Environment Canada
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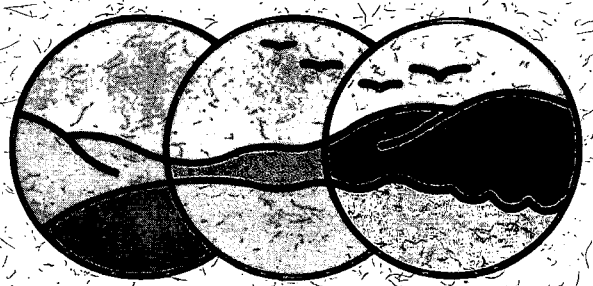
A Framework for Ecological Risk Assessment at Contaminated Sites in Canada: Review and Recommendations

C. Gaudet, EVS Environment Consultants,
and Environmental and Social Systems Analysts

The National
Contaminated Sites
Remediation Program



SCIENTIFIC SERIES NO. 199

ECOSYSTEM CONSERVATION DIRECTORATE
EVALUATION AND INTERPRETATION BRANCH
OTTAWA, ONTARIO, 1994

(Disponible en français sur demande)

Canada

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Disclaimer

This report contains background information pertinent to the development of the Canadian Council of Ministers of the Environment's (CCME) Ecological Risk Assessment for Contaminated Sites. This work was conducted under the direction of the CCME Subcommittee on Environmental Quality Criteria for Contaminated Sites in support of the National Contaminated Sites Remediation Program.

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This unedited version is undergoing distribution as a means to transfer information to people working in related studies.

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Environmental Quality Guidelines Division
Evaluation and Interpretation Branch
Ecosystem Conservation Directorate
Environment Canada
Ottawa, Ontario
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Printed on paper that contains recovered waste

Published by authority of
the Minister of the Environment

Cat. N° En 36-502/199E
ISBN 0-662-22156-7

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Abstract

A framework for ecological risk assessment (ERA) is proposed as a step in the provision of guidance and the promotion of consistency in site assessment and remediation in Canada under the National Contaminated Sites Remediation Program (NCSRP). This report fulfils two distinct functions: (1) it proposes a framework for ERA under the NCSRP, and (2) it critically reviews the ERA literature. Methods of human health risk assessment were not reviewed under this contract.

The ultimate goal of an ERA is to determine whether or not, and to what extent, remediation is necessary and, in cases where required, to help specify appropriate remediation targets. The ERA process is complex as it is concerned with estimating effects to populations, communities, and ecosystems, rather than a single receptor, as in human health risk assessment. The framework proposed in this report is similar to others developed for various regulatory programs, however, it has been adapted for use at contaminated sites in Canada.

The framework provides guidance on when ERA should be conducted through a series of questions and "triggers". The triggers can be grouped into three categories: (1) factors that pertain to significant ecological concerns, (2) issues concerning unacceptable data gaps, and (3) points that involve special site characteristics. Before ERA is initiated, problem definition assists in the planning process. This report emphasizes the importance of summarizing and reporting following each ERA.

The key components of the framework are exposure assessment, receptor characterization, hazard assessment, and risk characterization. It is emphasized that the overall goal of the ERA process is to result in remediation decisions and activities for sites where such action is needed. A three-tier (three-level) strategy composed of sequentially more sophisticated and complex evaluations is proposed for use in the NCSRP. Each level in this tiered approach to ERA has the same four components (Figures 2.1, 2.2, and 2.3).

The first tier, Level One, is essentially an advanced form of screening, characterized by simple qualitative and/or comparative methods and relies heavily on literature information and previously collected data. Level One studies are likely to be focused at the species level and are descriptive as opposed to predictive. The emphasis of such a study is on compiling and evaluating data and information, identifying critical information gaps, ascertaining whether further, detailed ERA studies are a prerequisite to design, and implementing remedial actions. An enhanced knowledge of the site-specific situation and improved understanding of key unknowns is also gained. When necessary, terms of reference for a Level Two ecological risk assessment are prepared.

Level Two provides semi-quantitative information including standard environmental methods and models, as well as specialized approaches developed for ERA. There is an increased emphasis on data collection and a focus on priority issues as determined by Level One investigations. This level concentrates on the population and community levels for assessment endpoints, and toxicity test data collected from the site are usually needed. Preliminary quantitative risk estimates should be produced for indigenous ecological populations exposed to chemicals at or near the site. Determination of an initial set of clean-up objectives appropriate for guiding the mitigative program will be made and, if necessary, terms of reference will be set for Level Three activities. A Level Two ERA will commonly be the highest level conducted.

Level Three relies on site-specific data and predictive modelling to supply quantitative information, particularly on complex ecosystem responses. Chronic effects, interactions between chemicals, and ecosystem level studies are encompassed in Level Three ERA. Precise, accurate, quantitative predictions regarding current and future risks to ecological populations, communities, and ecosystems due to migration of chemicals from the contaminated site are produced. An adaptive process for selecting unique, site-specific, quantitative remediation objectives is developed. Where concurrent, an effective interaction with human health assessment is facilitated.

Acknowledgments

EVS Environment Consultants and Environmental and Social Systems Analysts (ESSA) gratefully acknowledge the assistance of Dr. Connie Gaudet and Mr. Michael Wong of Environment Canada, who provided information and guidance during the course of this work. Mr. Michael Macfarlane of B.C. Environment, Lands and Parks, and his staff provided some of the risk assessment documents. Reviews of earlier drafts were provided by members of the CCME Subcommittee on Environmental Quality Criteria for Contaminated Sites: Dr. Lee Hoffmann (Chair, Ontario Ministry of Environment), M. Michel Beaulieu (Environnement Québec), Dr. Glyn Fox (B.C. Ministry of Environment), Dr. Connie Gaudet (Environment Canada), Ms. Simone Godin (New Brunswick Department of Environment), and Mr. Rod Raphael (Health and Welfare Canada).

This report was jointly written by Ms. Elizabeth Power (Sections 1.0, 3.0, 6.0, 8.0, 9.0, and 10.0) and Dr. Michael Paine (Sections 7.0 and 8.0) of EVS Environment Consultants and Messrs. David Bernard (Sections 2.0 and 5.0) and David Marmorek (Section 4.0) of Environmental and Social Systems Analysts (ESSA). Dr. Patrick Sheehan and Mr. Jamie Tull of ChemRisk provided review and helpful input at several points in the development of this work. Ms. Laila Suryodipuro and Ms. Kathy Kingston of EVS prepared the figures and provided technical support. The document was produced by Ms. Ursula Lowinger.

A Framework for Ecological Risk Assessment at Contaminated Sites in Canada: Review and Recommendations

1.0 INTRODUCTION

1.1 Background

The National Contaminated Sites Remediation Program (NCSRP) has been established to ensure a coordinated, nationally consistent approach to the identification, assessment, and remediation of contaminated sites in Canada which impact or have the potential to impact on human health or the environment. Under this program, a national set of interim environmental quality criteria for contaminated sites was developed as a basis for the consistent assessment and remediation of contaminated sites (CCME, 1991a). At a multi-stakeholder workshop held in November 1990, there was general agreement that the Canadian interim environmental quality criteria met the immediate needs of the NCSRP. It was also recognized that in order to fulfil the mandate of the NCSRP to promote consistency in site assessment and remediation in Canada, national guidance was needed in applying these criteria on a site-specific basis (i.e., establishing site-specific remediation objectives). Two complimentary but distinct approaches have been identified as the basis for the establishment of site-specific remediation objectives:

1. a ***criteria-based approach***, which incorporates such site-specific considerations as background levels of contaminants, technological capabilities, economic limitations, and site/situation-specific negotiations into the development of objectives. The CCME Canadian Interim Environmental Quality Criteria for Contaminated Sites represent values protective of specific land uses and, as such, can serve as the technical basis for the development of site-specific objectives.

2. ***risk assessment*** based on a detailed evaluation of hazard and exposure potential at a particular site. Risk assessment is an important tool in setting objectives for site remediation where, for example, national criteria do not exist for a contaminant, where clean-up to criteria-based levels is not feasible for the targeted land use, where criteria-based objectives do not seem appropriate given the site-specific exposure conditions, where significant or sensitive receptors of concern have been identified, or where there is significant public concern, as determined by the lead agency.

Though both of the above approaches may be seen as part of a single overall strategy or framework for establishing site-specific remediation objectives, due to the relative complexity of existing risk assessment techniques, these components are being considered by Environment Canada under separate terms of reference. This document is directed towards the second approach only (i.e., excluding human-health risk assessment) and provides review and recommendations for ecological risk assessment for the NCSRP.

1.2 Objectives

The overall objective of this document is to promote consistency in the protection of the environment within the NCSRP.

This document has the following specific objectives:

1. to critically evaluate existing methods of ecological risk assessment

2. to recommend appropriate ecological risk assessment approaches for the NCSRP;

3. to develop an NCSRP guidance document providing a comprehensive framework for consistent ecological risk assessment at contaminated sites in Canada

Note: Human health risk assessment methods were not reviewed under this contract.

1.3 Definition of Ecological Risk Assessment

Ecological risk assessment has various definitions given by different researchers and jurisdictions. A sampling of these definitions is provided below.

- The process of assigning magnitudes and probabilities to adverse effects of human activities (or natural catastrophes) (Barnthouse and Suter, 1986).

- A formal set of scientific methods for estimating the probabilities and magnitudes of undesired effects on plants, animals, and ecosystems resulting from events in the environment, including the release of pollutants, physical modification of the environment, and natural disasters (Fava et al., 1987).

- A subcategory of ecological impact assessment that (1) predicts the probability of adverse effects occurring in an ecosystem or any part of an ecosystem as a result of perturbation and (2) relates the magnitude of the impact to the perturbation (Norton et al., 1988).

- Ecological risk assessment is the process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors. This definition recognizes that a risk does not exist unless (1) the stressor has an inherent ability to cause adverse effects and (2) it co-occurs with or contacts an ecological component long enough and at sufficient intensity to elicit the identified adverse effect(s). Ecological risk assessment may evaluate one or many stressors and ecological components (U.S. EPA, 1992a).

Pastorok and Sampson (1990) found that there were common features in all such definitions: (1) prediction of the probability of adverse effects and (2) the concept of exposure–response relationships. No consensus definition of ecological risk assessment exists, and a whole set of terminology has sprung up for describing ecological risk assessment and its components. In this report, terms will be defined where they are first used, and definitions are generally consistent with those used by the U.S. Environmental Protection Agency (Norton et al., 1988).

Historically, potential adverse effects were evaluated by considering impacts only (e.g., toxicity testing). Acute toxicity tests were generally used, and then safety factors or application factors were developed to estimate chronically safe chemical concentrations (Parkhurst et al., 1990), which were assumed to adequately protect ecosystems. Environmental evaluation using only toxicity data does not consider probability of exposure. The process of hazard assessment includes this consideration, and has been the principle approach used to assess the safety of single chemicals (e.g., Urban and Cook, 1986). *Hazard* refers to the type and magnitude of effect caused by a stressor, and is usually evaluated by identifying biological effects associated with concentrations of the stressor in laboratory or field studies.

Barnthouse and Suter (1986) developed one of the first ecological risk assessment approaches during the mid-1980s for the Office of Research and Development, EPA. According to Parkhurst et al. (1990), a need for risk assessment arose with the realization that hazard assessments were generally associated with high degrees of uncertainty concerning the extent, magnitude, and probability of effects. Risk is a function of hazard and exposure. *Exposure* is the co-occurrence of a stressor with an ecological *receptor* (e.g., individual, population, community, or ecosystem). It is usually determined by understanding the fate of the stressor and then measuring or estimating the amount of the stressor in environmental compartments (e.g., soil, air, and water). *Risk* is the evaluation of whether an adverse effect will occur; an adverse effect is likely to occur in the natural environment only if exposure approaches or exceeds the levels associated with the adverse effects identified in the hazard assessment.

Early ecological risk assessments depended largely on concepts borrowed from the human health sciences and from engineering structure failure assessments. A fundamental difference between human health risk assessments and ecological risk assessments is that the former is concerned with estimating effects to individuals (one species—humans), while the latter is concerned with estimating effects to populations, communities, and ecosystems (multispecies). As a result, ecological risk assessment is a much more complex process (Parkhurst et al., 1990).

1.4 Classification Schemes for Ecological Risk Assessment

There are a number of classification schemes for ecological risk assessment. Use of classification schemes can aid in the selection of appropriate techniques for a particular site or objective. However, it must be recognized that each classification scheme merely provides a framework for looking at the same information. Classification schemes include the following: qualitative versus quantitative, predictive versus retrospective, empirical versus theoretical, and top-down versus bottom-up methods.

Qualitative versus Quantitative

Qualitative methods do not quantify magnitude. They often rely on professional judgement to integrate information from different sources and direct it towards the objectives of the assessment. For example, a ranking approach can be used to set relative levels of risk for screening a site or setting priorities. There is considerable reliance on the skill of the assessor, so the importance of qualified personnel cannot be overemphasized (see Section 3.3). Qualitative methods are limited for their use in developing remediation criteria or characterizing risks. However, they are cost-effective and, in many cases, meet the objectives of ecological risk assessment.

Quantitative methods provide discrete values (usually numerical) or a distribution of values for the components of the risk assessment. Much risk assessment literature deals with quantitative risk assessment, however, when one evaluates how risk assessment is actually being conducted, qualitative methods are most often in use. There are several contributing factors to this trend:

1. collection and analysis of quantitative data is generally more time-consuming and hence costly

2. the quantification of uncertainty is difficult

3. ecological risk practitioners may be unfamiliar or inexperienced with quantitative models

4. the objectives of many risk assessments do not merit a completely quantitative approach

This is further discussed in Section 2.0 and has been observed by other researchers (Parkhurst et al., 1990; Pastorok and Sampson, 1991).

Predictive versus Retrospective Methods

A *predictive risk assessment* attempts to anticipate future risks or effects; both the exposure and hazard assessments may contain predictive elements. The most obvious examples include evaluations of chemicals not yet manufactured, proposals for the industrial projects or processes, or proposed disposal of potentially hazardous waste. *Retrospective risk assessment* attempts to assess existing or past effects, or has variously been referred to as impact, damage, and hazard assessment. Although most reviews of risk assessment methods emphasize predictive capabilities (e.g., Norton et al., 1988; Parkhurst et al., 1990), most case studies outside of the regulation of chemical manufacture are retrospective studies. Ecological risk assessment for contaminated sites, the focus of this project and report, would be primarily retrospective as the contamination and presumably its effects would already exist.

Even though risk assessments for contaminated sites will be primarily retrospective, they will almost always include predictive elements. Predictive and retrospective (e.g., direct measurement) methods can be used to validate each other if both are applied to the same assessment. There are several kinds of predictive elements as described below.

1. Some existing effects may be unmeasurable or difficult to estimate precisely. For example, it may not be feasible to sacrifice endangered species during toxicity tests or field sampling, and effects would therefore have to be predicted (e.g., from data on other species or from models). As another example, population or higher level effects may be difficult or costly to measure, especially over large areas, and these effects may have to be predicted using models.

2. Predictive methods may be required to identify priority exposure pathways or chemicals where multiple pathways or chemicals exist. Retrospective methods such as toxicity testing and field monitoring focus primarily on combined effects of multiple pathways of chemicals.

3. The future is still very important when assessing existing contamination. In most cases, the consequences of various remediation alternatives will need to be predicted so that the best alternative may be selected. In order to set clean-up objectives or criteria, the effects of concentrations lower than those currently existing must be predicted.

Empirical versus Theoretical Methods

As defined in Pastorok and Sampson (1990), *empirical approaches* rely on observed correlative relationships without attempting to describe cause-and-effect relationships (i.e., a black-box approach). *Theoretical approaches* rely more on theoretical principles and include specific cause-and-effect relationships. Empirical methods would include direct measurements of effects or concentrations and extrapolation from effects on similar species or ecosystems. Theoretical methods are primarily models of populations, communities, or ecosystems. The distinction between empirical and theoretical approaches represents a gradient, as the impetus for developing the correlative relationships used in empirical approaches often comes from a consideration of cause-and-effect relationships, and models are often calibrated against observed correlative relationships and observational data. For example, there are many regression relationships in the

limnological literature which predict biomass of fish or benthos from physical characteristics (e.g., mean depth) and/or nutrient status of lakes [see Peters (1986) for a review]. These relationships are empirical in that they make no assumptions about the specific cause-and-effect relationships responsible for observed correlations. However, there are some simple theoretical explanations which could account for these correlations. The most obvious is that for energetic reasons, the biomass of species at higher levels increases with the biomass of primary producers, which in turn increases with the availability of nutrients. It is difficult to believe that the selection of predictor variables for the empirical relationships was not guided by consideration of this and other potential cause-and-effect relationships.

There are some parallels between the empirical–theoretical and predictive–retrospective distinctions. The best empirical relationship between contaminant concentration and effects for any site would be the one that actually exists. This relationship could only be measured by retrospective methods. Predictive risk characterizations are more likely to be based on theoretical approaches, if only because there are limitations on what can be measured. In general, empirical approaches are more common when more data are available for the study site (chemical or community, or other comparable sites, chemicals, or communities). One should recognize, however, that empirical approaches can be predictive and theoretical approaches can be retrospective.

Top-down versus Bottom-up Methods

Top-down and bottom-up usually refer to two different approaches to extrapolation between levels (individual, population, community, ecosystem), but could also refer to extrapolation from single- to multiple-chemical or stressor effects. *Bottom-up approaches* estimate effects at higher levels based on effects at lower levels. For example, effects on populations might be estimated by combining various effects on individuals. This is the approach adopted in most population models used in risk assessment (U.S. EPA, 1991). A *top-down approach* would be directly based on empirical or theoretical relationships between concentration and population-level effects (i.e., probability of extinction, intrinsic rate of increase, mean abundance). Similarly, a bottom-up approach to multiple chemicals would sum up the effects of the individual chemicals, whereas as top-down approach would depend on the observed or theorized effects of various mixtures. Classification of a method as top-down or bottom-up depends entirely on the levels considered. For example, a population model which is considered bottom-up because it combines individual effects to estimate population-level effects could also be considered top-down because it is based directly on effects on reproduction, growth, and survival and does not attempt to estimate by summing physiological effects or effects on specific organs. Predictive and retrospective, and empirical and theoretical approaches can be either top-down or bottom-up.

1.5 Study Approach

The first step (Task 1) in producing this report was to compile ecological risk assessment literature. This was accomplished by the following:

- in-house literature search
- on-line database search using DIALOG (conducted in October 1991 and then again in April 1992)
- discussions with numerous researchers in the ecological risk assessment field
- liaison with individuals from B.C. Environment, Lands and Parks, Environmental Protection Division, who are conducting a similar study
- attendance by study team members at risk assessment sessions of November 1991 meeting of Society of Environmental Toxicology and Chemistry (not funded by contract)

The documents were organized, as they arrived, by classification into categories and entry into a database (Q&A). The categories were as follows:

- *Methods* - complete methods covering all four components of ecological risk assessment; generally framework documents or in-depth reviews
- *Components* - thorough descriptions of at least one component; do not cover complete ecological risk assessment
- *Short Reviews* - useful in that they discuss ecological risk assessment, but not detailed documents; often cover special issues
- *Ancillary* - documents, often published in journals that provide background information on aspects of ecological risk assessment; interesting, but not central to the literature review

The information recorded in the database for each document included complete citation, category, and physical location. The project bibliography is provided in Appendix A.

The study team then set out to review each document (Task 2) using a set of standardized review criteria similar to those used by Parkhurst et al. (1990). The most useful documents were evaluated for their applicability in each component of ecological risk assessment to facilitate preparation of this report (Appendix B). The literature review (presented in Sections 4.0 to 7.0) triggered development of the proposed ERA framework which was presented in Toronto in late March 1992. Comments and discussions from that meeting have been incorporated in this report.

1.6 Report Structure

This report has two main parts, as shown in Figure 1.1, and it focuses on ecological risk assessment for the NCSRP in Canada, with examples which are relevant to contaminated waste sites (cf. Section 1.4). Sections 2.0 and 8.0 present an ecological risk assessment framework for Canada. The rest of the sections summarize the review of the literature. Section 3.0 discusses how to define and plan an ecological risk assessment. Sections 4.0, 5.0, 6.0, and 7.0 describe exposure assessment, receptor characterization, hazard assessment, and risk characterization, respectively. Section 9.0 considers reporting; Section 10.0 provides the references cited, followed by a Glossary and the appendices.

2.0 ECOLOGICAL RISK ASSESSMENT FRAMEWORK FOR THE NCSRP

2.1 Introduction

This section describes a framework to provide guidance on contaminated sites investigations as necessary to determine risk to ecological systems. The steps leading to the decision to take action are described in Section 3.0 (Problem Definition). The ERA

Section	Background and/or Literature Review	ERA Framework for NCSRP
1.0 Introduction	√	
2.0 ERA Framework for NCSRP		√
3.0 Problem Definition	√	√
4.0 Exposure Assessment	√	
5.0 Receptor Characterization	√	
6.0 Hazard Assessment	√	
7.0 Risk Characterization	√	
8.0 Application of Tiered ERA under NCSRP		√
9.0 Reporting an ERA	√	

Figure 1.1. Report structure to show the organization and emphasis of each section.

framework components are reviewed in detail elsewhere in this report (Sections 4.0 to 7.0), and the reader is referred to those sections for background material discussed in this framework section (Section 2.0). More detailed application of the framework under the NCSRP is described in Section 8.0.

This framework takes into account both scientific issues and the infrastructure of the NCSRP. This report is the first step in a long-term effort by Environment Canada to provide guidance on risk assessment for ecological systems. The framework is conceptually similar to that applied for human health risk assessment, but with two main differences:

1. ERA considers receptors and ecological effects beyond a single organism (i.e., humans). This may include individuals of several different species and/or population, community, and ecosystem level effects.

2. There is no single level of protection for ecological systems. The level of protection is developed site-specifically and takes into consideration both scientific and policy issues.

As a result, ERAs are highly site-specific and no single, standard design can be expected to apply equally to all contaminated sites in Canada. In many ways, each individual ERA will be unique and require an original, innovative plan of investigation and action. Nevertheless, the basic elements in an ERA can be standardized to ensure a comprehensive, nationally consistent approach to risk assessment so that each assessment not only provides answers to site-specific management questions, but also meets the NCSRP mandate. Standardization is important because it promotes development of a national program that ensures comparability between regions and facilitates national reviews and interpretation across all sites. The purpose of this section is to describe a proposed framework that can serve as a template for designing and conducting ecological risk assessments under the NCSRP.

The ultimate goal of an ERA for contaminated sites is to determine whether or not, and to what level, remediation is necessary, and, in cases where treatment is required, to help specify appropriate remediation targets. It is emphasized that policy for remediation is set site-specifically by asking the question: What do we want to protect?

Ecological risk assessments can be used to define problems, set priorities, focus investigations, and plan remediation efforts. To understand the ERA framework described in this and the following sections, it is first necessary to place ERA in context within the overall NCSRP process of contaminated site assessment and remediation. As illustrated in Figure 2.1, ERA is but one of three potential pathways through which remediation plans are derived under the NCSRP.

2.2 When is an Ecological Risk Assessment Required by the NCSRP?

Identification and preliminary site characterization precede all other steps in the NCSRP process (Figure 2.1). The Canadian Council of Ministers of the Environment (CCME) has developed a National Classification System for Contaminated Sites (CCME, 1991b) that is recommended as a tool for site prioritization. Each site is classified with respect to "need for further action", which may include additional site characterization, human health risk assessment, and/or ecological risk assessment. Classification categories are linked to risk potential and the level of remediation required. Under this classification scheme, sites which will require an ecological risk assessment are most likely to be found in either Class 1 (action required) or Class 2 (action likely required). Although many of the factors involved in an ERA are addressed to some degree in the CCME classification system, that procedure should not be used out of context as a substitute for site-specific ecological risk analyses (CCME, 1991b). Information and data collected during the CCME site classification process could, however, be used as part of the preliminary site characterization for ERA.

Once a site has received a CCME classification indicating the need for further action, a decision must be made regarding which path(s) to follow in developing the remediation program. As indicated in Figure 2.1, options facing the decision maker include

1. applying existing environmental quality criteria
2. conducting a human health risk assessment
3. conducting an ecological risk assessment
4. combination of 2 and 3, above

In most cases, this decision will be limited by the information that was available during the CCME classification process. Thus, an additional set of "triggers" is proposed in Section 2.3 that can be used by the decision maker when evaluating the third option above.

The decision point shown in Figure 2.1 consists of a set of questions and responses:

1. Will the application of existing regulations and/or criteria to the contaminated site provide adequate protection? If yes, go to 2; if no, go to 3.

2. Are existing regulations or criteria achievable as remedial targets? If yes, use a criteria-based approach; if no, go to 3.

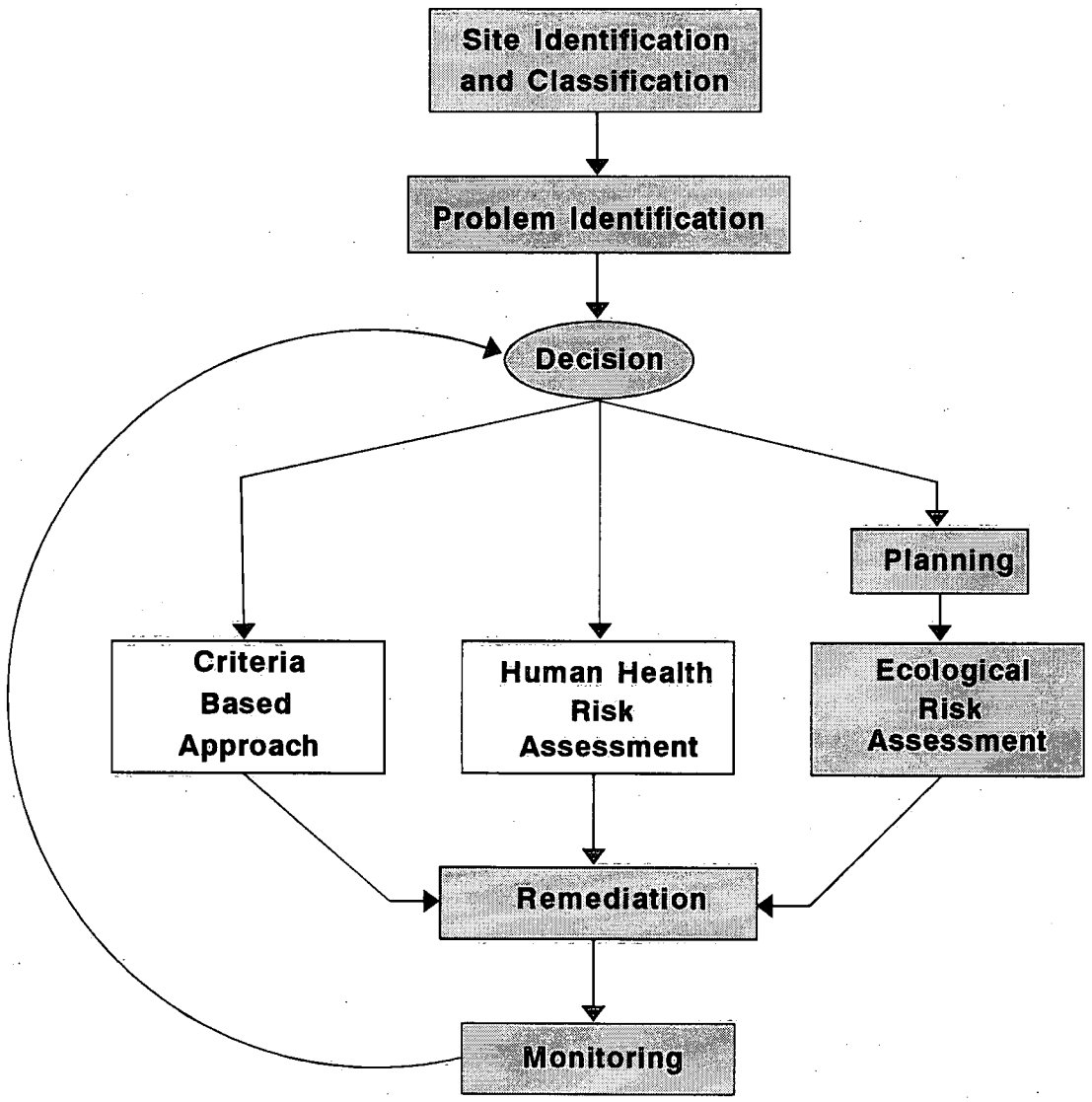


Figure 2.1. Overall scheme for contaminated sites, showing three paths to remediation stage.

3. If human health may be at risk, perform a human health risk assessment if ecological components may be at risk perform an ERA.

Question 1 ensures that the relevant criteria are not applied to a site for which they are not suitable (i.e., most soil criteria assume a minimum clay and organic matter content which may not be present at all sites). A decision may be made to conduct both human and ecological risk assessments simultaneously. In addition, the decision to conduct an ecological risk assessment may depend on nontechnical factors such as social, political, and economic considerations.

Taken together, the first three steps in Figure 2.1 constitute an initial evaluation for the contaminated site (described further in Section 3.0). These activities are an important first step in the NCSRP approach, and periodic attempts should be made to evaluate and improve their effectiveness.

2.3 Additional ERA "Triggers"

To assist decision makers faced with determining whether or not to select an ERA as part of the process of contaminated site assessment and remediation, a list of additional factors that may trigger an ERA is proposed. It is assumed that the decision will normally be based on a preliminary site characterization, and it is recognized that (1) priorities and available information to support an ERA may vary between different jurisdictions and (2) that local policy and public concern may shift the decision to conduct an ERA.

Additional ERA triggers can be grouped into three categories:

- factors that pertain to significant ecological concerns
- issues concerning unacceptable data gaps
- points that involve special site characteristics

2.3.1 Significant Ecological Concerns

An ERA should be seriously considered whenever a contaminated site includes, or is expected to impact, any of the following:

- critical or sensitive habitat for wildlife, migratory waterfowl, or fisheries
- rare, threatened, or endangered species, populations, or ecosystems
- lands designated as a natural area, park, or ecological reserve
- lands that are locally or regionally important for fishing, hunting, or trapping

2.3.2 Unacceptable Data Gaps

Whenever any of the following conditions are present at a contaminated site, an ERA should be considered:

- there are one or more chemicals present about which little is known
- exposure conditions are unpredictable or uncertain
- there is a high degree of uncertainty about hazard levels
- there are significant gaps in available information concerning ecological receptors

2.3.3 Special Site Characteristics

In addition, an ERA may also be a practical selection for sites where

- costs of remediation to meet existing environmental criteria are extremely high and priorities must be established
- existing criteria need field-testing or improvement
- the contaminated area is so large that an ecological risk assessment is needed to provide a framework for site investigation and to set remediation priorities

In addition to these triggers for ecological risk assessment, the ERA practitioner is encouraged to consider the question: When would ERA be inappropriate for the purposes of the NCSRP? For example, as understanding of the risk related to some sites improves, then the need for ERA is reduced (e.g., municipal landfills). The fate and effects of some chemicals may become predictable, and when this is combined with a well-characterized site (distribution of contaminants and documented receptors), then ERA may not be the best option. It must be emphasized that ERA is not necessarily superior to other approaches in the development of remediation strategies.

2.4 The NCSRP Ecological Risk Assessment Framework

2.4.1 Overview

The main purpose of the ERA framework proposed in this document is to give practical guidance and direction to investigations into the risks to on-site or nearby ecological systems at contaminated sites in Canada. Although this proposed framework contains many of the same elements found in frameworks used elsewhere (e.g., the United States and the Netherlands), it has been adapted for use at Canadian contaminated sites and differs from other approaches in two fundamental ways. First, several elements (problem definition, planning, and the link to remediation) have been emphasized in the framework. Second, and more importantly, a three-tier (three-level) approach that appears to be unique among jurisdictions practising ERA is proposed (Section 2.4.2) to apply these elements. Further discussion on the rationale for the proposed framework for ERA under the NCSRP is provided in Section 2.7.

Almost every ecological risk assessment document uses the same basic components, and these are based on the risk assessment framework first published by the U.S. National Academy of Sciences (National Research Council, 1983). The U.S. EPA (Risk Assessment Forum) is presently developing a document for national use that describes a framework for ecological risk assessment. Although drafts of this document are being circulated, the information cannot be cited or quoted at the time of publication of this report.

Approaches can include a combination of the following components:

- *problem identification* (identification of key issues, objectives of protection and significance)
- *site characterization* (assemble and review all available site use, geology, hydrology, available chemistry and toxicity data, etc.)
- *exposure assessment* (sources of stressors; magnitude, duration and frequency of exposure)
- *receptor characterization* (which are the important receptors and habitats?)
- *hazard assessment* (characterization of ecological effects, toxicity of stressors, modifying factors and measurement of responses)
- *risk characterization* (biological response to dose/concentration; magnitude, significance and probability of effects from the estimated exposure)

2.4.2 Recommended Framework

The recommended framework for an ERA under the NCSRP is diagrammed in Figures 2.2 and 2.3. Figure 2.2 shows the basic organization and flow in an ecological risk assessment for a contaminated site. It is emphasized that the ultimate goal of the ERA process is to result in remediation decisions and activities for sites where such action is needed. Figure 2.3 shows the components of ERA, which are identical for Levels One to Three (see Section 2.4). A unique feature to this proposed framework, compared with existing frameworks, is the linkage of receptor characterization to both exposure assessment and hazard assessment, as well as the link to remediation.

In practical application, the framework also contains two additional elements that are typically not explicitly emphasized by others: (1) problem definition and (2) reporting and summary. Problem definition establishes the site-specific goals and focus of the ERA and links the process to the appropriate regulatory process. There is a growing recognition that problem identification and planning for the ecological risk assessment is critical to its success and link to a remediation scheme. A systematic planning effort helps to identify major factors that must be considered in order to produce a technically defensible ecological risk assessment. Key steps to planning an ecological risk assessment are described in Section 3.0. Reporting and summarizing findings of an ecological risk assessment have not been well-emphasized in the literature. Risk communication and risk management can be enhanced by a well-organized summary of findings, as described in Section 9.0. Most important, at each step of the ERA process (e.g., problem identification, planning, and each ERA tier), a record of decision needs to be prepared before proceeding to the next step.

2.5 Tiered Approach

A three-tier (three-level) strategy composed of sequentially more sophisticated and complex evaluations is recommended for use in the NCSRP (Figure 2.4). Sequential evaluation and feedback allow sound scientific judgements and efficient use of resources by minimizing unnecessary data collection so that major effort can be focused in areas with the greatest benefit (Maki and Duthie, 1978).

Baker (1989) points out that the tiered approach is intended to maximize efficiency of data collection, but such an approach may require multiple field programs and time delays. It is important to recognize that logistical and cost considerations can outweigh the benefits of tiered testing, and that there are situations in which this approach may not be the most efficient.

Each level in this tiered approach to ERA under the NCSRP (Figure 2.4) has the same structure (Figure 2.3) and builds upon the data, information, knowledge, and decisions from the preceding level, and each level is progressively more complex and narrow in scope. A comparison of several characteristics between levels is provided in Figure 2.5.

Level One is characterized by simple, qualitative, and/or comparative methods, and relies heavily on literature information and previously collected data. Level One studies are likely to be focused mainly at the species level and to be descriptive, as opposed to predictive.

Level Two is intermediate between Levels One and Three and provides semi-quantitative information. ERA tools that fit within Level Two include standard environmental methods and models, as well as specialized approaches developed for ERA. There is an increased emphasis on data collection and with a focus on priority issues, as determined during Level One investigations. Level Two investigations concentrate on the population and community levels.

Level Three relies on site-specific data and predictive modelling to supply quantitative information, particularly on complex ecosystem responses. Chronic effects, interactions between chemicals, and ecosystem level studies are encompassed in Level Three ERA. This is the level at which a number of the more complex U.S. EPA procedures, methods, and tools operate. While the value of this refined and sophisticated approach is recognized, the resources required may not always be warranted.

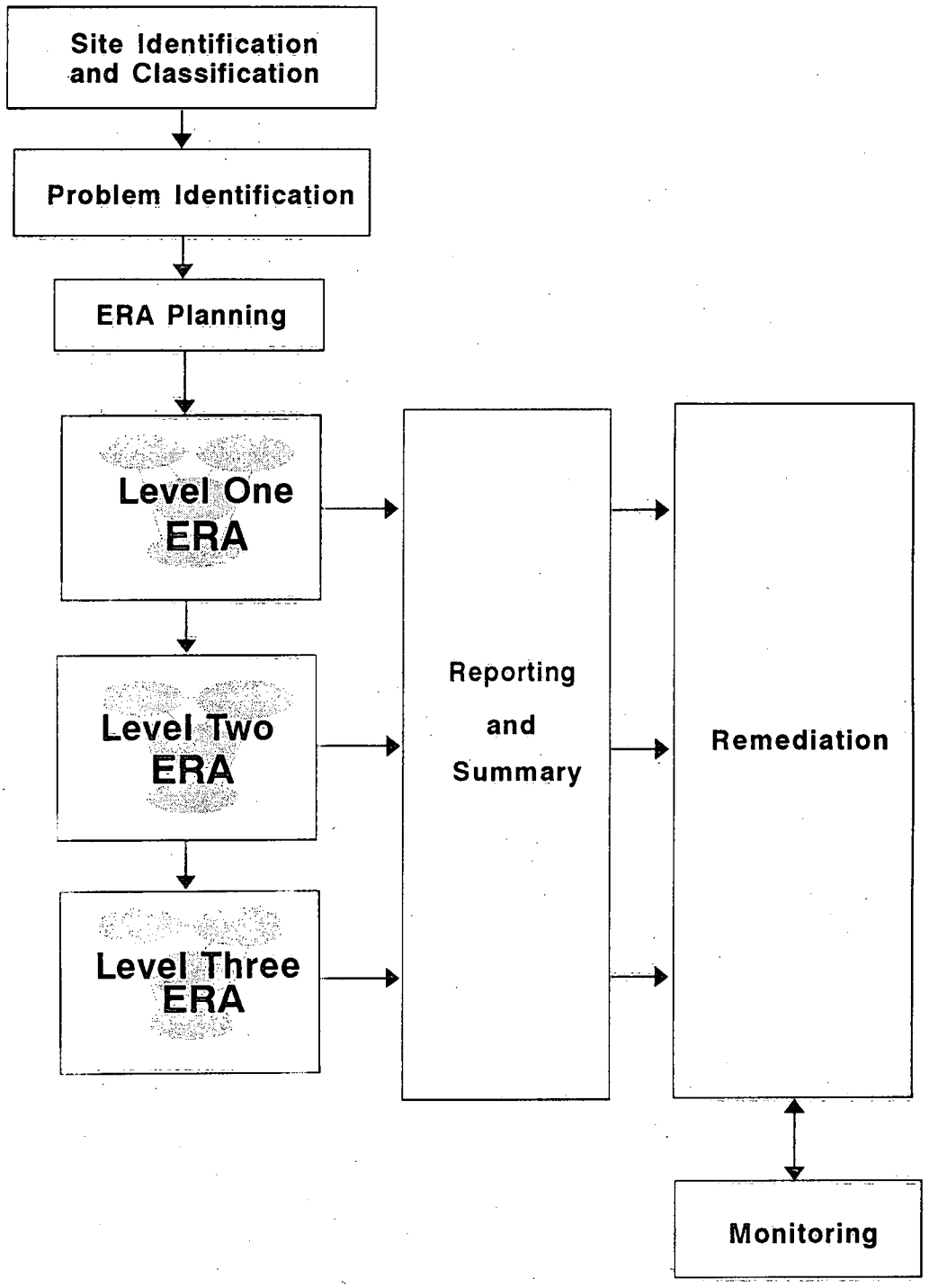


Figure 2.2. Recommended framework for ERA, showing tiered approach and emphasizing the stages before and after the core ERA process (Levels One to Three). The components of each level of ERA are shown in Figure 2.3. The conceptual structure for tiered ERA is shown in Figure 2.4.

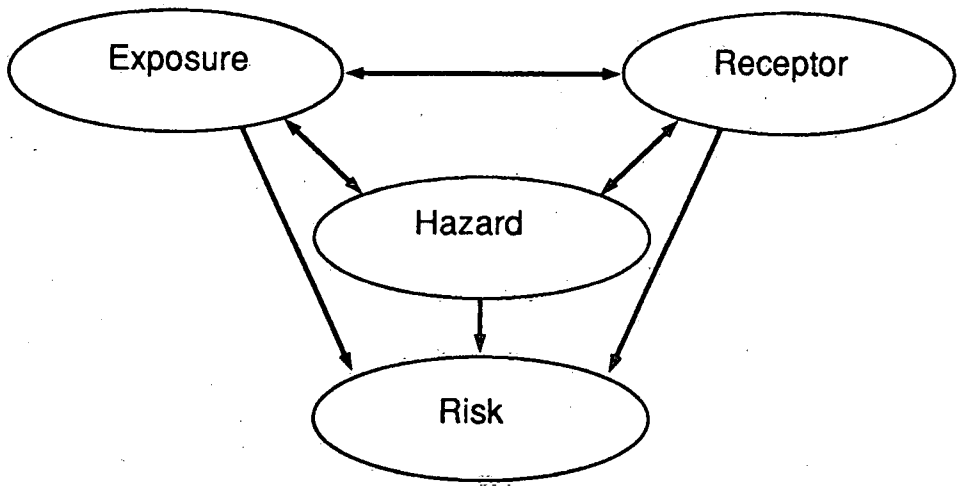


Figure 2.3. The relationship of the components for ERA. The same relationship exists for each level of ERA.

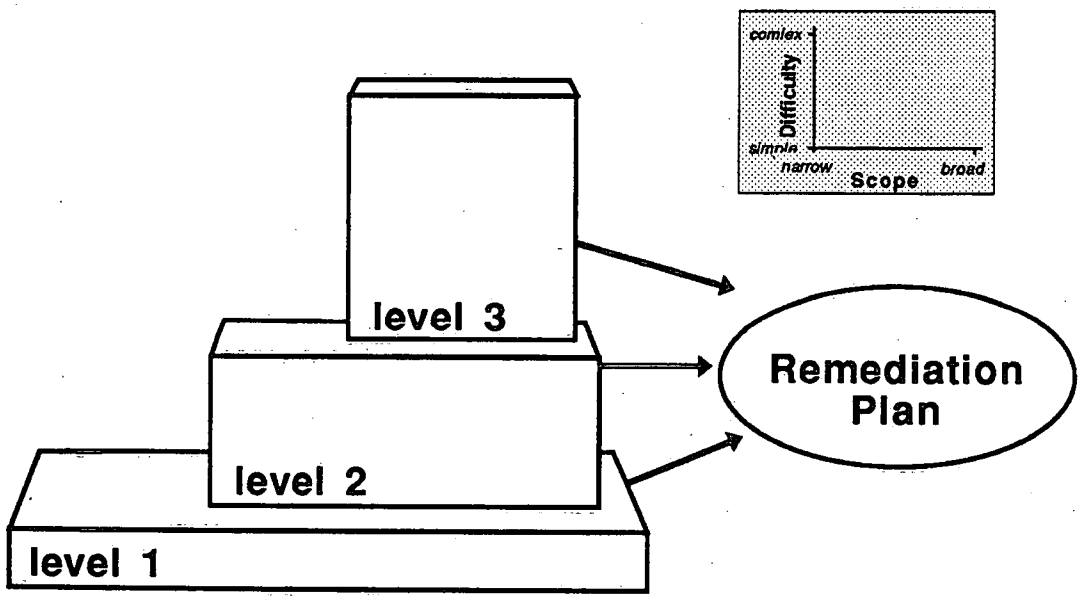


Figure 2.4. Conceptual structure of tiered approach to ERA.

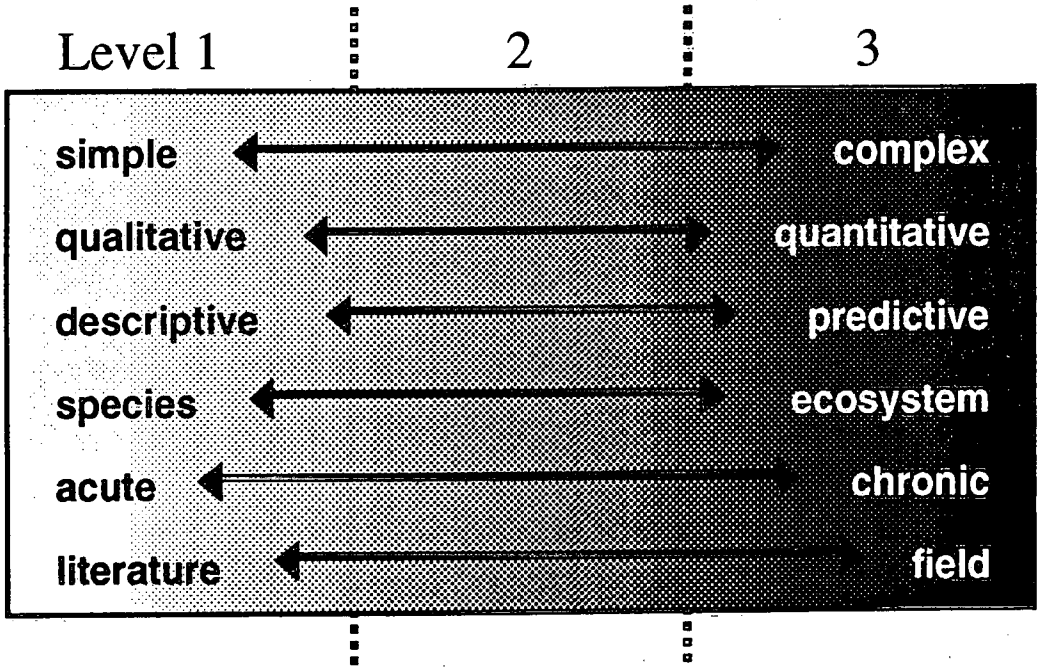


Figure 2.5. Characteristics of each level of ERA.

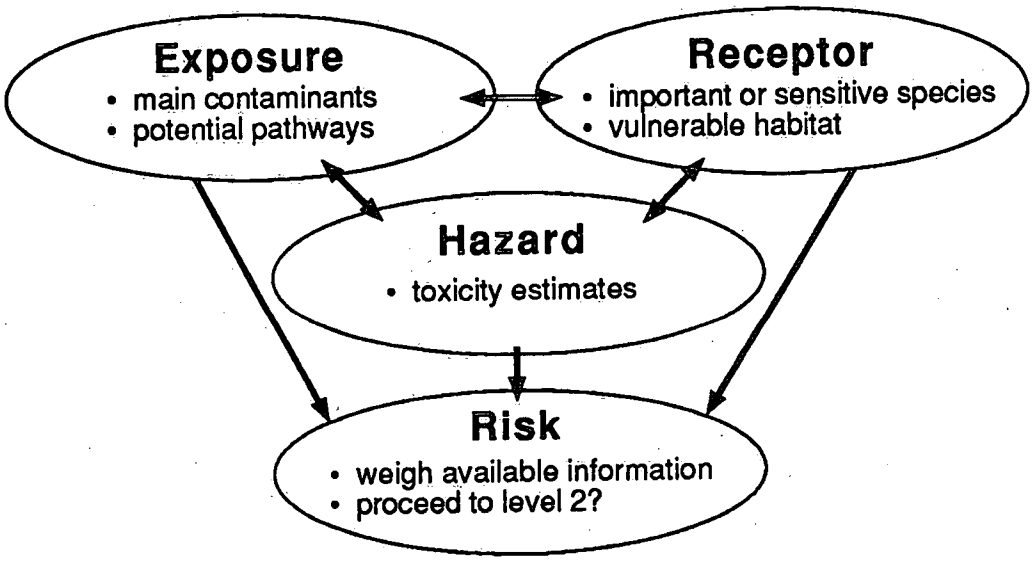


Figure 2.6. Examples of investigations for Level One ERA.

2.5.1 Level One

Level One activities are essentially an advanced form of screening (Figure 2.6). Emphasis is on

- compiling and evaluating available data and information
- identifying critical information gaps
- ascertaining whether detailed ERA studies are a prerequisite to design and implementation of remedial actions
- if necessary, setting terms of reference for Level Two activities

One of the first major activities of Level One is to develop a site-specific conceptual model of the problem, with particular focus on clarifying the necessary information and data. This conceptual model could take the form of a flow diagram or a list of action items.

A preliminary description of priority contaminants present at the site and potential exposure pathways will be developed. At the same time, the following will be identified: important or sensitive species, potentially threatened receptor communities (if possible), and areas of vulnerable habitat. Simultaneously, preliminary toxicity estimates will be obtained from the literature, if they exist. The extent and nature of risk will be derived by weighing all available information to determine whether or not the project should advance to Level Two. This qualitative estimate of risk will be based on the information developed from the exposure assessment, receptor characterization, and hazard assessment components of Level One.

It is also possible that at this initial level, general mitigation options would be considered, if remediation is required. All contributors to the ERA Level One would contribute to identifying key uncertainties that could impede development of a detailed remedial plan. If the perceived risk is negligible, then the ERA might end at Level One. Whether Level One serves as a problem definition and planning stage or as a final step, the effort is not lost since the findings are well-documented and action is taken based on the information assembled.

The main outputs from this level are expected to be the following:

- a detailed technical report containing a site-specific conceptual model of the problem, a preliminary description of the contaminants of concern (COC), a description of the receptors of concern, preliminary toxicity estimates, a general description of the main mitigation options, and a detailed list of key uncertainties
- enhanced knowledge of the site-specific situation and improved understanding of key unknowns
- when necessary, terms of reference for a Level Two ecological risk assessment

2.5.2 Level Two

The three main objectives for a Level Two ERA at a contaminated site are to

- produce a preliminary, quantitative risk estimate for indigenous ecological populations exposed to chemicals at or near the site
- determine an initial set of clean-up objectives appropriate for guiding the mitigative program
- if necessary, set terms of reference for Level Three activities

Figure 2.7 illustrates the dominant priorities in this level of activity. It is expected that a Level Two ERA will commonly be the highest level conducted.

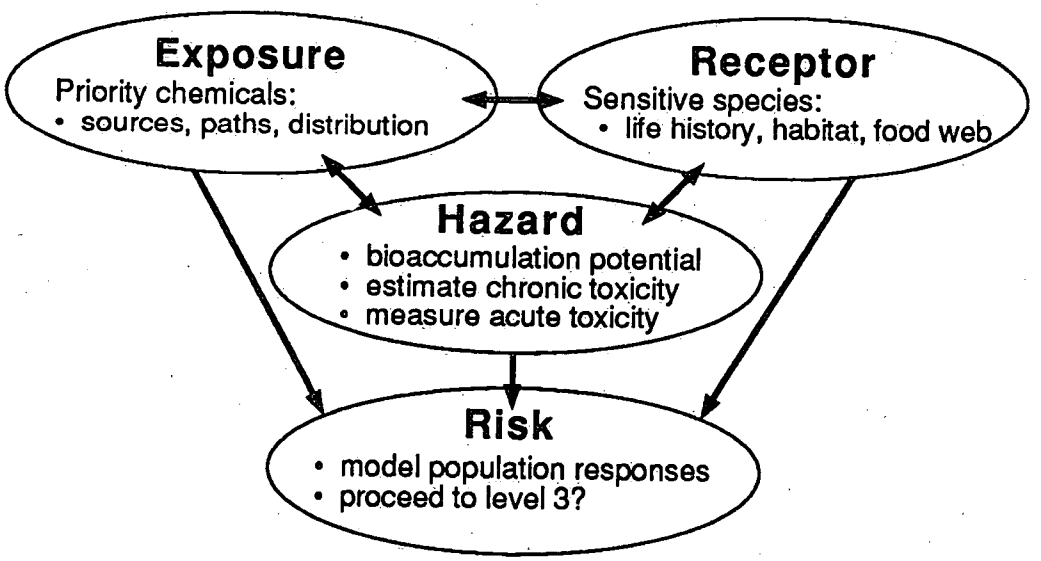


Figure 2.7. Examples of investigations for Level Two ERA.

Exposure Assessment: Sources, pathways, and distribution of chemicals around the contaminated site will be determined for all chemicals of concern. This may include providing preliminary quantitative descriptions of the mode and timing of contaminant releases, chemical transport and fate, and an integration of all exposure values. The key is to look at the level of exposure for the receptors of concern.

Receptor Characterization: Receptor characterization will include assembly of information on population life history patterns, habitat requirements, and food web interactions for sensitive or special status species at the study site. This could include generating preliminary quantitative estimates for overall population density, age-class structure, and mass values for individuals within specific age-classes. They may include population information such as preliminary quantitative estimates of the proportion of mature females, fecundity per female, and other measures needed to evaluate health at the population level.

Hazard Assessment: Hazard assessment includes collection of preliminary data describing expected toxicity (emphasis on acute) of the priority chemicals to the sensitive species. Preliminary quantitative information will be generated concerning bioaccumulation potentials. Finally, site-specific modifying factors will be identified that could be operating to either increase or ameliorate predicted effects.

Risk Characterization: Using information generated by the other three components of the Level Two ERA, simple quantitative methods will be used to determine population-level responses by the sensitive species to the priority contaminants. The decision whether or not to proceed to Level Three will also be made.

It is an option at this or at any other level to proceed to the next level of complexity for only one or a few elements in the framework. For example, at the end of Level Two, a decision may be made to proceed to Level Three only for exposure and hazard studies, if, for example, enough is already known about the sensitive species to warrant no further study (i.e., Level Three) on that ERA component.

Level Two studies should have the following outputs:

- a site-specific database pertaining to the priority chemicals, sensitive species, toxicity, and current environmental conditions
- a simple calibrated model (i.e., checked with actual data) predicting future biotic and abiotic conditions with and without mitigation
- a detailed scientific report specifying project activities, findings, conclusions, and recommendations

To achieve the second item in the above list, it will also be necessary to have a detailed engineering remedial action plan.

2.5.3 Level Three

In a Level Three ERA, there is a shift to population and community level effects, as well as on evaluating mixtures of chemicals and chronic effects (Figure 2.8). This is also the level where exposure is handled mainly through detailed, sophisticated computer models. At this level, overall objectives are to

- produce precise, accurate, quantitative predictions regarding current and future risks to ecological populations, communities, and ecosystems due to migration of chemicals from the contaminated site
- develop an adaptive process for selecting unique, site-specific, quantitative remediation objectives and revising them through time
- facilitate effective interaction with human health assessment, where it is concurrent

Exposure Assessment: Advanced quantitative models are used to describe present and future transport, transformation, and environmental partitioning for chemicals of concern.

Receptor Characterization: Receptor data are compiled for population and community modelling efforts. Data collection should support determination of factors such as presence of keystone species, biodiversity, estimation of ecosystem functions (e.g., primary productivity, respiration, decomposition, and nutrient cycling), and potential successional patterns likely to follow remediation.

Hazard Assessment: Hazard (chronic and sublethal endpoints) will be estimated for toxicity of chemicals, and toxicity estimates generated during Level Two activities will be adjusted to reflect modifying factors in the receiving environment. Precise toxicity data for the specific combination of chemicals and sensitive species found at the contaminated site should also be developed.

Risk Characterization: A computer simulation model will likely be required to produce quantitative predictions regarding current and future risks to ecological populations, communities, and ecosystems due to migration of chemicals from the contaminated site. This will form the basis for generating quantitative estimates

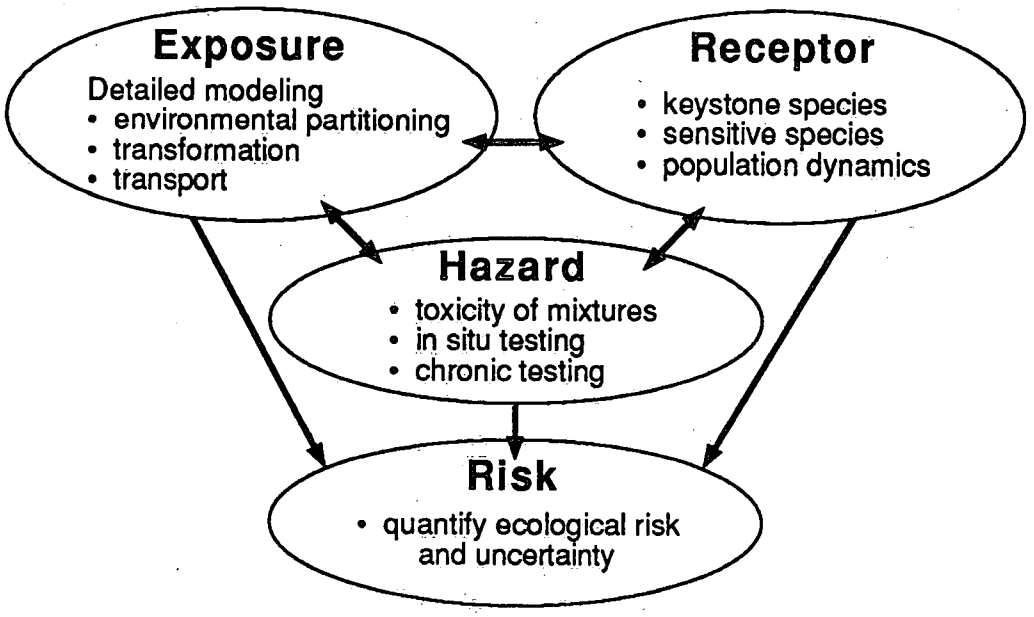


Figure 2.8. Examples of investigations for Level Three ERA.

of ecological risk spanning a range of situations from no mitigation to maximum possible control.

Remediation: Appraisals of inherent uncertainty in the ecological risk assessment estimates and estimation of "residual" risk associated with maximum possible control should be considered. This information will assist the engineers in developing an adaptive process for selecting unique, site-specific, quantitative remediation objectives. This process should also specify when and how the objectives will be reviewed and revised through time. The information on risk will be linked to any companion project assessing human health risks.

Expected outputs from Level Three ERA activities include

- a sophisticated, customized database pertaining to target chemicals, receptor biota and communities, toxicity, and environmental conditions
- calibrated, advanced models (i.e., using field data) predicting future biotic and abiotic conditions with and without various mitigation options
- if appropriate, preliminary engineering plans for several levels of remedial action to which the ERA process can respond
- summary of all of the above in a detailed scientific report providing a synopsis of all phases of the project and covering all activities, findings, conclusions, and final recommendations

At this level, the site of concern is probably severely contaminated, and aspects of the remediation program may be experimental in nature. An adaptive process in which the success or effectiveness of the mitigation program is checked through an environmental monitoring program is therefore required. There is great value in establishing an environmental monitoring program to generate information that, through time, will permit the ERA framework to be refined and the methods tested and improved.

2.6 Monitoring

The cornerstone to any adaptive process is a program to generate feedback on design and implementation successes and failures. Thus, as shown in Figure 2.1, the NCSRP process for ERA at contaminated sites has a monitoring feedback loop. Contributors to the ERA should have a direct and meaningful role in designing and implementing an environmental monitoring program to support adaptive management at the contaminated site. A sensitive environmental monitoring program should be implemented which is capable

of testing the effectiveness of the mitigation measures and providing early warning signals in cases where mitigation measures are ineffective.

2.7 Rationale for ERA Framework

It is important to acknowledge that for a number of years the U.S. EPA has been a leader in applying risk assessment concepts to human health issues. More recently, the EPA Risk Assessment Forum has been actively engaged in developing a framework for ecological risk assessment (U.S. EPA, 1992a, 1992b, 1992c). There are two main reasons why it was elected not to adopt EPA's ERA framework: (1) the U.S. framework is still evolving and the most recent versions have not yet been tested in practice, and (2) the U.S. framework is specifically and properly oriented toward meeting the American regulatory mandate. In the following sections, each of the proposed elements is compared with those used by others and, where differences occur, it is explained why an alternate route was selected.

For example, some frameworks from other jurisdictions combine receptor characterization and hazard assessment, or include receptors as part of the planning steps. This approach was not followed for the NCSRP because of the importance of receptors and their relationship to the objectives for protection. In Brown and Reinert (1992), the standard ERA components are not used; instead, they propose that three primary considerations determine ecological significance and, by extension, the risk of contaminants in the environment: (a) contaminant variables, (b) site-specific factors, and (c) exposure pathways. This is a useful conceptual approach, but not practical in application under the NCSRP.

A more detailed breakdown of each of the technical elements in the proposed framework is provided in subsequent sections. It is worth noting that the four key elements in the proposed framework are identical to those used by Norton et al. (1988), although the NCSRP framework calls for much more interplay between the elements. Likewise, in their review of aquatic risk assessment protocols, Parkhurst et al. (1990) identified and used the same four elements, although they used slightly different terminology in referring to them. The proposed framework was modified to incorporate Parkhurst et al.'s (1990) "special issues" (e.g., uncertainty, endpoint significance, protocol implementation) within each of the four main elements, as appropriate.

3.0 PROBLEM DEFINITION

This section addresses some of the steps that need to occur before ERA is initiated. In many cases under the NCSRP, these steps will already have been conducted as part of initial studies. This section stresses the importance of these initial steps as they often determine the overall success of ERA. In Figure 2.1, these initial steps are outlined as follows:

- site identification
- site classification
- problem identification
- planning

Strictly speaking, these problem definition steps are outside of the ERA process, but they are forerunners to the decision to conduct an ERA and so are discussed here. Problem definition collects enough information so that the decision in Figure 2.1 can be made (Sections 2.2 and 2.3).

3.1 Site Identification and Classification

Site identification can occur via a number of routes, but is usually triggered by knowledge of historic site use (e.g., identification of former industrial sites, landfills, etc.). This may be complemented by observation of an observed ecological effect or identification of contaminants of concern. The process will vary from jurisdiction to jurisdiction, but primarily will be driven by provincial and federal regulations. Initial site identification flags an area as requiring further study, but does not make any assumptions about the need to conduct an ERA or any other action. When a site has been identified as requiring further study, the next step is to classify the priority of the site.

In the broad sense, site classification is organizing available information to make a decision on need for further action. Under the Canadian National Classification System for Contaminated Sites (CCME, 1991b), much of the data for orphan sites under the NCSRP will already have been reviewed and organized. This classification scheme uses information required in a preliminary hazard assessment (both human and ecological), and the terminology in the CCME document is consistent with that used herein. Although not all contaminated sites in Canada will be subjected to this classification scheme, this approach is recommended as guidance to make a decision about whether a given site requires further attention. Depending on the site and the amount of information available, preliminary data collection may be necessary to decide whether the site requires further attention. If the site is classified as requiring further study, then the next step is to clearly identify the key problems.

3.2 Problem Identification

Clear statement of the problem at the potential contaminated site supports the decision making regarding further action (Figure 2.1). Problem identification documents the key issues and makes allowances for the uncertainty in the data available. The information collected to date for the site is evaluated for its sufficiency in the decision-making process. The statement of problem identification should become part of the reporting, should an ERA be conducted (see Section 9). This documents the background for the decision to conduct an ERA.

3.3 Planning an ERA

Once the decision to conduct an ERA has been made (Figures 2.1 and 2.2), the planning step becomes key in establishing the focus and breadth of the ERA. This is accomplished through the following:

Establish Purpose and Objectives

It is critical that the purpose and specific objectives be established for every ecological risk assessment. Articulating these in a written format will drive the design of the assessment and aid in selection of ecological endpoints of concern, the study methods, and the data quality objectives (U.S. EPA, 1989d). An ecological risk assessment may include any number of the following objectives:

- define extent of contamination
- determine the actual or potential effects of contaminants on species, habitats, or environments
- evaluate actual or potential threat to a particular component of the environment (e.g., endangered species, commercial fisheries, sensitive community) related to a contaminated site
- provide further information where existing information is inadequate to make a contaminated site management decision
- establish priorities in circumstances where there are limiting factors to remediation activities (e.g., costs are high, site is large)
- evaluate environmental quality at the site where applicable criteria are not available or require modification
- predict the results of remediation plans for contaminated sites. May need to consider if remedial alternative itself may do as much or more damage than the contamination
- develop remediation criteria

Establish Level of Effort

In most cases, there will not be enough data available to conduct the Level One ERA, and it is useful to establish a level of effort for this initial stage, as well as any higher levels of ERA. The objectives of the risk assessment will determine the focus of these studies, as well as their design. The study team must set the logistical boundaries. There is an infinite amount of information available, and data collection is potentially limitless. The study team should establish the constraints of the risk assessment as an iterative process. It is widely known that as the ecological relevance of information and the complexity of measurement methods increases, the feasibility of implementation decreases. At some point, hard decisions about logistical boundaries need to be made, and these should tie in with the level of the ERA (i.e., Level One, Two, and Three), objectives of the assessment, the exposure level, and the risk characterization.

The data available can determine the type of risk assessment procedures that will be implemented, particularly if there are schedule or budget limitations. For example, existing data may allow a qualitative risk assessment (Level One ERA); providing that this approach meets the objectives of the assessment, further data collection may not be required. However, as is more often the case, the planning phase may determine that the data available for receptor characterization are adequate, but that further studies are required for the hazard assessment and exposure characterization (Levels Two and Three ERA). This will drive the priorities for the time and effort available for further studies, as discussed within the context of the ERA framework proposed in Section 2.0.

Set Priorities

Each of the components can be planned, to a certain extent, before initiating an ecological risk assessment. This will result in savings of time and effort, since collection of new information will be based on priorities; information will be complementary, allowing for a natural flow between the different components.

In the planning phase, the study team should emphasize linkage between the receptor characterization and the hazard assessment. Based on the most important receptors, candidate toxicity tests (appropriate endpoints, test durations) and their ecological relevance should be selected. By tying these receptors in with exposure assessment, specifically the

route of exposure and bioavailability, the priorities for hazard data collection can be set. Reviewing existing exposure assessment data will also help focus the spatial extent of further data collection.

In identification of valued ecosystem components (VECs), consideration needs to be given to both use by humans and to resources that have particular value to society. The definition of VECs developed by Beanlands and Duinker (1983) has been adopted. VECs are resources or environmental features that

1. are important to human populations (intrinsic, economic, and/or social value)
2. have local, regional, provincial, national, and/or international profiles
3. if altered from their existing status, will be important in evaluating the impacts of development and in focusing management or regulatory policy

For the purposes of ecological risk assessment, it seems appropriate to include resources or environmental features that are also of local or regional importance. In performing a screening analysis of environmental fate, it is important to consider both direct and indirect pathways in deciding whether or not a contaminant could reach a VEC.

The planning stage is the point at which the study team should set the boundaries for the risk assessment and start to consider the elements of the Level One ERA. Spatial boundaries such as size of the contaminated site, its extent of influence (e.g., site, watershed, ecosystem), and the size of the exposed habitat will be determined. Temporal boundaries need to be established for all risk assessment components. For example, what seasonal changes (e.g., rainfall and temperature) need to be considered, particularly as they coincide with sensitive life stages or the presence of migratory species? For hazard assessment, should the focus be on acute and/or chronic effects? For the receptors, are there seasonal differences in the exposed communities that need to be taken into consideration? Discussion of these kinds of temporal differences needs to be incorporated during the planning of an ecological risk assessment. The outcome of this planning phase should be an assessment design that will ensure scientific defensibility of data and decisions based on those data, while remaining cognizant of the schedule and budget constraints faced by decision makers.

3.4 Staffing an Ecological Risk Assessment

As part of the planning process, individuals with expertise in each of the technical areas required by the risk assessment must be identified and included in the study team. The team should be coordinated by a scientist experienced in the risk assessment process and with good organizational skills. The intent is that risk assessments be conducted by technical experts for use as a decision-support tool for risk managers and risk communicators. When an ecological risk assessment is complete, it should be audited by an independent reviewer who runs through the entire process in a paper exercise to evaluate the conclusions of the assessment.

The U.S. EPA has set up a program called BTAGS (biological technical assistance groups) to assist ERA practitioners with the collection and evaluation of site information and to ensure that ecological effects are adequately considered. BTAGs represent a variety of disciplines (e.g., wildlife biology, fisheries, aquatic toxicology, avian physiology, wetlands science, hydrology, geology, remediation) and provide specialized expertise where required for any particular ERA. In the proposed NCSRP framework, a group like BTAG would be most likely needed for Level Two and Level Three ERA. Relative to the problem definition process, these specialists would review the objectives, planned level of effort, and priorities for an ERA, and provide comment.

Within the NCSRP process, it would be beneficial for BTAG groups (or their equivalent) to hold annual training workshops much the same as the EPA does. This facilitates dialogue on learned experience in ERA and provides a forum for discussing technical difficulties and possible adjustments to the process.

4.0 EXPOSURE ASSESSMENT

4.1 Definition and Scope

Travis et al. (1983, cited in Barnthouse and Suter, 1986) define exposure assessment for toxic chemicals as the "determination of the concentration of toxic materials in space and time at the interface with target populations". The U.S. EPA (1989e) operationally defines exposure assessment as an attempt to answer the following seven questions:

- What organisms are actually or potentially exposed to contaminants of concern?
- What are the significant routes of exposure?
- To what amounts of each contaminant are organisms actually or potentially exposed?
- How long is each exposure?
- How often does or will exposure take place?

- What seasonal and climatic variations in conditions are likely to affect exposure?
- What are the site-specific geophysical, physical, and chemical conditions affecting exposure?

The first question is treated in detail under Receptors (Section 5.0), while this section focuses on methods of answering the other six questions. This is not meant to imply, however, that receptors should not be considered in exposure assessments. The key elements of exposure assessment are summarized in Figures 4.1 and 4.2.

The most relevant and comprehensive reference on exposure assessment assembled and reviewed was the U.S. EPA Superfund Exposure Assessment Manual, or SEAM (U.S. EPA, 1988b). The SEAM was designed specifically for hazardous waste sites and includes a tremendous amount of detail on a wide diversity of techniques. It is extremely thorough in its documentation of input data requirements. The organization and content of this section is based largely on this reference, supplemented by other references where appropriate. Risk assessment practitioners should become familiar with this document.

Though the SEAM is oriented towards health risk assessment, virtually all the methods summarized therein are also applicable to ecological risk assessment. However, since ecological receptors may differ from humans in their habitats and exposure pathways, other types of analyses may be necessary.

In terms of exposure assessment, the major differences between humans and biota are in the modes of contact, and the spatial/temporal exposures to toxic substances. Primary modes of contact for humans are inhalation, dermal exposure, and ingestion of soil, food, or water; plants and animals may have modes of contact that are physiologically very different (e.g., transport across the membrane of a fish's gill - similar to inhalation). For terrestrial organisms, dietary pathways are generally the most important. Ecological exposure assessments also require a consideration of different parts of the environment than human health exposure assessments. For example, concentrations of toxic substances in sediments of a deep lake may not be directly hazardous to humans unless they enter drinking

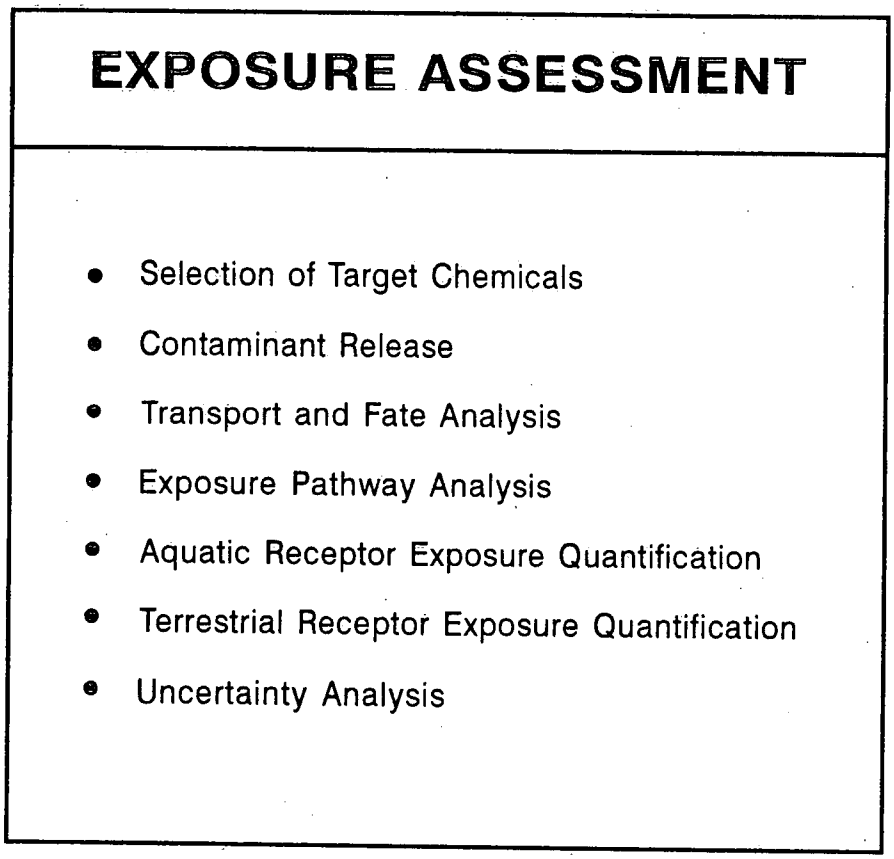


Figure 4.1. Key elements of exposure assessment.

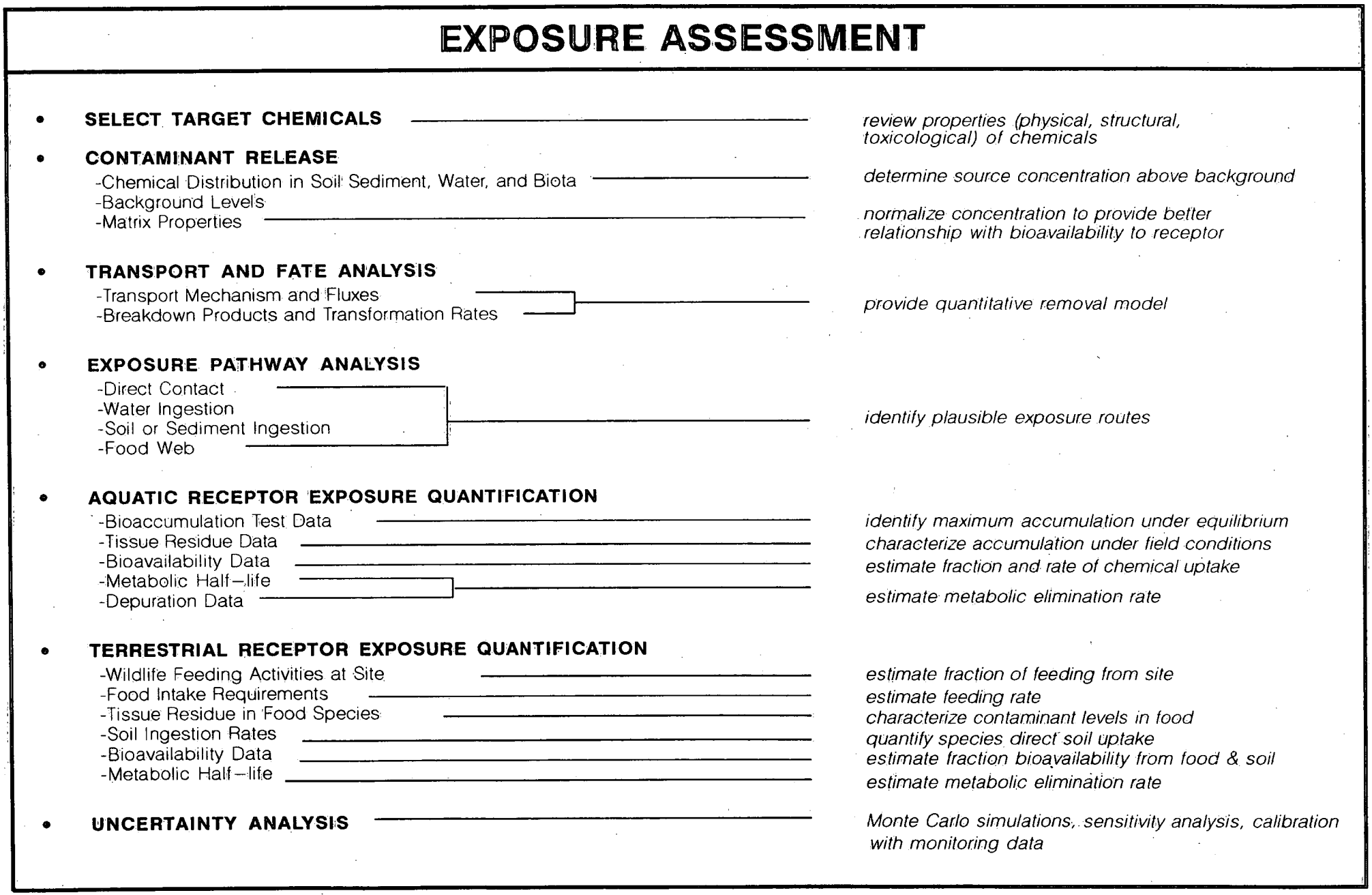


Figure 4.2. Steps to assess key elements of exposure assessment.

water or organisms that are eaten, but they may have significant direct impacts on benthic community structure (i.e., changes in the assemblages of organisms that live in these sediments). Exposure assessments for humans often assume 70 years of average or cumulative exposure; similarly, exposure assessments for ecosystems must consider the lifespan of key organisms.

4.2 Overview

The SEAM (U.S. EPA, 1988b) outlines six steps to the integrated exposure assessment process:

1. evaluation of contaminant properties and selection of target chemicals
2. multimedia contaminant release analysis, using monitoring data and/or modelling estimates
3. contaminant transport and fate analysis along key exposure pathways, generating through models or monitoring data an estimate of the environmental distribution and concentrations of contaminants
4. an analysis of exposed populations (here considered under Receptors in Section 5.0)
5. an integrated exposure analysis, which lists together the short- and long-term exposures expected via each pathway, for each contaminant
6. uncertainty analysis

These steps have been modified in Figures 4.1 and 4.2 to conform with ecological, rather than human health, risk assessment. Analysis of exposure pathways and quantification of exposure for aquatic and terrestrial receptors have been treated as separate steps. Note that a considerable amount of direct empirical evidence is required for quantification of exposure (Figure 4.2).

For each step in Figure 4.1, there are generally three categories of analyses which can be applied: simple qualitative analyses, preliminary quantitative analyses, and detailed quantitative analyses. In this section, these three categories of complexity are outlined for contaminant release, transport, and fate and exposure pathway analysis, the heart of the exposure assessment. Section 8.0 provides guidance on the selection of appropriate methods and the appropriate level of complexity for exposure assessments in the tiered approach to ecological risk assessment recommended in this report (Section 2.4).

4.3 Description and Evaluation of Available Methods

4.3.1 Selection of Target Chemicals

The objective of this step is to narrow the set of contaminants considered to those which pose either the greatest potential of release or the greatest toxic threats. The Superfund Public Health Assessment Manual (SPHAM) (U.S. EPA, 1985b), summarized in PRC Environmental Management Inc. (1985), specifies a four-step process which evaluates the environmental concentrations and toxicological approaches of contaminants:

1. identifying contaminants present at the site
2. recording environmental concentrations from site sampling data
3. calculating indicator scores for all chemicals (based on concentration and toxicity)
4. selecting indicator chemicals based on indicator scores

The scoring system used (step 3 above) may need to be modified using preliminary hazard assessment methods for representative organisms (Section 6.0). More recently, the Superfund Human Health Evaluation Manual (HHEM) (U.S. EPA 1989c), which superseded SPHAM, takes the position that all contaminants should be considered until they can be excluded based on scientific evidence. A screening approach is identified for reducing the number of chemicals carried through a risk assessment.

To date, a contaminant selection procedure specific to ecological risk assessments has not been identified by this review. Based on the Risk Assessment Guidance for Superfund Sites (U.S. EPA, 1989c, 1989d), the following three general principles for selecting target chemicals for ecological risk assessments are proposed:

1. determine the physical/chemical properties of the contaminants stored at the site
2. group contaminants according to their physical/chemical properties and predominant medium of concern (i.e. air, water, soil, biota)
3. choose one or more contaminants within each physical/chemical group that are likely to be the most toxic, based on available criteria, measured concentrations, and available dose–response information

Some of the key physical/chemical properties determining a contaminant's fate (and therefore its exposure pathways) are discussed in Thomann and Mueller (1987) and Connell and Miller (1984). These properties drive environmental persistence, which is one of the key elements in selecting a chemical for evaluation in an ecological risk assessment. They include

- the *n-octanol–water partition coefficient*, K_{ow} (octanol–water partition coefficient), which is strongly correlated with a contaminant's bioaccumulation potential
- the *water–sediment partition coefficient* and the *solubility of the chemical in water*, which affect the distribution of the chemical in soil/sediment versus water
- the *degradation* of the contaminant (rates of decay via *hydrolysis* in water, *microbial degradation* in water and sediments, and *photolysis* in water, sediments, or air), which affects the spatial and temporal horizon of the exposure assessment
- *volatilization*, as measured by Henry's constant, which affects the relative significance of atmospheric exposure pathways
- the *molecular weight*, which affects diffusion rates

The properties of chemicals will determine the medium of concern (e.g., air, soil, surface or ground water, animal tissue), and, conversely, the properties of the various media will determine the chemicals of concern. Chemicals with low values of K_{ow} and high water solubility could affect organisms inhabiting soils and surface waters, but have a low bioaccumulation potential. Transport through surface runoff and groundwater would be key exposure pathways for these chemicals. In contrast, chemicals with high K_{ow} values and low water solubility tend to sorb to particles in soils and surface waters and have a high bioaccumulation potential. These chemicals may have very different exposure pathways (e.g., adsorption to soil particles, followed by off-site transport through soil erosion or ingestion by terrestrial animals, environmental persistence).

4.3.2 Offsite Contaminant Release

Off-site contaminant release can be defined as the migration of contaminants across the site boundary (U.S. EPA, 1988b), but where critical habitat is contained within the borders of the site, the focus should obviously include the site itself. Possible release mechanisms include volatilization, wind erosion, surface runoff, leachate, and direct uptake by organisms on site. The following sections consider qualitative, preliminary quantitative, and detailed quantitative approaches, based on the SEAM (U.S. EPA, 1988b).

Aquatic biota are most likely to be exposed to contaminants through direct contact with water or through ingestion of surface water, sediment, and contaminated food (prey organisms). In aquatic systems, organisms are exposed to *concentrations* of contaminants. In some cases (e.g., plants, some soil organisms), the exposure for terrestrial organisms may also be to a contaminant concentration. Terrestrial animals can also be exposed through ingestion of contaminated surface water, soil, or foods, generally as a *dose*. These foods include plants that can take up contaminants from surface water, groundwater, soil, or air. Surface water, sediment, soil, and prey organisms can therefore be thought of as *exposure media*. Groundwater and air (e.g., dust emissions and volatilization), however, are likely only important as *transport media* (i.e., transporting contaminants to media from which chemicals are directly taken up by organisms).

4.3.2.1 Qualitative Methods

Figure 4.3 [from the HHEM (U.S. EPA, 1989c)] presents the questions which need to be addressed to focus on the most probable release mechanisms. These decision trees were originally prepared for human health risk assessments, but have been adapted for ecological risk assessments.

4.3.2.2 Preliminary Quantitative Analyses

As summarized in Table 4.1, there are five possible mechanisms for release of contaminants from a contaminated site: particulate release (i.e., dust emissions), volatilization, surface runoff (includes episodic overland flow), release to groundwater (includes leaching), and direct uptake by biota on site. The mechanisms of release will vary with the release source (Table 4.1). Measurement parameters for each of these release mechanisms are detailed in U.S. EPA (1988b).

Dust Emissions

For preliminary quantitative analyses of this transport medium, the SEAM recommends the following approaches:

1. Estimate the amount of dust generated by wind erosion, using either the U.S. Soil Conservation Service (SCS) equation for annual erosion rates (a function of soil erodibility, climate, soil roughness, field length, and vegetative cover) or the rapid assessment approach of Cowherd et al. (1985) for worst-case daily release rates.

FATE AND TRANSPORT ASSESSMENTS

(a) SOILS AND GROUNDWATER

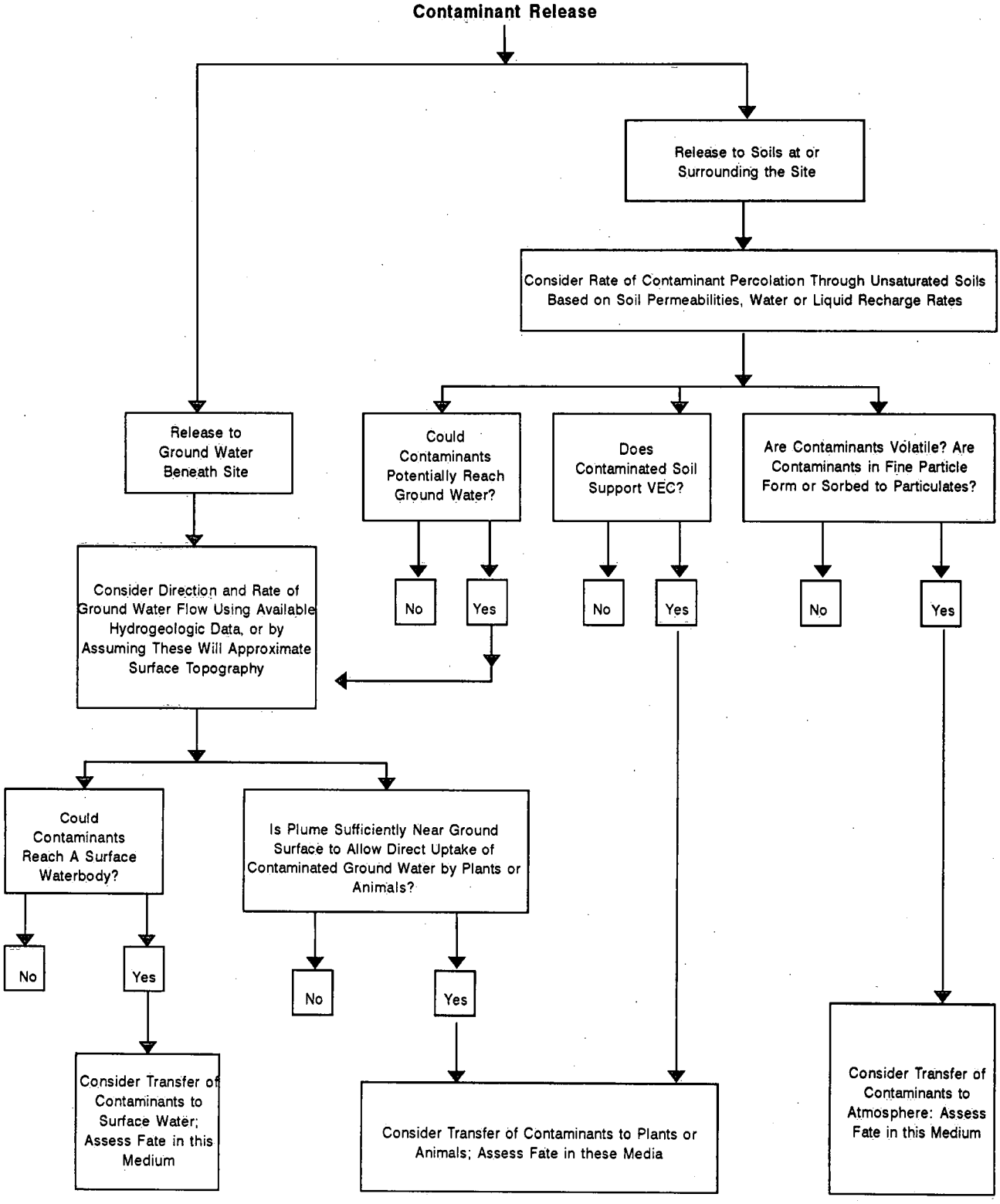


Figure 4.3. Fate and transport assessment – (a) soils and ground water (adapted from U.S. EPA, 1989c).

FATE AND TRANSPORT ASSESSMENTS

(b) SURFACE WATER AND SEDIMENT

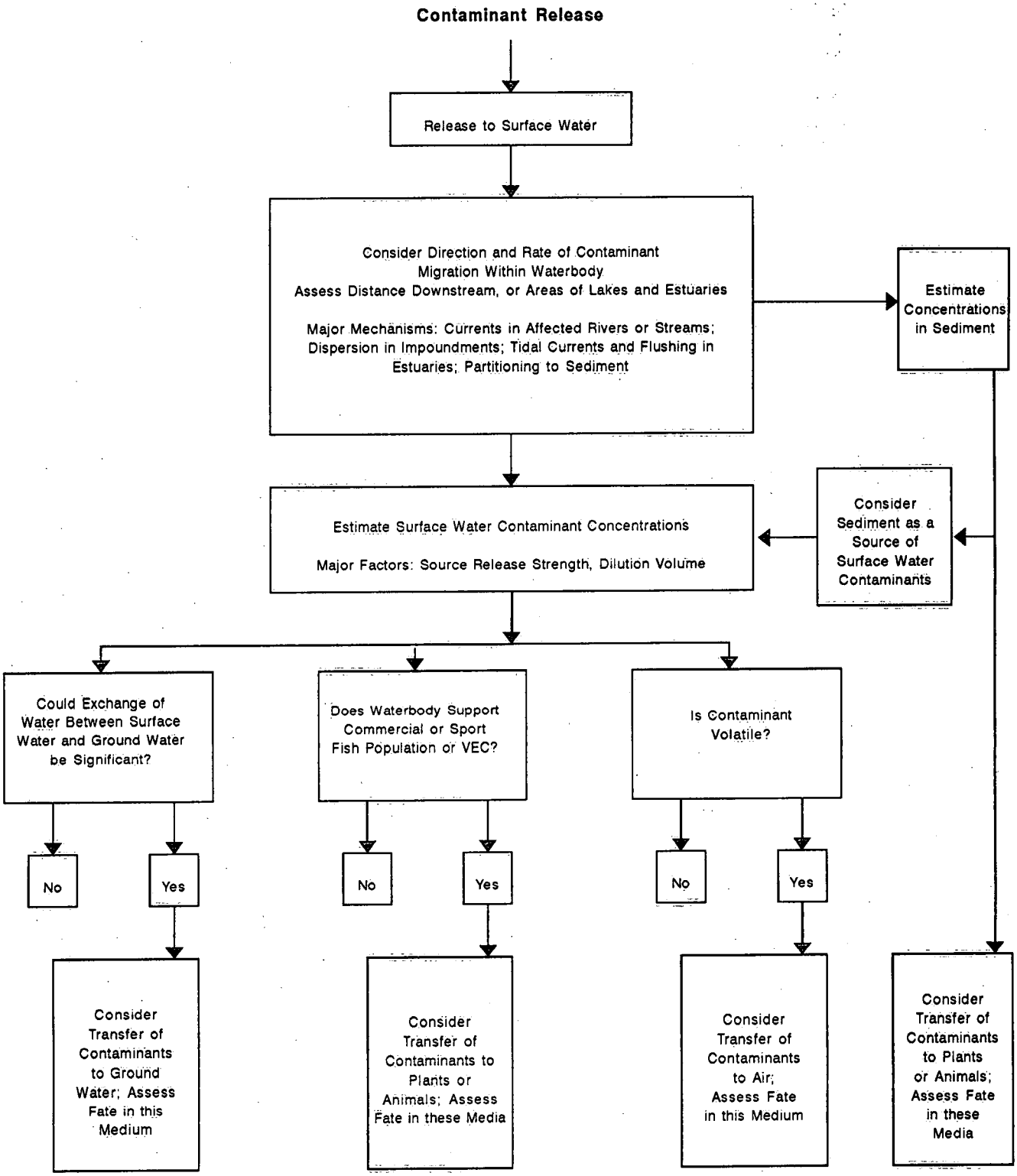


Figure 4.3. Fate and transport assessment – (b) surface water and sediment (adapted from U.S. EPA, 1989c).

Table 4.1. Common Chemical Release Sources at Sites in the Absence of Remedial Action (from U.S. EPA, 1989c)

Receiving Medium	Release Mechanism	Release Source
Air	Volatilization	Surface wastes - lagoons,ponds, pits, spills Contaminated surface water Contaminated surface soil Contaminated wetlands Leaking drums
	Fugitive dust generation	Contaminated surface soil Waste piles
Surface water	Surface runoff	Contaminated surface soil
	Episodic overland flow	Lagoon overflow Spills, leaking containers
	Ground-water seepage	Contaminated ground water
Ground water	Leaching	Surface or buried wastes Contaminated soil
Soil	Leaching	Surface or buried wastes
	Surface runoff	Contaminated surface soil
	Episodic overland flow	Lagoon overflow Spills, leaking containers
	Fugitive dust generation/deposition	Contaminated surface soil Waste piles
	Tracking	Contaminated surface soil
Sediment	Surface runoff, Episodic overland flow	Surface wastes - lagoons, ponds, pits, spills Contaminated surface soil
	Ground-water seepage	Contaminated ground water
	Leaching	Surface or buried wastes Contaminated soil
Biota	Uptake (direct contact, ingestion, inhalation)	Contaminated soil, surface water, sediment, ground water or air Other biota

2. Adjust total wind erosion soil loss rates to reflect the fraction that is suspendible and transportable over significant distances by wind.

3. Estimate dust releases from contaminated, unpaved roads, based on an equation which considers traffic volumes, the silt content of road material, vehicle speeds and weight, and annual precipitation rates.

4. Multiply the amount of dust generated by the weight percent of the toxic substances in soil or waste, or (preferably) in dust samples obtained with on-site air monitoring.

These methods are appropriate for computing annual release rates under average climatic conditions, but not under climatic extremes. Dust emissions are probably not very relevant to most terrestrial systems.

Volatilization

For volatile substances (e.g., chloroform), volatilization may be more important as a contaminant sink than as a transport medium. In either case, the methods recommended in the SEAM for quantifying volatilization rates require estimates of a number of site parameters, as well as chemical properties. The required chemical characteristics can be computed from first principles (equations provided in U.S. EPA, 1988b), from reference texts, or from computer software (e.g., the Graphic Exposure Modelling System - GEMS, developed by the Office of Toxic Substances). Equations are provided in the SEAM for a number of different volatilization situations:

1. *landfills without internal gas generation*, where it is assumed that concentrations remain constant (i.e., no biodegradation, water transport, or adsorption) and emissions occur through diffusion only

2. *landfills with internal gas generation*, where the upward movement of landfill gas is the controlling factor, and both soil and gas phase diffusion is insignificant

3. *spills and leaks of pure compounds onto soils*

4. liquid state controlled diffusion from *lagoons*

These equations assume that the system is at steady state (i.e., no constant additions of contaminant) and are generally quite conservative (e.g., they assume that there is no chemical degradation). The SEAM also provides equations for estimating the long-term volatilization rates (e.g., average rate over 70 years) for each contaminant. Volatilization is not generally a major route of contaminant release, relative to water and food.

Surface Water and Groundwater Contamination

The main pathways of surface water contamination from hazardous waste sites are through contaminated runoff, overland flow from storage leaks and spills, groundwater contamination, or lagoon failures (U.S. EPA, 1988b). This is one of the most important pathways for ecological risk assessment. On-site monitoring is the most reliable method of estimating most release rates to surface waters, though this may not always be possible. Where monitoring is not possible, several preliminary quantitative analyses are available for estimating surface runoff losses, which serve as input to environmental fate analyses (Section 4.3.3). These preliminary quantitative methods generally require no field sampling, though they also contain several restrictive assumptions [consult U.S. EPA, (1988b) for further details].

Many of the organic substances present at hazardous waste sites are relatively nonpolar and hydrophobic, and quickly sorb to soils. Estimates of the amount of these substances *released in runoff* can be calculated using the Modified Universal Soil Loss Equation (MUSLE). This equation uses sorption partition coefficients derived from each compound's octanol–water partition coefficient, basic information on soil types, and an estimate of storm event intensity. Generally, available long-term climatic data can be used to estimate long-term losses through the soil loss equation approach. Short-term losses can also be estimated using data for storms with a given return period (e.g., a 1-year return period, 24-hour storm event).

Prediction of the rate of *groundwater contamination* from facilities lined with clay or natural soil requires an estimate of both the contaminant concentration and the volumetric flux of leachate. The U.S. EPA (1988b) recommends the use of steady-state approaches to estimating release rates, since the equations are simpler and usually work just as well as dynamic approaches. For lagoons, the contaminant concentration of leachate is assumed to be the same as that in the lagoon, and the loading rate is driven by the hydraulic conductivity and gradient. In landfills, the leachate concentration is set equal to the equilibrium solubility of the solid waste, while the loading rate is a function of the rate of percolation of rainfall. For storage facilities surrounded by flexible membrane liners (FML), equations are available to estimate the rate of gas and liquid permeation through various polymers and the contaminant loading rate.

Direct Uptake by Biota

Organisms residing at or near the contaminated site may be directly exposed to contaminated soil or sediment, surface water, groundwater, or air. Contaminants may be released from the site if the organisms move or are consumed by other organisms. The various means of contaminant uptake are considered in more detail in Sections 4.3.5 and 4.3.6, and estimates of the contaminant release through uptake can be made using the methods given in those sections. In terrestrial systems, it is probably best to first directly measure the contaminant concentrations in the media to which the organisms are exposed. The U.S. EPA (1988b) recommends that contaminant concentrations in soils should be sampled directly, rather than estimated, and presumably the same conclusion applies for vegetation. For preliminary quantitative analyses, however, plant/soil bioconcentration factors may be available for specific combinations of contaminants, soil types, and

plant species. Field information provides a valuable reality check. Menzie et al. (1992) found that in-field bioassay tests with earthworms provided information on the spatial distribution of toxic soils as well as the potential for bioaccumulation in invertebrates. These field studies demonstrated that the soil invertebrate community was composed of vertical and horizontal strata which experienced exposure regimes that differed significantly from those evaluated in toxicity tests using composite or discrete samples of soil.

4.3.2.3 Detailed Quantitative Analyses

The following procedures are necessary for detailed quantitative analyses of contaminant release:

Dust emissions and volatilization: air sampling downwind and upwind of the hazardous waste site, calculation by difference of the particulate mass loading attributable to the site, and dispersion modelling to back-calculate emission levels at a "virtual point source" upwind of the site.

Surface water contamination: direct measurement of the contaminant flow (preferred approach) or estimation by difference from upstream and downstream monitoring can be combined with simple dispersion equations or sophisticated models (summarized in Section 4.3.3) to back-calculate to a virtual point source.

Groundwater contamination: sophisticated computer models (Section 4.3.3) are available; direct measurement is preferable, especially at the point where groundwater comes into contact with the receptors of concern.

Soil contamination: computer models (Section 4.3.3) are available for projecting the level of unsaturated zone contamination over time from surface placement of contaminants. Given the heterogeneous distribution of contaminants in soils, field verification (i.e., direct measurement) of predictions is essential.

Quantitative methods for calculating uptake by biota on or near the site are given in Sections 4.3.5.3 and 4.3.6.3.

4.3.3 Contaminant Transport and Fate

The contaminant release rates computed through one of the methods described in Section 4.3.2 provide the foundation for contaminant fate analysis. Generally, the average release rates to different media are used as input to fate and transport analyses (Figure 4.4). Note that the biotic pathways analysis requires input from all other media, and that there are other potential intermedia interactions. As in the previous section, the information contained in the SEAM (U.S. EPA, 1988b) has been organized into three levels of sophistication: qualitative methods, preliminary quantitative analyses, and detailed quantitative analyses.

4.3.3.1 Qualitative Methods

As discussed in the SEAM, a screening analysis (or qualitative assessment) of contaminant fate serves to

- identify each transport process governing the movement of various contaminants within and among environmental media
- determine the direction and roughly gauge the rate of contaminant movement from the site
- identify areas to which contaminants have been or may be transported

The qualitative assessment helps to scope out which pathways require more detailed quantitative analyses and provides a consistent approach across sites (Figure 4.4). The CCME National Classification System for Contaminated Sites is an example of such an approach and considers groundwater, surface water, and direct contact exposure pathways. Figure 4.3 presents a similar approach, including more questions on atmospheric pathways, but without the scoring system contained in the CCME system. The figure was revised from the U.S. EPA (1989c) HHEM to make it relevant to ecological risk assessment. The major change is considering biota to be of interest not only if they are used by humans (e.g., in agricultural, hunting,or fishing areas), but also if they are considered to be a valued ecosystem component (or VEC). There are, of course, many limitations to these qualitative approaches. For example, though the direction of contaminant movement may be clear for rivers and streams, and concentrations can be roughly estimated based on contaminant loading and dilution volumes, this is not the case for impoundments and estuaries. From the perspective of ecological risk assessment, a key set of endpoints are the contaminant concentrations in edible tissues. These concentrations are a function of "the level and type of biotic exposure to contaminants, the partitioning of contaminants between organic tissue and substrate media, the biodegradability of contaminants, organism-specific metabolic characteristics, and ecosystem characteristics" (U.S. EPA, 1988b).

4.3.3.2 Preliminary Quantitative Analyses

Atmospheric Fate

Where qualitative analyses suggest the atmosphere may be an important transport medium, or the

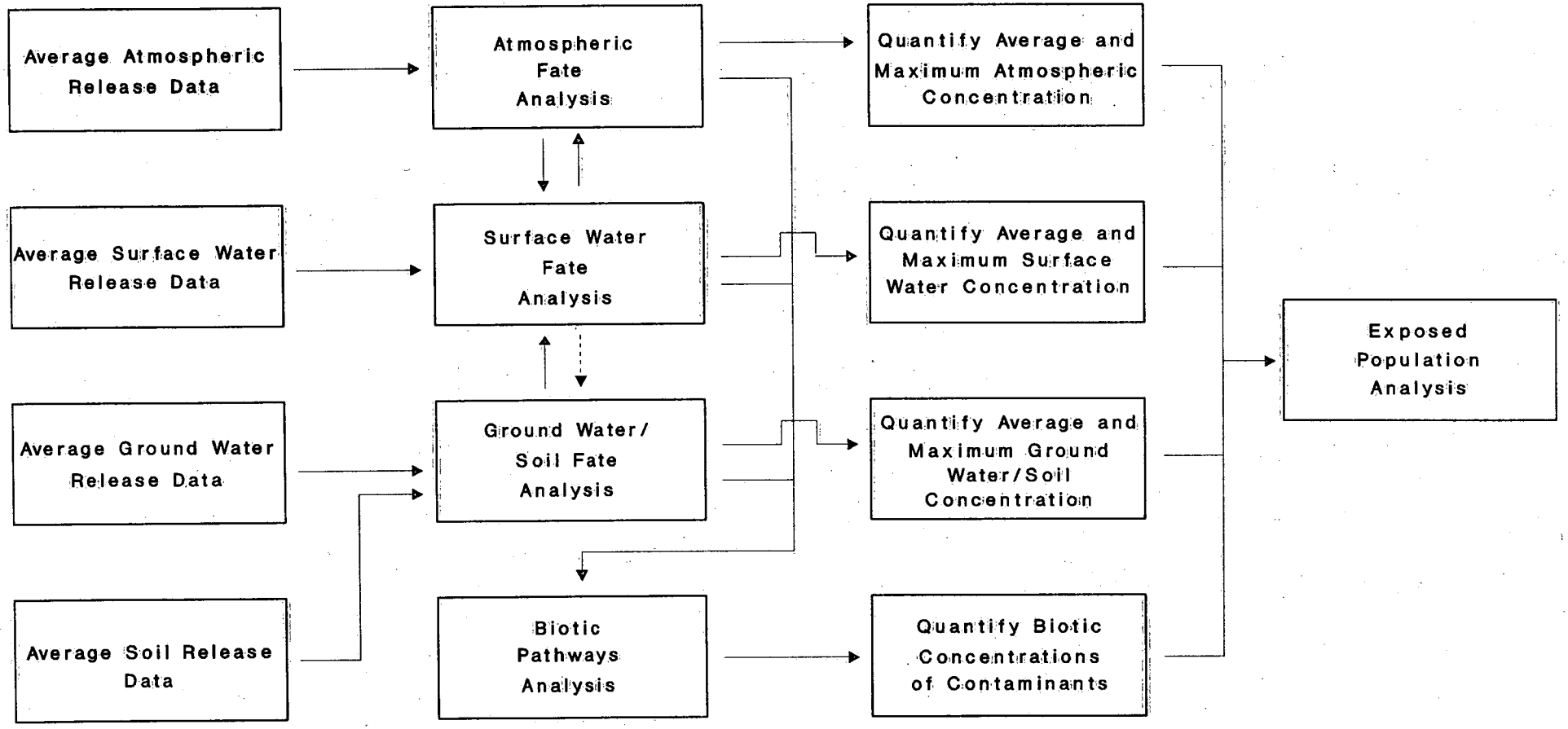


Figure 4.4. Overview of environmental fate and transport analysis for exposure assessments (adapted from PRC Environmental Management Inc., 1985).

gaseous form of a contaminant is particularly toxic to biota, quantitative analyses of atmospheric transport may be warranted. Ground-level concentrations downwind of a source can be estimated as a function of substance release rates to the atmosphere (Section 4.3.2), dispersion coefficients in lateral and vertical direction (a function of the atmospheric stability class and the distance downwind from the source of the plume), and the mean wind speed. The SEAM provides the necessary dispersion parameter values for this calculation, and also describes equations for computing maximum hourly concentrations and the area within which the ground-level concentration is above a predetermined critical concentration. Maximum short-term concentrations can be estimated by assuming the most stable atmospheric conditions, lowest wind speed, and greatest percent of wind flow toward the population or receptor of concern. These preliminary quantitative approaches make several simplifying assumptions:

- the hazardous substance can remain airborne indefinitely (i.e., is either gaseous or consists of particles less than 20 mm in diameter)
- steady-state conditions (i.e., constant wind speed and continuous contaminant release)
- negligible longitudinal dispersion
- no removal or decay processes
- substance is normally distributed in both vertical and lateral directions
- the air environment (wind speed, air stability) is homogeneous

Notwithstanding these obvious simplifications, these equations can be used to assess whether atmospheric concentrations pose potential hazards to humans or VECs. Dry deposition rates of hazardous materials to vegetation are often difficult to estimate, as they can be dependent on both meteorological conditions and the activity of the plant.

Surface Water Fate

The SEAM provides preliminary quantitative methods for rivers and streams, and refers analysts concerned with impoundments and estuaries to Mills et al. (1982). The simplest estimate of stream concentrations is the concentration in effluent divided by the dilution ratio (stream plus effluent flow : effluent flow). Intermedia transfers (i.e., from air, soil, groundwater, or nonpoint sources) can easily be added into this equation (i.e., mass added/flow). The SEAM also provides an equation for the length of the mixing zone. Note that this simple approach assumes steady-state conditions, complete mixing, and no removal or decay processes. It is nevertheless a useful basic model for conservative hazardous substances and a worst-case estimate for nonconservative substances. If concentrations are diluted to below levels of concern, and there are no important receptors (or potential links to receptors) within the mixing zone, then the exposure assessment may not need more detailed tools. However, the assumption of complete mixing should be carefully reviewed before accepting these preliminary estimates as reasonable.

Nabholz (1991) describes two simple quantitative approaches for estimating exposures of conservative substances in streams. The first method uses percentile stream flows from flow monitoring stations (i.e., the nearest similar gauged stream) to estimate the range of mixing available under different conditions (e.g., the 10th percentile low streamflow, 10th percentile mean streamflow). These dilution ratios are used to compute the range of concentrations, assuming instantaneous mixing and no losses after discharge. The second method uses daily streamflow measurements to predict how many days per year a critical concentration is likely to be exceeded, given the same assumptions.

For nonconservative estimates, simple equations assuming exponential decay can be used to estimate concentrations downstream of the mixing zone and the distance downstream over which the substance remains above a predetermined critical concentration level. The exponential decay rate can be based on rates available in the literature or estimated empirically from monitoring data. In the latter case, it is important to choose seasonally varying values (or a worst-case estimate) for the decay rate. Short-term concentration levels can be obtained by applying the lowest reasonable 24-hour flow rate or the 7-day, 10-year low flow rate (7Q10).

Groundwater Fate

Groundwater flow is extremely complex, and any simple summary is likely to miss key processes. The SEAM contains a detailed description of key processes and factors affecting them. Three key concepts are as follows.

- Precipitation flows vertically down through the unsaturated zone to the saturated zone and then roughly horizontally within the saturated zone.
- The rate of infiltration of water through the unsaturated zone is limited by hydraulic loading under dry conditions and by soil permeability under wet conditions.
- The rate of movement of water through the saturated zone is determined by the hydraulic

gradient (change in hydraulic head), the hydraulic conductivity (soil's ability to transmit water), and the cross-sectional area perpendicular to the flow direction.

There are two primary pathways by which hazardous wastes can join this flow: (1) leaching of solid wastes as the contaminant dissolves in infiltrating precipitation and (2) percolation of liquid contaminants to the water table through gravity. U.S. EPA (1988b) notes that liquid contaminants generally constitute 60% to 95% of the total wastes at hazardous waste sites, so the second pathway is generally more important. Groundwater contamination can also occur by gaseous contaminants and intermedia transfers (e.g., rain-out and wash-out from air, seepage from contaminated surface waters into groundwater), but these pathways are of much less significance. Some important features of groundwater contamination (U.S. EPA, 1988b) are as follows.

- A very small quantity of concentrated contaminant can contaminate a large volume of groundwater to the ppm or ppb level.
- The water solubility and specific gravity of a contaminant affect the form in which it travels (i.e., as a solute, colloid or separate, concentrated phase) and thereby its ultimate fate.
- Dilution is much lower in groundwater than in air or water because of the absence of turbulent flow.
- Longitudinal dispersion (stretching out) of the contaminant plume is much greater than lateral dispersion; longitudinal dispersion helps in the dilution of spills, but not continuous sources.
- Chemical transformation and retardation processes are difficult to model, but can reduce or delay (respectively) the risk of contaminants to people and ecosystems.
- Once contamination stops, soil desorption of contaminants to clean groundwater can cause a long delay in recovery.

The SEAM provides desk-top equations for calculating the velocity of infiltrating precipitation (unsaturated zone) and groundwater (saturated zone) through different types of soils and rocks. For contaminants, these basic equations are modified to account for different viscosities and densities, retardation effects on hydrophobic contaminants, and the different migration behaviours of different substances (i.e., hydrophilic versus hydrophobic, solid versus liquid, low, medium, or high density). A nomograph is provided to estimate time, distance, and concentration for any point along the principal direction of groundwater flow. Monitoring data are extremely valuable for estimating the spatial extent of contamination, particularly from monitoring wells which extract a small quantity of water and therefore do not influence the flow of groundwater.

4.3.3.3 Detailed Quantitative Analyses

Detailed quantitative analyses for projecting the fate of contaminants involves direct measurement and/or selecting, calibrating, and applying a computer model. Criteria for model selection include

- capability of the model to account for important transport, transformation, and transfer mechanisms
- the model's fit to site-specific and substance-specific parameters
- the model's data requirements compared to the availability and reliability of site information
- form and content of model output (relevance to particular needs of the human or ecological risk assessment)

The SEAM recommends the use of the Graphical Exposure Modeling System (GEMS), developed by U.S. EPA's Exposure Evaluation Division in the Office of Toxic Substances. This system, which runs on a VAX computer accessible by modem, includes the following components:

- models capable of assessing contaminant fate in air, surface water, groundwater, and soil
- pertinent data files (soil, land use, and meteorological data for all of the United States, as well as many rivers, lakes, and reservoirs)
- user-input data manipulation and storage capabilities
- statistical processing programs
- graphics capabilities

The SEAM lists several U.S EPA documents and other literature providing model selection criteria. Issues pertaining to modelling for each of the media described in Section 4.3.3.2 are described below.

Atmospheric Fate

Since models vary in their ability to incorporate different processes, the selection of an atmospheric

transport/fate computer model should involve a consideration of the most important processes at the particular site. These processes include both *intermedia transfers* (dissolution of gases into water droplets, adsorption onto particulate matter, gravitational settling, and precipitation) and *intramedia transformations* (photolysis and oxidation). As hazardous substances are generally released from ground level, the effects of *terrain* on wind currents can be very important.

The SEAM provides a summary of various atmospheric fate models. Also included in the SEAM are tables comparing the features and input data requirements of different models. The U.S EPA has included the Industrial Source Complex (ISC) and TOXBOX models in their GEMS system.

Surface Water Fate

The selection of models for surface water fate calculations must take into account the relative abilities of these models to simulate the *intermedia transfers* (volatilization, sedimentation, sorption) and *intramedia transformations* (photolysis, oxidation, hydrolysis, biodegradation) of greatest importance to the contaminants and site of concern. The rate controlling factors for each of these processes are discussed in the SEAM to help the analyst focus in on the critical model capabilities. Some of the key physical and chemical properties affecting these processes were discussed in Section 4.3.1.

The SEAM summarizes the resource requirements and information sources for various surface water fate models. The resource requirements for these models vary widely. At the simple end of the spectrum is WQAM, which is a desk-top methodology that does not require a computer. At the other extreme, EXAMS requires time for installation and setup **after** all data are organized. Data organization also often consumes a considerable portion of the time necessary for modelling. It is wise to carefully assess modelling needs before jumping into application of a particular model. Most of these models require estimates of average contaminant release rates, chemical partition coefficients, flow rates, water body physiography, water column and bed sediment degradation coefficients, substance physical/chemical properties, sedimentation/ resuspension velocities, and sediment size parameters. Some of these parameters can be estimated by calibration from monitoring data. Monitoring may also be necessary to characterize environmental factors which modify the rates of various processes (e.g., DO, pH, temperature, nutrients).

Groundwater Fate

U.S. EPA (1988b) provides a summary of modelling approaches for in-depth assessment of hazardous substances. Two of these models are included in the U.S EPA GEMS system: SESOIL and AT123D. The latter is a good example of the state of the art and the resources required to sustain this modelling activity. AT123D can simulate the transport and fate of hazardous material under 300 different user-selected situations (e.g., eight different source configurations, three different contaminant release dynamics, different aquitard locations). The model outputs the contaminant concentration at any point, at a specified downstream and lateral distance and depth, or as a function of time from the beginning of source release. The model does have substantial input data requirements, including lateral, vertical, and longitudinal dispersion coefficients; geometry of the aquifer, especially the configuration of aquitards; soil properties (bulk density, effective porosity, hydraulic conductivity); source type; release duration and strength; soil-waste stream partition coefficient; hydraulic gradients; and an overall decay constant for the substance studied. Some of the more recent models use Monte Carlo simulations (i.e., several thousand runs with varying inputs) to assess the effects of variation in environmental data.

4.3.4 Exposure Pathways Analysis

Exposure pathways analysis involves the identification of plausible exposure routes for each identified receptor (Figure 4.2). This analysis views the exposure pathways from the perspective of the organism, rather than that of the hazardous waste storage site. For each VEC, is exposure likely through direct contact, water ingestion, soil or sediment ingestion, or via the food web? Both direct and indirect pathways should be considered. Often certain pathways can be quickly eliminated from further consideration through simple calculations. For example, Fordham and Reagan (1991) determined from observed water concentrations and estimated daily water intake that bald eagles' bioconcentration of dieldrin through water ingestion was insignificant compared to their uptake from food. Another important consideration here is the proportion of the time an animal spends in the vicinity of the polluted zone. Fordham and Reagan (1991) assumed conservatively that the aquatic contaminant source provided the bulk of bald eagles' diet even though in reality only 10% of their feeding was based on the aquatic food web.

Ultimately one will need to add up all the different exposure pathways for a given ecosystem component, for both long-term and short-term (extreme) exposure calculations. The spatial and temporal horizon of these calculations will vary with different organisms.

4.3.5 Aquatic Receptor Exposure Quantification

4.3.5.1 Qualitative Techniques

Figure 4.5 demonstrates the steps to consider for potential exposures via food chains. The SEAM (U.S.

EPA 1988b) provides some useful questions for each of these steps, similar to those in Figure 4.2. Important food chains can be identified through the flow chart in Figure 4.3

4.3.5.2 Preliminary Quantitative Analyses

The concentration of contaminants in organisms is affected by the contaminant concentration in the environmental media, the metabolic rate of the organism, the bioavailability of the substance, and the characteristics of the species' metabolic processes. Transport and distribution are also affected by migration of organisms (or dispersal with advective flow), movement of contaminants through the food chain (biomagnification), and transport and distribution as a result of human commercial or sport activity. Though models have been constructed for particular contaminants and organisms (e.g., Gobas, 1991), there are few generalized simple approaches. The most common simple approach (U.S. EPA, 1991) is the use of bioaccumulation factors (BAF), based on simultaneous monitoring of water and tissue concentrations or (less preferred) literature values. The latter is less preferred because of the influence of site parameters on BAF (e.g., temperature, pH, and salinity).

Specifying a food chain for model analyses of ecological risk is a compromise between reality and the available data and understanding. Fordham and Reagan (1991) provide the following principles:

1. By organizing species with similar feeding habits into groups of key species, bioaccumulation by key species represents bioaccumulation by other organisms in that feeding group.

2. By selecting the most sensitive organisms (or organisms most likely to accumulate larger levels of contaminants) as sink species, a conservative approach is used in developing criteria for bioaccumulative contaminants.

3. By using a conservative approach, other less sensitive populations should also be protected.

The simplest models of bioaccumulation in food chains rely on five variables at each trophic level (Fordham and Reagan 1991):

1. the concentration of contaminants in prey organisms

2. the assimilation efficiency (mg contaminant absorbed/mg contaminant ingested)

3. the total daily diet (g food/g body weight/day)

4. the depuration or loss rate (/day)

5. the fraction of the organism's diet made up by each prey organism. Using this method, one can build up as many trophic levels as necessary, given reliable parameters for each layer.

4.3.5.3 Detailed Quantitative Analyses

Modelling bioaccumulation in aquatic food chains generally begins with planktonic and benthic organisms, or macrophytes, typically using simple approaches. These include the use of BAF, simple pharmacokinetic models (Gobas et al., 1991), or an assumed equilibrium between contaminant concentrations in the organism (e.g., lipid tissue of benthic organisms) and the environment (e.g., contaminant concentrations in sediment organic matter). BAF can be estimated from the literature (Level 2 approach) or estimated empirically at the site. Empirical estimates require that the contaminant is present in the source medium in measurable concentrations, which is often true for sediments but often not the case for water. BAF can vary seasonally due to changes in bioavailability and organism physiology or fluctuations in water chemistry (e.g., pH changes can affect the level of dissociation of the contaminant; changes in total suspended solids can affect sorption and bioavailability).

Assuming that the contaminant concentrations in these benthic/planktonic groups can be estimated or directly measured, the next step is to estimate the average dietary composition of each fish species of interest. This involves specifying the proportions of each benthic/planktonic group in fish diets, by season if necessary. The spatial distribution of each fish species across areas with widely varying concentrations must also be known, though this information is usually unavailable.

A considerable body of theory and empirical evidence is available for predicting contaminant bioaccumulation in fish using pharmacokinetic models (Gobas and Mackay, 1987; Thomann, 1989). The physical and chemical factors discussed above for benthos are equally important for fish and need to be considered in the exposure models which drive pharmacokinetic models. A typical modelling approach for assessing bioaccumulation of hydrophobic contaminants in lakes is that of Gobas (in press). In this model, the change in the fish's contaminant concentration over time is represented by

$$\frac{dC_F}{dt} = k_1 C_{WD} - k_2 C_D + k_D C_D - k_E C_F - k_G C_F - k_M C_F \qquad [4.1]$$

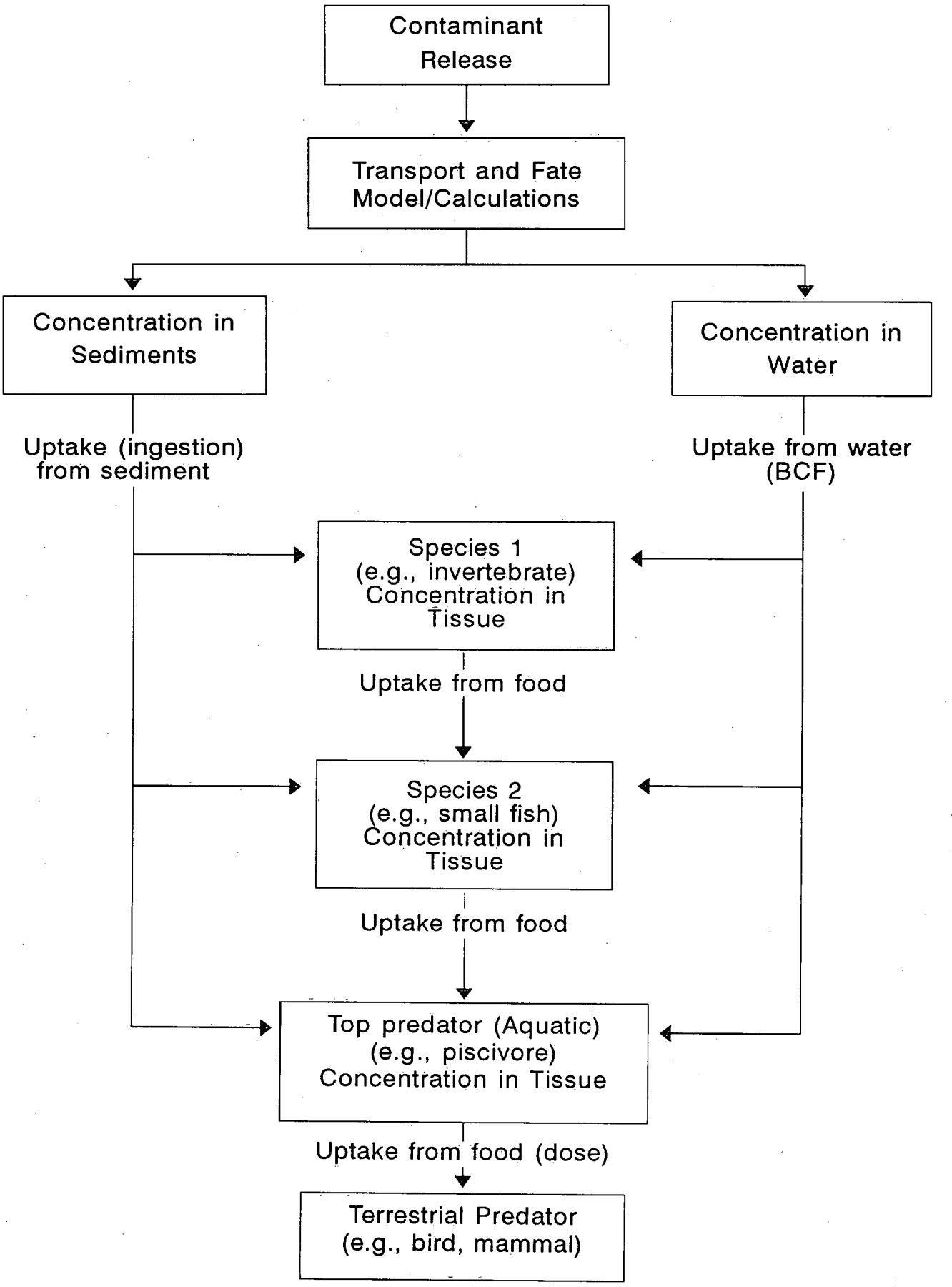


Figure 4.5. Exposure in food chains – (a) aquatic food chains.

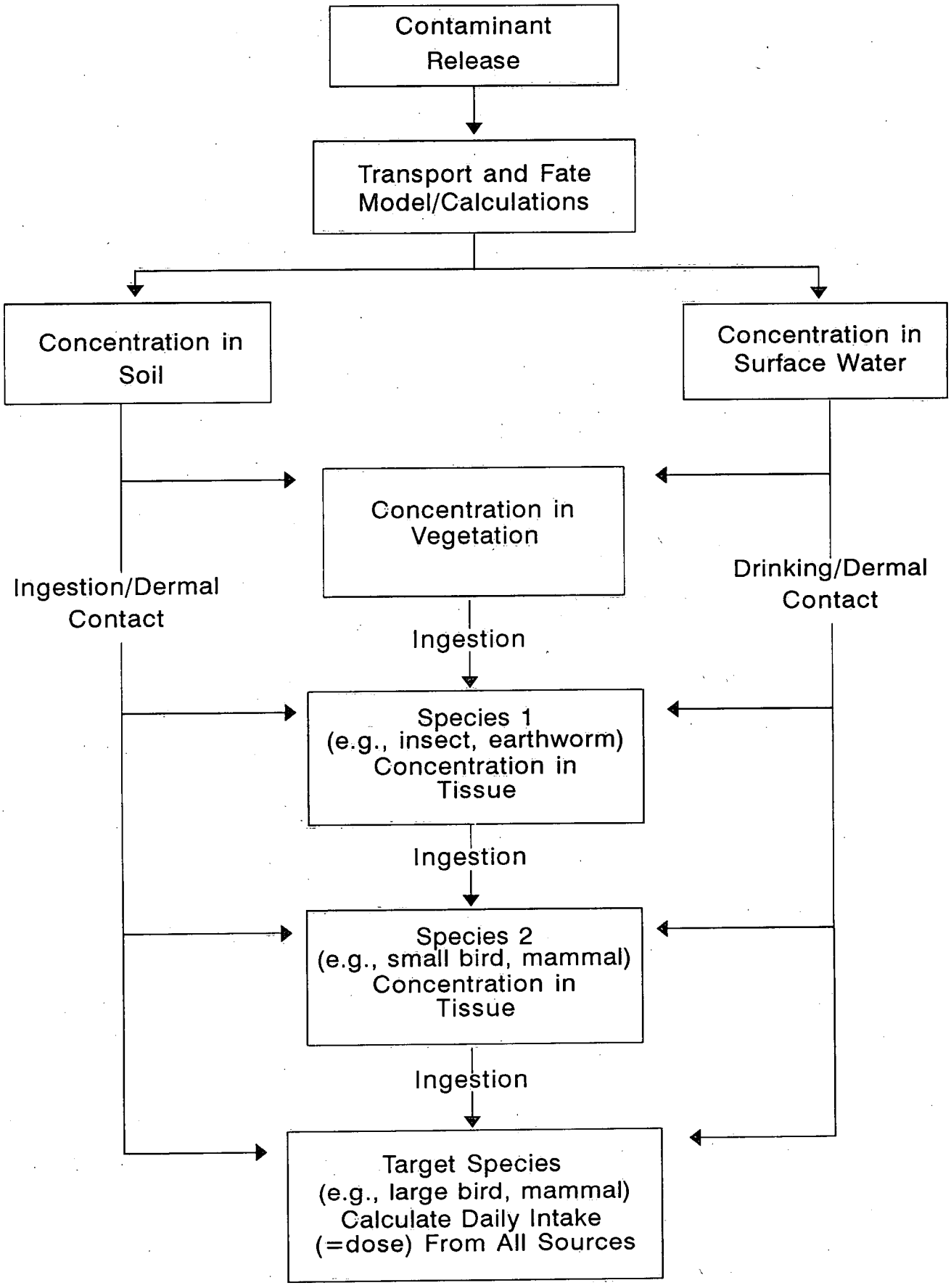


Figure 4.5. Exposure in food chains – (b) terrestrial food chains.

where:

k_1 is the rate of water uptake through the gill (L/kg/day);

k_2 is the rate of elimination via the gills to the water (1/day);

k_D is the rate of food consumption ((kg food/kg fish/day);

k_E is the rate of elimination (1/day);

k_G is the growth rate (/day);

k_M is the rate of metabolic breakdown of the contaminant, which is set to zero for persistent contaminants (1/day);

C_{WD} is the biologically available contaminant concentration in the water (mg/L);

C_F is the contaminant concentration in the fish (mg/kg fish); and

C_D is the average contaminant concentration in the fish's diet (mg/kg), calculated from a food-fraction-weighted average of the contaminant concentrations in diet organisms.

At steady state this simplifies to

$$C_F = \frac{(k_1 C_{WD} + k_D C_D)}{(k_2 + k_E + k_G + k_M)} \qquad [4.2]$$

or

$$C_F = BCF \times C_{WD} + BMF \times C_D \qquad [4.3]$$

where BCF and BMF are the bioconcentration factor $[k_1/(k_2+k_E+k_M+k_G)]$ and biomagnification factor $[k_D/(k_2+k_E+k_M+k_G)]$, respectively. Each of the rate parameters in equations 4.1 and 4.2 are derived from empirical equations which hold for many different species and are related only to a few simple inputs:the mass of the fish, its growth rate and diet preferences, water temperature, and the K_{ow} (octanol–water partition coefficient) of the contaminant (Gobas, in press). This makes these relationships generally applicable.

Once fish contaminant concentrations are estimated, the process is repeated for piscivorous birds and mammals. Though the theory and models of contaminant uptake are not so well developed for these groups, the problem is somewhat simpler in that only biomagnification, and not bioconcentration, needs to be considered. Clark et al. (1988) provide an example of a modelling approach for estimating contaminant concentrations in herring gulls. The eggs of birds are often the most convenient method of monitoring contaminants to calibrate these models; this assumes that the selected species is sufficiently abundant that sampling will not have a major ecological impact.

4.3.6 Terrestrial Receptor Exposure Quantification

4.3.6.1 Qualitative Techniques

Figure 4.5 demonstrates steps to consider for potential exposures via food chains. The SEAM (U.S. EPA 1988b) provides some useful questions for each of these steps, similar to those in Figure 4.2. Important food chains can be identified through the flow chart in Figure 4.3. In addition to these macro-organisms, there is an increasing interest in exposure of microbial communities, as these are an important terrestrial component.

4.3.6.2 Preliminary Quantitative Analyses

In terrestrial systems, exposure is expressed as dose, or the daily intake of contaminant. Both Urban and Cook (1986; U.S. EPA protocol for pesticide risk assessments) and Jones and Stokes (1991; California Department of Transport protocol for herbicide risk assessments) provide simple methods for calculating exposure of terrestrial birds and mammals. Urban and Cook (1986) provide empirical relationships between pesticide application rates and subsequent concentrations in forage plants. These relationships can be used to directly estimate the dose (daily intake of chemical) for herbivores. Kenaga (1980) provides relationships between chemical properties (e.g., solubility) and bioconcentration factors (BCF). These relationships could be used to estimate concentrations in herbivores and their predators from estimated concentrations in forage plants. These simple quantitative methods are at best approximate and rarely consider all exposure pathways.

4.3.6.3 Detailed Quantitative Analyses

Detailed models of contaminant uptake by terrestrial species are rare, and those that do exist have generally been adapted from human exposure models. As in aquatic uptake models, the first step is to construct a food chain or web which includes the species most likely to be exposed to the contaminant. There are

several important differences between aquatic and terrestrial food chain uptake models:

- Aquatic organisms are continuously exposed to dissolved contaminants in the water column; there is no counterpart to this exposure route in terrestrial systems.
- There are usually more exposure routes or pathways in terrestrial systems.
- The behaviour and spatial distribution of terrestrial organisms is usually more complex than that of aquatic organisms.

Because of these differences, estimating exposure is usually more difficult than in aquatic systems. Exposure routes for birds and mammals are ingestion of food, ingestion during grooming and preening, ingestion from drinking, absorption through the skin, and inhalation. The first three exposure routes are usually considered the most important, although the last two may be important directly after pesticide spraying. An uptake model must estimate uptake from most or all of these routes, and therefore requires

- estimates of concentrations in food/water/soil/air. The concentrations in food can be estimated by the model, as food items are generally the species in the food chain. However, these concentrations can also be measured directly in common plants or animals at the base of the food chain
- metabolic parameters (e.g., ingestion rates, clearance rates, contaminant absorption and depuration rates)
- behaviour (e.g., food habits or preferences, movement/migration/dispersal, potential avoidance behaviour)

The metabolic parameters control the fate of the contaminant in the organism, and contaminant transfer between trophic levels. Behaviour can determine the potential for uptake via different routes.

Three examples of uptake models specifically targeted to terrestrial ecosystems are described here and aquatic or human models could always be modified for terrestrial ecosystems. Tasca et al. (1989; cited in and reviewed by Pastorok and Sampson 1990) provide a food chain model designed for assessing risks from atmospheric emissions, but which could be adapted for exposure via other emissions or sources. The authors provide some standardized parameter values, particularly for metabolic rates. Menzie et al. (1992) compared modelling, bioassay, and field methods with regard to assessing conditions and risks to terrestrial biota at a Superfund site contaminated with pesticides. This paper should be required reading for anyone undertaking an ecological risk assessment of a terrestrial ecosystem. The bottom line is that models should be used only as screening methods to evaluate potential exposure; field methods are essential to accurately assess exposure. Pastorok and Sampson (1990) state that the U.S. EPA is currently developing a Terrestrial Ecosystem Exposure Assessment Model (TEEAM) which focuses on pesticide uptake by birds. U.S. EPA (1991; especially Appendix C) contains a good discussion of uncertainties, deficiencies, and difficulties in estimating exposure in terrestrial ecosystems. The difficulties/deficiencies revolved around the differences between aquatic and terrestrial uptake models noted above. The consensus of the discussion participants was that existing exposure models were not yet adequate for general use, but that continued development of such models was an important need for risk assessments.

4.3.7 Uncertainty Analysis

U.S. EPA (1988b) provides a good taxonomy of uncertainty for exposure assessments. The sources of uncertainty include

1. Input Variable Uncertainty
   - spatial variation in parameters (e.g., hydraulic conductivity in soils)
   - lack of data for key parameters
2. Model Structural Uncertainty
   - model simplification (e.g., homogeneous soils)
   - averaging hydraulic conductivities across different soil types (this creates errors, better to model as separate layers)
   - dispersion assumptions (e.g., depth of aquifers)
   - numerical versus analytical models
   - exclusion or simplification of degradation processes
   - selecting appropriate time step
   - shape of the contaminant source
   - assumption that the system is at steady state
   - appropriate dimensionality (1-3D)
3. Scenario Uncertainty

- combining conservative assumptions in many components may lead to overly conservative projections

- quantitative uncertainty estimates for release scenarios are usually not available

There are several approaches for dealing with these sources of uncertainty. Three common methods are sensitivity analyses, Monte Carlo simulations, and using monitoring data for model calibration. Qualitative and quantitative sensitivity analyses are very important to give the modeller a good understanding of the mathematical sensitivity of his/her model. With Monte Carlo analyses, one can specify uncertain input parameters as distributions rather than fixed values, and assess the effects of input variable uncertainty. However, this uncertainty can be substantial. One Monte Carlo study found that with no constraints on input parameter distributions (i.e., no data), estimates of the velocity of a solute varied over four orders of magnitude (Mercer et al., 1985). Some data are required to specify the input parameter distributions; otherwise the uncertainty in outputs is purely a function of the assumptions made about the uncertainty of input parameter distributions. Monte Carlo analyses must be careful to consider the correlation among parameters; assuming that all parameter distributions are independent will overestimate the level of uncertainty. Fordham and Reagan (1991) provide an excellent example of the application of Monte Carlo analyses to an ecological risk assessment at a hazardous waste site.

Monitoring data are invaluable for reducing uncertainty through model calibration. Biases in model output can also be corrected with monitoring data. Monitoring data are more useful, however, for reducing uncertainty in air and surface water modelling than for groundwater models. This is because of the time lags in groundwater movement. A groundwater model's predictions of future changes in water quality may be correct, but the contaminant plume may not have reached the point of sampling.

4.4 Conclusions

The use of successively more sophisticated approaches (i.e., qualitative methods, preliminary quantitative methods, detailed quantitative models) helps to focus on the critical processes and thereby reduce the uncertainty (and expense) of the overall exposure assessment. Decisions regarding the level of detail of exposure assessments should be made in concert with analogous decisions for receptor and hazard assessments. The levels of precision of different components of an ecological risk assessment should be more or less congruent. There is no point in having a very detailed quantitative model for exposures if the dose–response relationships used for the hazard assessment have enormous uncertainty. The importance of monitoring data to anchor exposure model projections in reality cannot be overemphasized. Finally, the modelling of exposure is an evolving science; it is very important that analysts keep abreast of current progress (i.e., new tools, field tests of existing approaches, model critiques, and intercomparisons) to select the most appropriate approach for the particular contaminants and site of concern.

There is a pressing need to attempt to validate simple exposure models at existing hazardous waste sites through case studies. The work done by Menzie et al. (1992) is an excellent example of the learning provided by this kind of exercise.

5.0 RECEPTOR CHARACTERIZATION

5.1 Definition and Overview

The term receptor, as used in this section, refers to an ecosystem component that is or may be adversely affected by a pollutant or other stress emanating from a contaminated site. Receptors may include biological or abiotic (e.g., air or water quality) components. For the purposes of this report, humans are not considered an ecological receptor.

Early in the ecological risk assessment process, it is essential that specific, well-articulated goals be developed (see Section 3.0). There should be a clear link between ecological risk assessment goals and the approach to receptor characterization. For example, to develop site-specific remediation objectives for a contaminated site, receptor characterization should focus not only on identifying sensitive or vulnerable receptors, but also on quantifying current conditions so that follow-up studies can determine whether or not the selected remedial actions produced the desired results.

Receptor characterization generally involves a tiered approach, as proposed in Section 2.0. First, preliminary screening activities are used to help identify ecosystem components most likely to be affected by those stressors believed to be present at the contaminated site. At this initial phase there is a continual interplay between preliminary exposure information and identification of potential receptor habitats and species. This screening-level assessment helps in selecting a starting set of assessment and measurement endpoints for both receptor characterization (see Section 5.2) and hazard assessment (see Section 6.3). In later tiers, efforts are concentrated on refining the list of selected endpoints, collecting applicable information through gathering field data, risk modelling, or laboratory investigations.

Considerable interchange is required between receptor characterization and hazard assessment, and investigators should capitalize on this interdependence. Review of Sections 5.0 and 6.0 will reveal that they have the same basic structural organization with differing emphasis on data use. As previously indicated, it is important that information generated by these two components of ecological risk assessment be complementary. Receptor characterization largely influences selection of hazard assessment techniques.

The main goal of this section is to summarize receptor characterization procedures. From a regulatory standpoint, the preferred strategy would be to always apply a uniform set of standard, rigorous techniques to receptor characterization at any specific location. Unfortunately, due to the natural variability in environmental systems, this is not possible. Thus, the approach proposed herein (Section 8.0) is at once both comprehensive and flexible. Ultimately, however, the proposed approach to receptor characterization relies heavily on expert judgement to cope with site-specific ecological complexity.

In preparing this framework, the following literature was reviewed: Barnthouse et al. (1986), Burmaster et al. (1991), Burns et al. (1990), Eschenroeder et al. (1980), Norton et al. (1988), O'Neill et al. (1986), Onishi et al. (1982), Parkhurst et al. (1990), Pastorok and Sampson (1990), Ramm (1988), Rodier (1987), Suter et al. (1986), Suter (1986), U.S. EPA OTS (1984), U.S. EPA (1991), U.S. DOI (1987), and Urban and Cook (1986). None of these authors present a methodical, systematic approach to identifying or characterizing receptors. In most cases, authors indicate that population-level receptor information is required in the ecological risk assessment process, but few indicate specifically how populations are to be selected or what population parameters are important. Usually, authors simply state that receptor characterization is to be accomplished and infer that some body of experts will provide the needed data. The key elements of receptor characterization are presented in Figure 5.1.

5.2 Qualitative Characterization

The main purpose of initial screening is to simplify the task of receptor characterization by limiting consideration to those habitats and species most likely to be affected by stressors associated with the contaminated site. Potential receptor habitats (aquatic, terrestrial) and ecosystem components (individuals, populations, communities) are identified through a process involving consideration of spatial and temporal overlaps between stressors from the contaminated site and components of adjacent and nearby ecosystems. Initial screening is usually based on a review of available data and information, field reconnaissance, and a qualitative evaluation of potential effects. Screening may be performed using a combination of expert judgement supplemented by computer tools such as geographic information systems (GIS) loaded with relevant data for the area of concern. During screening, an attempt should be made to catalogue all potentially significant or sensitive receptors at or near the contaminated site. The objectives of ecological risk assessment do not include generation of detailed habitat, species, and community data. Collection of this information, if required, can usually be done in later tiers or be extrapolated from similar systems.

Normally, the main focus of receptor characterization is on indigenous populations of living resources such as animals and plants. It is also important, though, to identify natural ecosystem processes (e.g., production, decomposition) that may be affected by the stressors, and to consider migratory species. Natural ecosystem processes are important since changes in ecosystem structure or function may, in turn, adversely affect the ability of ecosystems to generate products of value to humans (e.g., fish, fiber) or perform vital functions (e.g., flood and erosion protection). Migratory species, though only passing through an area for a short time, may be highly concentrated in particular habitats (e.g., bird staging areas along a migration route, fish spawning areas), which renders them potentially vulnerable to population level impacts. Contaminant loads in migratory species cannot generally be pinpointed to a particular source, unless this source has a unique signature. The juveniles of migratory species which are produced near the contaminated site are more comparable to an indigenous population, and their tissue concentrations are more likely to be the result of local sources. Contaminants can, however, be passed from females to their offspring through eggs, and this type of confounding influence should be considered.

Once vulnerable ecosystems, populations, and processes have been identified, they can be expressed as structured impact hypotheses (Bernard et al., 1990). One purpose of these hypotheses is to clearly illustrate linkages between stressors from the contaminated site and changes in receptors. The process of developing these hypotheses helps in selecting endpoints for the ecological risk assessment analysis.

There is considerable confusion in the literature pertaining to the issue of how endpoints are selected. To help clarify this matter, Suter (1990a) proposed distinguishing between two types - *assessment endpoints* (which have ecological, societal, and legislative or regulatory relevance) and *measurement endpoints* (which are surrogates that correspond to, or are predictive of, an assessment endpoint) (see also Section 6.3 and Table 6.1). In Canadian impact assessment terminology, assessment endpoints are typically referred to as valued ecosystem components (VECs) (Beanlands and Duinker, 1983). Whenever endpoints

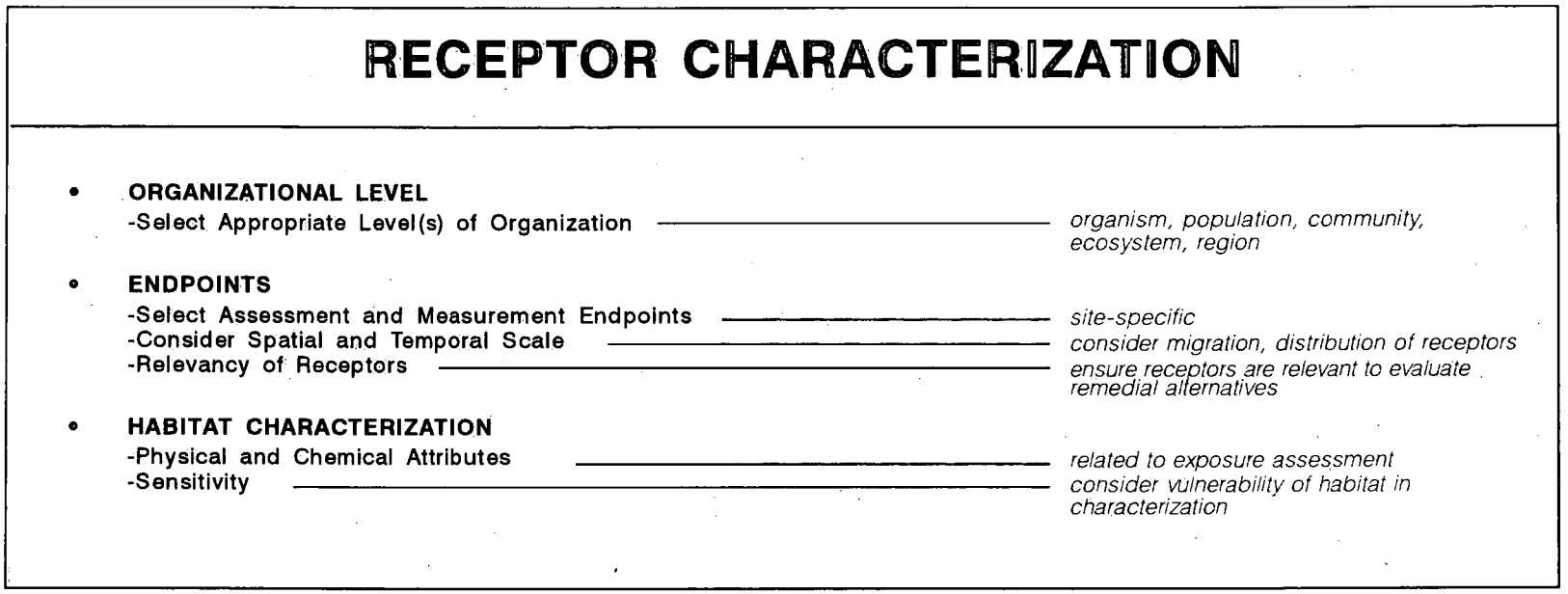


Figure 5.1. Steps to assess key elements of receptor characterization.

are selected, there is a trade-off between selecting those that are significant and those that are practical.

5.3 Quantitative Assessment

Once a preliminary set of measurement endpoints have been selected, then a program should be established for gathering the data and information needed for the ecological risk assessment. This program should identify the minimum data requirements, and there should be a clear rationale for proposed measurement parameters. The field sampling program should be designed to generate data of sufficient quality and precision that it will be suitable for the intended type of data analysis and interpretation. Before field work begins, a quality assurance and quality control program should be developed to guide sample collection and analysis.

To meet the ecological risk assessment objectives, it may be necessary in some cases to supplement the field program with computer modelling activities. This need should be identified prior to field work, since data and information may need to be collected in the field to support modelling activities.

In the following three sections, potential parameters are discussed that may be useful in receptor characterization, depending on (1) the ecological risk assessment objectives, (2) the selected level of analysis, and (3) site-specific conditions. No attempt is made to distinguish between parameters that apply to terrestrial or aquatic habitats. Standard measurement methods are not recounted here. Rather, the emphasis in the following sections is on offering a listing of potentially useful parameters that may be valuable in receptor characterization.

5.3.1 Habitat Characteristics

There are two main objectives for collecting habitat information. The first is to help describe species niches for the populations of concern. The second is to generate background data on structural/physical and chemical environmental attributes that may affect biotic responses to the stressors. The latter is largely covered as exposure assessment (Section 4.0).

Structural/physical characteristics include geographic proximity of each sensitive habitat to the contaminated site; local topography and three-dimensional configuration of the habitat at risk; watershed characteristics such as surface cover, soils, and geology; surface water and groundwater hydrology; and weather and climate data, especially information on conditions that can affect population levels of resident species (e.g., high rainfall, drought).

As well, if there have been physical habitat alterations, these should be noted, along with details concerning availability and location of suitable reference sites. Ideal reference sites are sites of similar habitat upstream from a hazardous waste site or on upstream tributaries unaffected by the contaminants of concern. Particularly sensitive habitats should be identified. These may be locations with relatively high exposures (e.g., wetlands potentially retaining released contaminants for long periods), sites with particularly sensitive life history stages (e.g., fish spawning or rearing areas, ground nesting areas of birds), or habitats of local or regional ecological significance (e.g., staging areas for waterfowl).

5.3.2 Populations and Species

The scope of most ecological risk assessments is limited to one or several species and occasionally to particular populations. Undoubtedly there are many underlying reasons for this emphasis, but they appear to be related to simplicity and ease, economics, and lack of data characterizing habitat and resident species.

As with ecosystems and communities, characterization of receptor species and populations can employ both structural and functional measures. These measures are quite different, though, from the ones proposed for use at the higher levels of ecological organization. As emphasized earlier, final choice of which attributes to measure should be made by experts familiar with the contaminated site, since there are a great many site-specific factors that can influence the selection process. The following attempts to outline most of the data/information options available for selection.

Structural Attributes

Perhaps the simplest, most accessible information is a list of species found at and around the contaminated site. These data are derived from taxonomic surveys which yield information about species presence/absence. Developing such a listing is the classic, routine first step in most biological investigations. While this information is indeed interesting and useful, for the purposes of an ecological risk assessment, it may be unnecessary to develop a full inventory of all species present. Instead, it may be more worthwhile to focus on identifying species that are

- potentially sensitive to the stressors from the contaminated site
- recognized by the federal or provincial government as threatened or endangered

- migratory birds or fish, where a significant proportion of the population is concentrated in the vicinity of the site during certain periods
- dominant within local biological communities, or functioning as keystone species within nearby ecosystems
- recognized as good indicators or surrogate species
- are of aesthetic value or are valued by the local population
- are of recreational or commercial importance

When conducting this investigation, it is important to explore whether or not migratory species use this area, perhaps at times other than when the initial investigation is performed.

Some useful structural descriptors for this level of biological organization include overall population density, mass of individuals, number and distribution of populations within a community, and age-class structure. Many of these measures are useful for hazard assessment (Section 6.0) in estimation of the percentage of the population that may be exposed to and harmed by stressors from the contaminated site.

Identifying whether or not a species listed as threatened or endangered is present at the site is relatively straightforward, but determining which of the many present species are potentially sensitive to the stressors is far more complicated and is the subject of Section 6.0. Rare species may be at the extreme end of their natural range, may migrate through an area only at certain periods, or may be declining due to natural or anthropogenic causes. The latter cause is probably the most significant, since further impacts from hazardous wastes could move the species into a threatened status. When selecting a list of species for inclusion in receptor characterization activities, it is preferable to risk making a Type II error (treating an insensitive species as if it were sensitive) than to overlook a truly sensitive species.

While there is great value in being able to distinguish dominant and keystone species at or near the contaminated site, such information is typically unavailable for most ecosystems. Nevertheless, these species will likely play a disproportionately large role in determining ecosystem responses, and they may be partially responsible for causing the system to respond in a nonlinear manner to applied stresses.

For all species identified as assessment or measurement endpoints, it is important to have life history data. This means providing information such as the proportion of mature females, fecundity per mature female, and cumulative probability of survival from the age of reproductive maturity to each future age. Such information will permit modelling population-level responses to stressors from the contaminated site (Emlen, 1989).

As part of exposure assessment (Section 4.0), tissue samples from biota at the site and at reference locations may indicate background and existing concentrations of stressor chemicals and aid in identifying receptors. This can also be very helpful in validating (or invalidating) the predictions of Level 2 exposure models (Menzie et al. 1992). In the case of threatened or endangered species, however, it may not be possible to acquire tissue samples without causing undue environmental impact. For migratory species, tissue samples of juveniles reared near the site will minimize (though not necessarily eliminate) confounding contaminatory influences from other parts of the species range.

Functional Attributes

There are many functional characteristics of species and populations that can be measured as part of receptor characterization as well as part of hazard assessment. The most important guideline in choosing among options is to ensure that each selected parameter is essential to the ecological risk assessment and is backed up by a clear rationale.

Some of the available functional measures for species and populations include food requirements and ingestion rates, bioaccumulation potential, and intrinsic rate of increase. Then there are a whole set of observations pertaining to factors such as the range of behavioural capabilities, activity patterns and habitat requirements. Finally, layered over all of these functional attributes are key questions relating to natural variability in both time and space. For example, do activity patterns and habitat requirements vary seasonally or with different phases of the life cycle?

5.3.3 Ecosystems and Communities

If specific ecosystems or communities have been identified as assessment endpoints, then the first step in characterizing them is to provide precise information on their location and specific type. The exact suite of measurements to describe the receptor will vary according to whether the ecosystem is a forest, grassland, wetland, floodplain, agroecosystem, stream, river, pond, lake, and so forth. Regardless of the ecosystem type, though, three types of information and data will need to be provided:

1. structural attributes of the ecosystem or community
2. functional properties
3. local, regional, or provincial significance

Structural Attributes

The main structural characteristics that may prove useful in describing an ecosystem receptor are biodiversity, biomass (by trophic level), functional guilds, successional stages present, and trophic linkages. None of these parameters are easily measured, so before any of them are selected for quantification, there should be a well-designed program to guide data collection and analysis, supported by a distinct need for the data.

Functional Attributes

Key functional attributes of ecosystems that may be relevant to ecological risk assessment include measurements of primary production, respiration, decomposition, nutrient cycling, and resilience. Again, some of these parameters are difficult to measure, so there should be in place a well-designed program to guide data collection and analysis, supported by a distinct need for the resulting data. However, since ecosystem functions such as nutrient cycling may be at risk before populations (Schaeffer, 1991), it is important to give adequate consideration to measuring ecosystem functions.

Local or Regional Significance

Data describing the frequency of occurrence of a particular type of ecosystem both locally and regionally help to provide a quantitative measure of uniqueness. In this regard, one must also consider the condition of the particular ecosystem near the site, relative to other local or regional examples of the same ecosystem type (Suter, 1990).

5.4 Discussion and Conclusions

As Parkhurst et al. (1990) point out, even the most comprehensive ecological risk assessment protocol will have little value if its complex procedures or its extensive data requirements prevent it from being implemented. As well, the complexity of most ecosystems is an effective barrier to creating a simple, yet thorough method for characterizing receptors, whether they be ecosystems or individual species. The tiered approach described in Section 2.0 extends both the breadth and depth of the receptor characterization; a wider range of species and/or communities may be examined, a more extensive area may be studied, and/or a more accurate quantitative assessment of measurement endpoints is obtained.

A preliminary framework that serves as a decision-support tool for experts who are charged with receptor characterization is provided in Figure 5.1. All of the parameters listed above can be measured with some degree of success using current methods. As well, some of the methods (e.g., taxonomic surveys) are in routine daily use throughout North America.

There are a number of key questions pertaining to receptor characterization that need to receive careful thought and consideration when designing an information and data collection program. In hierarchical order, they are as follows.

Organizational Level

What is the appropriate level to work at organism, population, community, ecosystem, region, planet?

Endpoints

How does the scale (spatial extent and resolution, temporal horizon and time-step) selected for the ecological risk assessment affect the selection of endpoints?

How does the suite of stressors selected for the ecological risk assessment affect the selection of endpoints?

Are there specific endpoints relevant to ecological risk assessments designed to evaluate remedial alternatives?

How can ecosystem resilience be measured and expressed? (or can it be?)

Variability in Space and Time (links receptor characterization to hazard assessment)

How should the distribution of individual organisms and their responses to the stressor be quantified?

Can all the responses be quantified?

Environmental Factors (links receptor characterization to exposure assessment)

What physical and chemical attributes of the environment affect exposure of biota to stressors?

What role does interaction between chemical and nonchemical (e.g., habitat fragmentation)

stressors play in affecting populations, communities, and ecosystems? Must cumulative effects be taken into account in ecological risk assessment?

What ecological connections exist between the site and adjacent habitats?

Uncertainty

What is an acceptable level of uncertainty in community composition and function for ecolo-gical risk assessment? In other words, how certain must information be concerning behavioural responses, life cycle patterns, population spatial distribution, and so forth? Is this level of uncertainty even acceptable?

6.0 HAZARD ASSESSMENT

6.1 Definition of Hazard Assessment

Hazard assessment describes the relationship between the contaminant or contaminants of concern and the most important ecological endpoints. During the last decade, environmental hazard assessment has been the dominant approach for assessing effects on nonhuman organisms (Suter, 1990b). According to Suter, hazard assessment is based primarily on the results of discussions at the first Pellston workshop (Pellston One) and the Association of Standard Testing and Materials (ASTM) standard for hazard assessment (E 1023-84). Within the context of ecological risk assessment, hazard assessment is usually accomplished by the measurement of toxicity of a substance to one or more species through toxicity testing. In this section, however, a number of other approaches (i.e., different levels of biological organization) which can be used are also described.

6.2 Approaches to Hazard Assessment

Hazard identification is the first step of hazard assessment, and follows from the planning phase of the ecological risk assessment (Section 3.0). Hazard identification qualitatively evaluates the relationship between a stressor and adverse biological effects. Ecological components affected or potentially affected by the contaminated site are identified in the receptor characterization. This information is used to select the best method for the hazard assessment. The objective is to link the contaminant (or mixture of contaminants) to the biological response(s). All existing site data should be reviewed with this objective in mind. Literature reviews, scientific publications, and useful sources of information on the toxicity of specific contaminants help guide an investigation to identify the likely mechanisms of toxicity. Literature information is useful for qualitative assessments. Hazard assessment data collected for a specific contaminated site are useful for semi-quantitative and quantitative assessments.

Once the focus of the hazard assessment has been determined, the next step is to develop a sampling and testing plan to assess the toxicity of site contaminants to potentially exposed populations and communities of plants and animals. Time, money, and personnel are always limited, so it is important to focus testing effort for hazard assessment on the sites and samples that need the most attention. It is not reasonable to assume that a single, rigid hazard assessment procedure will apply equally well to a range of contaminated sites. Obviously, a successful hazard assessment scheme tailors the testing program based on existing data, receptor characterization, and exposure assessment. A list of hazard assessment components is provided in Figure 6.1.

At each level, or tier, the decision to make is whether to proceed and how best to proceed based on the data collected up to that point. For example, at a contaminated site where leachate drains into a small stream with salmonid fish, the first level may involve collecting the leachate and testing a salmonid species for acute toxicity. If the short-term tests indicate that the fish survive, but show behavioural stress responses (e.g., swimming erratically, disequilibrium), the next level may involve a test that looks at behavioural responses, as potentially more sensitive measurement endpoints. Alternatively, if severe effects are documented in the first level, there may be no need for further testing to document the problem at the contaminated site.

Tiered assessments in hazard assessment can also be designed to focus on particular technical or public concerns. For example, the first level of assessment might involve a recreational fish population survey to determine population health in a potentially impacted stream near a contaminated site versus a reference area. If the survey finds that there are no differences in fish abundance, but that the fish downstream of the contaminated site have reduced biomass, the second level might involve looking at the availability of food supply to the fish. Invertebrate toxicity tests conducted at leachate concentrations similar to those in the field could also be conducted. Decisions regarding the order for determining hazard will be site-specific, depending on the information available and the key concerns.

6.3 Hazard Assessment Endpoints

6.3.1 Definitions of Assessment and Measurement Endpoints

The U.S. EPA makes a very important and useful distinction between assessment endpoints and measurement endpoints (Suter, 1989):

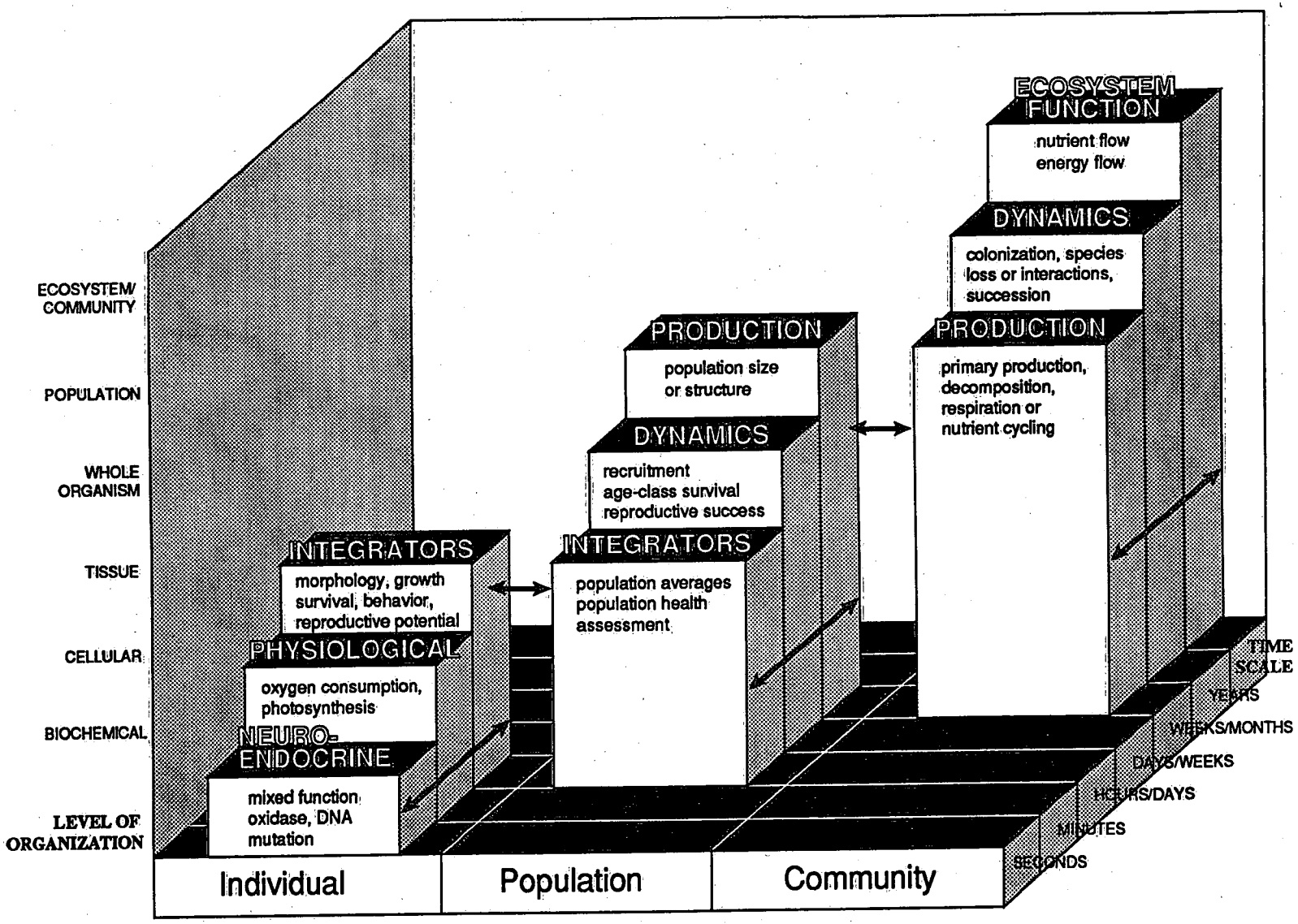


Figure 6.1. Hazard assessment components. The lowest impact levels, represented by the smallest boxes, respond to a low level of stress, have the fastest response time, the most reversibility, best early warning potential, and worst diagnostic potential. The highest impact levels, represented by the largest boxes, respond to the largest amount of stress, have the least reversibility, the lowest response time, the best diagnostic potential, and the lowest early warning potential. Arrows indicate direction of integration and prediction.

Assessment endpoints [emphasis added] are formal expressions of the actual environmental values that are to be protected. Ecological assessments . . . are concerned with describing the existing effects of a hazardous waste site on the environment. Therefore, the assessment endpoints are environmental characteristics, which, if they were found to be significantly affected, would indicate a need for remediation.

A *measurement endpoint* [emphasis added] is a quantitative expression of an observed or measured effect of the hazard; it is a measurable environmental characteristic that is related to the valued characteristic chosen as an assessment endpoint.

When the assessment and measurement endpoint are the same, the analysis of the relationship between the stressor and the response is straightforward. Because some potential assessment endpoints are not observable or measurable, and because assessments are often limited to using standard data, measurement endpoints are often surrogates for assessment endpoints. In this case, the quantitative relationship between the two needs to be established, and then extrapolations are used to predict changes in the assessment endpoint. (Extrapolation methods are described in Section 6.6.) In some cases, the quantitative relationship between the assessment and measurement endpoint is not known, and qualitative inferences must be made during risk characterization (see Section 7.0).

According to Suter (1989), in an unfortunately large number of monitoring programs, there are measurement endpoints, but the assessment endpoints are not clearly defined - which wastes time and effort. This can be alleviated in the planning stages of an ecological risk assessment. Essentially, assessment endpoints describe the effects that drive decision making (e.g., reduction in important populations like fish or unacceptable alterations to community structure). The question "Why is this measurement being taken?" needs to be addressed in the planning stage. If the hazard assessment is to be a useful part of the risk assessment, then assessment and measurement endpoints should be selected so as to be useful for prediction and relevant to the selection of remedial actions. Suter (1989) discusses criteria for good assessment and measurement endpoints, as provided in Table 6.1.

Table 6.1. Criteria for Good Assessment and Measurement Endpoints for Hazard Assessment (taken from Suter, 1989)

Criteria for Assessment Endpoint
• social relevance • biological relevance • unambiguous operational definition • measurable or predictable • susceptible to the hazard • logically relevant to the decision
Criteria for Measurement Endpoint
• corresponds to, or is predictive of, an assessment endpoint • readily measured • appropriate to the scale of the site • appropriate to the exposure pathway • appropriate temporal dynamics • low natural variability • diagnostic • broadly applicable • standard • existing data series

It is important to make a distinction between assessment and measurement endpoints, and be clear on their applicability to a particular contaminated site. In Sections 6.3.2 and 6.3.3, assessment and measurement endpoints are discussed with respect to their applicability to hazard assessment, but this concept applies equally well to receptor characterization (Section 5.0). Further details on hazard assessment methods are provided in Section 6.4.

6.3.2 Use of Assessment Endpoints

Assessment endpoints are generally at the population level and sometimes at the community or ecosystem level (see Figure 6.1). Responses at lower levels of biological organization are generally considered to have less social or biological significance. Local extinction is an example of a population-level assessment endpoint with great significance. Suter (1989) recommends using population-level endpoints for contaminated sites when

- individuals of a valued species occur on the site in exposed communities
- death or injury of those individuals are believed to cause significant effects on the population as a whole

Changes in the biological community at or near a contaminated site can have major significance and be used as assessment endpoints. For example, changes in community type, such as trophic status of a lake, which may in turn affect recreational fisheries, can be given clear operational definitions (Suter, 1989). Community-level assessment endpoints are applicable to ecological risk assessments for contaminated sites where a valued community exists on the site or receives site discharges (e.g., leachate), particularly when the affected portion of the community represents a significant portion of the entire community.

Ecosystem-level endpoints are rarely used in ecological risk assessments, primarily because they are challenging to predict or define. Both energetic and nutrient cycling parameters are sensitive to chemical perturbations, but few generalizations can be made in regard to their applications to the detection of stress effects in the field (Sheehan, 1987). According to Suter (1989), the only ecosystem property that is generally useful for contaminated site assessment is productive potential. However, the Netherlands (Denneman and van Gestel, 1990) uses "serious danger for soil ecosystems" as an assessment endpoint and discusses possible measurement endpoints. The particular ecosystem of interest will determine whether practical measurement endpoints exist at the ecosystem level.

6.3.3 Use of Measurement Endpoints

Measurement endpoints are generally at the individual level or population level and sometimes at the community or ecosystem level. Toxicity tests are widely used for hazard assessment, and the measurement endpoints are usually statistical summaries of the responses of test organisms (e.g., LC50, EC50, NOEC). Toxicity tests are further discussed in Section 6.5. An approach that uses a battery of tests (i.e., three or more toxicity tests) is recommended, and tests relevant to the site must be chosen. Other individual measures such as behaviour, growth, biomarkers, and fecundity can also be used as measurement endpoints. Mortality, reproduction, and growth data can be related to population-level assessment endpoints using population models (Section 7.0).

The standard population endpoints (abundance, biomass, etc.) are widely used for ecological studies and play a role in ecological risk assessment. According to Suter (1989), the scale of population responses is typically appropriate for very large waste sites or for populations with small ranges. Effects related to the contaminated site will be obscured by population-level measurements because of movement of individuals within the population.

Community measures have been standardized over the years to include endpoints such as species richness, diversity, and evenness/dominance; these measures summarize the data collected in ecological surveys. According to Suter (1989), the problem comes in relating these measures to assessment endpoints. Usually, the community assessment slips into population level assessment because changes in species diversity and community indices are driven by presence/ absence of populations. Community-level endpoints are useful, however, at sites where community alterations are striking. Indices of community quality can be useful in qualitative assessments, but field investigation through statistical evaluation is best. In addition, assessment of microbial communities and populations should not be overlooked. Measurement endpoints such as enzyme activity and oxygen consumption/ respiration are integrative and therefore provide information at the community and, sometimes, population level.

Ecosystem measurement endpoints such as nutrient and energy cycling are linked to the ecosystem assessment endpoint, production potential. However, the social value placed on community and population-level endpoints usually gets greater emphasis. Also, the scale of ecosystem effects is usually too large for a contaminated site, making measurements difficult to put into context.

6.4 Hazard Assessment Components

There is an overwhelming amount of information available on hazard assessment. Assessment of the impacts of contaminated sites are usually accomplished through toxicity testing, in some cases augmented with in situ community-level measurements. Toxicity tests are widely recognized as an assessment tool, but it is important to establish the ecological significance of sublethal effects and conduct field validation of toxicity test methods. This section describes various components of hazard assessment and their significance, and Section 6.5 summarizes actual hazard assessment methods. To organize this section, hazard assessment approaches have been categorized into levels of biological organization (Figure 6.1) similar to those described for receptor characterization. Obviously, these two components need to be compatible.

Levels of organization of hazard assessment can be categorized as individual, population, and community measurements. Within each of these, there are various levels of stress response, with different time spans and significance. For example, in Figure 6.1, the neuroendocrine changes are the most reversible and have the least diagnostic potential of any of the individual level measures; growth or survival are less reversible and more significant. The hazard assessment components outlined in Figure 6.1 provide the organization for Section 6.0.

6.4.1 Physiological Responses

The measurement of changes in the physiological responses of individual organisms forms an important component of any hazard assessment. Some biochemical responses can provide direct information on contaminant-induced changes, such as the induction of metallothionein or metallothionein-like proteins or changes in blood enzymes related to specific contaminant exposures. Other responses provide indirect information describing physiological status or nonspecific responses to foreign chemicals, such as changes in adenylate energy charge. Indirect changes in haematology, such as decreases in haematocrit, leucocrit, and mean corpuscular volume, and increases in haemoglobin concentration have also been used to characterize contaminant effects. For physiological responses to be useful measurements of biological effect in pollution studies, they should fulfil most of the following criteria (Widdows, 1985):

- they should be sensitive to environmental stress and pollution and have a large scope for response throughout the range from optimal to lethal conditions
- they should reflect a quantitative or other-wise predictable relationship with the toxicant
- they should have a relatively short response time, on the order of hours to weeks, so that the toxicant impact may be detected in its incipient stages
- they should represent nonspecific (general) responses to the sum of environmental stimuli, thus providing measurements of the overall impact of environmental change and complementing the more contaminant-specific responses at the cellular level
- they should be measurable with precision and with a high "signal to noise" ratio so that the effect of pollution may be detected above the "noise" of general variability
- they should have ecological relevance and be shown to be related to adverse or damaging effects on the population.

Perhaps the greatest potential weakness in the application of physiological techniques in biological effects monitoring concerns their variability (Bayne, 1985). Variability may be attributable to a range of sources such as seasonality, reproductive status, and test conditions. Variability among individuals is not well studied.

Examples of potential physiological endpoints are provided in Table 6.2. *Biomarkers* (indicators of exposure on a biochemical or cellular basis) include body burdens, indicators of DNA damage, stress proteins histological changes, and biochemical indicators of reproductive or bioenergetic status. Most of these measures demonstrate exposure, not effects. Although cellular and biochemical responses are the lowest level at which contaminant effects can be detected, these effects are also the most reversible and the least likely to exert effects at the community level. Biomarkers are more useful to look at the mechanisms of toxicity, as opposed to indicators of toxicity.

6.4.2 Individual Integrators

The organismic level of biological organization is a reasonable compromise in sensitivity and ecological interpretation relative to the biochemical/cellular level and the population and community levels (Figure 6.1). Survival is one of the primary concerns for hazard assessment, partly because it is easily measured; chronic survival is also important, but there are few methodologies for assessments of chronic effects. Sublethal effects at the individual level are generally biochemical in origin and expressed by histological,

Table 6.2. Listing of Examples of Potential Endpoints for Hazard Assessment (adapted from Power et al., 1991)

Response Level	Description	Parameters	Specific Examples (where applicable)
Physiological	Primary Metabolic Impact	Enzyme activities	Mixed function oxidase induction
		Respiration	
		Photosynthesis	
		Enzyme activities	
		Excretion	
	Primary Metabolic Responses	Metabolic rate	Adenylate energy charge
		Hematology	Hematocrit, leucocrit, hemoglobin
		Pigmentation	
		Osmoregulation	
		Ionoregulation	
		Hormonal changes	Changes in estradiol, testosterone
Individual Integrators	Survival		LC50, LD50, NOEL
	Growth	Feeding rate/nutrition	
		Scope for growth	
		Net growth efficiency	
		Body/organ weights	Liver and spleen changes
		Developmental rate/stages	Changes in sexual maturation
	Reproduction	Sexual maturation	
		Gamete viability/fertility	
		Larval development	
		Brood size/fecundity	NOEC
		Frequency of reproduction	
	Behavior	Sensory capacity	
		Rhythmic activities	Ventilatory/cough response
		Motor activity	Burrowing
		Learning/motivation	
		Avoidance/attraction	
		Reproductive behavior	
	Histopathology	Abnormal growths	
		Abnormal histological changes	Neoplasms/tumors, tissue somatic indices
Dynamics	Behavior	Recolonization/migration	
		Aggression/predation	
		Mating	
	Population Integrators	Age-class survival	
		Extinction	
		Reproductive success	
		Density/Abundance	
		Biomass	
		Productive capability	
	Community Integrators	Diversity	
		Pollution indices	
		Species richness	
		Succession	
		Nutrient cycling	
		Energy flow	
		Enzyme activity	Microbial communities
		Oxygen consumption/respiration	Microbial communities

morphological, or ethological response. Sheehan (1984) provides a useful characterization of biological responses at the individual level:

- acute toxicity causing mortality
- chronically accumulating damage resulting in death
- sublethal impairment of various aspects of physiology and morphology
- sublethal behavioural effects

These generally parallel the parameters shown in Table 6.2 for individual integrators. Any one of these might affect the success of the population, which in turn may cause effects at the community and ecosystem levels. Careful selection of the specific hazard assessment methods for application at a contaminated site will maximize the value of the assessment. Given the diversity of environmental conditions and issues of concern at contaminated sites, a single best design for hazard assessment cannot be defined (Baker, 1989). The following sections describe the importance of each individual integrator.

Survival

Mortality at the individual level can be described as direct (acute) or delayed (chronic). In the field of toxicology, the term *survival* has the connotation of acute lethality during a short term toxicity test. The term *toxicity test* generally refers to types of laboratory tests in which one organism (or several) is exposed to a sample (soil, sediment, water) for a defined period of time and a biological endpoint (e.g., survival) is measured. It is widely recognized that substrates which are not acutely toxic may exert chronic toxicity. The most useful information on site impacts would be field data on survival of individuals residing in a contaminated habitat over an extended time period. However, without marking individuals in a population, it is difficult to measure individual survival rates; therefore, the solution has typically been to measure survival in the laboratory in short-term experiments. Toxicity testing methods are described in Section 6.5.1.

Growth

Growth is a fundamental component of fitness and, therefore, is an important index of contaminant effects. Toxicants can affect growth rates indirectly by reducing the food available and directly by impairing metabolic pathways that convert food energy to tissue or by diverting energy from growth to metabolism of the contaminant. Effects on growth (and reproduction) can best be understood by considering the energy budget of an animal (Widdows, 1985). Food energy consumed is used for respiration and production of tissue or gametes. There is also some loss via the faeces and excretion. When production is estimated from the difference between the energy absorbed and the energy expenditure via respiration and excretion, it is referred to as the *scope for growth* (Warren and David, 1967; cited in Widdows, 1985). Scope for growth can range from positive values when there is energy available for growth and the production of gametes, to negative values when the organism is utilizing its body reserves for maintenance metabolism.

An additional index can be calculated from the physiological components of the energy allocation to provide further information on the efficiency with which an animal functions. The energy available for growth, as a proportion of the energy absorbed from the food, represents *net growth efficiency* and is a measure of the efficiency with which food is converted into body tissue. A reduction in this value is indicative of a stressed condition, since a greater proportion of the energy absorbed from the food is being used to maintain the animal, and consequently a smaller proportion is available for growth.

In aquatic systems, methods for measurement of scope for growth (SFG) and net growth efficiency (NGE) have been developed. SFG offers an instantaneous view of sublethal effects which, if extended over a period of time, would result in death. NGE values provide a long-term integration of physiological processes. Growth is viewed as a good integrative measurement of an individual's response to contaminants and has been widely used. It was concluded that analogous exposures and exposure–response relationships developed in the laboratory were not different than those in the field. The consequences of reduced growth include reduced fecundity, slower maturation, and a reduced ability to compete with other individuals; these consequences have population- and community-level repercussions.

The growth endpoint is most easily measured in aquatic systems and is not appropriate in systems where populations have a distribution greater than the study area (e.g., birds, mammals). In aquatic systems, growth can be measured in either laboratory or field experiments. Initial investigations should focus on laboratory investigations as they will indicate the potential for growth effects in the field. Toxicity tests with growth endpoints are described in Section 6.5.3.

Reproduction

Contaminants can affect reproductive processes in several ways, including the alteration of the availability of energy, metabolic disruption of factors affecting reproductive control, impacts on reproductive

behaviour, and changes in reproductive performance. Energy allocation can be affected by decreasing the amount of energy available for reproduction through food limitation or through the metabolic utilization of energy reserves for dealing with contaminant burdens. For fish, toxicological experiments on reproduction of species with a short life span have been described as the most productive for useful results (Sprague, 1976). This parameter is of ecological importance because it has a direct influence on recruitment and the maintenance of a population. In birds, phenomena such as eggshell thinning have been related to contaminant exposure. Contaminants may also affect the developing embryo in the avian egg. A potential field assessment method might include collection of eggs for laboratory analysis.

In invertebrates, similar perturbations in reproductive processes occur, but less work has been done on the response physiology/biochemistry. Most of the work in this area is oriented to toxicity tests, with the endpoints being measures of reproductive processes or success. These included delays in sexual maturation, delays in brood release, egg development time, brood size, frequency of reproduction, and complete inhibition of reproduction. The repercussions of these reproductive effects are seen at the population and community levels which integrate all of the processes discussed here. Toxicity tests with reproductive endpoints are described in Section 6.5.1.

Behaviour

It is clear that organisms can and do respond to contaminants by altering their behaviour. Basic behavioural patterns (e.g., locomotion and orientation) are essential to processes such as prey capture, feeding, predator avoidance movement, migration, courtship, and mating. The integration of these behaviours will, in part, determine the success of each individual and of the population. Behavioural responses to contaminants include a wide range of behaviour, such as avoidance, inhibited feeding, increased random movement, and other behaviours.

A behaviourial response is an integration of physiological responses to a chemical stimulus. For example, chemoreception in fish is believed to play a mediating role in reproductive migration and pairing, schooling, feeding, parental recognition, and predator avoidance (Hara, 1982). Contaminants that affect the normal function of neurosensory systems may affect how organisms move through their environment and respond to the normal range of cues that direct them toward food, shelter, and other necessities for population growth. Various behaviourial endpoints have been addressed, including spatial selection, response to food and feeding ability, predator–prey responses, aggression, displays, reproductive behaviours, feeding response, ventilatory and cough responses, and preference or avoidance to a variety of stimuli.

Histopathology

Histopathological effects such as lesions, neoplasms, and tumours in field populations of individuals exposed to contaminants can be used to document effects of contaminants. The presence/absence of such features has been related to contaminant exposure. Increases in the numbers of neoplasms and lesions have been related to residence of organisms in contaminated areas, however, little information is available on the ecological significance of such growths. In fish, it has been suggested that the presence of such tumours be used as a sentinel of environmental concern. For contaminated site assessment, information about histopathology could be collected during field studies, but it should not be a focal endpoint, except in cases where carcinogenicity of the contaminant is suspected.

6.4.3 Population, Community, and Ecosystem Dynamics

Evaluation of hazard at the population level and higher requires field assessment. Selection of the optimal level of organization depends on information such as background data, results of toxicity testing, and the specific issues at the contaminated site. Population and community measures are most often part of a tiered assessment (see Section 2.0).

Population Assessment

Organismic level changes related to contaminants (e.g., growth, reproduction) work through individuals to result in changes in the overall characteristics of populations. These changes are characteristically not easily reversible over a short time span, and if damage is discernable at the community level, then the probability for need of remediation of the contaminated site increases. Also, population-level effects of contaminants are considered to be of concern to society because value is placed on the population-level of biological organization (e.g., commercial fisheries, food species, local extinctions).

Some researchers have found that population indicators are more sensitive than individual level measurements, and population growth may integrate the other parameters as a sensitive indicator of impact. Presence or absence of species in habitats affected by a contaminated site can be used to infer changes associated with the site, particularly where historic data are available on the species' abundance. The term *bioindicator* refers to organisms that may, by their presence or absence, be indicators of environmental

ecoregions, pollution, and/or environmental degradation (sentinel species). The bioindicator concept is also intended to include the use of organisms as monitors or accumulators of toxic substances, such as heavy metals or organic compounds. Regulating or monitoring pollution effects based on the presence or absence of an indicator organism is no longer considered to be a viable alternative by many researchers. The identification of the absence of a species does not provide any information about whether the species was originally present, the time span associated with its demise (or conditions associated with eradication), or the costs involved in remediation attempts to restore the species.

Populations change in size through a combination of birth, death, immigration, and/or emigration. Contaminants can affect populations by affecting any of these four processes. Most obvious are decreases in population size related to mortality (e.g., from exposure to lethal concentrations of toxicants, from decreased birth rates, from reduced food supply). Population assessment can be used to field-verify toxicity test data. It is important to recognize that continual gradual contaminant input can lead to slow, gradual changes in population health. Evidence linking population decreases with pollutant toxicity in the case of a contaminated site might not be obvious due to the extended time frame over which adverse changes have occurred (Sheehan, 1984). Distinguishing pollutant-induced changes from those caused by natural environmental or noncontaminant-related anthropogenic factors requires extensive baseline data.

Population dynamics such as recruitment, age–class survival, and reproductive success can be used to characterize population health; however, it is also difficult to ascertain cause and effect in many cases. This level of effort should be expended only if other testing indicates there is cause for concern, and the evaluation must be carefully designed to screen out unrelated influences. For example, populations may fluctuate in size for reasons completely unrelated to toxicants (e.g., seasonality, competition, food supply).

Community Assessment

Population interactions, as influenced by contaminants, will affect the dynamics of the exposed communities. Communities fluctuate in their species composition and relative abundance of each species, and these fluctuations are affected by processes not thoroughly understood. Underlying all this change, however, is a certain range of possibilities that help to define a certain community (U.S. EPA, 1989d). In the absence of a major disruption, a given community can be expected to vary within certain boundaries.

Contaminants introduced into the environment significantly affect an exposed community when they create new boundaries. For example, some species may decline in abundance, causing others to become more dominant than usual. This will alter the community dynamics and potentially have effects at the ecosystem level. Professional expertise is required to interpret patterns of species composition and abundance in communities. Such interpretation may be aided by comparisons of contaminated site data to appropriate reference site data.

Community-level assessments may take place through field investigations (direct measurement) or through surrogates (e.g., community modeling, microcosms (Section 6.5.2)]. Community-level changes have received considerable emphasis in ecological assessment. Changes at the community level are difficult to reverse, are expressed only after a considerable time period, and allow little ability to trace cause and effect. As a hazard assessment tool for contaminated sites, community-level assessment is most useful in a top-down approach, or as part of a field verification program for predictions made on the basis of toxicity testing.

Ecosystem Assessment

Although the ecosystem is usually a level of biological organization that society wishes to preserve, ecosystem assessment abilities are not usually at the level where they can play a significant role in hazard assessment (see Section 6.3.3). Ecosystem health is not readily definable or measurable. Rapport (1989) describes the primary requirements for a healthy ecosystem as system integrity and sustainability, but describes ecosystem health as an "arcane concept", given the long time span ecosystems operate on (Rapport, 1990). Also, ability to determine stability or degradation is complicated by the natural, unknown dynamics of ecosystem processes.

If one takes a less academic definition of ecosystem health, however, such as that applied in the Netherlands (Denneman and van Gestel, 1990), then ecosystem measurement endpoints become more practical. Using their approach, "serious danger for soil ecosystems" can be measured by individual and community indicators, essentially requiring extrapolation to the ecosystem level.

Bruns et al. (1992) used a multimedia systems approach with five evaluation criteria to examine ecosystem health in both aquatic and terrestrial systems. Similar to the Netherlands approach, these five measurement endpoints required extrapolation to the ecosystem level, but did prove to be useful.

6.5 Hazard Assessment Methods

Within the framework for hazard assessment described in Section 6.4, there are a number of practical methods for hazard assessment. This section is not intended to be comprehensive, but it is intended to summarize available methods. Reference documents compiled by agencies for hazard assessment [e.g., Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference (U.S. EPA, 1989a)] are useful sources of methodologies for hazard assessment.

The biological level of organization in hazard assessment is usually at the individual level (e.g., physiological measurements, survival, growth) or at the population level (e.g., size of population, population dynamics, reproductive success). It is difficult to study higher levels of organization (e.g., ecosystem level). Community-level assessments can be accomplished, but it is difficult to relate changes in the community to effects of the contaminated site. As a result, the majority of hazard assessment data is for single species. If that species is not representative of the species we want to protect at the contaminated site, the results of the risk assessment may not be valid.

Hazard assessment generally focuses on the direct effects to receptors. Investigators should recognize that there are instances where field studies determine that a certain species is the one being impacted, but laboratory studies with that or a similar species, do not support the field studies. In such cases, site-related contaminants may have indirect effects on the species in question. For example, the chemical may affect the prey of the organisms, hence reducing the population size, although the chemical is not directly toxic to the species of focus.

6.5.1 Toxicity Testing

Background

Aquatic hazard assessment procedures, primarily with a mortality endpoint, have been in use since at least the 1970s (Parkhurst et al., 1990). The greatest emphasis has been on freshwater aquatic systems, and there is a large database of toxicological information. Terrestrial hazard assessment data are not as plentiful, but there has been an increase in emphasis on toxicity testing for soils in the past few years. Examples of application of toxicity data to hazard assessment are provided in Figure 6.2.

Most often, samples of soil, sediment, and/or water are collected from the contaminated site (as determined by the study design) and taken to the laboratory for toxicity testing using standardized procedures and protocols. Toxicity tests can also be conducted in mobile laboratories or in situ with resident species from the site.

In toxicity testing, distinctions are made between *acute*, *sublethal*, and *chronic* exposures/effects; there is considerable controversy over the definition of each of these terms. For the purpose of this project, the following working definitions will be applied:

Acute Toxicity Tests

Acute tests are designed to evaluate the relative toxicity of a chemical or sample on short-term exposure. Effects are manifested rapidly and tend to be severe. The common endpoint measured is mortality. Tests are usually conducted for a predetermined time period (e.g., 24 h and 96 h) such that the LC50 (lethal concentration, the concentration that is lethal to 50% of the test population) or the EC50 (effective concentration, the concentration that elicits a specific response in 50% of the population) can be determined (Rand and Petrocelli, 1985).

Sublethal Toxicity Tests

In the aquatic environment and in the terrestrial environment over time, organisms are rarely exposed to high, acutely toxic concentrations. Beyond the site of discharge, dilution and dispersion tend to decrease the concentration of a toxicant to sublethal or chronically toxic levels. Lower concentrations may not result in rapid mortality, but they may have a profound effect on the organism's potential for survival. Toxicity tests conducted using sublethal concentrations tend to be more ecologically significant than acute lethality studies because they approximate the exposure regimes that a greater proportion of the biomass will encounter in the receiving environment.

Chronic Toxicity Tests

Chronic tests provide a more sensitive measure of toxicity than acute toxicity tests. The fact that a sample does not elicit an acute response does not imply that it is not toxic. To determine the effects of long-term exposure to sublethal concentrations of a sample, chronic tests are conducted. Chronic toxicity tests generally encompass the entire reproductive life cycle of a test organism. From chronic toxicity data for chemicals (e.g., chemicals of potential concern), the maximum acceptable toxicant concentration (MATC) (or more recently, the chronic value, ChV) can be determined. The MATC is defined as the threshold chemical concentration that produces statistically significant deleterious effects. The MATC is the geometric mean of the no-effect concentration (NOEC) at the lower end,

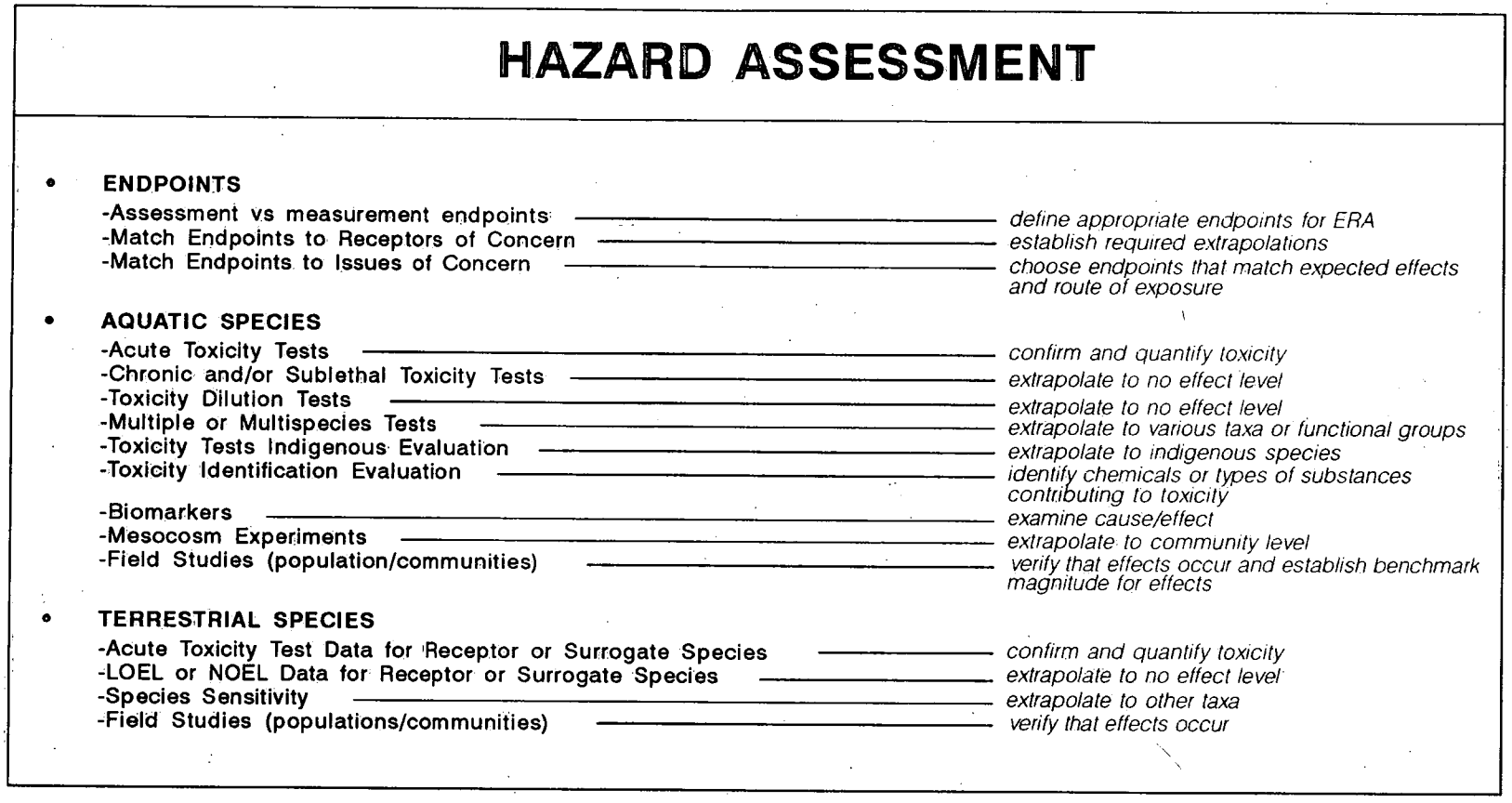


Figure 6.2. Examples of use of hazard assessment data.

and by the lowest-effect concentration (LOEC) on the higher end (Rand and Petrocelli, 1985).

Acute toxicity tests are probably most suitable for initial assessment to determine the extent and level of severity of toxic conditions at the site. Acute tests are generally rapid, simple, and relatively inexpensive, but they are not considered to be as sensitive as chronic tests. Therefore, one must be cautious in interpretation of acute toxicity data, since a lack of mortality response does not necessarily indicate that chronic or sublethal effects could not occur.

Evaluation Criteria for Toxicity Testing

Evaluation criteria for selection of toxicity tests should include the following:

- **sensitivity**: is the test sensitive to a wide range of toxicants; is it dose-responsive?
- **applicability**: is the test organism ecologically relevant to the contaminated site, has it been used previously, and can the results be extrapolated to the assessment endpoint?
- **repeatability**: are the results of the toxicity tests repeatable?
- **practicality**: from a logistical point of view, is it practical to conduct the toxicity test?
- **availability**: are test protocols and quality assurance/quality control standards available? If not, will this compromise the utility of the data?

Toxicity Tests for Contaminated Sites

A protocol for bioassessment of hazardous wastes was developed by the Corvallis Environmental Research Laboratory (Porcella, 1983) in response to demand for hazard assessment techniques for contaminated sites. Greene et al. (1989) build on that publication and provide detailed descriptions of testing procedures for contaminated sites. Examples of applications of these toxicity tests are provided in Miller et al. (1985), Thomas et al. (1986), and Athey et al. (1989). Table 6.3 provides examples of toxicity testing for soil, sediment, and water.

Test Battery Approach

Traditional toxicological investigations have relied heavily on single-species tests because they provide useful information on dose–response relationships. It is extremely difficult, however, to extrapolate population level effects from individual effects, and single-species toxicity testing is not necessarily protective of ecosystems. No single toxicity test can be used to detect ecosystem impacts due to the varying target sites and factors that influence sensitivity and differing temporal response times of ecosystem components.

Numerous investigators have emphasized the importance of using multiple toxicity tests in evaluation of pollutants (e.g., LeBlanc, 1984; Burton et al., 1989; Greene et al., 1989). A *toxicity test battery* or *suite of toxicity tests* is preferred because species sensitivity to toxicants varies between different levels of organization, modes of action, metabolic processes, etc. In general, toxicity tests are chosen for use in a test battery to offer a range of taxa, endpoints, exposure routes, and time spans. The toxicity tests listed in Table 6.3 can be used in various combinations as a test battery for contaminated site hazard assessment.

Toxicity Test Data Analysis and Interpretation

Greene et al. (1989) and Stevens et al. (1989) describe data analysis techniques for toxicity test data and use of toxicity test results. The importance of correct data analysis and interpretation cannot be overemphasized and will require separate guidance for national uniformity. In the NCSRP framework, the final products of toxicity testing under hazard assessment are the results of each toxicity test. These data can be used directly in the risk characterization or can be extrapolated (Section 6.6) to the organism or organisms of concern. Application of safety factors and consideration of risk is discussed under Section 7.0 (risk characterization).

Toxicity data for single chemicals must be used with caution because the contaminants of concern at contaminated sites are often mixtures of chemicals. Since toxicity tests are usually conducted for single chemicals, there are few data for chemical mixtures. When organisms are exposed to two or more chemicals at a time, the effects may be directly additive, synergistic (more than additive), or antagonistic (less than additive), depending on the toxicants, the test organisms, and the testing environment. Toxicity testing for contaminated sites involves evaluation of substrates (water, soil, sediment) which likely contain a number of contaminants, and identification of the chemical or chemicals of primary concern is not always possible.

Modifying Factors

Subtle differences in water quality can affect the behaviour, activity, and bioavailability of chemicals. *Modifying factors* are defined as any characteristic of an organism or the surrounding water which affects toxicity, and are usually divided into two descriptive groupings, biotic (intrinsic) and abiotic (extrinsic).

Table 6.3. Toxicity Tests which could Potentially be Used for Hazard Assessment at Contaminated Sites

Bioassay Organism		Sample Type	Test Duration	Effect Measured Endpoint	Comments	Reference
Microtox	*Photobacterium phosphoreum*	sediment elutriate soil elutriate soil/sediment water/leachate	5/15/30 min.	reduction in bioluminescence	• used for characterizing hazardous waste sites (sensitivity varies)	Beckman, Inc. (1982) Microtox System Operating Manual
Algae	*Selenastrum capricornutum*	sediment elutriate soil elutriate water	96 h static	inhibition of growth	• measures toxicity of hazardous waste solutions • provide an indication of sublethal and/or chronic effects • widely used	Porcella (1983) US EPA (1989) APHA (1989) ASTM (1988)
Duckweed	*Lemna*	water/elutriate	96 h static	inhibition of growth	• measures toxicity of hazardous waste solutions • provide an indication of sublethal and/or chronic effects • widely used	APHA (1989)
Lettuce Seed**	*Lactuca sativa*	sediment* soil	120 h static	germination	• estimates acute toxicity of solid hazardous wastes	Thomas & Cline (1985) Modification of the Neubauer technique to assess toxicity of hazardous chemicals in soils.
		sediment elutriate soil elutriate	120 h static	root elongation	• estimates acute toxicity of aqueous hazardous wastes and hazardous waste elutriates • more sensitive than seed germination test	Porcella (1983) Ratsch (1983)
Wheat	*Triticum aestivum*	sediment soil	120 h static	root elongation	• estimates acute toxicity of solid hazardous wastes	Thomas & Cline (1985) Modification of the Neubauer technique to assess toxicity of hazardous chemicals in soils.
Radish	*Raphanus sativa*	sediment soil	120 h static	root elongation	• estimates acute toxicity of solid hazardous wastes	Thomas & Cline (1985) Modification of the Neubauer technique to assess toxicity of hazardous chemicals in soils.

Table 6.3. Continued

Bioassay Organism	Sample Type	Test Duration	Effect Measured Endpoint	Comments	Reference
Honey bees *Apis* spp.	—	—	—	• used in regulatory programs other than hazardous waste site investigations • few (if any) field validations, however methods warrant consideration • may be useful to evaluate ecological effects associated with hazardous waste sites	Thomas et al. (1983) Bromenshenk (1985)
Tradescantia	—	—	—	• stamen hair mutagenicity assay and micronuclei formation • requires standardization and/or evaluation • when resident species used as *in situ* biological indicator, may provide opportunity for integration of field and lab tests	Grant and Zura (1982) Lower et al. (1983) Ma and Harris (1985) Lower et al. (1988)
Hexaploid virescent wheat assay	—	—	—	• for detecting cytogenetic effects • requires standardization and/or evaluation • used in laboratory situations to evaluate clastogenicity from exposure to single and multi-chemical mixtures	Redei & Sandhu (1988) Lower et al. (1988)
Sclerotia formation tests	—	—	—	• soil fungi response test • requires standardization and/or evaluation • limited use in site evaluations to assess formation in response to complex chemical mixtures	Thomas et al. (1983)

* can be used to test aqueous samples by using 100% artificial soil and using aqueous samples rather than deionized water to hydrate the samples
** lettuce seeds are generally more sensitive than other seeds.

Table 6.3. Continued

Bioassay Organism	Sample Type	Test Duration	Effect Measured Endpoint	Comments	Reference
Red Clover *Trifolium pratense*	sediment soil	120 h static	root elongation	• estimates acute toxicity of solid hazardous wastes	Thomas & Cline (1985) Modification of the Neubauer technique to assess toxicity of hazardous chemicals in soils.
Cucumber *Cucumis sativa*	sediment soil	120 h static	root elongation	• estimates acute toxicity of solid hazardous wastes	Thomas & Cline (1985) Modification of the Neubauer technique to assess toxicity of hazardous chemicals in soils.
Hyalella azteca	water/elutriate sediment	48 - 96 h 10 d static	mortality	• estimates acute toxicity of solid hazardous wastes	ASTM (1991)
Chironomus tentans	sediment	10 d static	mortality growth	• estimates acute toxicity of solid hazardous wastes	ASTM (1991)
Daphnia pulex & Daphnia magna	sediment elutriate soil elutriate water	48 h static	mortality	• measures the acute toxicity of hazardous waste solutions	Peltier & Weber (1985)
Ceriodaphnia dubia	water	7 d static-renewal	mortality reproductive decline	• evaluating the toxicity of freshwater discharges/receiving environments • indicator of chronic toxicity	Mount & Norberg (1984) US EPA (1989) Env. Canada (1990)
Nematode *Panagrellus redivivus*	water s/s extracts	96 h static	mortality growth maturation	• estimates the acute toxicity of hazardous waste solutions	Samoiloff (1983)
Earthworm *Eisenia foetida*	sediment* soil	14 d	mortality	• estimates acute toxicity of solid hazardous wastes	Edwards (1984) Goats & Edwards (1983)
Fathead minnow *Pimephales promelas*	water	48 h static	mortality	• estimates the acute toxicity of hazardous waste solutions	Peltier & Weber (1985) ASTM (1989)
	water	7 d static-renewal	mortality growth	• for testing the sublethal toxicity of freshwater effluents and surface waters • fairly extensively used	US EPA (1989)

Table 6.3. Continued

Bioassay Organism	Sample Type	Test Duration	Effect Measured Endpoint	Comments	Reference
Rainbow trout *Oncorhynchus mykiss*	water	96 h	mortality	• evaluating acute toxicity of freshwater chemicals or effluents/leachates	BC MOE (1982) OME (1989) Env. Canada (1980, 1990) ASTM (1989) APHA (1989)
	water	7 - 32 d	embryo & alevin mortality growth	• alevin yolk conversion efficiency bioassay measures the lethal and sublethal effects on rainbow trout alevins • no protocol has been developed	Hodson & Blunt (1981, 1986)
Chromosomal aberration assay - various wild mammal species	—	—	—	• examines mitotic cells arrested at metaphase for alterations and/or rearrangements in the chromosomes • this correlates well with the presence of mutagens and is closely associated with carcinogens	Brusick (1980) EPA (1985) Baker et al. (1982) McBee et al. (1987) Thompson et al. (1988)
Avian and small mammals	—	—	—	• only a few tests have been completed on hazardous waste site samples, but good potential • address chemical effects on avian and small mammal models	ASTM (1988) Butler (1987) Cholakis et al. (1981) McCann et al. (1981) Schafer & Bowles (1985)
Avian acute toxicity tests	—	—	—	• methods may be amenable to hazardous waste site toxicity assessments	ASTM (1988)
Amphibian acute toxicity tests	—	—	—	• methods may be amenable to hazardous waste site toxicity assessments	ASTM (1985)

Table 6.3. Continued

Bioassay Organism	Sample Type	Test Duration	Effect Measured Endpoint	Comments	Reference
Crickets *Acheta deomesticus*	–	–	–	• used in regulatory programs other than hazardous waste site investigations • few (if any) field validations, however methods warrant consideration • may be useful to evaluate ecological effects associated with hazardous waste sites	Walton (1980)
Grasshoppers	–	–	–	• used in regulatory programs other than hazardous waste site investigations • few (if any) field validations, however methods warrant consideration • may be useful to evaluate ecological effects associated with hazardous waste sites	Thomas et al. (1983)
Harvester ants *Pogonomyrmex* spp.	–	–	–	• used in regulatory programs other than hazardous waste site investigations • few (if any) field validations, however methods warrant consideration • may be useful to evaluate ecological effects associated with hazardous waste sites	Gano et al. (1983)

Modifying factors can act to either increase or decrease the concentration of a chemical required to produce a biological response, and the impact can vary dramatically between classes of chemicals and the organisms which are exposed. A biological response is detectable when the chemical reaches a sufficient concentration at the target site to affect the measurable performance of the organism. Threshold concentrations vary between chemicals and organisms, and modifying factors alter the rate at which chemicals reach the target site by changing the availability of the chemical to the organism or the internal transport rate at which the chemical reaches the target site. The target site can vary with the concentration of chemical affecting the organism.

Both abiotic and biotic modifying factors affect toxicity by altering the external concentration of toxicant required to achieve the threshold internal concentration at that target site, for that chemical, at that dose, and for that organism. Factors affecting chemical activity can interact either within the organism or externally. Internal factors are usually biotic and act to change the manner in which organisms deal with a chemical metabolically. By increasing the rate of metabolic breakdown or excretion rate of a chemical, the dose (exposure) required to achieve the threshold concentration at the target site increases. External factors are usually abiotic and affect the availability of the chemical for uptake. Chemicals, particularly metals, respond to some modifying factors by changing their speciation state, and some chemical species are able to reach target sites faster than others by crossing membranes more quickly or through preferential uptake by active mechanisms.

Examples of biotic modifying factors include species, life stage, sex, reproductive state, nutritional status, body size, diet, and acclimation. Abiotic modifying factors of toxicity include temperature, water hardness, alkalinity, humic acid, dissolved oxygen, chelating agents, suspended solids, amino acids, and the presence of organic matter. The hazard assessment design should take into account both abiotic and biotic factors, and recognize their potential contribution to uncertainty. Whenever possible, the effect of modifying factors should be minimized by using appropriate controls, test materials, and test organisms.

6.5.2 Microcosms

Microcosms provide the opportunity to manipulate experimental conditions and look at population level effects in aquatic systems. These systems allow the study of effects of chemical perturbations on aquatic and terrestrial ecosystems. Through the incorporation of replication in experimental design, microcosms provide data which can be analyzed statistically to determine significant changes in ecological structure or function (Sheehan, 1989). Microcosms and mesocosms have been most widely implemented under regulatory programs like TOSCA (Toxic Substances Control Act), where new chemicals are being evaluated (Cairns, 1979). Such studies have become the backbone of regulatory compliance testing for chemicals such as pesticides and herbicides. They allow investigation at a level of biological organization usually not possible in toxicity testing.

Microcosms are not always applicable for hazard assessment at contaminated sites for several reasons. First, setting up the treatments would require dilutions of effluent from the contaminated site, as opposed to spiking with a single chemical. Also, hazard assessment at a contaminated site is usually retrospective, so conducting a real community assessment would be preferable.

6.5.3 Field Assessment Methods

The importance of field surveys is described in Section 5.0. The contribution that a good field survey makes to hazard assessment is identification of the problem and its extent. The use of field assessment methods depends, in part, on the approach that the ecological risk assessment team has taken. In a top-down approach, community-level field assessment may be one of the first steps. In a bottom-up, tiered approach, the community-level work may be one of the last steps in the ecological risk assessment, as field validation for toxicity test data and extrapolations.

The importance of going to the contaminated site and collecting field data cannot be over-emphasized. Toxicity testing only serves to model the field situation and is not truly representative of the dynamics of populations and communities. However, the level of effort required to obtain useful field data usually means that investigators try other, more simple, means of hazard assessment first (bottom-up approach).

Field assessment data may be highly variable, reflecting natural fluctuations in ecological components with season, weather, time of day, etc. As a result of this high variability, field programs must be designed so that effects related to a contaminated site are actually be detectable.

Normally, investigators are concerned with the probability () of declaring an effect significant when it is not (= Type I error). This is a reasonable concern for routine scientific practice, as it focuses attention and resources on phenomena that are likely to be real and weeds out phenomena whose existence is equivocal or doubtful. However, environmental scientists must also consider , or the probability that an effect could be detected. The costs and consequences of Type II errors, or failing to detect an effect which actually exists, may be much greater than the costs and consequences

of Type I errors (Peterman, 1990). For this reason, impact and hazard assessments should include power analysis (power = 1 -), and ensure that sample sizes are adequate to detect effects considered biologically significant. Good discussions and reviews of power analysis are provided by Green (1984, 1989), Alldredge (1987) and Peterman (1990). There is also no reason why power analysis should be restricted to field studies; toxicity tests may also show high variability and consequently have surprisingly little power (Barnthouse et al., 1986; Suter et al., 1987).

The advantages of collecting field data for hazard assessment include the following (adapted from Kapustka et al., 1989):

- impacts of contaminated site on indigenous species are measured
- direct measurements are made (extrapolations from toxicity data are not required)
- results are interpretable
- results are more easily understood by decision makers and the general public
- the information can feed into the receptor characterization

For the purposes of this framework report, summaries of field assessment methods are not provided. There are numerous manuals that describe field techniques, specifically for risk assessment (e.g., Kapustka et al., 1989) or for monitoring or ecological assessment purposes (e.g., Plafkin et al., 1989). Again, ecological risk assessment relies on expert judgement by investigators such as ecologists.

It is critical that the field methods selected (measurement endpoints) match the assessment endpoints that were set during the planning stage of the ecological risk assessment or evolved during the course of the investigation. One of the temptations of collecting field information is to collect too much or the wrong kind; discipline must be practised in the design of field programs for contaminated sites.

6.5.4 QSARS

Quantitative structure activity relationship (QSAR) models are mathematical equations derived to estimate the toxicity or other property of a chemical from its structure. Each substructure of a molecule contributes to its toxicity in a specific way, and the QSAR equation describes this contribution. Models of this type have proven to be successful in estimation of carcinogenicity, mutagenicity, and toxicity to rats, mice, daphnids, and fathead minnows. QSARs are usually applied to predict the toxicity of new chemicals and, in the case of contaminated sites with multiple contaminants, it would be best to actually test the toxicity of the contaminated site, as opposed to predicting it. QSARs might have a role at a site where organisms are being exposed to a chemical about which little is known.

6.6 Extrapolations of Hazard Assessment Data

One of the largest sources of uncertainty in hazard assessment is data extrapolation. This section is not intended to provide in-depth information on extrapolation, but to familiarize the reader with the kinds of data extrapolation that are used for hazard assessment.

6.6.1 Species-to-Species Extrapolation

Toxicity tests conducted in the laboratory should use species representative of the ecosystem being assessed. There has been a great deal of discussion in Canada about the use of native species versus standardized toxicity test organisms in laboratory assessments. On one hand, data generated using species that live, or are expected to live, within the contaminated site will be directly applicable to the site and not require as much extrapolation to predict effects. On the other hand, the success rate with adapting standardized tests to native species is not good; control survival problems and high variability plague such laboratory work and confound data interpretation.

The most viable option at this point appears to be to use standardized toxicity tests, at least initially, and extrapolate from these results to the species of concern for the site. Selection of toxicity test organisms should be made with consideration of the sensitivity of the species, mode of action of the stressor, expected exposure period of natural populations, etc. Barnthouse et al. (1986) discuss the analysis of extrapolation error and provide practical examples (i.e., fish species, aquatic invertebrates) to demonstrate that species-to-species and taxa-to-taxa extrapolations can work. In U.S. EPA (1991), however, the uncertainty factors in hazard assessment were greatest for between-species comparisons (e.g., on the order of 1000 to 10 000 for acute toxicity and 100 to 1000 for chronic toxicity). Also as taxonomic similarity decreases, the extrapolation uncertainty increases.

The most common method for species-to-species extrapolation is to compile toxicological data for organisms in similar taxa (e.g., same family or class) and develop a range or confidence intervals of effects concentrations. Assuming that the untested species has a similar sensitivity to the test species, the untested species are expected to fall within the same range (Mayer et al., 1986; also, this assumption was the initial basis for development of water quality criteria). Species

within a similar taxa can have a wide range of response concentrations, but the more data one compiles, the more confidence one can place in the range or interval. For contaminated sites, this approach would be suitable, but the level of effort in testing is usually not practical. What happens in practice is that the relatively few toxicity tests that are available (relative to the number of species in existence) are used to represent a host of native species. For example, the earthworm test represents soil invertebrates, the rainbow trout test represents freshwater fish, and domestic poultry represents water fowl. There is a heavy dependency on the assumption that standard toxicity test organisms are sensitive.

6.6.2 Endpoint-to-Endpoint Extrapolation

Given that it is relatively easy to collect acute toxicity data, and that few true chronic toxicity tests are standardized, methods to extrapolate from acute to chronic endpoints have been developed. For example, no-observed-effects concentrations (NOECs) can be developed from an LC50. First, an analysis of acute-to-chronic ratios or regression analysis is conducted for species that have been tested to determine the relationship from empirical data for similar species. Then, the relationship derived can be used for other species for which only acute data are available. One must assume that the ratio or relationship of acute-to-chronic toxicity remains similar between species. These extrapolations should only be made for the same types of tests conducted under the same conditions (e.g., water quality, life stage) (Parkhurst et al., 1989).

Due to the nature of toxicity data, acute-to-chronic ratios often have high variability. Wherever possible (i.e., where a higher tier of investigation is warranted), chronic testing or field assessments should be conducted for contaminated sites. Investigators must evaluate the uncertainty that endpoint-to-endpoint extrapolation will be introduced into the risk assessment, and determine whether it is acceptable on a site-specific basis.

In addition to acute-to-chronic ratios, short-term tests such as early life stage tests can be used as predictors of chronic toxicities. By using sensitive life stages, good estimates of chronic toxicity endpoints can be obtained in much less time, at much less cost that full life cycle tests (Rand and Petrocelli, 1985). Parkhurst et al. (1989) provide a more optimistic outlook for use of short-term tests to predict chronic toxicity, as opposed to acute tests to predict chronic toxicity. Barnthouse et al. (1986) discuss the analysis of extrapolation error and provide examples to demonstrate that a life cycle threshold value can be determined from an LC50 value.

6.6.3 Laboratory-to-Field Extrapolation

Field surveys are useful to identify deleteriously affected populations and communities and, possibly, to identify specific environmental effects (e.g., reproductive problems in a fish population by examining age class structure and size of individuals). The link of cause and effect must be established, however, through experimentation, usually in the laboratory, although field experiments can also be conducted. Ideally, investigators will link the design of laboratory experiments to the field data, permitting extrapolation from the laboratory to the field.

One of the most frequently raised concerns is that single species toxicity testing in the laboratory does not measure higher level effects at the community and ecosystem level. The best must be done with the tools that are available, and toxicity tests provide useful information to identify the potential for toxicity from samples collected at a contaminated site. Parkhurst et al. (1989) make the case that assessments based on a single species should be adequate to identify problems at higher levels of biological organization. In the Netherlands, Aldenberg and Stob (1993) refined a statistical procedure to estimate 95% species protection from a small number of toxicity data.

To maximize extrapolation from the lab to the field, the test conditions should be as similar as possible to those in the field. Modifying factors such as water hardness, temperature, and organic carbon (see Section 6.4) should be considered when setting up toxicity tests so that appropriate controls are conducted. Despite the best intentions of investigators, however, the responses of organisms exposed in the laboratory often differ from those exposed under natural conditions; laboratory-to-field extrapolation provides some indication of the direction and magnitude of those differences.

Toxicity and field survey data can be compared using exploratory data analysis techniques (Parkhurst et al., 1989). These preliminary analyses should show the relationship between the field-collected and laboratory-collected data, and suggest cause–effect relationships. For complex mixtures, which will often exist in contaminated sites, it may be impossible to determine which chemical or chemicals is causing the toxicity (Parkhurst et al., 1989).

If the laboratory-to-field extrapolation appears to be the major component of uncertainty in an assessment, further field studies may be warranted to pinpoint the actual hazard. For example, if a field survey shows there are reduced numbers of benthic invertebrates, but the toxicity testing indicates that the leachate from a contaminated site is not toxic at field concentrations, a more in-depth field study to look at (1) substrate

characteristics (a determinant of benthic community structure) and (2) toxicity of field-collected water to native benthic species may be required.

6.7 Uncertainty in Hazard Assessment Data

The extrapolations discussed in Section 6.6 contribute largely to uncertainty in hazard assessment. Models have been developed for extrapolating among taxa, endpoints, and laboratory and field data with known degrees of uncertainty (see U.S. EPA, 1991). The ability to reduce uncertainty may be limited, however, by the following (U.S. EPA, 1991):

- variations in physical and chemical environmental factors (e.g., modifying factors)
- chemical interactions
- physical–chemical interactions
- nonchemical stresses
- biotic interactions
- indirect biological effects that are not explicitly determined in laboratory tests

Uncertainty for field assessments has traditionally been difficult to quantify. With statistical approaches such as power analysis (Section 6.5.3), techniques for monitoring uncertainty are beginning to be developed. It is another issue, however, whether the level of uncertainty in field studies is accepted. Regardless, it is clear that direct measurement of toxicity to the organisms of concern, combined with focused field assessment, provides the risk assessor the optimal combination of information for hazard assessment.

7.0 RISK CHARACTERIZATION

7.1 Overview

7.1.1 Definition and Scope

Risk characterization can be defined as the process of estimating the magnitude and probability of effects (e.g., Norton et al., 1988; Parkhurst et al., 1990; Pastorok and Sampson, 1990). Risk characterization combines the results of exposure assessment, which estimates the concentrations of contaminants in the environment, and hazard assessment, which estimates the effects associated with various concentrations. If the endpoints and target species or communities are properly chosen, the risk characterization will make an ecologically important statement. Obviously, the primary objective of risk characterization is to provide an estimate of the magnitude and probability of effects. Risk characterization integrates the other ERA components. Risk characterizations should also include a summary and discussion of strengths, limitations, and uncertainties arising from the data and models used to provide conclusions.

In many cases, it is difficult to define the boundary between risk characterization and other components of the risk assessment, especially hazard assessment. Hazard assessment and other components should be as objective as possible, and include only the assumptions and calculations necessary to fulfil their objectives. Additional assumptions and calculations, particularly those related to uncertainties, should be part of risk characterization. A hazard assessment should provide specific statements (or distributions) of measured or expected effects: "species X will suffer 10% mortality at concentration Y". The risk characterization should include steps such as dividing by a safety factor to account for various uncertainties. If this division is adopted, the results of the hazard assessment and other components can be used at other sites, by other investigators, and with different risk characterization methods. Any new effects data from subsequent monitoring or toxicity testing can easily be applied to the hazard assessment. The risk characterization will then contain the most contentious assumptions, including those specific to the method or approach adopted. If these assumptions are shown to be untrue, or if another approach or method of risk characterization is used, only the risk characterization process needs to be repeated.

7.1.2 Classification of Risk Characterization Methods

7.1.2.1 Classification Scheme Used in This Report

This report follows the classification scheme used by Norton et al. (1988) (Figure 7.1). Risk characterization methods are divided first into qualitative and quantitative methods. Qualitative methods usually characterize risks as high, intermediate, or low, and often depend on expert judgement.

Quantitative methods can be subdivided into quotient and continuous exposure–response methods. The quotient methods rely on the expected environmental concentration (EEC) divided by some benchmark concentration (BC): Quotient = EEC/BC). Benchmark concentrations are derived from hazard assessments and are specific concentrations at which some level of effects are expected. The effects associated with benchmark concentrations can vary, as these concentrations may be based on acute (e.g., LC50 or LD50) or chronic effects (e.g., MATC) for one or more species or endpoints.

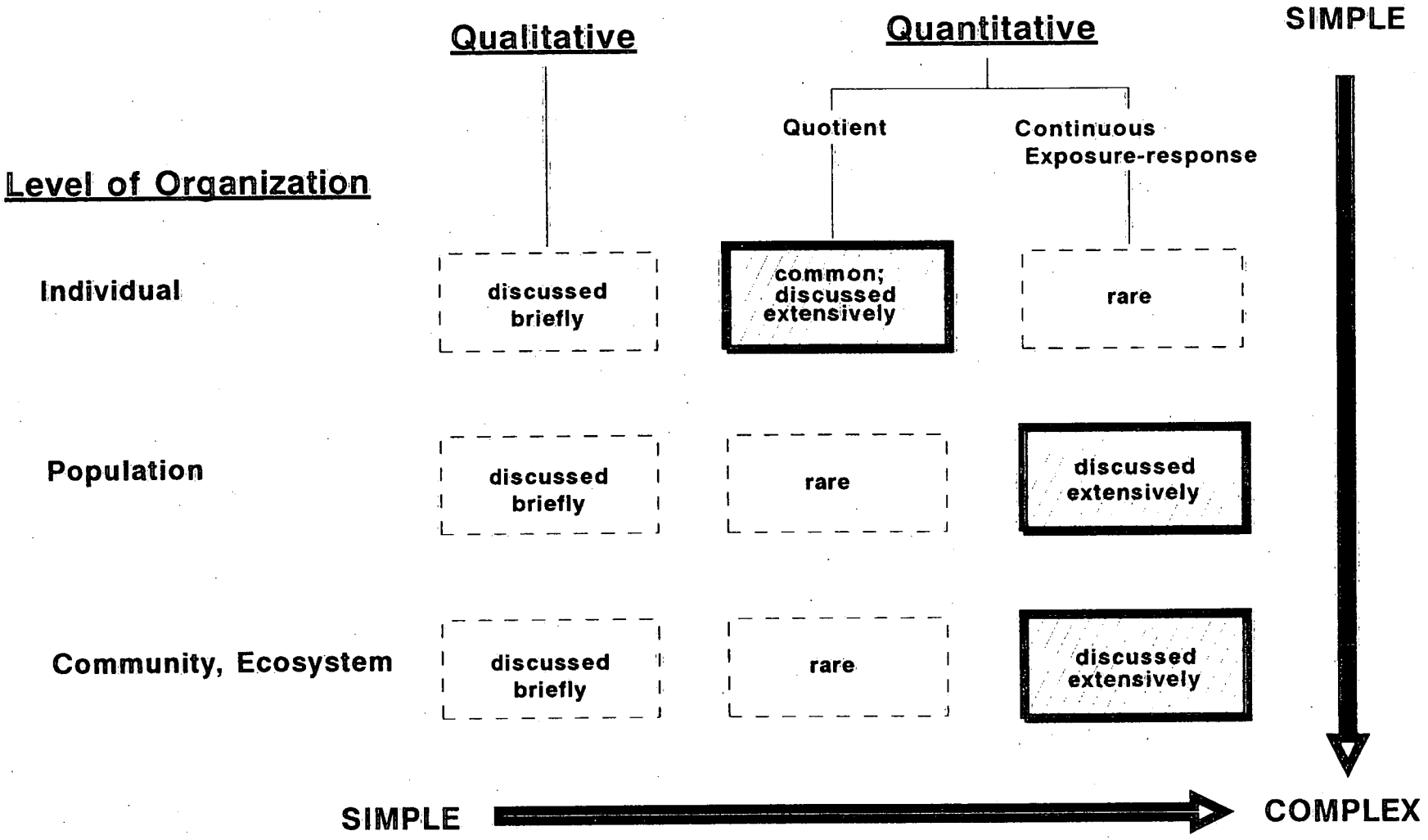


Figure 7.1. Classification scheme for risk characterization methods.

Continuous exposure–response methods do not rely on a single benchmark concentration, but instead use the entire relationship between concentration or dose and one or more responses. Thus, the risks of a broad range of effect magnitudes (e.g., 1, 10, 25, and 50% reduction in survival) are considered. Continuous concentration–exposure methods can be further subdivided based on the level (individual, population, community/ecosystem) to which they apply. Methods applying to the individual level do not consider effects beyond those considered in most bioassays and toxicity tests: reductions in survival, growth, or reproduction of individuals, usually of a single species. Some authors (e.g., Parkhurst et al., 1990) consider these methods as applying to the population, as well as individual, level. However, in this report, the category of population-level methods is reserved for methods (usually population models) which predict effects for more than one generation and consider population-level effects such as the probability of extinction. Similarly, higher-level (community, ecosystem) methods predict effects above the population level.

Although the classification provided in Figure 7.1 appears to divide risk characterization methods into discrete categories, the characteristics used for classification can be more continuous than discrete. As a result, some methods can be difficult to classify because there may be a gradient from one category to the next. These intermediate methods are noted in Section 7.2. Note also that only continuous exposure methods are subdivided on the basis of organizational level for the evaluation. Most quotient methods apply to the individual level, but there are some which apply to higher levels; these are noted in Section 7.2.2.1. Qualitative methods may also apply to any level.

7.1.2.2 Alternative Classification Schemes

The classification scheme in Figure 7.1 was chosen because it is based on important considerations, particularly the degree of quantification of the magnitude of effects, and because it also reflects a gradient from the simple to complex. There are, however, other alternatives (Pastorok and Sampson, 1990; Section 1.4 of this report):

- predictive versus retrospective
- empirical versus theoretical
- top-down versus bottom-up

The distinctions made by these alternatives can also apply to exposure and hazard assessment, and ecological risk assessment as a whole. These alternative classification schemes could be used to further subdivide some of the categories in Figure 7.1. They identify important distinctions worth making and are considered in the descriptions and evaluations of methods (Section 7.2).

7.1.3 Framework for Description and Evaluation of Methods

The framework and criteria used for the description and evaluation of risk characterization methods is summarized in Table 7.1 and discussed in more detail below. This framework and the actual evaluations in Section 7.2 are designed to assist in the selection of the most appropriate method(s) for specific risk assessments.

7.1.3.1 Description of Methods

The descriptions first consider the characteristics used for classification into the categories given in Figure 7.1, particularly the degree of quantification and the level to which the different types of methods apply. Relevant literature, including general reviews and specific examples, is cited or tabulated. Where appropriate, examples of predictive/retrospective or empirical/theoretical approaches or methods within a category are also provided.

7.1.3.2 Evaluation Criteria

The general categories of methods are evaluated according to the criteria listed in Table 7.1, and then an overall evaluation is provided. Practical considerations include data requirements, level of expertise, feasibility and ease of application, and cost and level of effort. The availability of computer software or instruction manuals for specific methods is noted, although this review was not intended to identify all programs or manuals. The scope and degree of integration (potential and realized) of methods or groups of methods were also considered to identify cases to which the methods could be applied. Finally, several related scientific issues were considered; these are discussed in more detail below.

The sources and magnitudes of uncertainties in risk characterization should be identified and reduced whenever possible. Barnthouse and Suter (1986) considered three sources of uncertainty:

- inherent variability
- parameter uncertainty
- model errors

Inherent variability refers to the variability inherent in ecological systems and in the measurement of ecological parameters. Examples would be variability in discharge, and measurement and sampling error.

Table 7.1. Approach for Description and Evaluation of Risk Characterization Methods

General Categories/Aspects	Specific Categories/Aspects
Description	• degree of quantification • level of organization • predictive/retrospective • empirical/theoretical
Evaluation	
Practical considerations	• data requirements • level of expertise required • feasibility/ease of application • level of effort required • cost
Scope/Integration	• scope - chemicals, ecosystems • integration - level of organization • applicable to multiple chemicals/exposure pathways?
Scientific considerations	• uncertainty (identification, quantification) • verification, calibration, validity
Overall evaluation	• advantages • limitations

Measurement and sampling error can be reduced by more precise measurements and proper sampling designs. Natural variability cannot be reduced, but can be quantified by providing variances as well as means, and by using these variances to calculate probabilities of effects. Parameter uncertainty refers to the uncertainty associated with estimating parameters. Examples would include estimation of chronic benchmark concentrations from LC50s and estimation of toxicity from chemical structure or activity. Parameter uncertainty can be reduced by developing more precise estimation procedures (e.g., regressions) or by directly measuring the parameter of interest. Model error refers to broad-scale sources of uncertainty, and would include errors associated with using few variables to represent many complex phenomena, using inappropriate functional relationships, and using inappropriate boundaries to define the system of study. These model errors are very difficult to quantify or even identify, and are consequently difficult to reduce because they deal with the "unknown" (true uncertainties).

The relative importance of these sources of uncertainty may vary among methods or approaches. For example, inherent variability may be the most important source of uncertainty for retrospective and perhaps empirical approaches, whereas parameter uncertainty may be more important for predictive and theoretical approaches. Al though the term "model error" suggests that this is an important source of uncertainty only for theoretical models, it is actually important for all risk characterization methods. All methods rely on a reduced set of variables, make some assumptions about functional relationships (or ignore them), and place boundaries on the system to be studied.

Uncertainty from different sources may also be correlated. A precise measure of some parameter will not only reduce inherent variability, but will also increase the precision of any other parameters estimated from that parameter. There is usually a trade-off between parameter uncertainty and some model errors. Including more variables in a model or characterization, and expanding the boundaries, increases the summed contribution of parameter uncertainties. The same consideration applies to empirical regression models. Increasing the number of variables increases the proportion of variance accounted for by the regression, but the residual mean square (which will determine the prediction or confidence intervals) may actually increase because of the reduction in degrees of freedom. Even retrospective analyses such as ANOVA in an impact assessment can rapidly become unmanageable if too many factors are included.

Verification, calibration, and validity are necessary to increase the precision of risk characterizations and to increase confidence in the final output of risk assessment studies. Verification of specific predictive risk characterizations by subsequent observation is important, although rarely done (e.g., Norton et al., 1988; Parkhurst et al., 1990; Pastorok and Sampson, 1990). Methods which are verifiable and which have been successful in past studies are more credible than those which are not verifiable or have not been verified in the past. Methods, especially those dealing with extrapolation or estimation, should also be based on valid or reasonable assumptions about relationships or processes. Many risk assessments go through a tiered process of prediction and subsequent verification/calibration, moving from the simple to complex. A tiered approach, coupled with verification of risk predictions through subsequent monitoring, is recommended in this report and described in Sections 2.0 and 9.0. Comparing predictions from several different methods is also an excellent means of verifying risk characterizations and estimating uncertainties.

The overall evaluation provides the strengths and limitations of each category of methods. The methods chosen for any risk assessment will depend on the objectives and other factors such as the data which are available or which can be collected. The choice of appropriate methods is an important part of the planning stage and is discussed in more detail in Sections 7.2 and 9.0.

7.2 Description and Evaluation of Methods

7.2.1 Qualitative Methods

Qualitative methods are defined as those which do not quantify the magnitude or probability of effects. The methods may still quantify risks on some rank or categorical scale. In many cases, qualitative methods depend on professional judgement and are used as a preliminary means of identifying sites or areas of concern. These methods are briefly reviewed in Norton et al. (1988). Several offices within the U.S. EPA use qualitative methods; these are listed in Table 7.2.

Table 7.2. Examples of Qualitative Risk Characterization Methods

Agency/Method	Description/Comments
CANADA	
CCME (1991a) National Classification System	• screening method/scoring system for contaminated sites • based on contaminant characteristics, exposure pathways and receptors
Environment Canada/Health and Welfare Canada (1991) - Canadian Environmental Protection Act Reports	• verbal risk characterization (e.g., "high", "low") • expert judgement/literature review • chemical classes
U.S.A.	
U.S. EPA Office of Water Regulations & Standards (U.S. EPA, 1983)	• verbal risk characterization of sites • expert judgement • based on combinations of key species, chemicals, locations
Office of Solid Waste (U.S. EPA, 1987a)	• based on proximity to sensitive environments - risk = inverse of distance to nearest sensitive environment = number of sensitive environments nearby • oil and gas/mining activities

The Argonne National Laboratory has developed a number of qualitative procedures which focus primarily on energy impacts (Ballou et al., 1981). The most obvious Canadian example is the method used by the CCME (1991a) to classify contaminated sites. These qualitative methods consider factors such as exposure, hazard, and sensitive species and environments. Other more formalized procedures such as fault tree analysis are also available but rarely used (Barnthouse et al., 1986).

Qualitative methods are not reviewed in detail in this report because a method for Canadian contaminated sites has largely been discussed elsewhere (e.g., CCME, 1991a). However, the value of qualitative methods and professional judgement as a preliminary screening tool for ranking or comparing sites or chemicals should not be underestimated.

7.2.2 Quantitative Methods

7.2.2.1 Quotient Methods

Description

Examples of quotient methods are provided in Table 7.3. The Standard Evaluation Procedure used by the U.S. EPA Office of Pesticide Programs (OPP) (Urban and Cook, 1986), which is used to conduct risk assessments to assist in decisions on pesticide registration, is probably the most commonly cited. This and other methods differ primarily in the benchmark concentration used, the safety or application factors applied to derive that benchmark, and the interpretation and manipulation of the quotient EEC/BC. For all methods, a quotient value <1 indicates low or no risk; a value ≥1 indicates the presence of risk. EEC can be measured directly, predicted through fate models or even back-calculated to set a certain EEC as a "safe" concentration or remediation criterion. For example, if the BC were 2 mg/L, a remediation criterion of <2 mg/L could be set to represent no or low risk. Benchmark concentrations are derived from the hazard assessment. The quotient method identifies the presence of potential risk, but does not characterize its magnitude.

Evaluation

Practical Considerations

The data, cost, and level of expertise required for quotient methods depend on the level of effort devoted to exposure and hazard assessment, as the actual risk characterization is a simple matter of dividing one concentration by another. Most of the references cited for the examples in Table 7.3 could serve as protocol manuals for conducting the entire risk assessment. Computer programs have also been developed for several of the methods; the programs should properly be considered exposure and/or hazard assessment programs, as the risk characterization calculation is usually trivial.

Scope/Integration

Most quotient methods apply to single chemicals and exposure pathways and to the individual level. These restrictions are major limitations of the methods, and attempts to remove the restrictions are discussed in detail below. Otherwise, quotient methods can be applied to any species, chemical, or site for which a BC and EEC can be calculated.

Summing quotients is one method used to deal with multiple chemicals (e.g., U.S. EPA 1987b; this method is used by the U.S. EPA Office of Solid Waste). The sum is then interpreted in the same way as a quotient for a single chemical: if the sum is ≥1, then a risk is assumed to exist. The underlying assumption is that toxicities (actually 1/BC) are additive. This is a reasonable assumption for lethal effects concentrations such as an LC50, and it forms the basis for the use of toxic units (which are EEC/LC50) (see U.S. EPA, 1985a for a discussion of toxic units). The same assumption of additivity, however, may not apply to sublethal effects concentrations such as NOEC or MATC. Summing quotients could also be applied to multiple exposure pathways (e.g., uptake from both water and food), although no examples were found. In that case, EEC and BC would be calculated for each pathway.

Any summing should be part of the risk characterization, rather than the hazard or exposure assessment (i.e., one should sum quotients rather than calculate a BC for a specific mixture). If an existing or predicted mixture of chemicals is used for hazard assessment, and a BC is calculated for that mixture, then that BC applies only to that specific mixture and cannot be used to generate remediation criteria. As well, the composition of any mixture may vary among media and over time. However, if the hazard assessment is restricted to calculating BCs for individual chemicals, then these individual BCs can be used for risk characterization of any mixture, existing or targeted. One important exception might be effluents of a reasonably constant composition, if exposure were largely restricted to water-borne contaminants. In that case, the hazard and risk characterization could deal with the effluent as a whole, and remediation criteria could be based on whole effluent toxicity or measured in-stream effects (i.e., the criterion or objective might be an effluent NOEC greater than the minimum concentration expected in-stream).

Table 7.3. Examples of Quotient Risk Characterization Methods

Agency/Method	Scope	Description	Comments
CANADA			
CCME Water Quality Guidelines (CCREM, 1987)	• aquatic; single chemical • could be applied to other media/ecosystems	• guidelines are BC/SF • SF vary depending on chemical properties, data available	• basic quotient/criteria method
U.S.A.			
U.S. EPA Office of Pesticide Programs Standard Evaluation Procedure (Urban & Cook, 1986)	• aquatic/terrestrial • single chemical/exposure pathway • scope could be expanded by modifying method	• risk = EEC/BC • SF (actually AF) applied if BC based on LC50/LD50 • no SF applied if BC based on NOEC • used as part of pesticide registration	• basic quotient method • programs available for PC
Chemical Migration Risk Assessment (Onishi et al. 1982,1985)	• aquatic; single chemical • potentially adaptable to other ecosystems/chemical mixtures	• BC fixed; EEC expressed as distribution • risk = probability of exceeding BC • several BC often used (e.g., acute, chronic)	• strength is exposure assessment • computer program (FRANCO) available; adaptable
Office of Water Regulations and Standards Natl. Water Quality Criteria (U.S. EPA, 1986)	• aquatic (extension to wildlife under consideration) • single chemical • exposure through water; but some consideration of dietary uptake	• risk = EEC/BC • BC applies to lowest 5th percentile of species ranked by sensitivity	• basic quotient/criteria method • programs available for PC
Waste Load Allocations (U.S. EPA, 1985a, 1987c)	• aquatic • single chemicals/effluents	• expressed in loads ($wt.\cdot d^{-1}$) rather than concentration • SF applied to acute waste allocation • chronic allocation based on low flow (7Q10)	• useful for effluents
Office of Solid Wastes Risk - Based Variance (U.S. EPA, 1987b)	• waste from hazardous waste tanks • aquatic; terrestrial • multiple chemicals	• risk = Σ (EEC/BC) for multiple chemicals • BC are EPA water quality criteria or MATC/SF	• basic method, but sums quotients

Table 7.3. Continued

Agency/Method	Scope	Description	Comments
Risk - Cost Analysis Model (U.S. EPA, 1984)	• aquatic/terrestrial • hazardous wastes • multiple chemicals present, but only most toxic used • allegedly applicable to community/ecosystem	• based on quotient(s) from most sensitive species • quotient(s) subject to further manipulation to give qualitative score estimating risk to community/ecosystem • BC may be EPA water quality criteria • complex set of SF applied	• some empirical support for method used to extrapolate individual/single sp.→community • difficult to describe and classify! • program available for PC (and needed) • also relies on extensive computer database (inventory of U.S. habitats)
Ohio EPA (1987a, b, 1988) Biological Criteria	• community level • aquatic • indirectly addresses multiple chemicals/exposure pathways	• based on indices of fish/macroinvertebrate community "well-being" • risk = Observed Index Value/Background or Criterion Index Value • risks/criteria for water quality are based on effects not concentration	• empirical method • requires data on Background Index Values
New York Dept. Ecology and Conservation Niagara River Fish Flesh Criteria (N.Y. DEC, 1987)	• piscivorous wildlife • single chemical	• risk = EEC/BC • EEC refers to expected or observed tissue residue in fish • BC refers to dose for birds/ mammals • various SF applied to BC	• takes advantage of large data set available for BC for birds/ mammals
Washington Dept. Ecology Apparent Effects Thresholds (AET) (Washington DOE, 1991)	• aquatic; sediments • single chemicals • multiple exposure pathways?	• risk = EEC/BC • BC = empirically derived AET, with SF often applied • AET = highest concentration associated with no effect in toxicity tests, benthic communities	• empirical method • requires large data set to establish AET
Oak Ridge Nat'l Laboratory Analysis of Extrapolation Error (Suter et al., 1986)	• aquatic; adaptable to terrestrial • single chemical/exposure pathway	• EEC, BC expressed as distribution • prediction limits for quotient • no SF applied to BC	• shown in Figure 7.2(c)

AF = Application Factor (acute → chronic)
BC = Benchmark Concentration
EEC = Expected Environmental Concentration
SF = Safety Factor

Two different approaches have been used to address higher level effects (i.e., above individual level):

- use of sensitive species, with the assumption that protection of these species will protect the remainder of the community
- development of empirical databases relating higher level effects to contaminant concentrations (e.g., apparent effects threshold (AET) methods)

These approaches are usually not part of the actual risk characterization, but instead part of the receptor characterization and/or hazard assessment. However, the assumption that protection of sensitive species will protect other species and prevent effects at higher levels should be noted when assumptions and uncertainties are discussed in reports generated from risk assessments. A more quantitative and probabilistic approach is that used by some Europeans (e.g., Wagner and Lokke, 1991). Benchmark concentrations are obtained (measured or estimated) for selected species representing the community. This sample of BC is assumed to follow some distribution, usually log-normal, and lower statistical tolerance limits are calculated. Thus, the lower 95% tolerance limit would protect 95% of the species in the community. The advantages of this method, relative to simply selecting the BC for the most sensitive species, are that tolerance limits are less variable and more precise than extremes such as minima and that the tolerance limits are quantitative and probabilistic.

The method used by the Ohio EPA for evaluating surface water quality is probably the most highly developed quotient method available for higher level (community, ecosystem) effects (Ohio EPA, 1987a, 1987b, 1988). The method is empirical and based on surveys of fish and macroinvertebrate communities. The state was divided into ecoregions, and within each of these ecoregions, three types of habitats based on size and water flow were sampled: wading sites, boat sites, and headwater sites. Three indices are used:

- Index of Biotic Integrity for fish (IBI; modified from Karr, 1981)
- Index of Well-Being for fish (Iwb)
- Invertebrate Community Index (ICI)

Each of these indices incorporates several measures such as total abundance and biomass, abundance of sensitive and tolerant taxa, number of taxa (richness), and diversity. Note that combining several measures to calculate the three indices makes the Ohio EPA method partially qualitative. Values of the index are compared to criteria values. The criteria values for warm-water habitats are the 25th percentiles for reference sites in the same ecoregion; the criteria values for exceptional warm-water habitats are the 75th percentiles. In risk characterization, risk would be expressed as a quotient: observed/criteria values (or criteria/observed if low index values indicate impacts). This method is retrospective, as index values would be almost impossible to predict for remediation or other scenarios. The value of the method lies mostly in retrospective assessments, in setting remediation objectives or criteria, and in measuring progress towards meeting those objectives or criteria.

Scientific Considerations

The simplest quotient methods make no statement about uncertainty or probability. Either an effect will (quotient ≥ 1) or will not occur (quotient < 1). If the benchmark concentration is a NOEC or an MATC, it may not even correspond to a specified magnitude of effect. It is possible, however, to make risk characterizations produced by the quotient method more quantitative and probabilistic by specifying the effect as a specific quantile (e.g., EC10 or LC10), and by attaching prediction or tolerance limits to the BC or EEC or both (see Figure 7.2). For example, the Analysis of Extrapolation Error method described by Suter et al. (1986) considers uncertainty associated with both the BC and EEC, to estimate the probability that EEC > BC (the formula used to estimate probability is given on p. 55 of their paper). This method corresponds with Figure 7.2 (part c), although the uncertainty about BC refers only to the error in extrapolating from acute to chronic effects or between species.

Quotient methods usually deal with uncertainty by establishing qualitative categories for quotients or by applying safety factors to the BC or less commonly, the EEC. In this report, a distinction is made between application factors (extrapolation; Section 6.6), which are used to convert acute (or lethal) effects concentrations to chronic (or sublethal) effects concentrations, and safety factors, which are used to provide some unspecified margin of safety. Application factors are considered part of hazard assessment, as they usually have some empirical support (e.g., Barnthouse et al., 1986). Safety factors are part of risk characterization because they are a substitute for probabilistic statements.

The quotient methods described in Barnthouse and Suter (1986) and in U.S. EPA (1987b) use qualitative categories for quotients:

- <0.1 = no risk
- 0.1–<10 = possible risk
- >10 = high risk

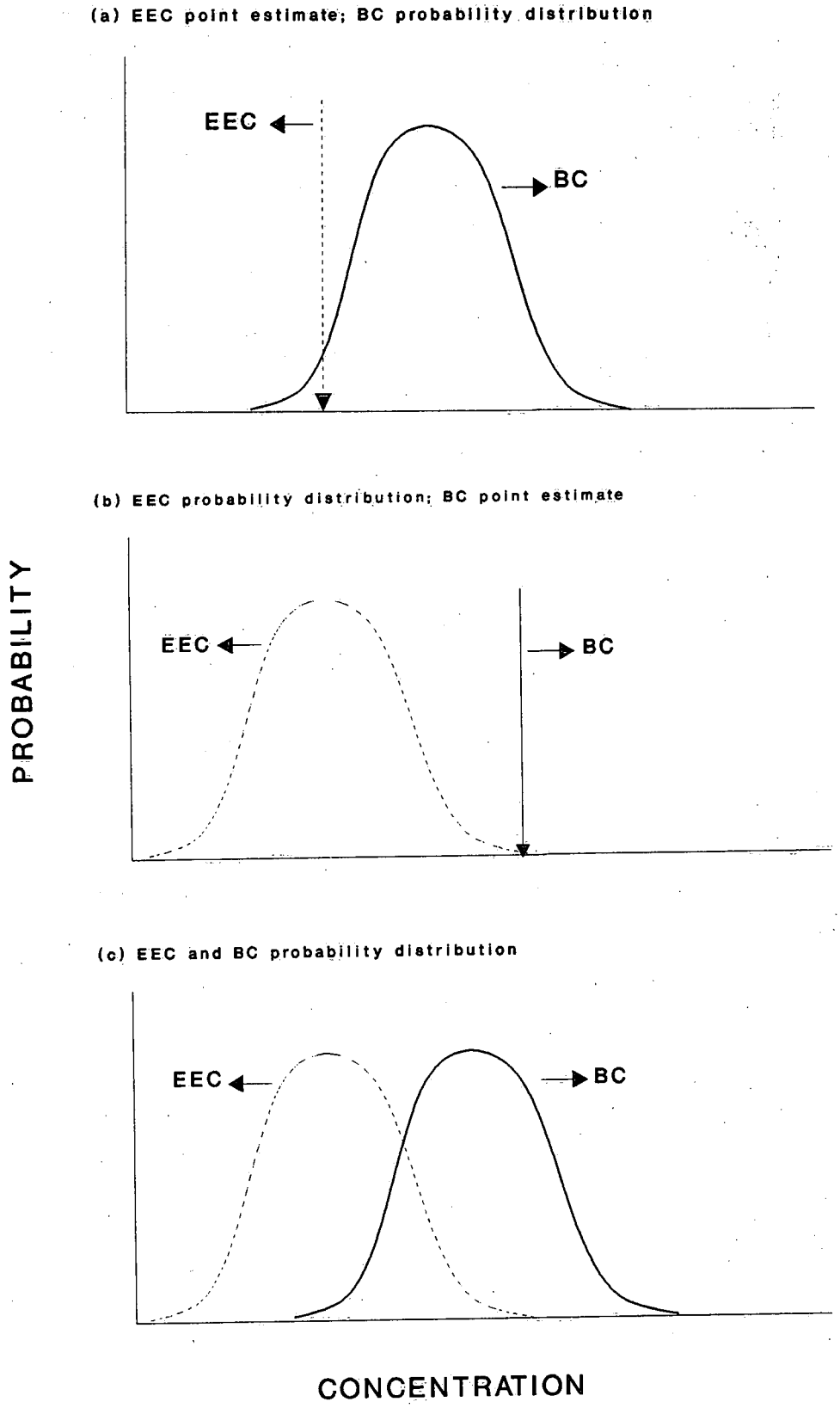


Figure 7.2. Degrees of quantification of uncertainty/probability for quotient risk characterization methods. BC = benchmark concentration; EEC = expected environmental concentration.

In the standard procedure used by the U.S. EPA OPP (Urban and Cook, 1986), a number of different safety factors are applied to the BC. For example, a safety factor of 2 is applied for aquatic organisms because they are considered less able to limit their exposure by migration or other behaviour, and safety factors of 10 and 20 are used for endangered terrestrial and aquatic species, respectively. Canada (CCREM, 1987) also uses safety factors in establishing water quality guidelines, as do many other agencies. Suter (1986) proposed that establishing categories for quotients is preferable to applying safety factors to benchmark concentrations. The categories can be (and often are) based on the same considerations and numerical values as are safety factors; the point is that any adjustments of this type should be clearly stated in the risk characterization rather than potentially concealed in the hazard assessment.

The assumptions of quotient methods discussed above have rarely been verified, partly because more verifiable and/or better supported assumptions have been deliberately classified as part of hazard assessment.

Opportunities for verification, using large data sets of many studies, certainly exist and should be pursued (Pastorok and Sampson, 1990). Quotient methods or derivative forms have been in use for several years in risk assessment and criteria development, and many risk assessments are retrospective. Therefore, there are numerous cases for comparisons of projected risk with actual or observed risk. It is suspected that many such studies are already under way or in the planning stages and should appear in the literature in increasing numbers. There is some evidence that water quality criteria or effluent load limits derived from single species toxicity tests are protective of in-stream macroinvertebrate communities (e.g., Eagleson et al., 1990). Depending on how the criteria or load limits are calculated, this could be taken as evidence that any safety factors used were adequate or that protection of one or a few species can also protect the entire community. Retrospective studies of sites with multiple chemicals offer an excellent opportunity to verify the quotient-summing approach discussed earlier, and extend it to chronic or sublethal effects concentrations. Chemicals of concern can be identified, environmental concentrations measured and BCs calculated for each, and the resulting quotients summed. The risk expressed by the sum can then be compared to measured effects of the mixture from either monitoring or toxicity tests of water, sediment, or soil from the site.

The semi-quantitative and nonprobabilistic nature of most quotient methods does not pose serious problems for verification using large data sets (i.e., the methods and their assumptions are verifiable). If large numbers of cases are available, both predicted and observed responses can be expressed as yes/no, effect/no effect responses for comparison. The power of such comparisons comes not from the precision of the individual responses, but from the generality of including many cases. This type of comparison can even be conducted when the predicted and observed responses represent different endpoints or different levels of organization; for example, when predictions based on single species toxicity tests were compared with observed in-stream macroinvertebrate community responses by Eagleson et al. (1990).

Unfortunately, the methods and assumptions of quotient methods are potentially unverifiable in cases involving one or a few studies. For example, consider the case of a projected risk calculated for a site with an endangered or rare species, which is to be followed up and verified by monitoring studies because of concern over the species. There may be few or no other sites at which risk projections for this species could be verified. Under these circumstances, a risk projection expressed as a quotient is virtually untestable. To illustrate, suppose the quotient EEC/BC were 0.1, categorized as no or low risk. Follow-up studies indicate a statistically significant 15% reduction in mean growth rate of the individuals. Arguably, the method failed; specifically by underestimating risk (predicting no effect when one was observed). However, if the BC were equivalent to an EC40, an investigator might conclude instead that the method was successful since a 40% reduction in growth rate was not observed (if the observed 15% reduction were significantly different from 0%, it would almost certainly be significantly different from 40%). In reality, most investigators would want to compare the confidence limits for the magnitude of the observed response (easily calculated but probably narrow) with the prediction or tolerance limits for the magnitude of the predicted effect. In other words, the observed effect should be stated as, for example, 15 ± 5%, and the predicted effect as, for example, 5 ± 20%. The prediction limits for the projected effect can only be obtained from continuous exposure-response relationships which account for uncertainty (variance) in both the EEC and the expected effect. Based on the overlapping confidence and prediction limits provided above, an investigator would conclude that the prediction was either successful or too imprecise to provide a meaningful test.

Overall Evaluation

The primary advantage of quotient methods is their simplicity, ease of implementation, and low cost. The hazard data required (usually LC50 or MATC) are more available or more easily estimated than other types of data. The actual risk characterization is trivial, and produces a single number (quotient) which can easily be used to rank priorities in terms of contaminants or species of concern. Establishing remediation criteria

is also simple, using the benchmark concentrations, possibly adjusted by a safety factor. The methods and associated assumptions could easily be verified using large data sets comparing predicted and observed effects. Although most existing quotient methods do not deal with multiple chemicals or higher level effects, there is no reason why methods cannot be developed or refined to deal with these issues.

The primary limitation of quotient methods is that predicted risks are semi-quantitative and nonprobabilistic. The magnitude of effect is often not specified; the probability distribution of the quotient is rarely specified; the probability distribution of different effect sizes is, by definition, never specified. As a result, it is argued here that the predictions of quotient methods at specific sites will be virtually unverifiable even if follow-up monitoring is conducted. A related limitation of quotient methods is the widespread use of safety factors to express uncertainty. These safety factors are often arbitrary, may vary among methods, and are sometimes concealed in the hazard assessment, reducing the validity and utility of that assessment.

7.2.2.2 Continuous Exposure–Response Methods

Description

Continuous exposure–response methods rely on the relationship between exposure (concentration or dose) and response (effect) and its associated prediction limits (Figure 7.3; examples are given in Table 7.4). These relationships are derived from toxicity data in the hazard assessment. Procedures used to calculate prediction limits should account for variance or uncertainty in the independent variable (exposure) as well as in the dependent variable (response) (Barnthouse et al., 1986). The relationship shown in Figure 7.3 (a), if it referred to a single species, would represent a risk characterization at the individual level. Despite the advantages of this type of risk characterization, discussed in Section 7.2.2.1 (Quotient Methods) and below under Overall Evaluation, not a single example was found in which the method was used. In most cases, exposure–response relationships at the individual level for a number of species or endpoints serve as input for models predicting higher level effects or risks.

Deterministic linear population models are the most common method used to predict population level effects. These models have traditionally been used in fish, wildlife, forestry, and pest management (see Getz and Haight, 1989; Emlen, 1989 for reviews). The models are usually age-, stage-, or size-specific, tracking abundance of different age or size classes or ontogenetic stages separately. A bookkeeping approach is usually followed, with birth, death, and growth rates applied to age, stage, or size class abundances to predict abundances at the next time interval (Figure 7.4). The most common interval is one year, because of the annual seasonal cycle of processes such as birth, but the interval may be shorter for smaller organisms with short life cycles. Modifications of basic population models include stochastic and nonlinear models. Stochastic models include variability in model parameters, an obvious desideratum for risk characterization. Nonlinear models provide an alternative to the traditional assumption that relationships between births or deaths and numbers are linear (i.e., constant birth or death rate). Thus, these nonlinear models can account for density-dependent processes.

Barnthouse et al. (1986, 1987) provide a good example of the application of population models to risk characterization. They use a fisheries model with output in terms of the reproductive potential of a one-year-old female. Reproductive potential is the expected lifetime reproductive output of the next generation (i.e., one-year-old females). If the reproductive potential averages 1, then each female will replace herself, and abundance will remain constant. If reproductive potential is <1, then the population will decline; if reproductive potential is >1, then the population will increase. This particular method indicates the value of expressing effects in a single simple integrative measure such as reproductive potential. Other possible effects measures are pseudoextinction (probability of falling below a specified density) and temporal mean density (Emlen, 1989).

Community and ecosystem models consider higher order processes such as competition, predation, and energy transfer through the food chain. The best-known ecosystem model is the Standard Water Column Model (SWACOM) described by O'Neill et al. (1986). This model applies to the pelagic zone of north temperate dimictic lakes, and includes ten phytoplankton populations, five zooplankton populations, three planktivorous populations, and one top carnivore population. These populations represent hypothetical species, although their characteristics can be matched with those of real species for which toxicological data are available. The phytoplankton populations are driven primarily by abiotic factors such as nutrients, light, and temperature, and the energy they produce is transferred by grazing and predation to higher trophic levels. The model can include interactions among species such as competition. The authors present their results as the probabilities of a fourfold reduction in algal biomass and a 25% reduction in game fish biomass (Figure 7.3, part b), but other effects measures or magnitudes can easily be generated.

Reviews by Norton et al. (1988) and Parkhurst et al. (1990) did not list any examples of empirical continuous exposure–response methods based on responses at the population or higher levels.

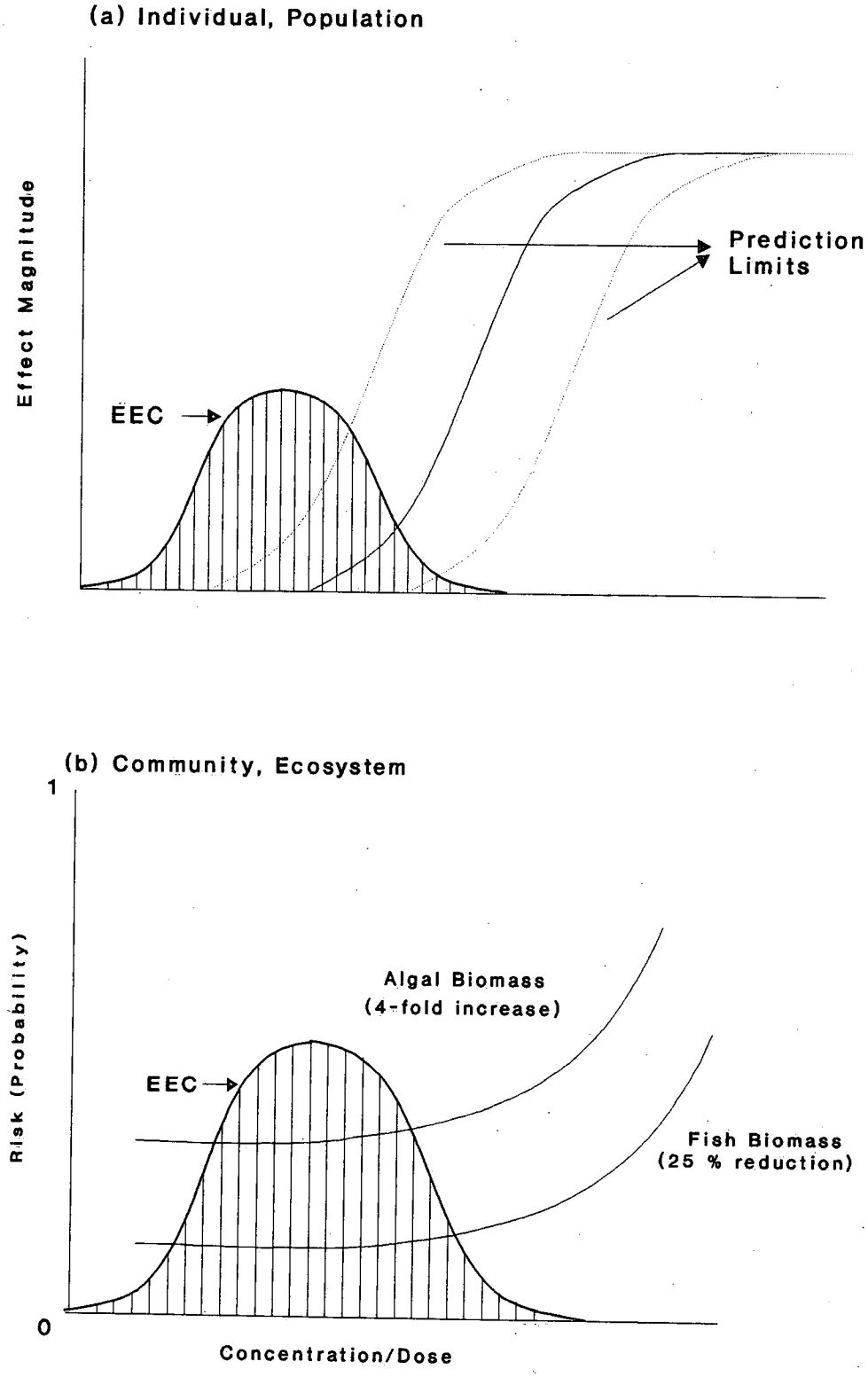
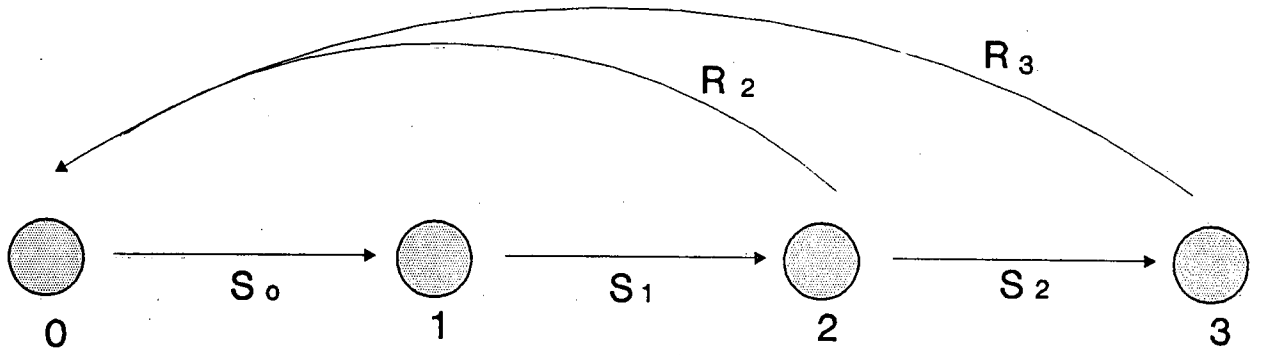


Figure 7.3. Risk characterizations from continuous exposure–response methods. The distribution of expected environmental concentrations (EEC) has been superimposed on the response curves. (Adapted from Barnthouse et al. 1986.)

Table 7.4. Examples of Continuous Exposure–Response Risk Characterization Methods

Agency/Method	Scope	Description/Comments
POPULATION		
Oak Ridge National Laboratory (Barnthouse et. al, 1986)	• aquatic - fish • single chemical/exposure pathway	• linear • output is female reproductive potential • adapted from models used in assessment of power plant impacts • requires data on survival, reproduction
COMMUNITY/ECOSYSTEM		
U.S. Dept. Interior CERCLA Damage Assessment (U.S. DOI, 1987)	• aquatic • oil spills, hazardous wastes	• deterministic, linear • retrospective (damage assessment), but also predicts long-term impacts • basically population models, but can pass on effects from algae to zooplankton • no estimates of uncertainty
Oak Ridge National Laboratory SWACOM model (O'Neill et al., 1986)	• aquatic (lake) • single chemical/exposure pathway	• transfers effects through trophic levels • simulations provide Ecosystem Uncertainty Analysis



Age	Abundance at time:	
	t	$t + 1$
0	N_0	$S_1N_1R_2 + S_2N_2R_3 + \ldots$
1	N_1	S_0N_0
2	N_2	S_1N_1
3	N_3	S_2N_2
.		
.		
.		
etc.		

Figure 7.4. Basic age- or stage-specific linear deterministic population model. S_i are survival rates and R_i are reproductive rates for the ith age class. The hypothetical organism shown does not reproduce until age 2, and reproduction occurs at the end of the interval from time t to $t + 1$.

Such models would predict higher level responses from contaminant exposures (concentration or dose), possibly in conjunction with other predictors such as nutrient levels. There are a number of regression models which correlate fish species richness in lakes with pH (e.g., Rahel, 1986; Matuzek and Beggs, 1988). Some existing quotient methods, such as that used by the Ohio EPA (1988), could be expanded into continuous exposure–response methods. If contaminant concentrations were available for streams within an ecoregion, the Indices of Well-Being for fish and macroinvertebrate communities could be regressed on contaminant concentrations. Most of the contaminated sites, however, would contain multiple chemicals, and the effects of individual chemicals would be difficult to estimate.

Evaluation

Practical Considerations

Continuous exposure–response methods all require continuous exposure–response data, which are usually less available than LC50 or MATC. Barnthouse et al. (1986, 1987) provide a method for estimating parameters of continuous functions from point estimates. Population models require toxicological data on growth, reproduction, and survival, rather than just one endpoint. These models also require data on the demography of the modelled species in the absence of contaminants; such data are easier to obtain if the model is already in use for fish or wildlife management. Community- and ecosystem-level models can be very

demanding of data, and often require types of data not normally provided in the toxicological literature. For example, the SWACOM model ideally requires data on contaminant effects on energetic and physiological processes or rates, but these data are often not available. In practice, numerous assumptions about the form and nature of exposure–response relationships must be made to implement the model.

Use of population and higher level models requires considerable expertise and effort beyond that required for the hazard and exposure assessments. The effort and costs can be reduced if an existing model can be used or adapted. There are population models available which can be run on personal computers (e.g., the RAMAS series of models described in Appendix D of U.S. EPA, 1991). Provincial fish and wildlife agencies and power utilities may also have models available. The costs of continuous exposure–response methods will always be greater than for quotient methods applied to the same data, although the additional costs for individual-level methods may be relatively trivial. In the case of assessments involving extensive field monitoring, toxicity testing, and especially chemical analyses, the additional costs associated with population or higher–level models may still represent a small percentage of the total. In such cases, the models may actually reduce overall costs if they are used to restrict the focus of further field work and testing to the major sources of uncertainty.

Scope/Integration

Continuous exposure–response methods and, specifically, population, community, and ecosystem models predicting effects of multiple chemicals or exposure pathways have not been developed. Survival probabilities for exposure to several chemicals or pathways can easily be combined by multiplication into an overall survival. Combining effects on reproduction or growth, however, might be considerably more difficult, as these effects are rarely expressed as binomial probabilities. It is suspected that developing models addressing multiple chemicals or exposure pathways is theoretically possible, but that in practice, it might be technically difficult and would require making and then verifying a number of assumptions about how exposure–response relationships should be combined. Population models can integrate effects on several different endpoints, such as survival, growth, and reproduction, and higher level methods can integrate effects on different species.

Theoretically, continuous exposure–response methods can be applied to any species, ecosystem, or chemical. In practice, the number of species or chemicals for which continuous exposure–response data are available will restrict the scope of the methods or increase uncertainty if extrapolations from species to species or chemical to chemical are used. The use of population models may be further restricted by the absence of suitable models for noncommercial fish and wildlife species. The use of community and ecosystem models has been restricted to aquatic ecosystems. The spatial scope of these models is usually broad, but site-specific models have been developed (Appendix D in U.S. EPA, 1991). The RAMAS series of models can deal specifically with the effects of spatial scale and differing spatial distributions (i.e., many small isolated populations versus a few large populations). Models also deal with a longer time span than do quotient methods.

Scientific Considerations

Individual-level continuous exposure–response methods provide measures of uncertainty in the form of prediction limits about the exposure–response relationships (Figure 7.3). These prediction intervals can be based on uncertainty about environmental concentrations as well as about effects. As discussed in the evaluation of quotient methods, the inclusion of prediction intervals makes it much easier to compare predictions with observed effects at specific sites. However, the prediction intervals address only a limited range of uncertainties, usually those related to extrapolations or assumptions in the hazard and exposure assessments. Higher level continuous exposure methods attempt to deal with other sources of uncertainty, particularly, of course, higher level effects.

The most common approach to analyzing uncertainty in population and higher level models consists of multiple simulations followed by sensitivity analysis (O'Neill et al., 1986). Monte Carlo simulation involves repeated runs of the model with parameter values randomly selected from probability distributions. These simulations indicate the uncertainty about model predictions or output, but do not indicate the major sources of uncertainty. The major sources of uncertainty are identified by sensitivity analysis, which determines which parameters have the greatest effect in determining the value of the output measure (see O'Neill et al., 1986; U.S. EPA, 1991 for descriptions of some specific methods). Sensitivity analysis is very important if models are to be used in risk assessments, because otherwise the models will only add additional uncertainty (and quantify the usually depressing effects of that additional uncertainty). There should also be some follow-up to the sensitivity analysis through additional hazard and exposure assessment and further model refinement to focus on and reduce the major sources of uncertainty.

The input parameter values used in models can often be verified or calibrated by direct measurement. The particular processes included in the model, such as transfer of energy from one trophic level to another,

should also be verifiable through direct measurement or valid in terms of being based on similar processes observed in the literature. Output measures, particularly those related to longer term effects such as the probability of pseudoextinction, may be more difficult to verify. Other sources of error, particularly model error, can be avoided by using simulations and sensitivity analysis to restrict the model to only the most important parameters and to explore the effects of expanding or contracting the boundaries of the model. In general, the best means of ensuring the validity of model results is to use models which have been applied previously and are credible to the scientific community, and to calibrate the models through an iterative process of simulation, sensitivity analysis, and direct measurement.

Although population and higher level models do account for some effects beyond the individual level, they cannot account for all such effects and are open to the criticism that important effects have been excluded. Reviews have suggested that density-dependent effects on mortality, growth, and reproduction may be the most important effects excluded from existing models (e.g., Barnthouse et al., 1986; Norton et al., 1988; Parkhurst et al., 1990; Pastorok and Sampson, 1990). There are models available which include density-dependent effects, and there is evidence for the existence of these effects (Getz and Haight, 1989). In most cases, however, the exclusion of density-dependent processes is conservative (i.e., overestimates risk). Density-dependent processes tend to move successive age or size classes towards a fixed abundance or biomass. For example, food availability in a stream might limit the number of available territories and, therefore, the recruitment of juveniles regardless of the number of eggs or alevins produced in any year (Elliott, 1987). If a contaminant affected primarily the survival of younger stages, the population density might remain relatively stable. The surviving juveniles would enjoy better growth and survival because they would have a better chance of securing territories and food. This type of compensatory growth or mortality would be especially important in migratory species, with only one life stage exposed to contaminants. Fisheries and wildlife management depends on the assumption that compensatory mortality and growth will counteract the effects of increased mortality from exploitation up to a certain level. In fact, exploitation will in some cases increase biomass or production. Even density-independent mortality from changes in climate or discharge may completely override toxic effects. Thus, inclusion of density-dependent effects is likely to reduce estimates of risk. Exceptions would occur in cases of reverse density dependence; for example, when low densities lead to an increased probability of failing to find a mate. If density-dependent processes are to be included in models, the objective should be to identify the critical contaminant concentrations and effects beyond which compensation is no longer effective.

Overall Evaluation

Continuous exposure–response methods at the individual level offer several advantages over quotient methods with little additional cost. It is difficult to understand why these methods are not used more frequently. The chief advantage is the quantification of a range of effect magnitudes and their uncertainties. As a result, the predictions of these continuous measures are easier to verify at a specific site than are the predictions of quotient methods. The chief disadvantage to the individual-level continuous exposure–response methods is that the dose–response relationships are less likely to be available than are point estimates such as LC50 or MATC. These data requirements are also a disadvantage of higher-level continuous–response methods.

By definition, population and higher level models attempt to estimate the magnitude and uncertainties of higher level effects. It follows that these models will be useful when

- these higher level effects exist and are large
- additional uncertainties are identified, quantified, and subsequently reduced

Models have identified effects which would not be predicted by individual-level methods. For example, the SWACOM model indicated that algal biomass may increase, even if contaminants negatively affect individual algae, because of greater effects on grazers and alteration of algal community composition (O'Neill et al., 1983, 1986). The model also indicated that effects could differ with timing of exposure initiation (spring versus fall). Barnthouse et al. (1987, 1990) used their fish population model to estimate and compare various sources of uncertainty. The greatest source of uncertainty was associated with estimation of long-term toxic effects from short-term effects or QSAR. Finally, both the SWACOM and fish population models indicated that risks at higher levels were greater than those at the individual level.

Models can also be useful for investigating alternative scenarios. The major costs are associated with development and initial calibration. Therefore, once this has been accomplished, exploration of additional alternatives by varying the relevant parameters or processes is relatively inexpensive. Alternative scenarios might include different remediation strategies or production/treatment processes, or varying levels of other stressors such as fishing pressure. Models can also be used as a research tool to define the magnitude of potential "problems" such as density-dependent effects through multiple simulations and sensitivity analysis.

Models also have their disadvantages in risk characterization, including:

- increased data requirements, level of expertise, and costs
- lack of suitable models for many non-commercial species and most ecosystems
- increased uncertainty associated with additional parameters
- difficulties in verifying long-term predictions

7.3 Current Practices and State of the Art

Table 7.5 summarizes current risk assessment practices in U.S. federal and state agencies, taken from Appendices E and F in U.S. EPA (1991). The survey indicated that most agencies use qualitative and quotient methods, and rely strongly on professional judgement. Quantification of uncertainty is rare. In fact, the consensus among the state agency personnel was that the EPA should omit any reference to quantitative uncertainty analysis and statistical significance of the final risk in guidelines produced for risk assessment. This consensus is in sharp contrast to the recommendations of reviewers (e.g., Norton et al., 1988; Parkhurst et al., 1990; Pastorok and Sampson, 1991), who argued for increased levels of quantification in risk characterization. The question of when or even whether the increased complexity and costs of quantification of uncertainty and use of higher level models is justified is probably the major issue in risk characterization. The U.S. EPA (1991) survey and the other reviews cited agreed that qualitative and quotient methods are adequate for an initial assessment of risk and for ranking the relative risks associated with different chemicals, sites, or species. Continuous exposure–response methods and models can be used for a more refined risk characterization and to explore higher level effects.

Two factors, unrelated to the scientific merits of qualitative/quotient versus more quantitative methods, probably contribute to the widespread use of the less quantitative methods:

- many agencies use risk assessments to establish criteria or assist regulatory decisions
- most toxicologists are not familiar with population and ecosystem models

Dichotomous (effect/no effect) risk characterizations are simpler to apply in a regulatory framework or in establishing criteria than are continuous values. More generally, simple risk characterizations are easier to understand and communicate to others. Even though the more quantitative methods can give a wide range of effects and associated uncertainties, the risk characterizations are usually expressed as the probability of only one or a few effect magnitudes. However, The U.S. EPA Scientific Advisory Board has recommended that the expression and communication of risks should be kept separate from the actual risk characterization (U.S. EPA, 1991, Appendix G). Thus risks can still be quantified in the main body of a risk assessment report, even if simplified in conclusions or summaries.

Ecological models have only recently entered into the toxicological field from other fields. Thus, lack of familiarity may be a major reason for toxicologists' reluctance to use models. The National Marine Fisheries Service, which uses population models extensively for other purposes, was one of the few agencies in Table 7.5 which indicated a desire to use these models in risk characterization. Population models have been widely used in assessments conducted for power plants, and it is not surprising that researchers at the Oak Ridge National Laboratory, particularly Barnthouse and his collaborators, have adapted those models for use in assessing the effects of synthetic fuel technologies.

Other current issues and deficiencies in risk characterization are

- quotient methods for higher level effects
- multiple chemicals and exposure pathways
- density-dependent effects
- the lack of models and methods for terrestrial ecosystems
- the need for more empirical models and methods
- verification and comparison of existing methods

These issues have been identified in previous reviews, usually as recommendations for future research (Norton et al., 1988; Parkhurst et al., 1990; Pastorok and Sampson, 1990), and were discussed in the description and evaluation of methods. All but the last issue identify current deficiencies. Some of these deficiencies are already being addressed as risk assessments become more common, although there may be a publication lag of several years before new methods and developments are generally available. In Section 7.2, some additional suggestions about how these deficiencies could be addressed are provided; none of the deficiencies appear to present insurmountable problems. Finally, there is no excuse for not addressing the issue of verification and

Table 7.5. Risk Characterization Methods Used by U.S. State and Federal Agencies (from appendices E and F in U.S. EPA, 1991)

Agency/State	Method(s) Used
STATES	
Michigan Dept. Natural Resources	• use water quality criteria; compare with existing concentration • Aquatic Chronic Value Terrestrial Life Cycle Safe Concentration • goal: protect 95% of spp. for 80% of chemicals

New Jersey Dept. Environmental Protection	• currently developing methods
	• have considered:
	  • Analysis of Extrapolation Error (quotient)
	  • Toxicity Quotient (basic quotient method)
	  • Mink and mallard risk assessments (quotient)

Ohio Environmental Protection Agency	• numerical biocriteria (see Table 7.3) • compare observed effects with predictions from basic quotient method
Washington Dept. Ecology	• qualitative methods for ranking priorities • qualitative risk estimates derived from models (dredge disposal) • AET (quotient; see Table 7.3)
Wisconsin Dept. Natural Resources	• focus on aquatic wildlife; fish in surface waters program • based on state water quality criteria (quotient) • have modelled contaminant uptake for birds (exposure assessment)
FEDERAL AGENCIES	
Food & Drug Administration (FDA)	• basic quotient method • BC divided by SF
Natl. Marine Fisheries Service (NMFS)	• focus is on physical rather than chemical stressors • extensive use of existing models planned, but have also used qualitative methods • qualitative method has survived court appeals

Table 7.5. Continued

Agency/State	Method(s) Used
Army	• effect-based approach; often retrospective • quotient or qualitative • exploring demographic models
Fish and Wildlife Service (FWS)	• stress retrospective/field assessments • rely on individual level • interested in biomarkers for exposure assessment • quotient/qualitative
Natl. Ocean & Atmospheric Administration (NOAA)	• primarily retrospective (sediments)
Forest Service	• quotient; SF used • must protect entire forest community/ecosystem; considering methods of doing so
Dept. Energy	• quotient with SF • Superfund requires only proof of adverse effect, regardless of level • therefore, higher level effects not priority

BC = Benchmark Concentration
SF = Safety Factor

comparison of methods because the data are currently available in the form of past risk assessments. Furthermore, some verification and comparison can be conducted within any individual assessment.

8.0 APPLICATION OF TIERED ERA UNDER NCSRP

A tiered approach to ecological risk assessment under the NCSRP is recommended and described in Section 2.0. The approach consists of three levels, increasing in complexity and scope. The ecological risk assessment for each level finishes with an estimate of risk for either existing conditions or remediation options and, if required, terms of reference for an ERA at the next level. Below, recommended procedures for each ERA level are provided, based on the objectives of each level (Section 2.4), and the reviews of ERA components provided in Sections 4.0 to 7.0. Section 8.0 is intended to provide guidance and methods for environmental scientists undertaking ecological risk assessments under the NCSRP. Anyone undertaking an ERA should be familiar with the procedures suggested, and considerable expert judgement will still be required on a site-specific basis. Furthermore, investigators should keep the following general considerations in mind before proceeding with specific methods:

- The most appropriate methods will vary from site to site, and all methods have their advantages and limitations.
- All components of a risk assessment should be designed to address the study objectives and should be integrated as much as possible with respect to degree of complexity/ quantification and level of effects (individual, population, community, ecosystem).
- Risk characterization depends on the quaity of the receptor characterization, hazard, and exposure assessments; therefore, improvements in data quality and output for these components are usually the best means of improving risk characterizations.
- Whenever possible, more than one method should be used for any estimate or prediction, and predictions should be compared among methods and with observations from subsequent toxicity testing or field monitoring.

8.1 Level One Ecological Risk Assessments

Level One ERAs are based primarily on data from the literature or from previous or preliminary studies on the specific contaminated site. Objectives are to establish whether exposed receptors are deleteriously affected or at risk. If a more detailed ecological risk assessment is required, terms of reference should be developed for Level Two assessments. In a Level One ERA, risk can be characterized qualitatively as "high", "intermediate", or "low", rather than quantitatively. Data requirements, suggested methods, and expected output for each component of a Level One risk assessment are summarized in Table 8.1.

The U.S. EPA (1988b) identifies the attributes of sites for which simple qualitative analyses are adequate; these attributes include

- available environmental standards or criteria
- a small number of chemicals
- a small number of exposure pathways
- relatively simple release and transport processes
- a limited need for detail and precision in assessment results

8.1.1 Exposure Assessment

Level One exposure assessments should identify the priority contaminants, exposure media, and exposure pathways, and identify the major uncertainties and data gaps which exist. Qualitative methods and simple quantitative methods would be appropriate for Level One. A key component of the exposure assessment would be an initial screening of potential contaminants of concern and preliminary selection of target chemicals as described in Section 4.3.1. Assessment of contaminant release, transport, and fate would consist of working through the decision tree in Figure 4.3 to identify potential routes of exposure. Similarly, potential exposure through the food chain would be identified using Figure 4.5. Some preliminary quantitative analyses of contaminant release (Section 4.3.2.2), transport and fate (Section 4.3.3.2), and uptake by biota (Sections 4.3.5.2, 4.3.6.2) would be necessary to support a preliminary risk characterization using quotient methods (see Section 8.1.4) and would assist in narrowing the range of priority contaminants for either remediation or further risk assessment. After a Level One exposure assessment has been completed, investigators should be able to develop a conceptual model for major exposure routes, which would serve as the basis of a quantitative model in Level Two or Three assessments (if undertaken).

The quality and quantity of available monitoring data also obviously affect the type of method which can be applied. It is usually appropriate to apply simpler methods to all pertinent exposure routes at the start of

Table 8.1 Summary of Data Requirements and Components of Level One Ecological Risk Assessment

EXPOSURE ASSESSMENT

- qualitative, preliminary quantitative methods
- based largely on literature review, existing data

- Selection of Target Chemicals
  - select target chemicals based on review/assessment of properties
- Contaminant Release/Transport and Fate
  - work through flowchart in Figure 4.3
  - provide preliminary quantitative estimates if possible
- Exposure Pathways Analysis
  - identify most important exposure pathways
- Aquatic or Terrestrial Exposure
  - identify most important exposure pathways/food chains
  - provide preliminary estimates of exposure or tissue concentration using BCF, BAF
- Uncertainty Analysis
  - identify data gaps, key uncertainties for Level Two exposure assessment, if necessary
- Output - preliminary, quantitative estimate of exposure via dominant pathway(s)

RECEPTOR CHARACTERIZATION

- qualitative, preliminary methods
- based largely on existing literature with a site visit

- Identify Receptors
  - identify habitats, communities, and ecosystems through data review and file reconnaissance
  - use structured impact hypotheses
- Select Endpoints
  - select assessment endpoints (VECs) and measurement endpoints with focus on individual and population levels
  - use criteria in Section 5.5.1
  - ensure priority receptors are emphasized
- Relate to Exposure Assessment
  - assess possible spatial/temporal overlap of receptors and contaminants of concern
- Output - basic life history information on species identified as potential receptors

HAZARD ASSESSMENT

- information largely obtained from literature

- Hazard Identification
  - review existing site data (chemistry and effects)
  - review toxicity of Contaminants of Concern identified in exposure assessment
- Endpoints
  - select measurement and assessment endpoints
  - choose species for which toxicity data are readily available (extrapolate to VEC)
  - focus on acute endpoints (e.g. mortality); collect chronic/sublethal information simultaneously
  - where data are available, examine population/community information
- Output - LC50, LD50, benchmark concentrations for selected chemical and species

RISK CHARACTERIZATION

- qualitative and quotient methods
- characterize risk as "high", "intermediate", "low"
- estimates of uncertainty restricted to safety factors
- identify key uncertainties, data gaps

an exposure assessment (Level One ERA) as a scoping technique to isolate those pathways requiring the most in-depth analyses. The CCME National Classification System for Contaminated Sites is an example of a simple, essentially qualitative method. It includes methods of scoring both contaminant characteristics (Category 1 of method) and exposure pathways (Category 2: groundwater, surface water, direct contact). In this report, it is considered a qualitative method because actual concentrations are not computed using mathematical representations of biophysical processes.

8.1.2 Receptor Characterization

Initial receptor characterization (Level One) should identify the species or taxa (VECs) that are most likely to be affected by the contaminant concentrations believed to be present on the site. This will be accomplished through review of available site information, reconnaissance visits, and local expert advice. Although various levels of biological organization (individual, population, community, ecosystem) should be considered, there is usually an emphasis in Level One on individual species (indigenous populations). The list of receptors of concern will be used to establish organisms to focus on in the hazard assessment. Life history information should be used to identify sensitive life stages and time periods relative to the contaminated site. Steps in Level One receptor characterization are summarized in Table 8.1.

8.1.3 Hazard Assessment

In a Level One hazard assessment, the primary emphasis is on obtaining toxicity information from the literature for the contaminant or contaminants of concern. The toxicity test species should be related as closely as possible to the VEC, but an exact match is rarely possible. In this initial stage of hazard assessment, any toxicity information is useful, particularly if it relates to the contaminated site of interest. Mortality data are most plentiful and provide clear measurement endpoints for use in the risk characterization.

8.1.4 Risk Characterization

Qualitative and quotient methods would be suitable for Level One assessments. Appropriate qualitative methods would include the CCME (1991a) National Classification System for Contaminated Sites or any simple scoring system based on expert judgement which could be developed by Environment Canada.

Quotient methods could be used whenever there was sufficient information to estimate an expected environmental concentration (EEC) in the most important medium or media and a benchmark concentration (BC) for local species or their close relatives. The qualitative categories of risk associated with quotient methods suggested by Barnthouse and Suter (1986) and the U.S. EPA (1987b), and provided in Section 7.2.2.1, would be adequate for Level One risk characterization. Safety factors might also be appropriate in Level One risk characterization, although it is recommended that the uncertainty associated with the use of these factors be applied to the establishment of categories of risk, rather than directly to the quotients (see Suter, 1986, and Section 7.2.2.1).

Quotient methods would also be useful for the following specific applications:

- determining priority contaminants when the site is grossly contaminated with many chemicals (i.e., many quotients >1)
- estimating relative risk of different exposure pathways or different media

8.2 Level Two Ecological Risk Assessments

The twin objectives of Level Two ERAs are to provide a quantitative estimate of risk and to develop site-specific preliminary remedial goals if remediation is necessary. Assessments are based on site-specific data. Data requirements, suggested methods, and expected output for each component of a Level Two ERA are summarized in Table 8.2.

8.2.1 Exposure Assessment

Level Two exposure assessments should provide quantitative estimates of exposure (dose or concentration) for important receptors via one or more important exposure pathways. Preferably, some estimate of uncertainty should be associated with these estimates of exposure. Appropriate methods for estimating contaminant release, transport and fate, and exposure through major pathways would include those classified as Preliminary or Detailed Quantitative Analyses in Section 4.0. Direct measurement of contaminant concentrations in important media would also be included in Level Two exposure assessments. Basically, Level Two exposure assessments should provide preliminary quantitative estimates for the various steps in the decision tree in Figure 4.3.

Level Two methods range from desk-top calculations using relatively simple equations to simple models. Estimates of uncertainty would come from confidence or tolerance limits about actual measured contaminant concentrations (e.g., in water or in food) or from simulations using known or estimated distributions for input parameters. The degree of quantification and

Table 8.2 Summary of Data Requirements and Components of Level Two Ecological Risk Assessment

EXPOSURE ASSESSMENT
- quantitative methods
- based on simple models, direct measurement (monitoring data)

- Selection of Target Chemicals
  - revise Level One selection, if necessary

- Contaminant Release/Transport and Fate
  - provide quantitative estimates from direct measurement, desk-top calculations, or simple models

- Exposure Pathways Analysis
  - identify most important pathways based on quantitative estimates of exposure

- Aquatic or Terrestrial Exposure
  - develop simple food chain models
  - estimate exposure via most important pathway(s)

- Uncertainty Analysis
  - provide estimates of uncertainty (confidence or tolerance limits) for exposure, if possible
  - verify/calibrate initial estimates using monitoring data

- Output - quantitative estimates of expected environmental concentrations (EEC); with estimate of uncertainty

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RECEPTOR CHARACTERIZATION
- quantitative methods, field data collection, and local expert knowledge

- Consider Data Requirements
  - identify information needed based on Level One ERA
  - field program design

- Characterize Habitat
  - describe VEC niches
  - background data on physical/chemical attributes that could affect receptor responses

- Characterize Receptors - Species and Population
  - structural attributes of VECs [population density, biomass, distribution, age–class structure, status (e.g., endangered) life history]
  - functional attributes of VECs (food requirement, ingestion rates, bioaccumulation potential, activity patterns)
  - consider community- and ecosystem-level effects

- Characterize Receptors - Community and Ecosystems
  - structural attributes (biodiversity, biomass, guilds successional stage, food web)
  - functional attributes (primary production, respiration, decomposition, nutrient cycling, resilience)
  - local, regional significance

- Output - detailed life history data, food web interactions

HAZARD ASSESSMENT
- data collection usually required

- Hazard Identification
  - confirm or modify list of contaminants of concern
  - review toxicity data compiled in Level One

- Endpoints
  - select measurement and assessment endpoints
  - establish link between exposure assessment (i.e., contaminant distribution) and sampling for hazard assessment
  - conduct toxicity tests, use surrogates as necessary
  - focus on population- and community-level field investigations

- Output
  - LC50, LD50, continuous exposure–response relationships obtained from toxicity testing
  - statistically analyzed population and/or community data
  - uncertainty estimates

Table 8.2. Continued

RISK CHARACTERIZATION

- quotient and continuous exposure–response (individual, population) methods
- quotient; EEC/BC for most sensitive endpoint(s); with estimate of uncertainty
- individual-level continuous exposure response; probability for several effect magnitudes (e.g., 5, 10, 25% reduction in survival, growth, or reproduction)
- population models: combine estimates of effects on survival, growth, and reproduction to provide average reproductive potential (± tolerance limits), probability of extinction or pseudo-extinction, or other appropriate estimate of effects/risks
- for all methods, explore effects/risks associated with remediation options
- set remediation objectives or terms of reference for Level Three, as appropriate

complexity should match that for other components, especially hazard assessment and risk characterization, although constraints would also be imposed by limitations (cost, logistical) on the data which could be collected. The exposure assessment should be relatively complete in terms of quantifying exposure for all priority chemicals and pathways.

8.2.2 Receptor Characterization

Level Two receptor characterization involves collection of field data on the receptors of concern. Once the measurement endpoints have been established, an appropriate field sampling program should be developed. Quantitative assessment can include measures described in Section 5.3 and listed in Table 8.2. Level Two investigations should focus on species and communities that were identified in Level One as VECs. The information collected in a Level Two receptor characterization is used to focus hazard assessment and may also be used in determining steps in the exposure assessment.

8.2.3 Hazard Assessment

Level Two hazard assessments should provide quantitative estimates of toxicity of field samples from the contaminated site. Where possible, the toxicity testing should be conducted with the receptors of concern, but extrapolation can be used to estimate toxicity. The toxicity endpoint is usually mortality, although chronic and sublethal endpoints that relate to the receptors are very useful (Sections 6.4.2 and 6.5.1). Where the emphasis is on population- or community-level assessment, direct measurement is invaluable (Sections 6.4.3 and 6.5.3).

In most cases, extrapolation of hazard assessment data is required (e.g., species to species, endpoint to endpoint, laboratory to field). This is an important component of a Level Two hazard assessment, since it is often one of the largest contributors of uncertainty (Section 6.7).

8.2.4 Risk Characterization

Appropriate risk characterization methods for Level Two would include quotient methods and continuous exposure–response methods at the individual or population level. Estimates of risk provided by quotient methods should be more quantitative than those use in Level One. The use of safety factors should be discouraged, unless these factors are empirically supported. Confidence or tolerance limits should be provided for the EEC, the BC, or both (see Figure 7.2). Comparability of risk characterizations would be enhanced if the BC referred to a standard effect magnitude (e.g., LC10, EC20, or some other quantile rather than NOEC, MATC, or LOEC). Note that if quantile responses are routinely determined, it is relatively simple to proceed to the next level of complexity: continuous exposure–response relationships.

Quotient and individual continuous exposure–response methods would be most suitable for the following specific applications:

- developing remediation criteria
- characterizing risk for small sites or where contamination is limited to a few areas

Most existing Canadian criteria and objectives/guidelines are calculated using a quotient type of approach, set at some BC divided by a safety factor (SF). This provides a consistent approach to deriving guidelines or criteria, including remediation criteria. However, site-specific remediation criteria developed by quotient methods should be evaluated by subsequent monitoring or by comparison with criteria based on other methods such as population models.

Estimates of population-level effects or risks may be unnecessary in cases where contamination is restricted to small areas. Small contaminated areas may contain only a few individuals, especially of larger species, or in extreme cases, the contaminated area

may be smaller than the home range of an individual bird or mammal. In these small areas, immigration and emigration, rather than survival or reproduction, will control numbers, and traditional population models will not apply.

Population methods should be used whenever the contaminated site is large enough that numbers of organisms are largely controlled by survival and reproduction within the site, rather than by immigration and emigration. Also, at these larger spatial scales, actual field measurements of numbers or reproduction may not be feasible. Population models are specifically recommended for

- large sites and regional studies
- sites where field sampling or toxicity testing of endangered, rare, or threatened species is inadvisable
- setting priorities when extensive field monitoring, toxicity testing, and chemical analyses are planned as follow-up or as part of a retrospective study
- exploring alternatives, especially costly remediation alternatives
- verifying or evaluating quotient methods/ criteria

These applications include cases in which population-level effects are important and in which the costs of the models are small relative to the costs of other parts of the ecological risk assessment, remediation alternatives, and monitoring programs. The primary limitations on the use of population models will be the availability of exposure–response relationships for survival, growth, and reproduction, and the availability of suitable models (and computer programs for those models).

8.3 Level Three Ecological Risk Assessments

Level Three ecological risk assessments address more complex issues, such as community or ecosystem effects and risks, and the effects of chemical mixtures or exposure through multiple pathways. All components require computer models. The spatial scale of Level Three assessments will usually be large, involving sites containing entire communities or ecosystems. Data requirements, suggested methods, and expected output for each component of a Level Three risk assessment are summarized in Table 8.3.

8.3.1 Exposure Assessment

Level Three exposure assessments would be quantitative and involve advanced computer models. Appropriate methods are those described as Detailed Quantitative Analyses in Section 4.0. Because the spatial scale of Level Three risk assessments would be large, exposure assessments would have to consider several different release mechanisms and exposure pathways. More complex, quantitative analytical methods are required for sites with

- many contaminants
- no available environmental standards or criteria
- multiple exposure pathways
- complex contaminant release and transport processes
- a requirement for analytical results in great detail and precision

The models used for Level Three exposure assessment could be existing models available from various agencies or researchers (described in Section 4.0); modifications of those models; or models developed specifically for the site under investigation. The models should be integrated with models for other components (e.g., risk characterization), and would be used to predict exposure conditions under various remediation options, as well as to characterize existing exposures. Estimation of uncertainty through Monte Carlo simulation, sensitivity analysis, and calibration with monitoring data (Section 4.3.7) would be an important part of Level Three exposure assessment. The major limitations for Level Three exposure assessment are likely to be the availability of data (e.g., for input parameters) and suitable models (especially for terrestrial ecosystems) (see Research and Development Needs; Section 8.4).

8.3.2 Receptor Characterization

Level Three receptor characterization is expected to be conducted infrequently since Level Two is usually sufficient. This most detailed level would be used to address specific issues with highly valued species (e.g., endangered species) or communities. Some of the more quantitative and data-intensive community and ecosystem studies would be reserved for Level Three investigation (Section 5.3.3).

Table 8.3 Summary of Data Requirements and Components of Level Three Ecological Risk Assessment

EXPOSURE ASSESSMENT
- detailed quantitative methods
- based largely on monitoring data and detailed computer models
- models must be able to predict exposure for remediation alternatives as well as for existing conditions
- models should be integrated with those used for hazard assessment/risk characterization
- multiple exposure pathways/chemicals

• Selection of Target Chemicals
- revise from Level Two, if necessary
- consider groups of chemicals likely to behave similarly

• Contaminant Release/Transport and Fate
- detailed models combined with direct measurement (monitoring data), e.g., GEMS, EXAMS
- explore long-distance transport; long-term persistence

• Exposure Pathways Analysis
- integrate exposure from several pathways

• Aquatic or Terrestrial Exposure
- detailed food chain models, integrated with transport and fate models
- quantitative estimate of exposure from different pathways

• Uncertainty Analysis
- provide estimates of uncertainty for exposure
- use Monte Carlo simulations, sensitivity analysis, calibration with monitoring data

• Output - advanced quantitative fate models incorporating most important pathways of individual chemicals, mixtures

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RECEPTOR CHARACTERIZATION
- rarely needed, usually Level Two receptor characterization is sufficient

• Detailed Study
- in-depth community structure analyses
- improve accuracy and precision of quantitative information collected in Level Two
- field measurements of ecosystem functions
- assess successional trajectory following remediation

• Output - specific to completed studies

HAZARD ASSESSMENT
- information obtained from field investigations

• Endpoints
- select measurement and assessment endpoints, with focus on community and ecosystem levels
- use sophisticated hazard assessment methods (e.g., mesocosms, microcosms, QSARS, field experiments, growth (reproduction tests with indigenous species, ecosystem assessment)
- establish extrapolation relationships if necessary, to reduce uncertainty
- assess mixtures and multiple exposure pathways, as applicable
- develop well-documented exposure–response relationships

• Outputs - exposure–response relationships for survival, growth, and reproduction of all VECs
- exposure/response relationships for population, community and/or ecosystem
- uncertainty analysis

RISK CHARACTERIZATION
- ecosystem models; in rare instances, quotient methods (see Section 7.3.2.2)
- quantitative ecosystem-level responses
- provide probability of several effect magnitudes at ecosystem level
- use Monte Carlo simulations to estimate uncertainty, sensitivity
- explore effects/risks associated with remediation options
- indicate major sources of uncertainty for any predictions and provide a monitoring program to verify and evaluate these predictions

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8.3.3 Hazard Assessment

Level Three hazard assessment would allow investigators to focus on specific issues related to deleterious biological effects on the contaminated site. At this level, the measurement endpoints would closely approximate the assessment endpoints (see Section 6.3). A list of potential Level Three tools for hazard assessment are listed in Table 8.3, as described in Section 6.0. Level Three requires sophisticated experimental design with clear testable hypotheses. Higher levels of biological organization are usually examined to address concerns that toxicity testing will not cover.

8.3.4 Risk Characterization

The most appropriate risk characterization method would be ecosystem-level models based on continuous exposure–response relationships. There are, however, two specific instances in which quotient methods might be suitable, if only by default:

- estimating risk from multiple chemicals by summing quotients
- estimating risk and developing remediation criteria for aquatic communities

As indicated in Section 7.2.2.2, development of ecosystem models for cases in which there are multiple contaminants has not been attempted and may be difficult. Until such models are developed, summing quotients is the only alternative available for estimating risk. Summing quotients may be adequate for assessing risks to individual species, but inadequate for assessing risks at higher levels unless the quotients are based on effects at the ecosystem level. There are higher level quotient methods available for aquatic communities, such as that used by the Ohio EPA (1987a, 1987b, 1988; discussed in Section 7.2.2.1). More generally, there is a large amount of literature on impacts on benthic macroinvertebrate communities (Klemm et al., 1990). Provided that data are available for reference sites, risks to aquatic communities can be estimated, and remediation criteria developed, for contaminated sites. Methods such as that used by the Ohio EPA, however, cannot be used to predict effects associated with remediation alternatives and do not account for transfer of effects at one level (e.g., macroinvertebrates) to the next (e.g., insectivorous fish) or higher levels.

As indicated in Section 2.4.3, Level Three risk assessments and ecosystem models will most commonly be used for highly contaminated sites. The models would be used to guide monitoring efforts and explore remediation alternatives, perhaps more than to estimate existing effects or risks. As with population models, these are cases in which the costs of models are small relative to other costs. Ecosystem models would be recommended for

- large sites (drainage basins, ecoregions)
- sites containing critical habitats with unique communities or ecosystems
- verifying or evaluating quotient methods/ criteria

The primary limitations of ecosystem models would be the absence of data on transfer of energy and effects through trophic levels, and the absence of available models, particularly for terrestrial systems.

8.4 Research and Development Needs

Major research and development needs for ecological risk assessments under the NCSRP include

- development of simple empirical quantitative methods, particularly those based on past retrospective assessments
- assessment of safety factors used in quotient methods, and development of alternatives to these safety factors
- development of models for assessing risk from multiple chemicals
- development of models for terrestrial and noncommercial species/ecosystems

These have been identified by other authors (Section 7.3.1). Other issues such as density-dependent effects and exposure through multiple pathways are probably less important. Density-dependent effects may certainly exist, but if included in risk characterization will usually lower risk estimates. Regulators may be reluctant to accept these lowered risk estimates unless these effects can be conclusively demonstrated in field studies. Multiple exposure pathways are likely to be important for only a limited set of compounds, as in most cases one pathway will dominate (LaKind and Rifkin, 1990).

9.0 REPORTING AN ECOLOGICAL RISK ASSESSMENT

Most literature on ecological risk assessment methods overlooks the important step of reporting the results of the investigations. The document that results from a risk assessment is the record of how the risk assessment was conducted and what the findings were.

Standardizing risk assessment documents and ensuring they are assembled at a central location will ensure the NCSRP develops a useful library of examples. In the United States, *records of decision*, are prepared that document the ERA process; it is recommended that this approach be applied under the NCSRP.

Although it is recognized that each risk assessment is unique, there are standard features that the documentation should include. Obviously, there are sections, such as table of contents, list of figures, list of tables, acknowledgements, references cited, and appendices, that need to be included in all reports. Depending on the expected readership, it is recommended that a *glossary* be prepared for the document because risk assessment terminology is not yet in common usage in many scientific circles.

Given that risk assessment information often needs to be communicated to nontechnical decision makers and the general public, an *executive summary* should be included that summarizes the study and its findings for a lay reader. The executive summary should have the following elements: background to the study site, rationale and objectives for conducting the risk assessment, description of which level of ERA was conducted, description of the elements of risk assessment, short methods description, and a description of the key findings of the study. The executive summary needs to use nontechnical language and define any specific terms. The author of the executive summary needs to keep in mind that the reader should be able to understand the approach and results of the risk assessment, independent of the rest of the document.

The *introduction* to the document should include the following elements:

- description of the events leading to the decision to conduct a risk assessment, and the level of ERA to that point. Rationales such as the triggers for ecological risk assessment described in Section 2.0 should be documented in detail
- clear statement of the objectives for the investigation (Section 3.1)
- section describing the overall approach used to the risk assessment (figures and flowcharts are useful)
- site description and history
- a section that describes the organization of the report

The introduction sets the tone for the whole document, and authors are encouraged to prepare this section before the risk assessment is initiated. If the readership is unfamiliar with risk assessment, a short summary of risk assessment theory could be included.

The *body* of the risk assessment will consist of five main sections: site characterization and problem identification, exposure assessment, receptor characterization, hazard assessment, and risk characterization. Within each of these sections, there should be the following elements:

- introduction to the particular component of the risk assessment
- specific methods used [or citation of methods (e.g., models or toxicity test protocols)]
- assumptions
- findings, with emphasis on presentation of information in figures and tables (details in appendices)
- consideration of uncertainty, including main sources
- conclusions, with particular emphasis on information that will be needed by other components of the risk assessment (e.g., the results of a receptor characterization would be needed by the hazard assessment component)

The body of the risk assessment should be detailed enough that a risk assessment practitioner can judge if the work met its objectives and was conducted properly. It is more important to put effort into the actual risk assessment than producing a detailed report, but the report becomes the only documentation of the completed risk assessment.

Depending on the ERA and its level, it may be appropriate to include a section on remediation. Ideally, each level of ERA is conducted with remediation as an endpoint, and decisions regarding options for remediation should be documented.

The *overall conclusion* section of the risk assessment should be brief and use the information provided in the conclusion sections for each of the components of the body of the report. Conclusions should be integrative in nature, pulling together all aspects of the assessment. The most important thing to keep in mind when preparing the conclusions is to summarize the results within the context of the objectives of the study.

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GLOSSARY

application factor - A numerical, unitless value, calculated as the threshold concentration of a chemical for chronic effects divided by its threshold concentration for acute effects. An AF is generally calculated by dividing the limits [no-observed-effect concentration (NOEC) and lowest-observed-effect concentration (LOEC)] of the maximum acceptable toxicant concentration (MATC) by the LC50. The AF is usually reported as a range and is multiplied by the median lethal concentration of a chemical as determined in a short-term (acute) toxicity test to estimate an expected no effect concentration for chronic exposure.

benchmark concentration - Specific concentration at which some level of effect is expected (e.g., LC25, MATC). These concentrations are derived from hazard assessment.

biomarkers - Biochemical or cellular indicators of exposure (e.g., body burdens, indicators of DNA damage, enzyme activity, and biochemical indicators of reproductive or bioenergetic status).

ecological risk assessment - (1) The process of assigning magnitudes and probabilities to adverse effects of human activities (or natural catastrophes) (Barnthouse and Suter, 1986). (2) A formal set of scientific methods for estimating the probabilities and magnitudes of undesired effects on plants, animals, and ecosystems resulting from events in the environment, including the release of pollutants, physical modification of the environment, and natural disasters (Fava et al., 1987). (3) A subcategory of ecological impact assessment that (a) predicts the probability of adverse effects occurring in an ecosystem or any part of an ecosystem as a result of perturbation and (b) relates the magnitude of the impact to the perturbation (Norton et al., 1988). (4) The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors. This definition recognizes that a risk does not exist unless (a) the stressor has an inherent ability to cause adverse effects and (b) it is coincident with or in contact with the ecological component long enough and at sufficient intensity to elicit the identified adverse effect(s) (U.S. EPA, 1992a).

endpoint, assessment - The characteristic of the ecological system that is the focus of the risk assessment.

endpoint, measurement - An effect on an ecological component that can be measure and described in some quantitative fashion.

exposure - The process by which a chemical is delivered to an organism, resulting in a dose (the amount of a chemical either in the organism as a whole or in a target tissue). Exposure is a result of the concentration and form of a chemical in the environment, coupled with the presence of the organism.

exposure assessment - The process of estimating the dose received by an organism, population, or ecosystem. It may be prospective, in which case estimates of the chemical concentrations and forms in various media or habitats are combined with estimates of the organism's behaviour to predict dose. It may also be retrospective, in which case dose is estimated from body burdens of the chemical or changes in the organism caused by the chemical (biomarkers).

hazard assessment - The overall process of evaluating the type and magnitude of adverse effects caused by a stressor.

lowest-observed-effect concentration (LOEC) - The lowest amount or concentration of a stressor for which some biological effect is observed.

maximum acceptable toxicant concentration (MATC) - The maximum concentration at which a stressor can be present and not be toxic to the test organism. The MATC is normally calculated as the geometric mean of the lowest concentration for which an adverse effect was observed (LOEC) and the highest concentration that did not yield any adverse effects (NOEC).

median effective concentration (EC50) - The concentration of a stressor in water that is estimated to be effective in producing some biological response, other than mortality, in 50 percent of the test organisms over a specific time interval (e.g., a 48-hour daphnid EC50).

median lethal concentration (LC50) - The concentration of a stressor in water that is estimated to be lethal to 50 percent of the test organisms over a specific time interval (e.g., a 96-hour fish LC50).

mesocosm - A composite physical and biological model of an ecosystem, intermediate in scale between a microcosm and a macrocosm, with a level of organization as similar as possible to the natural world.

microcosm - A laboratory simulation of a portion of an ecosystem (e.g., microbial community in a beaker).

modifying factors - Any characteristic of an organism or the surrounding environment which affects toxicity.

Monte Carlo simulations - An interactive modelling technique where parameter values are drawn at random from defined probability distributions and the process repeated until a stable distribution of solutions results.

no-observed-effect concentration (NOEC) - The amount or concentration of a stressor that does not result in any adverse effect.

quantitative structure activity relationship (QSAR) - A method of estimating unmeasured physical and toxicological properties for a chemical on the basis of chemical structure, functional groups, and similarity to known chemicals.

receptor - The entity (e.g., organism, population, community, ecosystem) that might be adversely affected by contact with or exposure to a substance of concern.

risk - The chance of a prescribed undesired effect, such as an injury, disease, or death, resulting from human actions or a natural catastrophe.

risk assessment - A set of formal scientific methods for estimating the probabilities and magnitudes of undesired effects resulting from the release of chemicals, other human actions, or natural catastrophes.

risk characterization - The evaluation of the likelihood that adverse ecological effects may occur as a result of exposure to a stressor, including an evaluation of the consequence of these effects.

route of exposure (exposure pathway) - The means by which organisms are exposed to contaminants. Routespathways would include uptake of contaminants from solution, ingestion of contaminated foodprey, inhalation of contaminated particles, etc. More generally, routes of exposure include exposure via water, soil, sediments, food, and other media.

site characterization - Evaluation of available data and information concerning the site (e.g., site use, geology, hydrology, available chemistry and toxicity data, etc.).

tiered testing - A testing procedure in which all testing is not done synoptically, or even concurrently. Initial testing is done to determine areas for in-detail study, which may (or may not) involve a more thorough step.

valued ecosystem components (VEC) - Each of the environmental attributes or components identified as a result of societal values and considerations.

Appendix A

Project Bibliography

Appendix A

Project Bibliography

Methods

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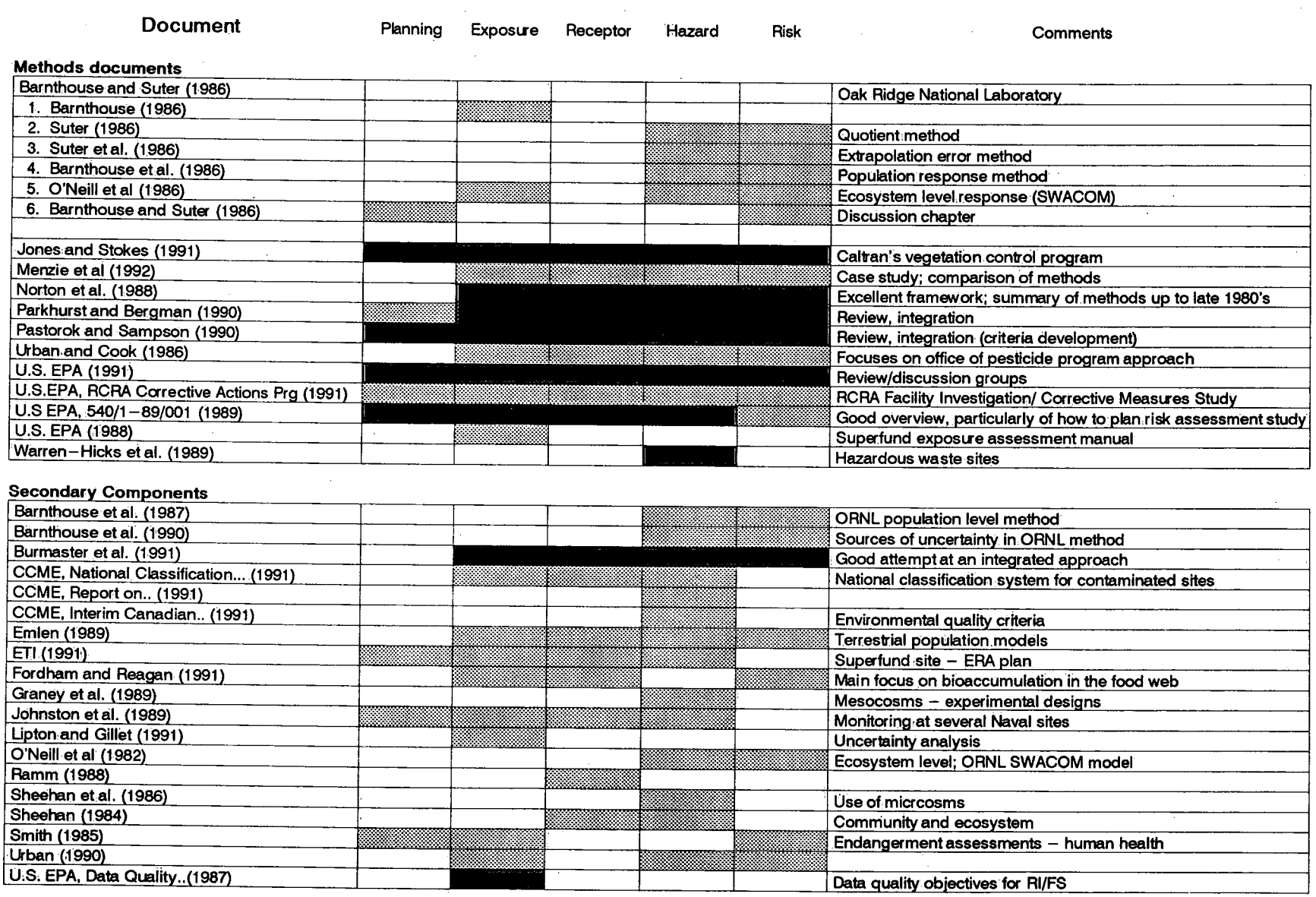
Appendix B

Evaluation of Documents

ECOLOGICAL RISK ASSESSMENT

LITERATURE EVALUATION



Document	Planning	Exposure	Receptor	Hazard	Risk	Comments
Methods documents						
Barnthouse and Suter (1986)						Oak Ridge National Laboratory
1. Barnthouse (1986)						
2. Suter (1986)						Quotient method
3. Suter et al. (1986)						Extrapolation error method
4. Barnthouse et al. (1986)						Population response method
5. O'Neill et al (1986)						Ecosystem level response (SWACOM)
6. Barnthouse and Suter (1986)						Discussion chapter
Jones and Stokes (1991)						Caltran's vegetation control program
Menzie et al (1992)						Case study; comparison of methods
Norton et al. (1988)						Excellent framework; summary of methods up to late 1980's
Parkhurst and Bergman (1990)						Review, integration
Pastorok and Sampson (1990)						Review, integration (criteria development)
Urban and Cook (1986)						Focuses on office of pesticide program approach
U.S. EPA (1991)						Review/discussion groups
U.S.EPA, RCRA Corrective Actions Prg (1991)						RCRA Facility Investigation/ Corrective Measures Study
U.S EPA, 540/1–89/001 (1989)						Good overview, particularly of how to plan risk assessment study
U.S. EPA (1988)						Superfund exposure assessment manual
Warren–Hicks et al. (1989)						Hazardous waste sites
Secondary Components						
Barnthouse et al. (1987)						ORNL population level method
Barnthouse et al. (1990)						Sources of uncertainty in ORNL method
Burmaster et al. (1991)						Good attempt at an integrated approach
CCME, National Classification... (1991)						National classification system for contaminated sites
CCME, Report on.. (1991)						
CCME, Interim Canadian.. (1991)						Environmental quality criteria
Emlen (1989)						Terrestrial population models
ETI (1991)						Superfund site – ERA plan
Fordham and Reagan (1991)						Main focus on bioaccumulation in the food web
Graney et al. (1989)						Mesocosms – experimental designs
Johnston et al. (1989)						Monitoring at several Naval sites
Lipton and Gillet (1991)						Uncertainty analysis
O'Neill et al (1982)						Ecosystem level; ORNL SWACOM model
Ramm (1988)						
Sheehan et al. (1986)						Use of microcosms
Sheehan (1984)						Community and ecosystem
Smith (1985)						Endangerment assessments – human health
Urban (1990)						
U.S. EPA, Data Quality..(1987)						Data quality objectives for RI/FS

LITERATURE EVALUATION

Document	Planning	Exposure	Receptor	Hazard	Risk	Comments
Short Reviews (selected)						
Barnthouse and Suter (1984)				▒	▒	Endpoints, risk quantification
Barnthouse et al. (1986)				▒	▒	Reviews population and ecosystem models, nice historical review
Cardwell (1989)		▒		▒	▒	Review, comparison of methods
Christopherson et al. (1987)				■		Overview of bioassessment methods
Denneman and Van Gestel (1990)					▒	Netherlands; soil clean-up levels
Graham et al. (1991)	▒	▒			▒	Regional ERA
Hakanson (1984)		▒		▒		Empirical approach
Howells et al. (1990)	▒					Long-term effects of low levels; qualitative schemes
Hunsaker et al. (1990)	▒	▒				Regional ERA
Jenkins et al. (1989)				▒	▒	Reviews safety factors
Lewis (1991)		▒		■	▒	Focus on surfactants
Suter (1990a)	▒		▒	▒		Endpoints, receptors
Suter (1990b)				▒	▒	Definitions, comparison
U.S. EPA (1991)	■	▒	▒	▒	▒	EPA framework for ERA
U.S EPA, 230/03-89/046 (1989)	■	■	■	■	■	Brief overview of methods and issues

■ Thorough methods
▒ Description of one or more methods/approaches