

Appendix 1A

Overview of risk assessment

1.1 Background

The use of risk assessment for assessing the significance of soil and groundwater contamination in New Zealand forms the basis for guidance released to date, and a risk-based approach is implied in the Resource Management Act 1991 (RMA). The RMA is framed in terms of “adverse effects” on the environment. However, “adverse effect” is not rigorously defined. Risk assessment is consistent with the focus on effects in the RMA, providing a tool for the assessment of the adverse impacts. The RMA also incorporates requirements for the sustainable management of resources, again focusing on effects. After the RMA, the guidance document of most relevance to the assessment of contaminated land in New Zealand is the ANZECC/NHMRC (1992) *Australian and New Zealand Guidelines for the Assessment and Management of Contaminated Sites* (ANZECC Guidelines).

While the ANZECC Guidelines have found most direct application in Australia, New Zealand has also adopted the ANZECC Guidelines as part of its policy framework. In practice the ANZECC Guidelines play a minor role in New Zealand policy, the primary requirements being found in the RMA. However, the ANZECC Guidelines do set out a risk based approach to the assessment of health and environmental impacts and this has been adopted in New Zealand by the Ministry for the Environment and the Ministry of Health.

The use of risk-based approaches for the assessment of health and environmental effects associated with contaminated land is widespread. In the development of these guidelines, reference has been made to the following guidance:

- USEPA guidance for Superfund, including the *Risk Assessment Guidance for Superfund, Parts A and B*; and the *Technical Background Document for Soil Screening Guidance*
- *ASTM Standard Guidance for Risk-Based Corrective Action Applied at Petroleum Release Sites* E 1739-95;
- Ministry for Housing, Spatial Planning and the Environment (The Netherlands) *Environmental Quality Objectives in the Netherlands* and associated documentation.

The development of similar risk-based guidelines for the New Zealand timber industry by the Ministry for the Environment and Ministry of Health (*Health and Environmental Guidelines for Selected Timber Treatment Chemicals* MfE, MoH, 1993) provides a useful precedent and provides several policy positions of importance in the development of guidelines for the oil industry.

1.2 Definitions

Some definitions of importance in the field of risk assessment and criteria development are presented below:

Risk: The probability of an adverse outcome in a person, a species, a group, or an ecosystem that is exposed to a hazardous agent. Risk depends on both the level of toxicity of hazardous agent, and the level of exposure.

	<p>Various levels of risk may be defined as a guide to decision making including:</p> <ul style="list-style-type: none">• Negligible or <i>de minimus</i> risk• Unacceptable risk• Tolerable or acceptable risk <p>Refer to Module 4 for a discussion of risk acceptability in the context of human health and ecosystem protection.</p>
Ecological Risk Assessment	<p>Ecological risk assessment is the process of estimating the potential impact of a chemical or physical agent on a specified ecosystem under a specific set of conditions.</p>
Health Risk Assessment:	<p>Health risk assessment is the process of estimating the potential impact of a chemical or physical agent on a human population under a specific set of conditions.</p>
Risk Management:	<p>The process of evaluating alternative actions and selecting options in response to risk assessments. The decision making may incorporate scientific, social, economic and political information. The process requires value judgements, e.g. on the tolerability of risk and the reasonableness of costs.</p>
Hazard:	<p>The capacity to produce a particular type of adverse health or environmental effect, e.g. one hazard associated with benzene is leukemia.</p>
Toxicity:	<p>The quality or degree of being poisonous or harmful to plant, animal, human or other life.</p>
Exposure:	<p>Contact with a chemical, physical or biological agent.</p>
Exposure Assessment:	<p>The estimation (qualitative or quantitative) of the magnitude, frequency, duration, route and extent of exposure to a chemical substance or contaminant.</p>
Ecosystem:	<p>An area of nature including living organisms and non-living substances interacting to produce an exchange of material between the living and non-living parts. The term ecosystem implies interdependence between the organisms comprising the system.</p>
Receptor	<p>An organism, plant, human or physical structure which may be exposed to a chemical or other hazardous agent.</p>

1.3 General risk assessment process

The risk assessment process may be considered as a four step process, as follows:

- **Data Collection, Evaluation and Hazard Identification**

The results of sampling and analysis of soil, groundwater and other environmental media must be collated and analysed to determine nature and extent of contamination at the site.

A preliminary assessment of the chemicals of concern at the site must be undertaken based on the chemicals which have been stored or handled at the site, the concentrations measured in soil and groundwater, and preliminary consideration of the hazard associated with each chemical.

- **Exposure Assessment**

Exposure assessment involves:

- identification of receptor groups both on-site and off-site (i.e. those exposed)
- identification of complete exposure pathways
- estimation of concentrations in media to which humans or environmental species may be exposed (e.g. indoor air)
- estimation of the exposure likely to be experienced by receptors, whether human or ecological.

- **Toxicity Assessment**

Toxicity assessment involves an assessment of the possible adverse effects that may be associated with exposure to a given chemical or mixture of chemicals, and the level of exposure associated with the onset of appreciable adverse effects. The level of exposure at which appreciable adverse effects may occur is characterised using dose-response factors.

In considering possible adverse effects on human health, information is drawn from epidemiological studies (i.e. studies of human populations occupationally or environmentally exposed), animal bioassays (conducted in the laboratory) and a range of cellular tests, e.g. genotoxicity assays.

- **Risk Characterisation**

The results of the exposure assessment and toxicity assessment are combined to provide an estimate of risk to human health, or the environment.

The risk assessment process is illustrated in Figure 1A1.

The above process was originally developed in the context of health risk assessment, but it also serves as a useful framework for the assessment of risk to the environment.

The objective of any site assessment program is to manage or minimise risk rather than simply to assess the risk to human health and the environment. Risk assessment should not be seen as an end in itself but rather as a tool for risk management. This view affects the way in which risk assessment is approached and is consistent with the tiered approach to risk, which minimises the effort expended in risk assessment where the risk is low and maintains the focus on risk assessment.

1.3.1 Health risk assessment

Health risk assessment is the process of estimating the potential impact of a chemical or physical agent on a specified human population system under a specific set of conditions.

Historically risk assessment has focussed primarily on assessing the risk to human health, although now the focus is broadening.

An important tenet of health risk assessment is that the underlying objective is to effectively protect “almost all” individuals in the exposed population. This objective is evidenced in the commonly adopted levels of acceptable cancer risk used for regulatory purposes; usually in the range one in 1,000,000 to one in 10,000 per lifetime, i.e. one additional case of cancer per 10,000 - 1,000,000 people per lifetime.

Health risk assessment seeks to determine the intake of a chemical by an individual, and whether it is less than or above a nominal dose that is considered acceptable. With respect to soil contamination exposure may be estimated via a range of routes, including ingestion of soil, inhalation of volatiles or particulates, dermal absorption and food-chain exposure.

In assessing possible adverse effects on human health consideration is given to a range of carcinogenic and non-carcinogenic effects although often the carcinogenic effects are limiting.

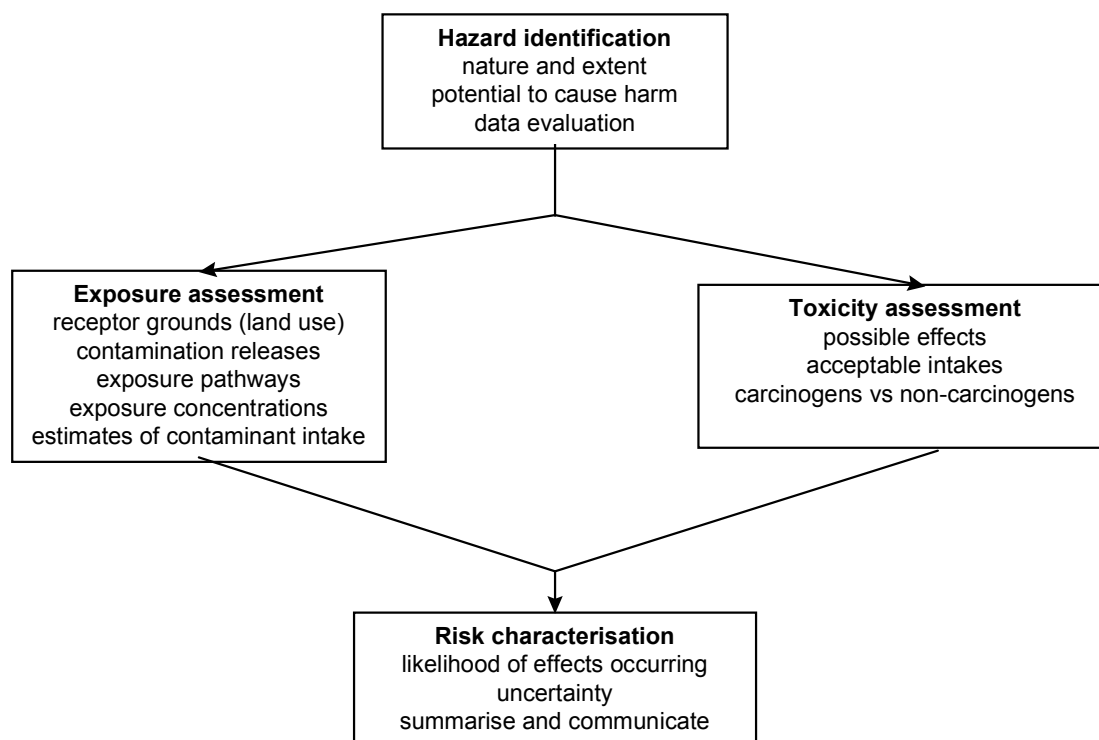


Figure 1A1 Health and environmental risk assessment model

1.3.2 Ecological risk assessment

Ecological risk assessment is the process of estimating the potential impact of a chemical or physical agent on a specified ecosystem under a specific set of conditions.

While the development of ecological risk assessment methods have been slower than the methods for health risk assessment, the use of ecological risk assessment is gaining importance, particularly in New Zealand in the context of the RMA.

Ecological risk assessment necessarily focuses on the protection of populations of species and ecosystems rather than individual organisms. In contrast, health risk assessment has an objective of providing effectively full protection to nearly all individuals. Rather than nominating doses or intakes that are deemed to be without any appreciable risk of adverse effects, No Observable Effect Levels and Concentrations (NOEL and NOEC) for a range of representative species are used directly, usually without the imposition of the same number of safety factors used in health risk assessment. Ecological

risk assessment may focus the protection of representative species, or where more detailed consideration is warranted, the interactions through the ecosystem and food-chain effects, may be considered.

Ecological risk assessment can be undertaken on a range of levels, including:

- species level
- population level (i.e. to protect populations of individual species)
- community level (i.e. focus on protection of communities of multiple species)
- ecosystem level.

The range of levels at which ecological risk assessment may be undertaken increases the complexity of such assessments compared to that of health risk assessment.

While health risk assessment usually focuses on the risk to users of the site, users of adjacent sites and possibly remote groundwater users the ecological risk assessment necessarily considers the impact on the broader ecosystem and surrounding land use and sensitivity may be more important than that on-site.

The size and significance of an ecosystem are important considerations in the ecological risk management process, demanding value judgements regarding the level of protection to be afforded a given ecosystem.

1.4 Risk management

The process of risk management involves deciding whether the predicted health or environmental risk is acceptable, or whether some form of risk mitigation is required. In doing so, it is important for the risk manager to consider social and economic issues that may influence the acceptability of risk.

Risk management necessarily involves value judgement and balancing competing demands, e.g. risk reduction, cost and public opinion.

The establishment of acceptable risk levels to assist in the risk based decision making necessarily involves an element of value judgement. A number of precedents are available to assist in such decisions and these are discussed in Module 4.

It can be useful to compare the typically adopted level of acceptable risk in an environmental context, i.e. one in 10,000 to one in 1,000,000 per lifetime, with that tolerated in different circumstances (refer Table 1A1). However, care must be exercised in such comparisons as risk perception influences the acceptability of environmental risk. For example, the public may be more concerned about imposed risks than risks that they voluntarily accept or those over which they have some control. Risks derived from human-produced sources such as those associated with synthetic chemicals are generally regarded differently by the public to those from natural sources or events. The public are generally more concerned with consequences than likelihood of the event or effect occurring.

Table 1A1 Summary of estimated fatality risk

Activity/Hazard	Lifetime Risk	Annual risk (per million)
Death from cancer (all causes)	~ 0.2	
Leukemia	0.004	50
Voluntary activity		
Smoking (20 cigarettes/day)	0.35	5000
Drinking (1 bottle wine/day)	0.005	75
Taking contraceptive pill	0.001	20
Involuntary Activity		
Run over by road vehicle- NSW	0.005	80
- USA	0.004	50
- UK	0.004	50
Flood (USA)	0.0002	2.2
Bushfire (Australia)	0.00007	1.0
Lightning (UK)	0.000007	0.1
Typical acceptable cancer risk for contaminated land	0.0001 to 0.000001	

The relatively low levels of acceptable risk in the management of contaminated land reflects the objective of protecting all individuals, and the uncertainty in chemical risk assessment (which is also addressed by the incorporation of safety factor when deriving risk estimates).