Health Risk Assessment in Western Australia

Health Impact Assessment - Department of Health

Delivering a **Healthy** WA

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This document has been designed to introduce the reader to the basic concepts of health risk assessment. It provides an introduction to the topic and an overview of the potential uses and limitations of health risk assessments. An outline of the process is intended to clarify the core issues of health risk assessment and provide a range of references where more technical and detailed information is available.

The document focuses on delivering information that can be used to consider the potential health effects of proposed projects in a logical and objective manner. It highlights the role and benefits of health risk assessments in protecting the health of ourselves, our community and our environment.

Health risk assessment is about providing us with the information to make informed decisions. We hope that this document helps you to do just that.

Acknowledgements

This document has drawn primarily from the 2004 enHealth document "Environmental Health Risk Assessment: Guidelines for assessing human health risks from environmental hazards." The enHealth guidelines are over 200 pages in length and cover many of the technical and scientific aspects of health risk assessment that are beyond the scope of this introductory document. For those readers seeking a more detailed understanding of health risk assessment, the enHealth guidelines are recommended.

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Message from the Environmental Health Director

Development is going on all around us in Western Australia. Yet developments such as land use developments, industrial activities or clean up of old waste sites can put communities at risk and possibly cause ill health.

Health Risk Assessment is the process the Department of Health in Western Australia requires of developers to use to demonstrate that their proposals will not adversely affect the health of the surrounding community. It requires proponents to consider each aspect of their proposed development, to determine whether the proposal has any risks associated with it, and to consider what could be done to ensure that the community is protected from the risks.

The Australian procedures for Health Risk Assessment have been developed through collaboration of experts across the country and published by the National Environmental Health Council (enHealth Council) as the:

> *Environmental Health Risk Assessment: Guidelines for assessing human health risks from environmental hazards.*

We have felt in WA, that a document was needed which clarified what Health Risk Assessment is, why it is important to assess the risks from development and to provide proponents and the community alike as to what is required of the process for us to be assured that people are protected.

We hope you find this document meets these needs and assists all involved.

Jim Dodds

Director Environmental Health

Glossary

Taken from enHealth, Environmental Health Risk Assessment 2004.

Dose-response assessment - Determination of the relationship between the magnitude of the dose or level of exposure to a chemical and the incidence or severity of the associated adverse effect.

Environmental Health - Those aspects of human health determined by physical, chemical, biological and social factors in the environment. Environmental health practice covers the assessment, correction, control and prevention of environmental factors that can adversely affect health, as well as the enhancement of those aspects of the environment that can improve human health.

Hazard - The capacity of an agent to produce a particular type of adverse health or environmental effect.

Health - Health is a state of complete physical, mental and social well being and not merely the absence of disease or infirmity. (World Health Organisation (WHO), 1946).

Health Impact Assessment - A systematic process to assess the actual or potential, and direct or indirect, effects on the health of individuals, groups or communities arising from policies, objectives, programs, plans or activities.

Health Risk Assessment - The process of estimating the potential impact of a chemical, biological, physical or social agent on a specified human population system under a specific set of conditions and for a certain time-frame.

Risk - The probability that, in a certain timeframe, an adverse outcome will occur in a person, group of people, plants, animals and/or the ecology of a specified area that is exposed to a particular dose or concentration of a hazardous agent. i.e. it depends on both the level of toxicity of the agent and the level of exposure.

Risk Communication - An interactive process involving the exchange among individuals, groups and institutions of information and expert opinion about the nature, severity, and acceptability of risks and the decisions taken to combat them.

Risk Management - The process of evaluating alternative actions, selecting options and implementing them in response to risk assessments. The decision making will incorporate scientific, technological, social, economic and political information. The process requires value judgements, e.g. on the tolerability and reasonableness of costs.

Contents

Section 1

1.1 Introduction

Most people in Western Australia would agree that we enjoy a good quality of life. A range of social, economic and environmental factors, including our lifestyle, our unique natural environment, a strong economy and high standards of health and education all contribute to our way of life and high standard of living. Protecting and preserving this for current and future generations is a common goal of individuals, communities and governments.

Health is one of the cornerstones of our quality of life and people place greater value on their health than most other priorities. Protection of our health needs to be achieved in an environment of technological, industrial, economic and social change. Whilst such changes bring many benefits, they may also bring hazards that have the potential to harm the environment or the health of our community.

The National Environmental Health Strategy (1999) states that 'protection of health involves analysing the risks involved, evaluating interventions and developing appropriate management strategies.' This risk based approach recognises that all situations carry some degree of risk and that analysis of these risks can contribute to decisions aimed at minimising harm to individuals and communities.

As individuals we learn to minimise risks to our health from a very early age. We learn to recognise hazards, assess them for their likelihood to harm us, make judgements about the acceptability of the risks and take measures to minimise them. Examples range from simple actions such as looking before we cross the road, applying sunscreen and wearing seatbelts, to major lifestyle factors that affect our health, such as diet, exercise and smoking.

It is important at this stage to clarify our use of the terms risk and hazard, as they are terms that will be used throughout this document and are frequently confused. In terms of health risk assessment, a risk is the probability that an adverse health outcome will occur in a given situation in a certain timeframe. A hazard is the capacity of an agent to produce a particular type of adverse health effect. If we use an everyday example, the distinction between the two becomes clear. The hazard of a particular prescription drug may be severe breathing difficulties in the case of an overdose. An open packet of this drug sitting on the kitchen bench poses a significant risk to the health of a young child in the household. The same drug, in a locked medicine cabinet, is a negligible risk. The hazard of the drug in both situations is the same, yet the risks of the two situations are very different. By understanding these differences, we can see that the risk to our health from a hazard can be controlled through appropriate measures, to an acceptable level.

Health risk assessment uses a risk based approach and applies it to risks associated with environmental health hazards. Environmental health refers to 'those aspects of human health that are determined by physical, chemical, biological and social factors in the environment. It also refers to the theory and practice of assessing, correcting, controlling, and preventing those factors in the environment that can potentially affect adversely the health of present and future generations' (WHO, 1993). Environmental health hazards can occur in a wide range of situations and examples include chemical contaminants in air, water, soil and food, biological hazards such as viruses, bacteria or insects and physical hazards such as noise and traffic.

Health risk assessment provides us with the information to make informed decisions. It is about acknowledging and addressing the potential effects on our health that many projects have. A health risk assessment will collect and evaluate available and relevant information about the potential health effects of environmental health hazards in a specific situation in a logical and objective manner. This information can then be used in the risk management process, where decisions about how to best manage risk are made.

The following information will highlight the role and benefits that health risk assessment can provide in protecting the health of our community, our environment and ourselves.

1.2 Why carry out a health risk assessment?

The protection of public health lies at the heart of health risk assessment. Health risk assessment provides us with a systematic approach for characterising the nature and magnitude of the risks associated with environmental health hazards (enHealth, 2004).

To understand how health risk assessment can minimise the risks to our health, it needs to be considered in terms of its relationship with risk communication and risk management (Figure 1). Risk communication is a consultative process that considers all stakeholders and gives each of them the opportunity to exchange information about the risks being assessed and about the decisions taken to combat them. The scope and nature of the consultation should reflect the potential effects on the community and the level of community concern. Ideally, consultation should begin before health risk assessment and continue right through to the risk management stage. Effective consultation will provide information that is useful for risk assessment and risk management.

Risk management makes decisions based on a range of scientific, technical, economic, environmental, cultural and political information, including health risk assessments and input from the risk communication process.

One of the crucial differences between the health risk assessment process and risk communication and management is that the assessment process is objective – it provides available and relevant information about the nature and magnitude of potential risks of a particular situation, it does not however make decisions about the management of those risks. In contrast, both risk communication and risk management are subjective – they make value judgements and decisions, such as prioritising issues and actions, based on a wide range of factors, including the health risk assessment.

The nature and the quality of the decisions in risk management, and the confidence we have in them depends on the quality of the information provided by the health risk assessment. A health risk assessment that provides the best and most objective scientific information available about health risks will enable the best possible discussions and decisions to follow. If the risk management process is based on flawed information, then subsequent decisions will be flawed.

The greater the confidence in the risk assessment process, the greater the confidence we have in decisions made to minimise the risk to our health.

Protecting public health requires careful consideration of potential differences in susceptibility or sensitivity to hazards. Not all individuals or groups will experience the same level of risk from the same hazard. Certain groups such as children, the elderly, indigenous groups or people suffering an illness or certain medical conditions, may be more susceptible to particular hazards. Consideration also needs to be given to those individuals or groups that may be exposed to higher levels of a hazard. A health risk assessment ensures that these different degrees of susceptibility and exposure are taken into account.

Figure 1: Relationship of risk assessment, risk management and risk communication.
(Adapted from enHealth 2004)

Whilst the main focus of health risk assessment is the protection of human health, the benefits are not restricted to issues of health. If failure to conduct a thorough, well managed health risk assessment ultimately leads to a situation where significant adverse health effects are experienced, the flow-on effects can be significant. If the community believes that the appropriate steps to assess and minimise the risk to their health have not been properly carried out, then the level of community mistrust and anger can be very high. Regaining community trust in such situations is extremely difficult. Economic costs can also result and are not necessarily limited to the proponent. Loss of productivity and income, clean-up and monitoring costs, work required to ensure the situation does not occur again, cost of potential litigation, financial penalties and medical costs are all possibilities.

Adverse health effects from environmental health hazards will possibly be accompanied by adverse environmental effects that also have a range of associated costs. All of these possibilities demonstrate the overlap between health, environmental, social and economic issues.

Our experience of situations where health has been adversely affected by environmental health hazards has taught us that prevention of these events is more cost effective than treatment. Time, effort and resources spent on identifying and assessing risks to human health are justified when we consider the potential human, environmental and economic costs of inaction.

1.3 When to carry out a health risk assessment?

A major focus of the National Environmental Health Strategy was the development of the Australian Charter for Environmental Health. One of the guiding principles of the Charter is to "protect human health by identifying threats posed by environmental hazards as early as possible and by introducing appropriate safeguards. Ideally these should be sustainable and cost-effective." The Charter highlights the basic entitlements and responsibilities required to maintain and improve the quality of health for all Australians. Those responsibilities and entitlements operate at the individual, community, business, industry and government level.

In terms of activities or projects that can cause harm through environmental health hazards, it is clearly the responsibility of the proponent to address these concerns. If there are health issues, they need to be identified and a determination made as to whether a health risk assessment will effectively address those concerns.

A health risk assessment is not the answer for all situations where there is a risk of adverse health effects. Projects or activities may have obvious health effects that are well understood and effectively controlled by existing standards. In such cases, protection of public health would be better served by putting resources into improved management of the known risks rather than a health risk assessment that will not provide any new information.

Most activities or projects in our society require some type of planning approval. The nature of this approval will often dictate the need for and the level of health risk assessment required. Some situations may have specific guidelines, such as the Department of Environment's Contaminated Sites Guidelines. Large complex projects or situations will require more complex approvals systems and more detailed health risk assessments. They will usually require approval at state government level and may involve a number of different agencies that assess proposals and make recommendations to decision making authorities. These decision-making authorities consider the recommendations and make the final decision on whether the project can proceed and under what circumstances. Often the decision is dependent on the imposition of regulations. Health risk assessment carried out for these types of projects will generally be detailed and situation-specific.

Simpler projects may be addressed at a local government level and in some cases potential risks to our health will be addressed in a generic manner, using previous experience of similar situations. In these cases simple and rapid assessments of issues and risks can be made without the need for a new health risk assessment. Local government regularly deals with potential risks to our health in a range of situations without the need for a detailed health risk assessment. An example is assessing the potential health risks of a new restaurant. Poor hygienic practices in restaurants can potentially endanger public health through contaminated food. This type of environmental health hazard is effectively controlled through enforcement of a range of environmental health criteria, which have been derived using risk assessment techniques. In such cases, there is no need for either a detailed health risk assessment or widespread community consultation.

The enHealth guidelines provide a list of situations where there is a 'plausible increased risk of significant health consequences for the human population' and where health risk assessment may be needed. Whilst the following list is not exhaustive, it gives some examples to illustrate the point.

- changes where impacts on environmental health factors may be permanent and irreversible
- situations where there is a high level of public interest in and/or concern about environmental health issues.
- situations where vulnerable populations may be affected by environmental health issues e.g. placement of schools
- locating intensive horticulture
- locating new power generation plants
- locating toxic waste disposal plants
- locating sewage treatment plants

Past experience plays a crucial role in our evaluation of situations for potential adverse health effects. The Health Act (1911) classifies a range of noxious industries. Situations with a higher potential for contamination are identified in 'Potentially contaminating activities, industries and landuses,' (DoE, 2004). Examples include abattoirs, chemical manufacturing, oil and gas production, mining, landfill sites and airports.

1.4 Who is involved in a health risk assessment?

Each project undergoing a health risk assessment will involve a range of stakeholders. These typically include those proposing the project (the proponent); members of the community or workers potentially affected by the project, government representatives from all levels of government, other experts and consultants, environmental planners and other health officials.

Any health risk assessment should consider relevant stakeholder concerns. The level of involvement of each of the stakeholders will depend on the nature and size of the project and the level of community concern. The appropriate level and extent of consultation should be carefully considered as early as possible. Each stakeholder may have a range of issues, some of which will be common to all groups whilst others may reflect the concerns of specific groups or individuals. Each concern should be acknowledged and addressed. Not all issues will necessarily be part of a health risk assessment – they may already be adequately addressed through other processes or health risk assessment may not adequately address the issue. For such issues, the reasons for their omission from a health risk assessment should be clearly stated.

A health risk assessment that is not inclusive of all stakeholders' concerns may be seen to be less objective than one that has actively considered all stakeholders from the very first stages. Failure to consider all stakeholder concerns may also result in potential health issues being overlooked. The need for effective consultation highlights the importance of risk communication and its role in health risk assessment.

Effective risk communication will ensure that the level and type of consultation adequately reflects the situation. Proper management of communication between all stakeholders will help to develop a productive and meaningful relationship between all groups. Effective community consultation has been addressed in a range of publications from the Citizens and Civics Unit, Department of Premier and Cabinet, including Consulting Citizens: A Resource Guide (2002) and Planning for Success (2003).

Given the depth and breadth of knowledge required for an extensive health risk assessment, it is usually not realistic for any one person to effectively address all aspects of all issues. The range of medical and health experts that provide information, advice or expertise reflect the complex nature of some health risk assessments. For complex assessments, agreement between stakeholders on what experts will be used for specific aspects of the health risk assessment may be helpful.

Independent peer reviews of health risk assessments for major or potentially controversial projects can bring added benefits. A review process that supports the findings of an assessment and is independent of all stakeholders can potentially increase the level of confidence in the findings. This strengthened confidence can extend to all stakeholders – proponents, community groups and government agencies, and may contribute to the level of acceptance and decision making processes surrounding a proposal. Ensuring that peer reviewers have an appropriate level of expertise and independence is critical to the success of the process.

1.5 What makes a good health risk assessment?

A good health risk assessment aims to provide the best and most objective scientific information about the risks of a specific situation. If this is the aim, how do we achieve it?

The process itself is the first key and follows four main steps, as outlined by enHealth (2002):

- Issue Identification
- Hazard Assessment
- Exposure Assessment
- Risk Characterisation.

This framework is used in most health risk assessment models around the world and provides a uniform approach to assessing and quantifying risks from environmental health hazards. These steps will be covered in detail in Section 2.

In addition to the basic process, there are a number of fundamental principles that should be followed to ensure the best possible quality health risk assessment.

Transparency of the process is vital. Clearly detailing each step of the process, to those reviewing the assessment, is essential. A health risk assessment conducted behind closed doors, without open access to the information upon which its conclusions are based, cannot be defended and will generally lead to more questions than answers. In contrast a transparent health risk assessment that has used the most reliable and relevant information available and that has ensured additional investigation where necessary, will provide the best possible assessment of potential health risks for any project.

The quality of the information used in the process needs to be clearly stated. This will include disclosure of the source of the information, details of the studies from which data was used and quality assurance systems for collection and analysis of data and samples. Different sources of data are considered to carry more weight than others. The enHealth guidelines categorise sources of toxicological data into 3 levels, in order of preference, as indicated in Table 1 and state that 'all documents, particularly those in the second and third categories require rigorous appraisal for relevance, validity and accuracy.'

The quality of data from samples collected specifically for a situation under assessment should also be adequately addressed. Section 8.7 in the enHealth guidelines provides a detailed description of environmental sampling methods and quality control. Sampling regimens for specific situations are often available, for example, the 'Development of Sampling and Analysis Programs' (DoE, 2001). Gaps in available knowledge may also occur in health risk assessment and the effect of these gaps on the quality or certainty of the data needs to be addressed.

Table 1: Levels of Sources for Toxicological Data.

Level	Description	Examples
1	High level of scientific agreement.	National Health and Medical Research Council (NHMRC) Acceptable Daily Intake list from the Therapeutic Goods Administration. National Environment Protection Measure (NEPM) Australia and New Zealand Environment and Conservation Council (ANZEEC) World Health Organisation documents.
2	Varying levels of scientific agreement. Use should be clearly justified, for example, by lack of Level 1 data and appraised for levels of uncertainty.	Peer-reviewed journals. Industry publications. Occupational health and safety sources.
3	Lower level of scientific agreement. Use requires justification that other sources are unavailable. Should be appraised for levels of uncertainty.	Unpublished information. Non-peer reviewed information – magazines, newspapers, and internet.

Justification for why particular data or methods were used in the assessment needs to be clearly stated at each step of the process. If conflicting data exists, why was one set of data chosen over another? Why was one type of study chosen over another? Why was a particular model of exposure used?

The health risk assessment process is usually situation-specific and care should be taken at each step to use information and models that are most relevant to the situation. Any information used, including toxicological data, routes of exposure, exposure assessment and health or population data, should reflect the situation as closely as possible. For example if the most likely route of exposure is by inhalation, then data based on inhalation pathways should be used. If this data is not available, the use of data from other routes of exposure needs to be justified and any additional assumptions or uncertainties arising from its use, clearly stated.

Any health risk assessment will include assumptions. These assumptions may be part of the models used in the assessment or may be made when there are gaps in the available knowledge. These assumptions should be clearly stated and justified.

Uncertainty may arise because of incomplete information, the uncertainty inherent in areas such as data collection, sampling and measurement and uncertainty in the models used in the process. Uncertainty needs to be clearly addressed at each step of the process. An overall assessment of uncertainties can be useful for planning future studies or monitoring that will fill in gaps in the current knowledge and sensitivity and potentially reduce levels of uncertainty.

These basic principles recognise that health risk assessment is not an exact science. However, adherence to these principles provides a process in which the potential health risks of any project are assessed in an open and objective manner. Such an approach is crucial to the establishment of a process that is trusted by the community, the government and proponents alike

In summary, the key points that are important for the development of a good health risk assessment are:

- Transparency
- Objectivity
- Consideration of all stakeholder concerns
- Appropriate consultation
- Ensuring quality of the data
- Justification for methodologies
- Justification for reference standards and for modelling
- Relevance of data and models to the situation
- Clear indication of assumptions
- Clear indication of limitations and uncertainties

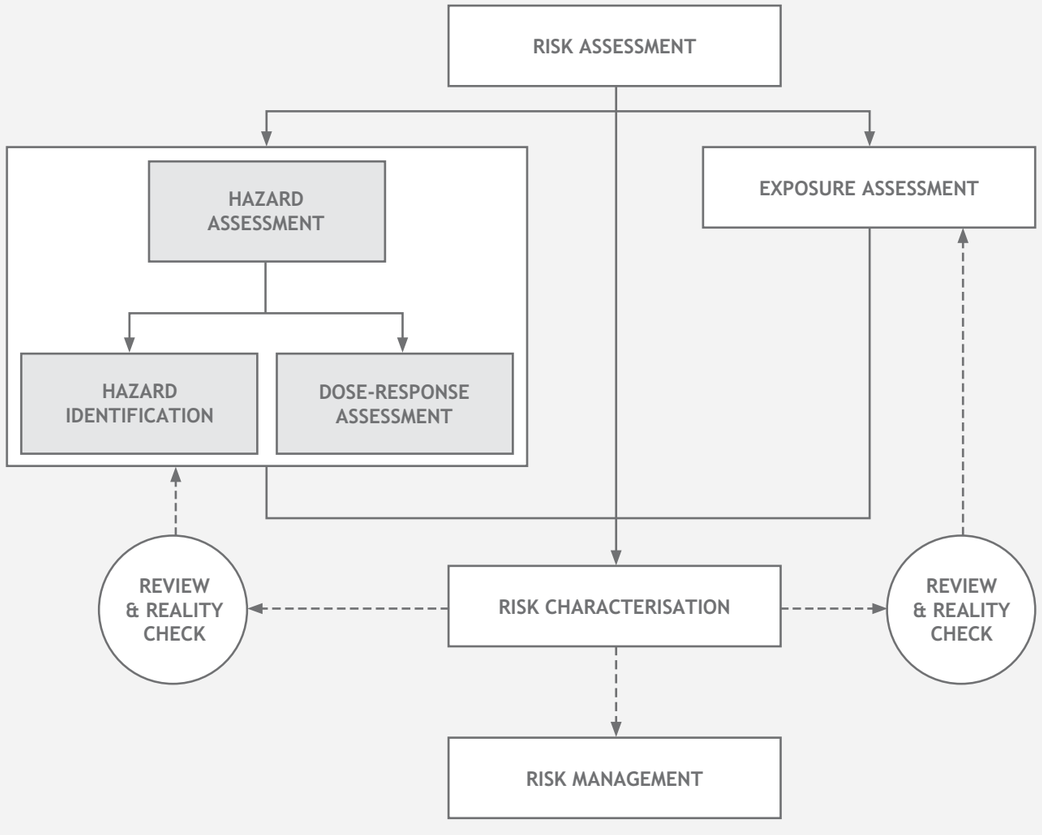
Section 2:

2.1 The Health Risk Assessment Process

The four steps of the health risk assessment process are issue identification, hazard assessment, exposure assessment and risk characterisation. Whilst these steps can be applied to all hazards, whether they are chemical, physical, biological or psychosocial in nature, they have been developed primarily for chemical hazards. Application of the process to the different types of hazards will require different methods, models and assumptions and these should be clearly stated at all steps.

The assessment of social and psychological hazards and their risks to health require different approaches. The ongoing development of these is part of the evolving use of more integrated approaches to health, such as health impact assessment.

Figure 2: Health Risk Assessment Process *(from enHealth 2004)*



2.1 Issue Identification

What are the issues relating to a particular project or development for which health risk assessment is useful?

A thorough approach to this step is critical to any health risk assessment. The questions and issues raised here will provide the overall working plan for the assessment. Failure to address all issues at this point can result in an incomplete and poorly accepted assessment.

Issue identification comprises several phases:

- identification of environmental health issues and determining whether there are hazards amenable to risk assessment;
- relating the hazards to their environmental health context (clarification and prioritising of problems and hazards);
- identification of potential interactions between agents; and
- stating clearly why risk assessment is needed and the scope and objectives of the risk assessment.

Issues are different from hazards and are influenced by perceptions, economics, science and social factors. Examples are community concern over emissions from a power plant, assessment of a new food additive or local opposition to the expansion of a landfill facility. Different stakeholders may have different issues – this is often because perceptions of risk vary widely. Recognising and understanding the different perceptions of risk is a crucial aspect of issue identification.

Consideration of all stakeholder issues is the key point here. The level of consultation required for this consideration generally reflects the level of community concern and the potential effects on the community. Some situations may have well-recognised issues that can be easily identified and there will be no need for direct involvement or consultation with all stakeholders. Other more complex situations, such as a proposal for a major mining project, will have a range of complex issues that require a greater degree of stakeholder involvement. For example, local residents may be most concerned about increased traffic and the proximity to local schools, workers may focus on adequate protection in the workplace and toxicologists may be particularly concerned with air emissions. In complex situations, all of the issues need to be considered for their suitability for health risk assessment and to be prioritised.

The main aim at this stage should be the development of a useful health risk assessment – one that will provide information that will be helpful in making decisions about the management of risk associated with a project. Careful planning and consideration of the scope and objectives of a health risk assessment are crucial. For complex health risk assessment, effective risk communication is crucial at this stage.

In terms of potential environmental health issues, the range is immense and will vary according to the project. Our experience and knowledge of previous similar situations will help to identify issues. These issues will arise from environmental health hazards that are physical, chemical or biological in nature. Putting these hazards into their environmental health context, as outlined in the enHealth guidelines, will involve a consideration of:

- Whether there are single or multiple sources of the hazard;
- Whether the contaminant affects multiple environmental media (e.g. lead smelter emissions contaminating soil, air, water and food);
- How do stakeholders perceive the problem? Do different groups have different perceptions?
- How do the hazards compare to other environmental hazards affecting the community?

2.1 Hazard Assessment

Hazard assessment comprises two aspects: hazard identification and dose-response assessment.

2.1.1 Hazard Identification

Does the substance or situation have the potential to cause adverse health effects?

The previous step of issue identification will have identified those environmental health hazards that are to be considered by the health risk assessment. Hazards addressed by a health risk assessment can be physical (e.g. noise, mechanical hazards, radiation and vibration), chemical (either naturally occurring or synthetic substances) or biological (e.g. viruses, bacteria and vermin).

Information about the hazards can be collected from a range of sources including human or animal studies and chemical information. The range of information available will vary with the situation and the type

of hazard. Animal toxicity data, human data or biochemical activity data may all be available for chemical, biological and physical data.

The reliability and quality of the studies and other sources of information used at this stage should be addressed in the health risk assessment.

2.1.2 Dose-response Assessment

The dose-response assessment examines the relationship between the dose of a particular hazard and the adverse health effects in humans. This relationship is conveyed by the accepted toxicological principle of 'the dose makes the poison.' An example is an everyday substance such as Vitamin A, which in small doses is an essential part of our diet, but which can be toxic if consumed in large quantities.

Dose-response relationships need to take into account a range of potential variables. The relationship between dose and the health effects of a substance is often very different for different substances. These different relationships are dealt with by using different models and by using data analysis and interpretation that are appropriate for the data at hand.

Some people may be more sensitive to a substance or a situation than others. Experience shows that groups that can be more susceptible to potential hazards include children, the elderly and those with existing medical conditions. Children may be more sensitive to certain hazards for a range of reasons including higher metabolic and breathing rates than adults, an immature immune system and behavioural factors such as a greater tendency to ingest soil. Asthmatics and people with heart or respiratory conditions are more sensitive to a range of hazards, particularly air pollutants, which may trigger asthma, shortness of breath and coughing. Other diseases, which result in a decrease in immune system response, can also result in greater sensitivity to some environmental health hazards.

The type of exposure can also influence the dose-response relationship – a continuous low dose of a substance over a long period will have a different dose-response than a series of high intermittent doses. If we take the example of Vitamin A again, ingestion of a small amount of Vitamin A every day over a lifetime plays an essential role in our vision, growth and development, yet ingestion of a lifetimes worth of Vitamin A in a single dose would be likely to result in liver failure and possibly death.

The route of exposure is another variable. The health effects of a substance will often differ depending on whether they are inhaled ingested or in contact with skin and data used should attempt to reflect the situation under assessment. The possibility of multiple routes of exposure should be addressed.

The type of data used should attempt to take all of these variables into account with the usual considerations of relevance, quality and uncertainty.

2.2 Exposure Assessment

What exposures are likely to be experienced under anticipated conditions?

This step gathers information about how much of a particular substance different groups will be exposed to, exactly how that exposure takes place - by breathing, eating or drinking - and for how long the exposure will occur. This information is then combined with known information such as breathing rates, food or water consumption and life expectancy to estimate total exposure.

In essence, this step puts the previous two steps into a meaningful context. If hazard assessment has concluded that a particular substance can cause breathing difficulties at 150 parts per million (ppm) in the air, we cannot draw any conclusions until the final part of the equation, the expected exposure, is calculated. In this case, an estimated exposure assessment of 5ppm indicates minimal risk of breathing difficulties whilst one of 300ppm indicates a significant risk. We can see from this how reports about substances toxicity, if used out of context, can cause unnecessary alarm.

It is important that the exposure assessment takes into account different levels of exposure that may be experienced by different groups. Exposed populations will include the general population, those most exposed and those most susceptible. The most exposed will be those who for some reason are likely to be exposed to higher levels of the hazard than the general population. This may include workers on the project, those living near known sources of the hazard and those who may be exposed to other sources of the hazard. The possibility of multiple exposure routes may arise from exposure to a combination of air, water, soil and food sources, from occupational sources and even from lifestyle factors such as diet and tobacco smoking. The level of exposure is also influenced by the environmental persistence of a substance. The longer a substance persists in the environment, the longer it persists as a potential source of exposure.

Susceptible groups are not necessarily exposed to higher levels of the substance, but for some reason they are more likely to experience adverse health effects than the general population. This susceptible group may be different for different hazards and can include children, the elderly, women, the sick and people with particular medical or genetic conditions. The notion of different exposure levels is relevant for all types of hazards - physical, chemical and biological.

Existing projects or situations may use environmental samples that have the potential to give the most direct measure of exposure levels. Proposed projects usually rely on experience from similar projects in existence and the use of transport and fate models that forecast what happens to a substance after it is released into the environment. The data used for these models, the choice of model and the uncertainties and limitations associated with each, should be clearly stated.

2.3 Risk Characterisation

What is the estimated incidence of the adverse health effects in a given population?

This final step brings together all the information from the previous steps to describe the risks to different groups. It will make conclusions by weighing up all the information, taking into consideration the quality of the data, the amount of evidence and levels of uncertainty, to prepare an overall picture of risk. Whilst the scope of the health risk assessment should be agreed upon early in the process, there may be instances where new information, new perspectives or new issues emerge during the process that prove to be significant in terms of human health. The health risk assessment process should have the capacity to feed back significant issues to earlier steps in the process to gather new and relevant information.

This is a complex step. Judgements need to be made about the strengths and weaknesses of evidence at each step of the process. There is no magical equation that will calculate an accurate figure for risk. Quantitative estimates for risk, at hazard identification, dose-response and exposure assessment steps, will include confidence intervals that take into account the uncertainty of the assessment. Qualitative measures of risk for issues where quantification is difficult may be justified. For example current uncertainty regarding 'safe' levels of dust and the highly subjective nature of odour, makes quantification of these issues difficult.

Risk characterisation will often make comparisons between the exposure assessment and established environmental health criteria. It should be ensured that these criteria have been endorsed by the appropriate agencies or otherwise appropriately justified. The protection of public health requires the incorporation of safety factors that guard against uncertainties. Guidelines such as 'accepted daily intakes' or 'tolerable intakes' typically incorporate safety factors into their calculation.

Whilst strictly speaking, the health risk assessment process stops with the characterisation of risk, there is a natural progression to risk management, which may use information from the health risk assessment to apply management decisions such as the introduction of measures to reduce the level of risk.

2.4 Health Risk Assessment Reports

The findings and details of a health risk assessment need to be reported in a clear and logical manner. Reports should contain sections on issue identification, hazard assessment, exposure assessment and risk characterisation. Standardised formats may be required by different agencies.

An in-depth coverage of the key aspects and requirements of a health risk assessment report are covered in Chapter 10 of the enHealth guidelines. A checklist for each step in the health risk assessment process is included and the general attributes of a good report are stated as:

- the scope and objectives of the report are explicitly stated;
- the content is laid out impartially, with a balanced treatment of the evidence bearing on the conclusions;
- inclusion of a description of any review process that was employed, acknowledging specific review commentary;
- the key findings of the report are highlighted in a concise executive summary;

- the report explains clearly how and why its findings differ from other risk assessment reports on the same topic; and
- the report explicitly and fairly conveys scientific uncertainty, including a discussion of research that might clarify the degree of uncertainty.

Health risk assessments are not meant to gather dust on a shelf. They are designed as a working tool for risk management and should be used as such. Health risk assessments can contribute to decisions made in risk management such as prioritising issues and actions according to risk, setting of specific health based criteria for projects and developing plans to reduce certain risks. If measures to reduce risk are implemented, health risk assessment can be used as an effective tool to re-assess the impact of the reduced or residual risk. As well as providing a revised estimate of risk this provides stakeholders with information regarding the effectiveness of the measures that have been implemented.

Health risk assessment should be seen as a process that can serve all stakeholders. Whilst health risk assessments can address situations where stakeholders hold a range of conflicting views, each with legitimate arguments, it is essential that the process is independent of these viewpoints and provides an objective assessment. Health risk assessments that are accepted as objective by all groups will provide far greater benefits than an assessment that is considered subjective. A well accepted, objective assessment can provide valuable information for proponents, for communities and for government departments. Decisions based on such information will generally be held in greater confidence by all stakeholders and contribute to more effective management of the project.

Health risk assessment needs to work in a changing environment. New developments, new science and new information will continue to impact on our health. As health risk assessment responds to these changes, it too, can contribute to our knowledge about the potential effects of existing and emerging environmental health hazards. These improvements in our knowledge and understanding of such matters can be used to better manage future situations and ultimately contribute to a safer and healthier society.

It is important to realise that the information provided by a health risk assessment is one of considerations that will be taken into account in making decisions about new projects. Other considerations and sources of information – technical, economic, environmental, cultural and political – can all contribute to the effective risk management of any project. This is all part of the integrated approach to risk management that attempts to reflect the complex nature of our world.

Section 3: A Framework for Health Risk Assessment

3.1 The Use of Health Risk Assessments in Western Australia Today

These guidelines have been written in a general fashion to give the reader background knowledge about the health risk assessment process. That knowledge can be applied to a wide range of situations and activities with the potential to affect our health. These situations may include mining, agriculture, all types of industry, manufacturing, food-production, waste-disposal, planning and many others. In general, the nature of the project will dictate what level and areas of government are involved in any health risk assessment.

An example of the increasing recognition of the complex nature of many development projects is the introduction in 2004, of the Integrated Project Approvals System. This system, specifically for projects within the State Development Portfolio, was developed to coordinate the approval process for complex projects, requiring agreement from numerous Government agencies. The Department of Health or the Environment Protection Agency, may state the need for a health risk assessment. The Office of Development Approvals Coordination, based at the Department of Premier and Cabinet, will assist in the coordination of the approvals process.

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General Framework for a Health Risk Assessment*

	Questions to Address	Results
Issue Identification	What are the issues, why are they an issue and what is causing them? What issues are priorities? What are the possible adverse health effects and when are they likely to occur? What questions do we need to answer? What information is needed to answer these questions and is this information available? Will a health risk assessment answer these questions? What are the boundaries of the assessment and what level of effort is justified?	Overall scope and plan of the health risk assessment.
Hazard Identification	What are the hazards and their likely health effects? How long is the hazard likely to last? What data was used?	Major conclusions. Level of uncertainty Clear statement of methods. Quality of data. Major assumptions Relevance of information or data used.
Dose-Response Assessment	What data was used? What models were used and why? Does the route & level of exposure in the data used reflect the situation? If not, how are these differences taken into account?	
Exposure Assessment	What are the most significant sources and pathways? What populations have been assessed-general, exposed and susceptible groups? What monitoring or modelling was used? How was exposure described and calculated?	
Risk Characterisation	What are the risks to different groups? Feedback information or questions to previous steps. Summarise major conclusions and strengths of each of the main steps. Provide information to risk management team	Overall picture of risk Major conclusions Uncertainty

**This framework gives examples of the type of questions that a health risk assessment may address. It is not intended to cover every aspect of every situation.*

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