0.05 or greater should be a concern.

GWP estimates are useful in developing a weight-of-evidence approach under Section 11(a) of CEPA for assessing trace gases that could disrupt the radiative

balance of the Earth. Further consultations will be necessary to derive "toxic " thresholds under Section 11(a) of CEPA for these substances.

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# Chapter 7

# Complex Substances

## *7.1 Introduction*

*Goals and Objectives*

The objective of this chapter is to provide guidance on how to conduct an ecological risk assessment of a complex substance. While the chapter emphasizes the differences between assessments of complex and individual substances, it also provides examples of similarities in assessment approaches.

*Relationship with Other Phases*

Some of the guidance and considerations, such as the use of models and a weight-of-evidence approach, addressed in other chapters may also apply to the assessment of complex substances. To avoid repetition, assessors should refer to appropriate chapters when clarification or additional information is needed on a particular issue.

*Background*

Most of the work in environmental toxicology and ecological risk assessment has focused on individual substances. However, in nature, biota are often exposed to complex substances such as mixtures or effluents[1].

There are three types of complex substances:

- 1) those composed of related substances having similar physical and chemical properties (*e.g.*, PAHs, PCBs, dioxins);
- 2) those that are generated or released at a given time and place (*e.g.*, emissions from smelters, effluents), that have a relatively defined and constant composition, but that are not necessarily composed of related substances (*i.e.*, constituents); and
- 3) those, that are often commercially or chemically unrelated (*i.e.*, having different physical and chemical properties), and that occur by coincidence at a given time and place (adapted from U.S. EPA 1986, 1988; Vouk *et al.*, 1987).

[1] See definition in glossary

For the purposes of this manual, complex substance refers to either type 2 or 3 as described above. This chapter focuses on complex substances composed mainly of classes of unrelated substances. However, guidance in this chapter can be used to conduct an ecological risk assessment of related substances--often released from diffuse sources. An example would be discharges of effluents or emissions from a facility where related constituents are believed to be the cause of potential environment effects. These assessments would be source specific such as those involved with type 2 and 3 substances.

Studies needed to conduct an ecological risk assessment of complex substances are not always available. In such cases, research should generate the appropriate data. Research needs can be identified using computer-based models. However, such models are less useful in the assessment of complex substances because they often have to be site specific. If site-specific models are available, model outputs can be used as long as the outputs are supported by empirical data; a weight-of-evidence approach should be used. When computer-based models are used, model experts should be consulted with regard to advantages, limitations and assumptions.

## *7.2 Data Collection and Generation*

Most of the guidance and information sources presented in chapter 2 apply to complex substances.

Complex substances are not usually assigned a Chemical Abstracts Service Registry Number. They are often referred to under various technical names. In stage 1 of data collection, assessors should be aware of the various technical names that represent a particular complex substance. For example, while searching for data on waste crankcase oils, technical names used as keywords include: waste crankcase oil, used crankcase oil, waste oil, used oil, waste lubricating oil, used lubricating oil, waste motor oil, used motor oil, spent oil, etc.

Group parameters[2] of a complex substance are also useful when searching for data. For example, technical names and group parameters (see underlined keywords below) for chlorinated wastewater effluents include: chlorinated wastewater effluent, chlorinated effluent, chlorinated sewage, residual chlorine, chlorine residual, chlorination, etc. Key constituents of complex substances could be used as keywords during data collection. For example, if sulphur dioxide is a key constituent of a mixture released from a stack, sulphur dioxide should be used as a keyword during data collection. These strategies increase the probability of obtaining all available data. However, by using such an array of keywords, particularly during electronic database searching, many irrelevant data may be retrieved. To reduce their number, Boolean

[2] See definition in glossary

Logic (*e.g.*, operators such as OR, AND, NOT used to group, connect or eliminate specified terms) could be used during the search. In addition, assessors can use, as a second type of key word, the source of release of a complex substance to the environment.

Once stage 1 of data collection is completed, assessors must determine whether data essential to the assessment are available. Assessors must identify data gaps in order to request such data during stage 2 and stage 3 of data collection. When such data are unavailable, data gaps must be identified as early as possible since some approaches may require long lead times to generate data.

## *7.3 Problem Formulation*

In problem formulation the goals, breadth and focus of the assessment are established; data gaps are identified; and a strategy for proceeding with the assessment is devised. This phase includes *initial scoping*, *pathways analysis*, consideration of *receptor sensitivity*, an analysis of the *ecological relevance* of potential receptors, selection of *assessment endpoints* and associated *measurement endpoints*, and the development of a *conceptual model* .

A complex substance must be thoroughly characterized in the problem formulation stage. The characterization is carried out in initial scoping and pathway analysis where entry and exposure are identified. Continuous refinement of this characterization is necessary throughout the assessment process.

During initial scoping, the characterization involves identifying various technical names of the substance and, on a qualitative basis, identifying key constituents, potential constituents of concern, group parameters and sources of release.

Data needed to characterize environmental releases for complex substances, in addition to those required for individual substances, include volumes or flow rates (*e.g.*, $L \cdot day^{-1}$, $kg \cdot day^{-1}$) or quantities (*e.g.*, $mg \cdot kg^{-1}$ waste, $g \cdot day^{-1}$) of the complex substance emitted to the environment.

Physical and chemical properties of constituents and group parameters indicate possible fate, transport and composition of the complex substance following release. Computer-based models can also predict the environmental fate of complex substances. However, practical applications of model outputs are less useful than those for individual substances. The behaviour of complex substances cannot necessarily be predicted based on behaviour of individual constituents. Data on physical and chemical properties, interactions between constituents, and between constituents and the receiving environment are often unavailable. Such approaches may, therefore, only be used for a qualitative fate assessment.

Once the substance and its release are sufficiently characterized, its environmental partitioning, fate and geographic distribution can be determined. To do this, data are needed on chemical monitoring of constituents and group parameters obtained from field and laboratory studies involving chemical analysis (Sections 7.5 and 7.6).

Understanding how constituents and group parameters in complex substances behave is essential in considering receptor sensitivity, identifying assessment and measurement endpoints, and assembling a conceptual model.

## *7.4 Entry Characterization*

Entry characterization identifies sources of release and quantifies the amounts released to the Canadian environment using a lifecycle approach.

*Identification of Sources*

Sources can be identified by updating a substance's lifecycle and by identifying domestic and transboundary sources of entry.

A lifecycle approach may not be necessary for substances with predetermined sources of release (*e.g.*, air emission from a specific smelter). For substances with no predetermined source of release, an evaluation of the lifecycle is essential for characterizing entry.

*Characterization of Releases*

Once the sources of release have been identified, entry characterization should focus on a quantitative analysis of the release characteristics with the following objectives:

- refining the classes of constituents, potential constituents of concern and group parameters;
- identifying the frequency and pattern of release (*e.g.*, continuous, intermittent);
- refining amounts and forms generated or produced;
- using monitoring data to 1) update volumes or flow rates or quantities from all sources emitted to the environment, and 2) identify concentrations of major constituents, constituents of concern and group parameters in the releases using chemical monitoring data;

- using the above to quantify amounts in the release.

Outputs from site-specific computer-based models can estimate releases. The model outputs must be supported by empirical data and used as part of a weight-of-evidence approach. In general, site-specific monitoring data provide the most accurate means of estimating substance concentrations and rates of release in stack gases, effluents, spills, etc. However, monitoring data are often unavailable. In such cases, mass-balance type models or emission factors can be used to estimate releases or data might have to be generated.

## *7.5 Exposure Characterization*

Exposure characterization quantifies the relationship between a complex substance's source inputs and its resulting geographic distributions in space and time (spatial and temporal scale), and identifies populations at risk.

For complex substances, measures of exposure include constituents and/or group parameters that determine the fate and spatial and temporal scale of the assessment. Such data are also used in the effects and risk characterizations.

*Fate and Spatial and Temporal Scales*

Because of the complexity involved in assessing mixtures and effluents, the physical and chemical properties of constituents and the receiving environment can only be used on a qualitative basis to predict the fate of complex substances. Fate and exposure models can predict the fate of complex substances and the spatial and temporal scales of the assessment. However, model outputs are less practical than those for individual substances because models are site specific. For this reason, the model outputs must be supported by empirical data and used as part of a weight-of-evidence approach.

Chemical field monitoring of key constituents and group parameters are the preferred approaches that quantitatively determine the fate and spatial and temporal scales of the assessment. If chemical field monitoring studies are unavailable, monitoring data may be obtained from field and laboratory-ambient toxicity tests. In the latter type of study, samples of complex substances taken from the receiving water at various distances from the release point undergo chemical analysis and toxicity bioassays in a laboratory. Results from field toxicity tests and laboratory-ambient toxicity tests can determine the potential for exposure at a given distance from the release point and used directly in the effects and risk characterizations.

These approaches can identify the persistence and bioavailability of constituents and group parameters and the environmental media most likely to be affected. They can also determine the spatial and temporal scales of the assessment.

*Identification of Organisms Exposed to Complex Substances*

Organisms selected for evaluation should be among those most at risk because of high exposure to the substance. Potential for exposure should be based on knowledge about how a substance is distributed in the environment and major routes of exposure for different types of organisms. Data should be collected on the spatial and temporal distributions of potentially exposed organisms in Canada and their preferred habitat. This will ensure that organisms selected for evaluation are likely to have been present in the areas of concern prior to the onset of contamination. Other factors that could affect exposure such as diet, mobility, and body size should also be considered when selecting organisms for evaluation (see Appendix III of the resource document).

## *7.6 Effects and Risk Characterizations*

Effects characterization determines whether complex substances are causing adverse effects to exposed organisms. By using field and laboratory-ambient toxicity tests that compare exposure and effects data, assessors can directly conduct a risk characterization.

The occurrence of constituents in complex substances can influence toxicity in two ways. First, the interactions of constituents can cause a toxic effect that is qualitatively or quantitatively different from that of any of the constituents acting alone, as is the case with additive, antagonistic or synergistic effects. Second, the effects of one constituent may influence the kinetics of uptake, metabolism, and excretion of other constituents (Suter 1993). Because of these factors, complex substances require different approaches for assessing ecological risks.

The preferred methods for this phase of the assessment are, in order of preference:

- field toxicity tests (*e.g.*, *in situ* biological testing, community surveys)
- laboratory-ambient toxicity tests, and
- laboratory toxicity tests using whole effluent or whole mixture samples.

Constituents of complex substances often partition into different environmental compartments, such as soil, water, biota, etc., and single species tests are customarily conducted in only one of these compartments. Field studies at the community and

ecosystem levels could provide a more realistic assessment of effects (Vouk *et al.* 1987). However, such studies are often unavailable and other types of field toxicity tests, including population level studies and *in situ* bioassays, can be useful.

Field toxicity tests, laboratory-ambient toxicity tests and whole effluent and mixture tests have a number of advantages:

- Field toxicity tests can provide direct evidence of effects to organisms in the environment.

- Field toxicity tests and laboratory-ambient toxicity tests can provide data on the fate of complex substances, exposure concentrations of constituents and group parameters, effects and risk to organisms. They do so by taking into account the characteristics of the constituents and the receiving environment that are difficult to characterize by other means (Porcella *et al.*, 1986).

- Whole effluent and mixture tests can provide worst-case estimates of adverse effects.

In order to use such studies, assessors must demonstrate that the observed effects are due to the complex substance and not to substances released from other sources.

Other laboratory methods can identify and assess the potential adverse effects of constituents. These include microcosm and mesocosm tests, effluent and mixture fractionation methods (also known as Toxicity Identification and Evaluation), the representative substance class method and the individual substance method. These methods are discussed in chapter 7 of the resource document.

If a complex substance is composed of only a few constituents, then the individual substance method could be used to assess potential effects. This method, also called the hazard index method, estimates the total effects of such substances by assuming additivity of the constituents. The individual substance method can be used as a Tier 1 risk analysis (Chapter 8).

While field toxicity tests, laboratory-ambient toxicity tests and whole effluent and mixture tests are the preferred methods to assess complex substances, assessors should use a combination of these tests to build a weight-of-evidence approach. Such an approach can also include the other laboratory methods outlined above.

Ecological effects models are not available for the assessment of complex substances (Vouk *et al.*, 1987).

### 7.6.1 Effluents

There are no standard protocols or approaches for directly determining the effects of effluents on the structure and function of natural populations, communities and ecosystems. However, there are approaches, including some that have been used for effluents previously listed on the Priority Substances List, that have proven to be successful for assessing the ecological risk of effluents. These approaches are discussed below.

*Field Toxicity Tests*

- Spatial Controls
  - *in situ* toxicity studies using caged organisms located upstream and downstream of the discharge, and
  - surveys of community structure, population survival, or other biological endpoints upstream and downstream of the discharge.
- Temporal Controls
  - *in situ* toxicity studies using caged organisms located upstream and downstream of the discharge and conducted before and after a process change (*e.g.*, switching to discharges of non-chlorinated effluents), and
  - surveys of community structure, population survival, or other biological endpoints conducted before and after a process change upstream and downstream of the discharge.

These approaches compare the results of upstream (*i.e*, control site) and downstream surveys and/or toxicity tests and determine if adverse effects have occurred.

*Laboratory-Ambient Toxicity Testing*

Samples of receiving water are taken at various distances downstream of the point of discharge and laboratory toxicity testing and chemical analysis are performed on these samples. This approach can provide data on the fate, exposure concentrations and effects of the complex substance, and therefore of the risk that the substance poses to exposed organisms.

*Laboratory Toxicity Testing Using Whole Effluent*

Whole effluent toxicity tests are usually conducted in the laboratory and involve either short-term (acute) or long-term (chronic) exposures. Toxicity can be measured by using effluent samples obtained at the point of discharge and by conducting toxicity tests on the samples. This approach can be used as a worst-case scenario to screen effluent for potential toxicity (*i.e.*, effects at 100% effluent concentration). If no toxicity is observed, no adverse effects are expected to occur downstream of the discharge.

When effects are observed, dilutions of the 100% effluent can be used to estimate, for example, a $LC_{50}$. The most difficult aspect of characterizing risk using this approach is linking the inherent toxicity of the effluent, as measured in the laboratory, to concentrations in the environment and demonstrating that biota are exposed or have the potential to be exposed to the effluent or its constituents. To do this, assessors must demonstrate that potentially harmful constituent concentrations measured in the dilution samples also exist in the field.

### 7.6.2 Mixtures

As with effluents, there are no standard protocols or approaches to determine the effects of mixtures on the structure and function of natural populations, communities and ecosystems.

The main difference in designing approaches to assess the ecological risk of mixtures, as compared to effluents, is that effluents are usually discharged to water bodies whereas mixtures can be discharged to various environmental compartments including air, land and water. Therefore, the experimental design of the preferred testing methods will not only depend on the use, physical and chemical properties and ultimate fate of the mixture, but also on the type of environmental compartment that is receiving it. Based on these considerations, approaches to assess the ecological risk of mixtures are determined on a case-by-case basis.

*Field Toxicity Tests*

Aquatic Ecosystems

Approaches used to conduct an assessment of mixtures discharged to water bodies are similar to those of effluents, particularly for continuous water flow systems (*e.g.*, rivers).

Spatial and temporal controls can also be used for mixtures discharged to aquatic systems having little or no water flow (*e.g.*, lake) . However, the difference between this approach and that used for continuous water flow systems is choosing a

proper control site (since there are no upstream sites) for both the *in situ* toxicity tests and the community and population surveys. The control sites must have similar characteristics (*e.g.*, naturally occurring biota, physical and chemical properties of the sediments, water, etc.) to those of the affected study sites.

Terrestrial Ecosystems

Since approaches used to determine the ecological risks of mixtures are designed on a case-by-case basis, examples using waste crankcase oils (WCOs) are presented below (Environment Canada and Health Canada 1994). During the WCOs assessment, an attempt was made to follow its lifecycle from the point of collection to ultimate disposal. Three scenarios outlined ways in which WCOs enter the Canadian environment--road oiling, burning and land disposal (Table 1). The examples are not meant to be an exhaustive list of approaches. Expert judgment must always be used when designing an approach to assess a particular mixture.

Table 1. Approaches and type of controls to conduct field toxicity studies of WCOs.

| ***Use and Disposal Scenario*** | ***Approach*** | ***Control*** |
|---|---|---|
| road-oiling used for dust suppression | *in-situ* tests using caged organisms in nearby streams and fields | spatial and/or temporal controls |
| burning as fuel | *in-situ* tests using caged organisms in fields | spatial and/or temporal controls |
| disposal to land | *in-situ* tests using vegetation and/or microorganisms | spatial and/or temporal controls |

In the first example, leachates of WCOs enter roadside streams where spatial (upstream) and temporal (before the application of WCOs) controls can be used. Some constituents of WCOs applied to roads are likely to volatilize or be transported via particulate matter to neighbouring fields. Spatial and temporal controls can also be used in this instance, but choosing a proper control site is likely to be more difficult than that involving discharges of complex substances to water systems. One reason for this is that water flow as a vehicle provides a more uniform distribution of constituents of an effluent (Vouk *et al.*, 1987). Choosing a control site for constituents transported via air can involve analysis of wind currents. A control site should have similar physical,

chemical and biological characteristics to the site of interest. If wind current data are not available, the data should be generated.

In the second example, wind currents can also play an important role in choosing a proper control site.

In the disposal to land scenario, temporal controls can be used by conducting a biological survey of microorganims before and after application. Spatial controls can be used for volatile constituents and constituents transported by particulate matter to nearby vegetation. This case can also involve an analysis of wind currents to determine an appropriate control site.

*Laboratory-Ambient Toxicity Testing*

Adverse effects can be determined by collecting air, soil or water samples containing constituents of the mixture from various sites near the release and conducting toxicity tests on the samples using the assessment or measurement endpoint(s).

Using the scenarios presented in Table 1, laboratory-ambient toxicity tests could involve, for example, the collection of particulates near facilities burning WCOs. Using these samples, deposition levels of WCO constituents could be determined and applied to laboratory biota. In this example, deposition levels could be collected over a specified time period or per volume of WCOs burned and applied to vegetation living near the facility. Another possibility could involve the collection of contaminated sediments from nearby streams where road runoff of WCOs has accumulated. Laboratory toxicity tests using these samples and local benthic invertebrates could determine the mixture's potential adverse effects and risks, and provide data on fate and exposure.

*Laboratory Toxicity Testing Using Whole Mixture*

Whole mixture toxicity tests are usually conducted in the laboratory and involve either short-term or long-term exposures. Whole mixture samples are used directly in laboratory toxicity testing.

Examples include applying WCOs directly to the organisms likely to be exposed (*e.g.*, bird eggs), feeding organisms diets containing WCOs, or applying WCOs to laboratory soil plots to observe the response of organisms living in the soil.

This approach can be used as a worst-case scenario to determine potential adverse effects. If no toxicity is observed for whole mixtures, no adverse effects are expected to occur to the assessment endpoint. If adverse effects are observed,

assessors must demonstrate that the assessment endpoint(s) has the potential to be exposed to the whole mixture. Such data can then be used in risk characterization.

## *7.8 References*

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# Chapter 8

# Risk Analysis

## *Goals and Objectives*

The objective of an *ecological risk analysis* is to determine the likelihood and magnitude of adverse effects to assessment endpoints as a result of exposure to the priority substance (definition adapted from Suter 1993). This chapter describes a tiered approach for estimating risks of priority substances to assessment endpoints. The second step of risk characterization, summarizing and describing the results of the risk analysis for the risk manager and other interested parties, is discussed in Chapter 9 (Risk Communication).

## *Relationship With Other Phases*

Risk analysis combines the results of the characterization of entry, exposure and effects (Figure 8.1). Such results may be combined in a number of ways. The most common approach is to estimate exposure based on monitoring studies and toxicity based on laboratory bioassays and then compare the two. Other lines of evidence should also be used in a weight-of-evidence approach whenever possible. For example, if field observations indicate a correlation between the absence of sensitive species and levels of the priority substance, this evidence should be used in characterizing risk. Similarly, if several toxicity studies or QSARs corroborate the critical toxicity value, or if fate model predictions support the monitoring data, these lines of evidence should be highlighted in the risk characterization. Several lines of evidence can strengthen our confidence in the risk estimates and reduce the uncertainties inherent in using only one approach.

## *Overview*

Quantitative methods for risk analysis may be subdivided into deterministic and probabilistic methods. A *quotient* is calculated by dividing the *estimated exposure value* (EEV) by the *estimated no effect value* (ENEV). The ENEV is calculated by dividing the *critical toxicity value* or CTV (see Chapter 6) by an appropriate *application factor*. Several extrapolations are required to convert the CTV for a measurement endpoint to an ENEV for the corresponding assessment endpoint. Application factors are used to account for the uncertainties inherent in such extrapolations. The first part of this chapter (Section 8.1) describes the quotient method in more detail and the application factors to be used in calculating an ENEV and discusses the calculation of worst-case quotients (*i.e.*, Tier 1).

*Probabilistic* risk estimation methods (*i.e.*, Tier 2) integrate entry, exposure and effects by comparing distributions of input values rather than point estimates. This

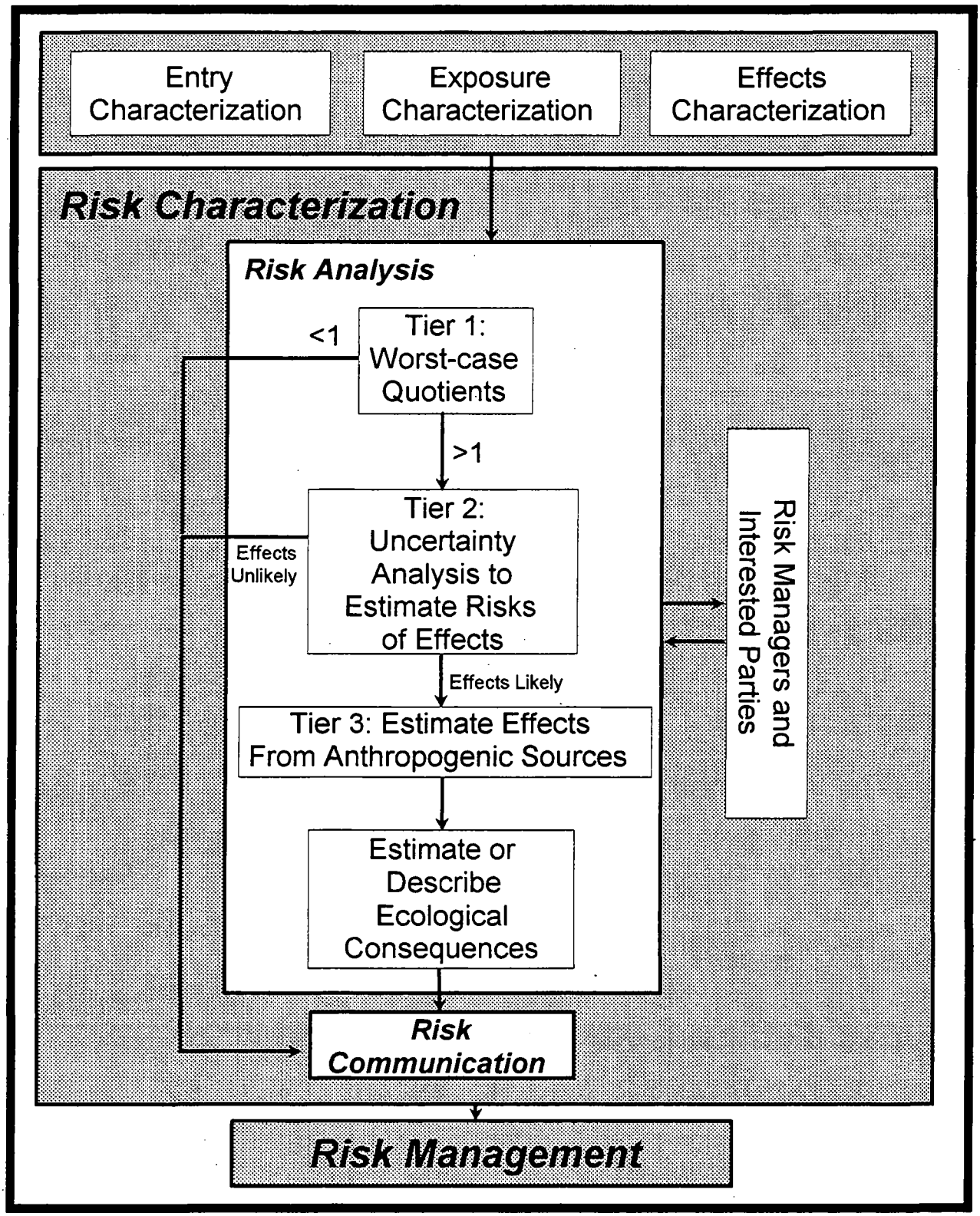


***Figure 8.1.*** Risk characterization in ecological risk assessments of priority substances.

approach facilitates a more explicit consideration of the sources of uncertainty in the risk analysis. Rather than focussing on the risk of exceeding the ENEV, these methods consider the entire relationship between dose and response. Thus, the probability of adverse effects of a broad range of magnitudes may be considered. Section 8.2 describes methods for conducting a probabilistic analysis and provides guidance on how and when to use them.

For many naturally occurring substances, there are naturally enriched areas in Canada. In these areas, resident organisms will have developed tolerance to the substance of interest. However, there is a potential for harmful effects to these resident organisms if exposure is further increased as a result of anthropogenic contamination. A Tier 3 analysis attempts to account for these issues by adjusting ENEVs to account for expected tolerances in naturally enriched areas, and by partitioning exposure into its natural and anthropogenic components (Section 8.3).

Risk analyses may be applied at the individual, population or community levels of organization. Methods applied at the individual level do not consider effects beyond those considered in most toxicity tests. To estimate effects at higher levels of organization generally requires linking toxicity test results with population or community level simulation models. Less often, field tests may be carried out. Section 8.4 provides guidance on how simulation models may be used to estimate the ecological consequences of exposure to priority substances at higher levels of organization.

In carrying out a risk analysis at any tier, key sources of uncertainty must be identified and described either qualitatively or quantitatively. Smith and Shugart (1994) examined uncertainty in relation to the three phases of ecological risk assessment -- problem formulation, analysis, and risk characterization. Problem formulation involves uncertainties in the choice of appropriate endpoints, in the choice of model and modelling approach, in the choice of scale, and in the availability of information. In the analysis and risk characterization phases, potential sources of uncertainty include:

- variation in the composition, magnitude, frequency and duration of releases and discharges,
- knowledge of the physical and chemical properties of the substance,
- temporal and spatial scales of exposure, and matching those scales with the ecological scales of the risk assessment,
- knowledge of substance transformation due to chemical, physical, and biological actions,
- heterogeneity of the populations at risk,

- interactions among multiple stressors,
- reproducibility of laboratory and field studies,
- extrapolation of laboratory toxicity test results to field conditions, and
- extrapolation of toxicity test results for measurement endpoints to assessment endpoints.

In deciding whether these or other sources of uncertainty are critical to the decision-making process, assessors should communicate regularly with Environment Canada risk managers and interested parties throughout the risk characterization phase. Assessors and managers will need to consider which analyses will ultimately be the most useful during risk management. They will also need to decide when the analyses have proceeded far enough. Regular communications with risk managers and interested parties will help to ensure that the risk assessment plays a central role in the decision-making process.

## *8.1 Tier 1: Worst-Case Quotients*

The first tier of an ecological risk assessment involves calculating a worst-case quotient (*i.e.*, EEV/ENEV). If the worst-case quotient is less than one, there is a very low probability of an adverse effect to the assessment endpoint. Typically, worst-case scenarios overestimate the risk posed to assessment endpoints (Cullen 1994). Therefore, if a worst-case quotient is one or greater, more detailed analyses are required to estimate the potential risks posed by the substance.

For a tier 1 quotient, the EEV is usually the maximum total observed or predicted concentration or dose in the environment, and the application factors used in deriving the ENEV are large (Table 8.1). For worst-case quotients, the total of all application factors multiplied together should not exceed 5000. If the worst-case quotient is <1 for all assessment endpoints, there is little justification in proceeding to more detailed analyses. The substance is declared not "toxic" as defined in Section 11 of CEPA. Worst-case quotients cannot be used as justification for declaring a substance "toxic".

## *8.2 Tier 2: Quantitative Uncertainty Analyses*

If one or more quotients from the first tier worst-case analysis exceed one, the analysis proceeds to Tier 2. Several approaches that assessors may use to refine the analysis and overcome some of the conservatism and assumptions involved in worst-case scenarios are discussed below.

***Table 8.1.*** Recommended application factors for converting critical toxicity values to estimated no effects values.

| ***Available Information*** | ***Factor*** |
|---|---|
| Acute toxicity to measurement endpoint(s)[a] | |
| Lethality (*e.g.*, $LD_{50}$), if log $K_{ow}$ <4 | 20 |
| Lethality, if log $K_{ow} \geq 4$ | 100 |
| If nonlethal, but toxic effects occur | between 10 and 100 |
| $EC_{10}$, LOEL or NOEL for measurement endpoint(s) | 10 |
| Modifying factor[b] | |
| Data quality (*e.g.*, unmeasured concentration, LOEL > 30% mortality, conversion between life stages or endpoints) | 1-10 |
| Data quantity (number of acceptable studies) | 1-10 |

[a] Acute-chronic ratios (ACR) can be used as an alternative approach. In this case, the 50% acute effect is divided by the ACR to convert the value to an estimated chronic LOEL. The resulting value is divded by an application factor of 10 to derive the ENEV.
[b] The modifying factors depend upon professional judgment regarding the scientific uncertainties of the critical toxicity value and the effects database. The default values are one.

Quantitative estimates of uncertainty are obtained by using statistical and computer models. With statistical models, uncertainty is expressed by measures of variance and power. Quantitative uncertainty associated with computer models can be estimated by Monte Carlo simulation, Baye's theorem, fuzzy numbers or a variety of other techniques. These methods produce a single number that estimates uncertainty or a distribution of output that provides information on the range and magnitude of uncertainty (Covello and Merkhofer 1993; ASTM 1994; Smith and Shugart 1994). The type of method selected by the assessor will depend on the nature of the problem and the available information. For substances where the determination of "toxic" is not clearcut, it is impossible to specify probability cutoffs that are sufficient for a "toxic" determination, since issues of magnitude of effects, spatial scale of effects and availability of supporting lines of evidence all play a role in the decision. Professional judgment is required.

*General Mechanics of a Quantitative Uncertainty Analysis*

Finkel (1990) developed a set of guidelines for quantifying uncertainty that includes the following six sequential steps:

- Identify the desired *numerical expression* and *characteristic* of risk for each assessment endpoint (*e.g.*, 25% percent mortality to pelagic fish species, 10% growth rate impairment in diving ducks)(Section 4.5). The remaining five steps need to be followed separately for each measurement and/or assessment endpoint.

- Specify the equations that will estimate risk. Risk equations may be simple (*e.g.*, risk = EEV/ENEV) or complex. Some of the more complex risk equations can involve entire food webs (*e.g.*, Bartell *et al.* 1992; MacIntosh *et al.* 1994). Care must be taken at this stage to avoid equations that are overly simplistic or overly complex. Simple equations may ignore major sources of quantifiable uncertainty or misrepresent the system they are trying to emulate (Covello and Merkhofer 1993). Complex equations have the potential to incorrectly estimate risk because of dependencies among input variables. They can also have so many degrees of freedom that it is difficult to collect the necessary input data (Covello and Merkhofer 1993).

- Generate an uncertainty distribution for each input variable (also referred to as probability density functions or PDFs) in the risk equation. The choice of distribution generally depends on: (i) the form of the observed data, which may be determined by graphical or statistical curve-fitting techniques, and (ii) a basic understanding of the system which allows assessors to theorize about the distributions that will best describe the underlying reality. For example, a lognormal distribution is usually appropriate for any variable that is the product of a large number of random variables such as concentration in a particular medium or intake rate (Hattis and Burmaster 1994). Some of the difficulties in selecting appropriate distributions, particularly when data are lacking, are discussed by Haimes *et al.* (1994). In any type of uncertainty analysis, a rationale must be provided for each input distribution.

- Generate the output variable distribution by combining the uncertainty distributions of the input variables as specified in the risk equation. This step typically involves Monte Carlo simulation, but there are a variety of other possible techniques (Chapter 8 in the resource document).

- Fine tune the analysis. At this point, assessors may use the results of a sensitivity analysis to determine those input variables that had an important influence on the output variable. Such input variables should be re-examined to ensure that the data and distributions are scientifically acceptable. Often the tails of the input variable distributions need to be truncated to eliminate physically or logically impossible values. Input distributions may also have to be adjusted to account for dependencies between important variables. Once the input distributions and, if necessary, the risk equation have been fine tuned, the

simulation is repeated and a refined output generated. Fine tuning the risk analysis often involves numerous iterations.

- Summarize the results, highlighting important implications for risk managers. The major output of the analysis is a quantitative or graphical description of the uncertainty or probability of an effect (see Appendix V of the resource document for an example). Such outputs may be summarized as probability density functions, cumulative probability distributions, ranges and box plots, pie charts, histograms, summary statistics, or risk indices. The objective is to ensure that the risk manager understands the results of the uncertainty analysis, and the impact of these uncertainties on the conclusions of the risk assessment and subsequent risk management decisions. The manager should also be briefed on any unresolved scientific controversies and provided with information on the magnitude and relative importance of uncertainties not captured in the quantitative uncertainty analysis (Finkel 1990; Covello and Merkhofer 1993).

*Estimation Methods for Quantitative Uncertainty Analysis*

In simple cases, input variable distributions (or PDFs) can be combined using simple mathematical relationships (Finkel 1990). For example, exposure to a substance may be calculated by multiplying the substance concentration in a medium by the ingestion rate and dividing the product by body weight. If these input PDFs are lognormally distributed, the uncertainty analysis can be completed with a few simple calculations (Slob 1994).

More often, complex quantitative uncertainty analyses will be required. The classical approach to estimating uncertainty requires that input parameter estimates be derived from available data, where probabilities are numbers associated with events and risk is a measurable property of the physical world. Monte Carlo simulation estimates probability using this classical approach. In most analyses of priority substances, Monte Carlo simulation is the preferred method. Appendix V in the resource document shows the results of a Monte Carlo simulation that estimated the probability of adverse effects on mink exposed to hexachlorobenzene in the St. Clair River in Ontario (also see Moore *et al.* 1996). In cases where Monte Carlo simulation is not necessary, appropriate or feasible, other methods such as Baye's theorem and fuzzy numbers may be used to estimate probability.

For each quantitative uncertainty analysis, there must be a clearly defined assessment endpoint and all relevant information regarding the analysis must be recorded so that a knowledgeable person can reproduce and evaluate the analysis. An uncertainty analysis working group in the Chemicals Evaluation Division, Commercial Chemicals Evalation Branch at Environment Canada has been created (currently, D.

Moore and B. Elliott), and assesors considering a quantitative uncertainty analysis should consult with this group to evaluate the feasibility and steps involved.

### *8.3 Tier 3: Estimating Risks Due to Anthropogenic Sources for Naturally Occurring Substances*

A Tier 3 analysis takes into account the tolerance of organisms occupying naturally enriched areas. It is required only when a Tier 2 risk analysis indicates a potential for harmful effects, and there is evidence of areas being naturally enriched in Canada. In such cases exposure should, if possible, be separated into its two components: the natural component ($EEV_n$) and the anthropogenic component ($EEV_a$). Appendix III of the resource document describes methods that may be used to accomplish this separation.

If the $EEV_n$ for bioavailable forms of the substance exceed the estimated no effects values (ENEVs) for sensitive endpoints, the ENEV should be refined. This involves:

- defining a lower bound for the ENEV,
- evaluating the choice of assessment and measurement endpoints, and
- evaluating the relative tolerance of assessment and measurement endpoints.

These steps arose from a workshop on effects to organisms in naturally metal-enriched areas, held at Trent University in August, 1995 (Hutchinson 1996).

*Bounding the ENEV*

When natural exposure ($EEV_n$) has been elevated for an extended period, resident organisms evolve to tolerate such exposure. In such areas, the ENEV should not be below the $EEV_n$. Unfortunately, estimating the $EEV_n$ can be difficult. When the $EEV_n$ can only be estimated as a single mean value, the lower boundary of the tier 3 ENEV should be the mean $EEV_n$. In cases where the $EEV_n$ can be characterized as a distribution, the lower boundary of the tier 3 ENEV should be the 90th percentile EEV for the area of concern[1].

[1] Depending upon the shape of the EEV distribution, setting the minimum tier 3 ENEV at the maximum EEV could result in a tier 3 ENEV that is much higher than typical exposure values. Thus, using the maximum EEV would seem inappropriate. Alternatively, setting the minimum ENEV equal to the median EEV would imply that assessment endpoints are adversely impacted by natural levels of the substance in up to half of the area of concern - an unlikely occurrence.

*Evaluating the Choice of Endpoints*

Assessment and measurement endpoints should be representative of classes of organisms that are the least likely to develop high tolerance, but are still relevant to the site of exposure. Potential for tolerance in different strains of a species or in related types of species may be evaluated by reviewing the literature to determine whether high effect thresholds have been reported, particularly when test organisms were pre-exposed to a substance. When assessment endpoints are found to belong to a class of organisms that is highly tolerant, different endpoints may be chosen. For example, aquatic invertebrate species might be substituted for algae, if review of the literature indicates that invertebrate species are much less likely to develop high tolerance than algal species.

*Evaluating the Relative Tolerance of Assessment and Measurement Endpoints*

Assessment endpoints should exhibit tolerances that are similar to those of corresponding measurement endpoints. When assessment endpoints are likely to be more tolerant than measurement endpoints, consideration should be given to reducing or even eliminating the application factors employed to derive the ENEV. If this approach is inappropriate because of large uncertainties, new toxicity studies may be required. Ideally area-specific organisms would be chosen for testing. A bioassay protocol for obtaining toxicity data relevant to plants inhabiting naturally enriched areas has been proposed by Hutchinson (1996).

The quotient method, or preferably, an uncertainty analysis may be used to combine the Tier 3 EEV and ENEV. If the quotient is <1 or effects from anthropogenic sources are deemed unlikely, the substance is not declared "toxic". If the quotient is ≥1 or effects are likely, the substance is declared "toxic".

## *8.4 Estimating Ecological Consequences*

If ecological risk assessors were only asked to determine the probability of exceeding a toxicity threshold or other specified effects level, modeling at the population and community levels would not be necessary (Barnthouse 1993). However, it is usually necessary to estimate the 'ecological costs' of exposure so that these 'costs' can be compared to the social and economic costs of different risk management alternatives.

Three approaches to modeling population dynamics are generally used to assess ecological effects: individual-based models (DeAngelis *et al.* 1991), demographic models and bioenergetics models (Bartell *et al.* 1992). Each approach is generally accepted in the scientific community. As well, there are user friendly software packages capable of propagating uncertainty (*e.g.*, RAMAS/age, RAMAS/stage). For

each approach, data requirements are usually extensive, and complete data sets are rarely available for the types of toxicological assessments carried out by regulatory agencies. Considerable expertise is required to use population models and to correctly interpret the results.

Community and ecosystem models can be used to explore how substances could affect higher order endpoints such as community composition, productivity, and nutrient cycling. Suter and Bartell (1993) concluded that there are 15-20 aquatic and 5-10 terrestrial community and ecosystem models that could be used or slightly modified to estimate higher order effects. Few of these models are easy to use and few have received adequate field testing to evaluate model structure and predictions.

Notwithstanding the difficulties in using and evaluating models, population and community models can strengthen the weight-of-evidence for conclusions established by other means. They can also identify key functional and structural aspects of the system under consideration (Oreskes *et al.* 1994). For priority substances already shown to be "toxic" under CEPA, and where adequate data exist, assessors may use appropriate population and higher level models to better understand the ecological consequences of exposure. Because of the level of expertise required, assessors should work with recognized experts to carry out such analyses.

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# Chapter 9

# Risk Communication

## *9.1 Introduction*

Risk assessments are increasingly influential in shaping risk management decisions, and serving as a basis for communicating risks to stakeholders, the media and the public (Hoerger 1990). For the assessment of priority substances, assessors should focus on:

- integrating and summarizing the results to support the decision of whether a substance is "toxic or capable of becoming toxic" under CEPA.

- characterizing the risk and the uncertainty associated with the estimates, and research that would reduce these uncertainties (Gray 1994; Smith and Shugart 1994). The more complicated the problem, the more careful assessors must be in admitting and communicating uncertainty and its implications on the assessment conclusions (Ludwig 1994). And,

- explaining the conclusions in terms useful to the risk management process.

The assessment report's key function is to provide the science-based determination of whether a substance is considered toxic or capable of becoming toxic according to the CEPA definition. For substances determined to be toxic under CEPA, risk managers will need to use information in the reports in making decisions to reduce environmental risks.

The following recommendations can make a risk assessment scientifically credible and useful to the decision-making process . The recommendations are adapted from the American Industrial Health Council (1989) and are intended to serve as guidance as opposed to a rigid checklist.

## *9.2 General Recommendations*

- Explicitly state the scope and objectives of the assessment.

- Set out the content impartially, with a well-balanced treatment of the evidence bearing on the conclusions.

- Describe the review and approvals process and acknowledge peer reviewers.

- Highlight the key findings in a concise summary.

- Convey uncertainty explicitly and fairly. Where possible, include a discussion of the research that might clarify the degree of uncertainty.

### 9.3 Recommendations for Problem Formulation

- Consult other interested parties and involve them in the scoping process.

- Identify and involve experts in the assessment. Assessors often feel that opening up the process leads to additional out-of-scope requirements and could adversely influence the scientific integrity of the assessment. Although such concerns are sometimes warranted, the risk assessment is far more likely to lead to effective risk management decisions if assessors and interested parties have a clear understanding of the assessment objectives and methods at the outset (Hope 1995).

- Present and review all relevant information.

- Present the rationale for choosing assessment and measurement endpoints.

- Present the conceptual model used for risk analysis and risk characterization.

### 9.4 Recommendations for Analysis (Characterization of Entry, Exposure and Effects)

- Identify and quantify potential sources, levels in the environment, pathways and routes of exposure, and acknowledge uncertainties in these values.

- Clearly describe the purpose and scope of the exposure characterization and underlying methodologies.

- Critically evaluate exposure data and express the degree of confidence in the data. Present the rationale for excluding data.

- If exposure models are used, describe their benefits, weaknesses and limitations.

- Describe the central estimates and upper and lower confidence limits on exposures; note and support the use of any preferred estimates.

- Describe uncertainties in exposure estimates, and highlight the relative importance of key assumptions and data.

- Describe research or data necessary to improve the exposure assessment.

- Present all relevant data sets and models regarding toxicity to assessment and measurement endpoints.

- For dose-response curves, include both upper and lower confidence limits and some measure of central tendency.

- Indicate how dose-response relationships change with alternate data sets, assumptions and models.

- Give a rationale for preferred data sets and models used in the effects characterization. Discuss the strengths and weaknesses of preferred data sets, and indicate the scientific consensus or lack thereof for critical issues or assumptions.

### *9.5 Recommendations for Risk Characterization*

- Present a summary statement for each of the major components of the risk assessment, along with estimates of risk, to give a combined and integrated view of the evidence.

- Clearly identify the key assumptions, their rationale, the extent of scientific consensus and uncertainties, and the effect of reasonable alternative assumptions on conclusions and estimates. In quantitative assessments, also include the rationale for model selection, and information about parameter sensitivities, stochasticity and model uncertainty (Smith and Shugart 1994).

- Outline ongoing or potential research projects that would significantly reduce uncertainty in the risk estimation.

- Provide a sense of perspective about the risk. In doing so, avoid unrelated or inappropriate risk comparisons, such as risk of mortality due to benzene exposure versus risk of mortality due to natural causes (Freudenberg and Rursch 1994; Shrader-Frechette 1995). Instead, discuss effects in terms of ecological consequences for the assessment endpoint of interest. Environmental quality guidelines or other environmental benchmarks may be useful here to help focus risk management efforts. At this point, risk assessors may wish to indicate logical groupings of substances and possible priority actions for best managing environmental risks.

Achieving these goals may appear to be a formidable challenge. However, the intent is to encourage a complete explanation of the results from each step in the assessment process so there is a logical flow from one step to the next. Often, the final

step is deficient in its preparation and presentation (Hoerger 1990). Assessors should focus on:

- integrating and summarizing the results to support the decision of whether a substance is "toxic or cpable of becoming toxic" under CEPA,
- giving an overall characterization of the risk, the uncertainty associated with the estimates, and research that would reduce these uncertainties (Gray 1994; Smith and Shugart 1994). The more complicated the problem, the more careful assessors must be in admitting and communicating uncertainty and its implications on the assessment conclusions (Ludwig 1994), and
- explaining the conclusions in terms useful to the risk management process.

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# Appendix I

# Glossary

**Absorption:** The penetration of one substance into the inner structure of another.

**Acute/chronic ratio:** A species mean acute value divided by the chronic value for the same species. Such ratios can be used to convert the median lethal results of a short-term study to an estimated long-term no-effect concentration.

**Acute toxicity test:** A toxicity test of short duration in relation to the life span of the test organism (*e.g.*, usually ≤4 days for fish).

**Adsorption:** Adherence of the atoms, ions or molecules of a liquid or gas to the surface of another substance.

**Advection:** A transport process involving the physical entrainment of a substance in mobile media such as air or water.

**Alpha (α):** The symbol for a Type I error in hypothesis testing expressed as a probability or proportion (*e.g.*, 0.05 or 5%). A Type I error is the probability of rejecting the null hypothesis when in fact the null hypothesis is true. In hypothesis testing, α is specified by the user prior to carrying out the analysis.

**Atmospheric lifetime** (or natural lifetime (τ)) : The time it takes for the reactant concentration to fall to 1/e of its initial value (e is the base of natural logarithms, 2.718), or 36.7 % of the original concentration. The lifetime is related to the rate constant and to the concentrations of any other reactants involved in the reactions.

**Atmospheric window:** A portion of the electromagnetic spectrum (7-13 $\mu$m) where water vapour and carbon dioxide absorb weakly, allowing transmission of thermal radiation from the Earth's surface and lower atmosphere back into space.

**Beta (β):** The symbol for a Type II error in hypothesis testing expressed as a probability or proportion. A Type II error is the probability of accepting the null hypothesis when in fact the null hypothesis is false. The magnitude of the Type II error is generally inversely related to the magnitude of the Type I error that will be tolerated.

**Bioaccumulation:** The net accumulation of a substance by an organism as a result of uptake from all routes of exposure.

**Bioaccumulation factor (BAF):** The ratio of the steady state concentration of a substance in an organism due to uptake from all routes of exposure, to the

concentration of the substance in the medium to which the organism was exposed.

**Bioavailable substance:** A substance that is present in a form that can be readily taken up by exposed organisms.

**Bioconcentration:** The net accumulation of a substance directly from aqueous solution by an aquatic organism.

**Bioconcentration factor (BCF):** The ratio of the steady state concentration of a substance in an organism due to uptake via contact with water, to the concentration of the substance in the test water; and/or the ratio of the uptake rate constant to the depuration constant, assuming first order kinetics.

**Body burden:** The amount of a substance that has accumulated in the tissue of an exposed organism, usually expressed as the concentration of the substance in a particular organ, or in the whole organism.

**Carrier and non-carrier controls:** Toxicity tests for certain substances may use a carrier to aid in dispersing the test substance evenly in the test medium. Carrier and non-carrier controls are conducted with and without the carrier, respectively, in order to determine the effects of the carrier on the test organisms.

**Complex:** Dissolved species formed from two or more simpler species each of which can exist in aqueous solution.

**Complex substance:** Consists of an heterogeneous association of many substances (*i.e.*, constituents) that are not necessarily related and are either released at a given time and place or occur at a given time and place; see definition of mixture and effluent.

**Chronic toxicity test:** A toxicity test that spans a significant portion of the life span of the test organism (*e.g.*, 10% or more) and examines effects on such parameters as metabolism, growth, reproduction and survival.

**Critical body burden (CBB):** The minimum concentration of a substance that causes an adverse effect on the measurement endpoint (*e.g.*, reproductive potential of *Daphnia*) of interest.

**Critical toxicity value (CTV):** The quantitative expression (*e.g.*, $EC_{10}$) of low toxic effect to the measurement. CTVs are used in risk characterization for the calculation of an Estimated No Effects Value (ENEV).

**Cumulative probability distribution:** A curve or mathematical expression that

quantifies uncertainty over a variable. It associates a probability with all values in the set of possible values. The probability associated with each value of the variable is that of the occurrence of a value less than or equal to the specified value.

**$EC_x$:** The concentration of a substance that is estimated to have a specified effect (*e.g.*, immobilization, reduced growth) on x% of the test organisms. The duration of the test must be specified.

**Ecological Risk Assessment Review Group:** A group of risk assessors, risk managers and other interested parties who will review the problem formulation stage and data gaps and recommend research priorities for PSL2 substances.

**Effluent:** A liquid complex substance composed of many substances *(i.e.*, constituents) that are not necessarily related and that emerge from a pipe or similar outlet and are discharged primarily into aquatic systems (*e.g.*, industrial discharge, sewage effluent).

**Elutriate:** An aqueous solution obtained by adding water to a solid substance (*e.g.*, sediment, tailings, drilling mud, dredge spoil), shaking the mixture, then centrifuging or filtering it or decanting the supernatant.

**Endrocrine disrupter:** A substance that interferes with the production, release, transport, metabolism, binding, action or elimination of natural ligands in the body responsible for the maintenance of homeostasis and the regulation of developmental processes.

**Enhanced radiative forcing:** This effect, known as global warming, results from re-radiation of infra-red energy released from trace gases in the atmosphere.

**Equilibrium:** A condition in which the ratio of the concentrations of a substance in two or more phases (*e.g.*, pore water and particulate phases of bottom sediments) is constant.

**Flow-through toxicity test:** A toxicity test in which solutions in test vessels are renewed continuously by the constant inflow of a fresh solution or by a frequent intermittent inflow.

**Food web structure:** Consists of many interlinked food chains (*i.e.*, organisms forming a series through which energy is passed). A typical food chain structure consists of: producer (*e.g.*, green plant) → primary consumer (*e.g.*, herbivore) → secondary consumers (consisting of smaller then, at subsequent trophic levels, larger carnivores).

**Genotoxicity:** The ability of a substance to damage the genetic material of an organism which is then passed onto the next generation.

**Group parameter:** Group parameters are based on analytical-chemical techniques and determine specific elements or chemically defined groups of harmful constituents in complex substances. Examples of group parameters are Dissolved Organic Carbon (DOC) and Adsorbable OrganoHalogen (AOX).

**Halocarbon gas:** Hydrocarbon gas containing at least one atom of halogen (*e.g.*, bromine, chlorine, fluorine).

**Hydrolysis reaction:** For organic substances, a reaction involving the introduction of a water molecule or a hydroxide ion into an organic molecule, resulting in the cleavage of a chemical bond in the organic molecule. For inorganic substances, a reaction involving a water molecule and an inorganic substance, resulting in the cleavage of the water molecule.

**Immune suppression:** The suppression of the immune reaction of the immune system by a substance which leaves the organism vulnerable to infection, disease, etc.

**Interpolation:** The process of estimating a value between two or more known values.

**$LC_{50}$:** The concentration of a substance that is estimated to be lethal to 50% of the test organisms over a specified period of time.

**$LD_{50}$:** The dose that causes mortality in 50% of the organisms tested.

**Life table data:** A description of the age-specific survival of cohorts of individuals in relation to their age or stage of development.

**LOEC:** Lowest observed effect concentration. The lowest concentration in a toxicity test that caused a statistically significant effect in comparison to the controls.

**LOEL:** Lowest observed effect level. The lowest dose in a toxicity test that caused a statistically significant effect in comparison to the controls.

**MATC:** The maximum allowable toxicant concentration, generally presented as the range between the NOEC(L) and LOEC(L) or as the geometric mean of the two measures.

**Mean:** The arithmetic average of a set of numerical observations calculated as the sum of the observations divided by the number of observations.

**Mineralization:** Breakdown of an organic substance to form carbon dioxide, water, nitrate and phosphate ions.

**Mixing zone:** A defined area both in space and time of effluent mixing in the receiving water. Points within this zone are affected by short-term exposure to the greatest concentrations of the effluent.

**Mixture:** A liquid, solid or gaseous complex substance composed of many substances (*i.e.*, constituents) that are not necessarily related and are released into various environmental compartments including water, air and land (*e.g.*, waste crankcase oils, creosote-impregnated waste materials, landfill leachate, smelter emissions).

**Mode of action:** The manner in which a substance causes an adverse effect in an organism (*e.g.*, narcosis, acetylcholinesterase inhibition, central nervous system seizure).

**Narcotic substance:** Any substance that induces narcosis (*i.e.*, a reversible state of stupor, insensibility or unconsciousness) in an organism. The mechanism of narcosis is non-specific and, consequently, a narcotic substance's toxicity is entirely dependent on its tendency to partition to the tissue of the organism.

**NOEC:** No observed effect concentration. The highest concentration in a toxicity test not causing a statistically significant effect in comparison to the controls.

**NOEL:** No observed effect level. The highest dose in a toxicity test not causing a statistically significant effect in comparison to the controls.

**Nutrient cycling:** The dissipation of energy in ecosystems through the transport, decomposition, and recycling of materials bound up in the biomass, living or dead, of system components. Nutrient cycling can often be constrained by the availability to primary producers of essential raw materials, including macronutrients (*e.g.*, phosphorus, nitrogen, calcium) and trace nutrients (*e.g.*, iron, manganese, molybdenum).

**Pelagic biota:** Aquatic organisms living in the water column of a body of water, rather than along the shore or in the bottom sediments.

**Photolysis - Direct:** The decomposition or reaction of a substance on exposure to light. Occurs when sunlight is absorbed by a substance and the energy is used to form excited or radical species, which react further to form stable products.

**Photolysis - Indirect (or photooxidation):** The reaction of a substance with intermediate oxidants formed during photolysis of dissolved organic matter in water or soil, or photolysis of ozone or $NO_2$ in the atmosphere.

**Photosynthesis:** The elaboration of organic matter (carbohydrate) from carbon dioxide

and water with the aid of light energy.

**Phytoplankton:** The plant component of plankton.

**Plankton:** Minute plant and animal life passively floating or weakly swimming in a body of water.

**Pore water:** Water occupying the space between sediment particles. The amount of pore water is expressed as a percentage of the wet sediment, by weight.

**Probability density function:** A probability distribution describing a continuous random variable. It associates a relative likelihood to the continuum of possibilities.

**Regression analysis:** An analysis based on empirical data of the relationship between a dependant variable and one or more independant variables that takes into account the degree of correlation among the variables.

**Sediment:** Natural particulate matter that has been transported to, and deposited at the bottom of a body of water. The term can also describe a substrate that has been experimentally prepared, and into which test organisms can burrow.

**Sensitivity analysis:** The computation of an output distribution's sensitivity with respect to the input probability distributions.

**Solid phase sediment:** The whole, intact sediment rather than a derivative of the sediment such as an elutriate or a resuspended sediment.

**Sorption:** A surface phenomenon that may be either absorption or adsorption, or a combination of the two.

**Spiked sediment:** A control, reference, or other clean sediment to which a test substance (such as a chemical, or mixture of chemicals) has been added then mixed throughout the sediment.

**Spiked sediment toxicity test:** An assay using a test organism that is exposed to specified concentrations of a substance-spiked sediment over a specified time period to determine any effects.

**Standard deviation:** A measurement of the variability of a distribution. The standard deviation is the square root of the variance.

**Steady state concentration:** A condition in which the concentration of a substance in a particular medium is constant.

**Vapour pressure:** The pressure exerted by the vapour phase of a substance when it is in equilibrium with the liquid or solid form from which it is derived. Vapour pressure may be considered a measure of a pure substance's tendency to volatilize.

**Variance:** A measure of the dispersion, or spread, of a set of values about a mean. When values are close to the mean, the variance is small. When values are widely scattered about the mean, the variance is larger. Variance is the mean of the squares of the deviations from the mean of the distribution.

**Volatilization:** The transfer of a substance from a liquid or solid to a vapour phase.

**Zooplankton:** The animal component of plankton.