Chapter 1: Introduction to environmental health risk assessment

Virtually all aspects of life involve exposure to risks (National Research Council – NRC 2008). Understanding the nature of risk, including the way people perceive threats to their health and the rational and emotive factors that govern that perception, is vital to developing appropriate ways to manage environmental health risks. Risk assessment can be a useful tool in managing environmental health risks.

1.1 WHAT IS RISK ASSESSMENT?

Risk assessment is the process of estimating the potential impact of a chemical, physical, microbiological or psychosocial hazard on a specified human population or ecological system under a specific set of conditions and for a certain time frame.

The scope of environmental health risk assessment (EHRA) can cover health impacts of:

- chemical pollutants and contaminants in air, water, soil and food
- pathogenic microbiological contaminants in food and water
- radiation sources
- electromagnetic fields (EMFs)
- climate and climate change

In all cases of the above impacts, priority is attached to evaluating the potential human health impacts. This update of enHealth guidance on EHRA focuses primarily on hazardous chemicals (and to a lesser extent, microbiological hazards). Risk assessment relating to radiation hazards, EMFs and climate change are covered elsewhere.

Risk assessment is intended 'to provide complete information to risk managers, specifically policymakers and regulators, so that the best possible decisions are made' (Paustenbach 1989 p. 28).

There are uncertainties related to risk assessment and it is important to make the best possible use of available information. It is equally, if not more important, to be able to explain to stakeholders in the EHRA processes how these uncertainties have been identified and managed.

Risk assessment gathers and organises information and enables:

- risks at a point in time (including baseline risks) and changes in risk over time to be estimated and to establish whether action is necessary
- assessments of new and different types of risk
- the identification and comparison of different factors that affect the nature and magnitude of the risk
- issues to be prioritised according to their levels of risk
- health guidance values (GVs) to be estimated for environmental hazards that can be used and will adequately protect public health, as a preface to setting risk-based standards for regulatory exposure limits as well as clean-up standards
- a comparison of the potential health impacts of various environmental health interventions (thus enabling cost-effectiveness estimates)
- risk-based policy making and consistent, transparent appraisal and recording of public health risks
- questionable theories, methods and data to be challenged and addressed by providing a clearly documented and open process (Covello & Merkhofer 1993).

Risk assessment is significantly influenced by science policy considerations (see NRC 2008 for an outline of American EHRA policies). Science policy on EHRA in Australia is somewhat fragmented, with various Commonwealth and state or territory authorities applying risk assessment policies and default approaches, which are often not explicitly laid out in legislation or regulations. The objective of this enHealth document is not to enunciate specific science policy relating to EHRA but to provide information to risk assessors on different approaches to EHRA methodology, and to provide guidance on how to use default values at various stages of an EHRA. The difficulties in establishing such defaults within a science policy context are discussed in some detail in Section 5.16, where there is a discussion on the selection of 'target risk' in the EHRA of carcinogens.

Risk assessment may be done as a relatively rapid 'desktop' study or 'screening' study for simple issues, or may be a large and complex process where there are significant health concerns. These processes may be designated as Tier 1, 2 or 3 processes (see Section 1.9). There are numerous models of risk assessment to suit the many contexts in which risk assessments are undertaken. Even limited measures of the level of risk can be valuable for identifying complex cause-and-effect processes and the most efficient means of addressing the risks.

In this context, the methods used in EHRA are inherently conservative[1] and highly protective of public health. This is especially true of 'screening' type risk assessments, which tend to use the most conservative assumptions about exposure and risk. These are generally termed Tier 1 risk assessments. A conservative approach is also taken when the EHRA is used as a basis for establishing environmental guidelines or standards. Conservatism is often built into an EHRA by using exposure estimates that represent 'worst case' or at least the upper percentiles of parameter distributions, rather than mean, average or typical values. Furthermore, exposure is usually considered to be constant over a substantial period of time (sometimes

1 In this context, 'conservative' is intended to imply a cautious approach to evaluating and managing the uncertainties inherent in a risk assessment, which reduces the probability of harm occurring.

an entire lifetime), whereas many environmental exposures are episodic, and may decline over time due to loss or degradation of the contaminant.

The conservatism in EHRA can sometimes lead to the development of risk-based GVs that are so far below the capacity of contemporary analytical techniques that compliance monitoring becomes impossible or impractical. In some cases, conservative risk-based GVs may be driven to levels below background concentrations, casting doubt on the credibility of the process.

It is important that assessors, users, regulators and members of the public recognise risk assessment may not always provide a compelling or definitive outcome. Some of the criticisms of risk assessment are as follows:

- Default values and assumptions are not realistic – a series of such unrealistic values or assumptions compounds the inaccuracy so that risks may be seriously overstated or understated if the default values are too conservative or insufficiently conservative, respectively.
- Interactions between agents (i.e. mixtures of agents) and the variability of response between individuals are commonly unknown and may be insufficiently taken into account.
- The use of default values and assumptions may become too rigid so that situation-specific data is not applied.
- The nature of the population to whom the risk assessment is to be applied regarding its exposure characterisation or susceptibility is often poorly defined.
- The uncertainties of risk assessment are often inadequately described, for example, specific point estimates are given that do not recognise uncertainty, or simplistic upper-bound estimates of uncertainty are used.
- There is an emphasis on cancer risk to the possible neglect of other adverse effects, for example, reproductive and developmental outcomes.
- In some situations, there may be insufficient scientific knowledge to be able to perform credible risk assessments.
- Risk assessment can be perceived to be tailored to provide a desired or predetermined outcome (NRC 1994).
- Excessive emphasis is given to the process of risk assessment rather than its content.
- The risk assessment process can become so 'bogged down' (NRC 2008) that it takes far too long to achieve useful or timely outcomes.
- The risk assessment process is used as a 'whitewash' or used to justify the continuation or increase of polluting activities.
- The efforts in risk assessment may be inappropriately distributed in cases where enormous effort is spent on complex modelling in cases where some targeted data collection could provide much more relevant and credible evidence.

Tal (1997) indicates that environmental groups identify a number of problems with the way risk assessments have been practised, including disempowerment and potential regulatory delays. Risk assessments should be designed and undertaken in ways that minimise these pitfalls.

1.2 WHEN TO UNDERTAKE RISK ASSESSMENT

The issues identification phase (see Chapter 2) will determine when to undertake a risk assessment. The need to undertake a risk assessment will be influenced by situation-specific factors. As such, the following list is indicative and not exhaustive. In general, risk assessments will be needed for products, processes, situations and activities where there is a plausible case that there could be an increased risk of significant health consequences for the human population from the product, process, situation or activity. A risk assessment can also be used to inform the selection of the safest option when making decisions about how to achieve a particular aim. A screening level comparative risk assessment could be used to compare the risks associated with various options when, for example, formulating a particular product or controlling pests.

Examples are:

- new additives to food or potable or recreational waters
- introduction of a new chemical under the NICNAS (National Industrial Chemicals Notification and Assessment Scheme) program (see Section 17.2)
- assessment of a contaminated site
- assessment of a major planning development, especially where hazards are anticipated
- assessment of pollution impacts at existing facilities
- changes to climate, landform, geography or demography that may impact on disease vectors and parasites
- situations where environmental standards or guidelines are unavailable
- environmental changes that will increase traffic flow and may increase the risk of injury or air pollution, such as new traffic corridors
- changes where impacts on environmental health factors may be permanent and irreversible
- changes that may impact on the microbiological or chemical safety of food chains and food supplies
- situations where there is a high level of public interest in or concern about environmental health issues
- situations where vulnerable populations may be affected by environmental health issues such as the location of schools
- legislative or policy changes
- designating housing setbacks from industry and transport corridors
- where health impact assessments are undertaken.

Risk assessment is inappropriate when it is a ritual rather than a meaningful process and should not be undertaken when:

- there is no data or an insufficient amount of data
- it is clear that the proposal, situation or activity is seen by health and other experts as having few potential risks to health
- risks may be likely, but the evidence is already well documented and it may be possible to develop evidence-based recommendations without the need for a comprehensive assessment
- there is an inability to take action or it is too late to take action
- there are insufficient resources
- the proposal is clearly politically or socially unacceptable.

Of relevance to risk assessment is Bardwell's reference (cited in Thornton & Paulsen 1998 p. 799) to a study that indicates that 'about 90 per cent of real world problem solving is spent:

- solving the wrong problem;
- stating the question so that it cannot be answered;
- solving a solution;
- stating questions too generically; or
- trying to get agreement on the answer before there is agreement on the question'.

1.3 TYPES OF RISK ASSESSMENT

1.3.1 Individual and population risk assessments

Risk assessments generally make risk estimates for defined groups or populations. The term 'receptors' is often used to designate people who may be exposed to an environmental hazard, and to whom the EHRA would be directed. Identification of 'receptor' locations and pathways by which they might be exposed is an integral part of any EHRA.

Individual risks are usually estimated for a hypothetical person with assumed characteristics for various durations of exposure (e.g. per year or per lifetime) or for different locations. The hypothetical individual is designed to represent the average person in the situation or the maximally exposed person. However, such risk estimates cannot be targeted to a specific person. The distinction between 'there is a risk' and 'I am at risk' is often difficult to explain to both the public and by regulators, especially when discussing very small probability estimates and this can lead to serious misunderstanding among stakeholders about the meaning of quantitative risk estimates (McAuley & Hrudey 2006. In the case of a lottery, a winner may be found, despite the small odds of winning, whereas in most quantitative risk assessments the probability of anyone being at risk is small and the probability of a specific individual being at risk is very much smaller.

Population risk may relate to the number of adverse health effects (e.g. fatalities, cancers or illnesses) in a population over a specified period of time or the rate of adverse effects for a given location or sub-population (Covello & Merkhofer 1993).

1.3.2 Qualitative and quantitative risk assessments

The level of risk can be described either qualitatively (i.e. by putting risks into categories such as 'high', 'medium' or 'low') or quantitatively (with a numerical estimate). Practical guidance on how to manage risks is the approach taken in AS/NZS ISO 31000:2009 (Standards Australia, 2009) and in the *Risk analysis framework* used by the Office of the Gene Technology Regulator to manage risks associated with genetically modified organisms (GMOs) (OGTR 2009). (See Sections 5.3, 17.6 and 17.7.)

Current risk assessment methods do not enable accurate quantitative estimates of risk for low levels of exposure to environmental hazards. Numerical estimates of risk can be presented, but caution must be exercised in assigning strict meaning to the numbers:

> *... a number is a number is a number ... and yet exactitude should not be confused with accuracy.*
>
> (Langley 2003 p. 166)

Complexity of the exposure conditions, variability in the environmental agents and exposed populations, and any inherent limitations in toxicological data may limit the accuracy of numerical risk estimates. While a degree of quantification may be possible for some components, such as data collection and exposure assessment, it is important that all uncertainties are reflected in the EHRA outcomes. Further discussion of qualitative and quantitative risk assessment appears in Chapter 5.