

Decision Making

A Technical Guide to Identifying, Assessing and Evaluating Risks, Costs and Benefits

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Preface

This guide is the lead document in a series of technical guides produced by ERMA New Zealand to help people involved with the HSNO Act. It will be primarily helpful for those people who are reviewing applications and those involved in decision making. It may also be useful for applicants and other people interested in HSNO related decision making more generally. People with a less technical interest in HSNO are advised to start with other series of documents we publish, especially:

- the quick guides (aimed at a very general audience or for an introduction to the HSNO Act and ERMA New Zealand)
- the user guides (aimed at those directly involved with HSNO particularly the application process).

Publications in this series are intended to provide a technical point of reference. Most of the documents are primarily authored by a member of staff, but in some cases, there may be an external author.

This guide addresses the broad requirements of the decision making process, and includes definition of the overall process, and the individual steps within the process, that is the identification, assessment, and weighing-up of adverse and beneficial effects (risks, costs and benefits). It also includes further clarification of how the Authority will address the consideration of private and public costs and benefits, and the matters that will have an impact on the Authority's attitude towards risk. Since the guide is applicable to all decisions made by the Authority the tools and techniques discussed cover a wide range.

A range of technical guides has been or will be produced to provide comprehensive guidance in particular areas. If you want more detailed guidance in an area covered briefly within this guide, please contact us.

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1 Introduction

This guide has been developed firstly to provide guidance to the Authority and to Agency staff, and secondly to provide stakeholders with assurance that the Authority is adopting best practice approaches.

This Guide addresses the elements of the decision making process, and includes definition of the overall process, and the individual steps within the process, that is the identification, assessment, and weighing-up of adverse and beneficial effects (risks, costs and benefits). It also includes clarification of how the Authority will address the consideration of private and public costs and benefits, and the matters that will have an impact on the Authority's attitude towards risk. Since the Guide is applicable to all decisions made by the Authority a full range of tools and techniques is included. This does not preclude the use of additional tools not specified in the Guide as such tools and techniques become available.

In addition to guiding the processes used by the Authority in making decisions, the guide will also be used by the Agency staff in the preparation of the *Evaluation and Review* reports. Where appropriate these reports are used to provide technical support to the published decisions of the Authority, therefore it is important that their structure should be consistent with the framework described in this guide.

The Methodology Order (ERMA, 1998) describes how the Authority will make decisions on applications lodged under the Hazardous Substances and New Organisms Act (HSNO, 1996). As the Methodology is primarily a legal document, it does not contain details of the particular tools or techniques that the Authority will apply to the different tasks required by the decision making process. This guide is a best practice guide and addresses this gap. However, it is not a statutory document and does not include comprehensive cross-references to statutes. Some particular references are made for the purpose of aligning the statutory process with best practice.

Thus, the guide is intended for use by:

- The Authority in making decisions
- Agency staff in preparing Evaluation and Review reports on applications
- Stakeholders in making submissions
- Applicants in preparing applications.

For simplicity, all references to 'the Act' refer to the HSNO Act, 1996, and all references to 'the Methodology' refer to the Methodology as specified by Order in Council, 1998. 'The Agency staff' refers to staff of ERMA New Zealand, and 'the Authority' refers to the decision makers, the members of the Environmental Risk Management Authority.

2 The overall decision making process

This Chapter describes the context for making decisions. It covers the statutory framework as well as the risk analysis framework which is discussed in more detail in the following Chapters.

2.1 Background

The purpose of the Hazardous Substances and New Organisms (HSNO) Act 1996 is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms.

The principles relevant to the purpose of the Act oblige the Authority to recognise and provide for:

- (a) *The safeguarding of the life-supporting capacity of air, water, soil, and ecosystems*
- (b) *The maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural wellbeing and for the reasonably foreseeable needs of future generations (section 5).*

In addition, in making decisions under the Act, the Authority must take into account of:

- (a) *The sustainability of all native and valued introduced flora and fauna*
- (b) *The intrinsic value of ecosystem*
- (c) *Public health*
- (d) *The relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga*
- (e) *The economic and related benefits and costs to be derived from the use of a particular hazardous substance or new organism*
- (f) *New Zealand's international obligations (section 6).*

Sections 7 and 8 of the Act also include decision-making criteria. Thus, the Authority must ‘take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects’ (section 7) and ‘take into account the principles of the Treaty of Waitangi (Te Tiriti o Waitangi)’ (section 8).

2.2 Decision making process

The Authority's process for making decisions on applications is defined by the Act and the Methodology.

The steps of the process are:

1. application received
2. further information is obtained from the Agency staff, submitters, experts and other agencies
3. the decision maker (the Authority) considers all the information in the context of the Act and the Methodology and makes a decision
4. the decision is published.

The Agency staff prepares an *Evaluation and Review* report incorporating submissions where relevant. The Authority's consideration uses the information from the application, the Evaluation and Review report, any submissions (including those from government agencies), any information obtained from experts, and the results of a hearing if one has been held. Chapter 2.5 discusses the information requirements in more detail.

The consideration process is specified in the Methodology. It has two basic steps: assessment and evaluation. These are defined in the Methodology as follows:

- **Assessment** means a process of identifying and assessing risks, costs and benefits associated with the introduction of hazardous substances or new organisms in the context of applications made under Part V of the Act.
- **Evaluation** means the evaluation by the Authority of the combined assessments of risks, costs and benefits associated with applications made under Part V of the Act for the purposes of deciding whether the application should be approved with conditions, or declined.

Thus, evaluation can be described as the weighing-up of adverse and beneficial (positive) effects¹ as is required in sections 29, 38, 38C, 45 and 50 of the Act. Other decision making sections of the Act only require consideration of adverse effects, and where the term 'evaluation' is applied in these circumstances, other criteria are applicable that do not require consideration of beneficial or positive effects.

The definition of 'effect' in the Act includes:

- (a) *Any potential or probable effect; and*
- (b) *Any positive or adverse effect; and*
- (c) *Any temporary or permanent effect; and*
- (d) *Any past, present, or future effects; and*
- (e) *Any acute or chronic effect; and*

¹ The Act refers to adverse, beneficial and positive effects. In this guide positive and beneficial effects are deemed to be equivalent.

- (f) *Any cumulative effect which arises over time or in combination with other effects.*

The definitions of risk, cost and benefit in the Methodology are:

- **Risk** means the combination of the magnitude of an adverse effect and the probability of its occurrence.
- **Cost** means the value of a particular adverse effect expressed in monetary or non-monetary terms.
- **Benefit** means the value of a particular positive effect expressed in monetary or non-monetary terms.

While only the definition of ‘risk’ refers explicitly to probability, Clause 32 states that:

‘Where the Authority considers there is uncertainty in relation to costs, benefits, and risks (including, where applicable, the scope for managing those risks), the Authority must attempt to establish the range of uncertainty and must take into account the probability of the costs, benefits, and risks being either more or less than the levels given in evidence’.

The definitions in the Act indicate that effects are not necessarily certain outcomes, while Clause 32 of the Methodology makes it clear that the probability or likelihood of occurrence of risks, costs and benefits is an important element that must be considered in the weighing-up process.

The Authority, the Agency, and the applicant share responsibility for identifying, analysing, and controlling risks, costs and benefits. The applicant has primary responsibility for identifying and assessing risks, while the Authority has responsibility for evaluating risks and making decisions based on a combined consideration of risks, costs and benefits.

2.3 Links to risk management processes

The risk management process as specified in AS/NZS: 4360 (from here on referred to as the Standard) comprises a series of steps as shown in the following diagram.

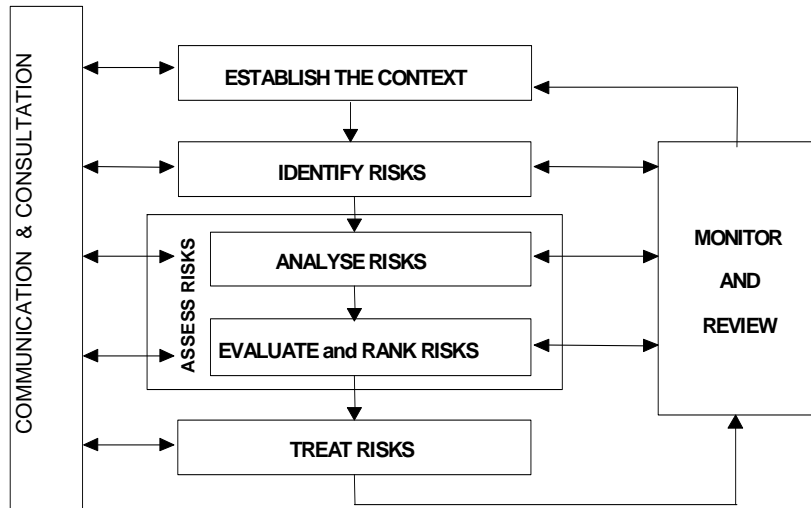


Figure 1: The basic risk management process (AS/NZS 4360: 1999)

The steps in the decision making process applied by the Authority are clearly consistent with the basic risk management process specified in the Standard. The Methodology incorporates identification into assessment, and the Agency ‘assessment’ process is analogous to the identification and analysis steps. ‘Evaluation’ in the Standard process consists of ranking the risks that have been analysed in terms of magnitude and likelihood of consequence, and then determining which of these are deemed acceptable, which require further ‘treatment’ (varying forms of reducing the risk) to make them acceptable, and which are such that no treatment will make them acceptable. This step includes consideration of costs and benefits and is thus similar to the evaluation or weighing-up of effects that is part of the Authority’s decision-making process.

Communication and consultation is undertaken as part of the statutory requirements of the Act for those applications that require public notification. Consultation with relevant government agencies is also an integral part of the decision making process.

Risk treatment involves applying controls to the risks until they are reduced to an acceptable or tolerable level, where this is possible or appropriate. Under the HSNO Act, this option is available for applications for new organisms in containment (including field-testing) and conditional release, and for hazardous substances. It is not available for applications for release of new organisms. Risk treatment includes consideration of the cost effectiveness of controls.

Similarly, review and monitoring is not applicable to applications for new organisms for full release, and nor can the decision itself be revisited except where a substance or organism is reassessed.

Table 1 illustrates the alignment between the process detailed in the Methodology and the risk management Standard process.

Table 1: The Methodology and risk management

The Methodology	AS/NZS 4360 process
Context (set by Act)	Context
Assess	Identify
	Analyse
Evaluate	Evaluate
Apply controls (where relevant)	Treat
Public notification of applications and decisions Hearings Consultation with other agencies (joint responsibilities with other agencies)	Communicate and consult
	Monitor and review

2.4 Context

Establishing the context is an important first step in the technical risk management process as described in the Standard. Context determines the type of risks that will be considered and includes organisational, strategic, and risk management context. This step includes setting the criteria for determining the levels of acceptability of risk, identifying the stakeholders, and considering and preparing a communication plan.

In the Authority’s decision-making process, the general aspects of the context are defined by the Act and the Methodology, while the specific aspects are determined by the particular application being considered.

Using the terminology of the Standard, the **organisational context**, is provided by the HSNO Act, the Methodology, and policies developed by the Authority. These provide the framework for decision-making, and specify the types of risks, costs and benefits to be included in the decision making process, and how they are to be considered. In addition, the application forms provide the structure for ensuring that the applicant operates within the required organisational context.

In particular, establishing the organisational context means:

- defining the project or activity (identifying the hazardous substance or new organism and why an application is required);
- defining the extent of the project or activity in time and location (specifying the purpose of the application and in case of containment applications and conditional release, how the substance or organism will be contained); and
- identifying any studies needed, their scope, and the resources required (noting relevant research and areas where relevant research either is in progress or might be useful).

The **strategic context** is defined by the applicant, the purpose of the application, and the institutional environment within which the applicant operates or plans to operate. For example, an applicant may be a university, a research organisation, a government agency, a commercial company, a non-commercial organisation such as a zoo, or an individual.

The applicant may have lodged an application for direct financial gain, for research purposes (indirect financial gain), to assist in eradicating a pest, for medical purposes, or for indirect benefit. Defining the benefits, the recipients of those benefits, and associated costs is an important part of establishing the strategic context (and overlaps with establishing the risk management context).

The **risk management context** relates to the particular new organism or hazardous substance for which the application has been made. Part of establishing the risk management context includes specifying the life cycle of the substance or organism, and typical (generic) management processes that might be part of the controls placed on it. The type of application will be an important part of the risk management context, that is, whether the application is for containment, manufacture, importation, field trial, or full or conditional release.

The results of considering all these components come together to provide the overall context within which risks, costs and benefits are identified.

2.5 Information

This section discusses the source of the information used to inform the decision making process, and provides some advice on presenting that information.

Information is provided, by the applicant, by submitters, and by expert reviewers and comes in a wide range of type and quality. In addition, where deemed necessary and appropriate the Agency staff will seek supporting or supplementary information from direct and indirect sources.

All available information is compiled into an *Evaluation and Review* report (see 2.2) by the Agency staff. The *Evaluation and Review* report is a comprehensive document that analyses and appraises but does not duplicate the information in the application. A primary purpose of the report is to verify the validity and relevance of the information.

Some of the questions that the Agency staff needs to ask when reviewing the information are²:

- is the material provided deemed to be information³
- how are these things grasped and defined
- what is authoritative and to be taken seriously

² Parliamentary Commissioner for the Environment Discussion Paper, *Illuminated or Blinded by Science*, July 2003

³ Following Websters Dictionary, information is considered to be knowledge or intelligence, knowledge obtained from investigation, study or instruction, intelligence or news, facts, data, physical or mental experience.

- the different ways in which things might be relevant to environmental policy and decision making
- how things are most appropriately expressed and communicated.

Technical information may be verified through references, expert knowledge, and consultation with outside experts. Where scientific (including economic) data is based on models, then the assumptions and parameters of the models may need to be tested through sensitivity analysis⁴.

Information on social and cultural matters may be more difficult to verify, and may need to be addressed in a different manner to scientific and technical information (see 5.3).

In theoretical terms, all technical information should be given the same weight. However, in practical terms there will be differences in the quality of information depending on the source. While there will always be an element of judgement in this, there are some rules that may be applied in terms of acceptability of scientific information.

There are three different types of information that will be relevant to the decision making functions of the Authority:

- data (required for applications);
- descriptions of the processes used to obtain the data; and
- records of decisions in other jurisdictions (based on the data presented).

With respect to each of these types of information, the Authority will examine the appropriateness, content and quality of the information (in line with the requirements of Clauses 8, 10 and 11 of the Methodology).

The criteria for judging quality will be directly linked to the source of the information. Scientific information will be judged acceptable if it derives from a recognised international agency such as the United States Environmental Protection Agency. It should be noted, however, that while the quality of such information will be considered acceptable the content might not necessarily be acceptable since it may have been developed for a different purpose.

Technical information may also be provided in the form of scientific research papers. The quality of this information will be judged according to the quality and status of the journal or publication (including whether the paper has been refereed), and the appropriateness of the placement. Another criterion may be the weight of the body of knowledge associated with the topic, for example, whether the results are consistent with a significant field of research, or whether the research or results are new or ‘novel’. Cited references may be checked.

⁴ Sensitivity analysis is the process of changing model parameters and assumptions in a systematic manner and revising the model outcomes. The purpose of sensitivity analysis is to test which assumptions are critical to the model, and which input parameters are the most sensitive (those where changes will have the most effect on the outcome).

Where the papers are not supported in this way, then additional checking may be required to determine the status of the research. Where there is insufficient backing for the results then a lesser weight or credence may be given to this information.

Non-technical information⁵ may be either quantitative or non-quantitative. The main differentiation between technical and non-technical information is that in many cases the basis for non-technical information may be more difficult to verify (this may be an over-simplification). For example, community interests may be reported either in the form of survey results (quantitative) or as narrative of meetings (non-quantitative). Once again, criteria may be set as to the value (and relevance) of this information, but in general it will require judgements.

Where differential weights are applied to different information available to the Authority then a clear statement must be made stating the criteria applied in making this decision.

⁵ Note that the distinction is between technical and non-technical information, rather than scientific versus non-scientific since non-technical information may be 'scientific' in that it may derive from scientific processes.

3 Identification of risks, costs and benefits

This Chapter describes how the Agency staff and the Authority will address the identification of risks, costs and benefits. It discusses the process of identification, and some of the techniques that might be used to identify risks, costs and benefits. For further detail and examples see the Technical Guide *Identifying Risks for applications under the Hazardous Substances and New Organisms Act 1996* (ER-TG-01-1 9/99).

3.1 Overview

In the Authority's decision making process, risks, costs and benefits are identified within a defined context that takes account of the type of organism or substance, the purpose of the application, and the requirements of the Act and the Methodology.

Effects, including risks, costs and benefits, arise because of interactions between people, their activities, and the general social and physical environment. Comprehensive identification of effects requires a combination of lateral thinking, and a rigorous structured analysis of the organism or substance, its environment, and how it interacts with its environment.

The Methodology incorporates 'identification' within the 'assessment' of risks, costs and benefits. However, the identification process is usually conducted as a first step prior to estimating measures for the components of risks, costs and benefits, therefore it is described separately.

During the identification process all risks, costs and benefits should be identified. However, an additional aspect that is specific to the HSNO process is that a second step be taken; the identification of those risks, costs and benefits deemed to be potentially significant and to require further consideration. Thus, the identification includes a decision step.

The primary responsibility for identifying risks, costs and benefits lies with the applicant. In preparing the Evaluation and Review report the Agency staff review the identification presented in the application and undertake their own process to identify any gaps or areas overlooked by the applicant. During the consideration process, the Authority may also identify further effects.

For efficiency reasons, it is sensible for these processes to be additive; for Agency staff and the Authority to look for gaps, omissions and mistakes, rather than redo the whole process.

3.2 Process of identification

Identification of risks, costs and benefits involves examining all sources of effect, potential areas of impact, and exposure pathways. The aim is to undertake a systematic and wide-ranging review.

To ensure completeness, the analysis should firstly look at all possible sources of effect and work through the possible pathways to determine the areas of impact⁶. Secondly, beginning with the possible areas of impact, the analysis should work backwards to see what might be the source of such an effect⁷.

The areas of impact are defined by sections 5 and 6 of the Act, and include the natural environment, human health and public health, social and community matters, cultural and spiritual aspects and economic aspects.

The sources are the characteristics of the substance or organism, and the processes involved in its importation, manufacture, development, storage, field testing, release, use, or disposal.

Possible sources may also include:

- the nature of the science or technology (whether the processes and the outcomes are well-known)
- human behaviour (affecting management or containment procedures)
- socio-economic issues
- political and legal issues
- commercial and legal relationships
- financial or market aspects
- management activities and controls
- operational aspects of the application
- occupational health and safety
- security
- natural events.

This is not an exhaustive list and all applications should be addressed individually.

Where sources of effect are negative, they are sometimes called hazards.

Pathways are ways in which the source may intersect with the area of impact so that the potential effect is realised. The existence of a pathway provides an indication of the likelihood of the effect occurring. While pathway analysis is primarily relevant to identifying (and assessing) risks, it is also relevant to identifying and assessing benefits, since benefits are not certain and the likelihood of their realisation needs to be considered. If there is no feasible pathway then no effect can be identified⁸. At times, the intersection between sources and area of impact may also require a trigger or an incident to make the pathway active. Such 'triggers' may be caused by one or more unusual events⁹, for example the breaching of a chemical storage tank as the result of an accident within a plant.

⁶ Analogous to event tree analysis.

⁷ Analogous to fault tree analysis.

⁸ This concept derives from risk analysis where the existence of risk requires a source of risk (hazard), an area of impact (effect), and a feasible pathway between them.

⁹ Fault tree analysis and event tree analysis are used to examine cases where a series of events is required before the effect is realised.

Meaningful and reliable information is important in identifying effects and in understanding the source and the areas of impact.

The identification of risks, costs and benefits will be undertaken iteratively with the assessment (estimation) of the magnitude and likelihood. Firstly, all possible risks, costs and benefits should be identified. Secondly, a preliminary assessment is made to decide which risks, costs and benefits need to be addressed further. In some cases the likelihood of the effect occurring and the magnitude if it did occur are both so low that the effect does not need to be considered further.

Risks and benefits that are deemed not to be potentially significant and therefore not addressed further should be recorded.

A simple process for relating the source of effect, the areas of impact and potential pathways is to create a table with source and area as the two dimensions. The cells of the table can be completed with a simple marking procedure where a pathway is known or suspected to exist, as shown in Table 2.

Table 2: Example of simple matrix approach to identifying effects

Source Area of impact	Aerial spraying of substance	Cleaning of equipment	Application technique
Aquatic species (specify)	X		
Users			X
Waterways		X	
Groundwater		X	

3.3 Selecting a technique

The following techniques may be used for identifying risks, costs and benefits:

- brainstorming and common sense assessment;
- past agency experience (including analogy to known cases);
- reported overseas experience;
- databases of incidents;
- checklists;
- lifecycle assessment;
- scenario analysis, decision trees (including fault trees and event trees);
- toxicology studies;
- epidemiological surveys;
- interview/focus group discussion, consultation;
- safety audits or physical inspections;
- flow charting, systems analysis;
- SWOT analysis (Strengths, Weaknesses, Opportunities and Threats).

Appendix B gives short descriptions of each.

The particular tool used by an applicant will depend on the nature of the application and the experience and expertise of the analyst.

Applicants may use any of the above tools. Agency staff and the Authority may also apply any of these tools, but in practice will most commonly be restricted to the first seven. The level of analysis will depend on the type of application. Brainstorming and commonsense assessment will be applied in all cases. Information on the intrinsic hazardous properties of a substance is very important. This is especially so if an area of impact (e.g. a waterway) and a pathway (e.g. aerial spraying) are identified. In this case, information about the intrinsic eco-toxicological properties of the substance is essential. Unavailability of such data would lead to an uncertainty that would be assessed (see 4.4.5 and 6.3).

4 Assessing risks, costs and benefits (general)

This Chapter describes how the Agency staff and the Authority will address the assessment of risks, costs and benefits. It reviews the general approaches that are used to assess or estimate risk components, across a range of disciplines. The difference between quantitative and qualitative analysis is discussed along with issues relating to the distribution of effects, the impact of controls, comparative analysis, and the special issues that relate to consideration of beneficial effects. Chapter 5 looks at the specific techniques used in different relevant areas.

4.1 Overview

Risks, costs and benefits may be assessed qualitatively or quantitatively, and the choice will depend on the amount of data available, how much is known about the severity of the effects, and (in the case of hazardous substances) the data requirements for the class of substance.

As for the identification of risks, costs and benefits, the primary responsibility for assessment lies with the applicant. In preparing the *Evaluation and Review* report the Agency staff review the assessment presented in the application and make recommendations as to whether or not the assessment is adequate. In some cases, the Agency staff will make their own assessments based on the information available.

The Authority's decision-making process requires the assessment of risks, costs and benefits. Risks are assessed in terms of Clause 12 of the Methodology –

When evaluating assessment of risks associated with the substance or organism in an application, the Authority must take into account—

- (a) The nature of the adverse effects; and*
- (b) The probability of occurrence and the magnitude of each adverse effect; and*
- (c) The risk assessed as a combination of the magnitude of the adverse effect and the probability of its occurrence; and*
- (d) The options and proposals for managing the risks identified; and*
- (e) The uncertainty bounds on the information contained in the assessment expressed quantitatively where possible, but otherwise through narrative statements.*

While costs and benefits are assessed in terms of Clause 13 –

When evaluating the assessments of costs and benefits associated with the substance or organism in an application, the Authority must take into account—

- (a) The costs and benefits associated with the application and whether the costs and benefits are monetary or non-monetary; and*
- (b) The magnitude or expected value of the costs and benefits and the uncertainty bounds on the expected value; and*
- (c) The distributional effects of the costs and benefits over time, space, and groups in the community.*

Thus risks are assessed in terms of likelihood of occurrence and magnitude of consequence should they occur. Costs most often arise from risks, and therefore the assessment of risks and costs can be grouped. Benefits are also assessed in terms of consequence and likelihood, through the calculation of the expected value and the uncertainty specification of Clause 32 (see 2.2).

4.2 General approaches

Risk assessment is the process of analysing a wide range of possible outcomes of an activity (in this case approval of an application) to determine what might happen and how. This process can be extended to the assessment of risks, costs, and benefits.

Risks and benefits are therefore **assessed** by estimating the magnitude and nature of the possible effects and the likelihood of their occurrence. For each effect, the combination of these two components determines the **level** of the risk associated with that effect, which is a two dimensional concept. Because of lack of data, risks are often presented as singular results. In reality, they are better represented by ‘families’ of data which link probability with different levels of outcome (magnitude).

While the level of effect is estimated or assessed in terms of magnitude of consequence and likelihood, in most cases there are a number of additional factors that need to be taken into account in making decisions about the weight to put on the terms, particularly in light of the Authority’s approach to risk.

The Methodology discusses how risk averse the Authority will be in making decisions based on a set of characteristics associated with the identified and assessed effects. How these factors are incorporated into the Authority’s decision-making is discussed in 6.2.

Two elements need to be addressed in assessing effects:

- magnitude of the effect if it should occur
- likelihood of the effect occurring.

Estimating the likelihood of the event occurring requires considering the potential exposure pathways, and analysing the ‘chain of events’ leading to the final environmental impact or effect. Each event in the chain is dependent upon the previous event occurring in the first place.

The likelihood term applies specifically to the resulting effect or the final event in the chain. The frequency or probability solely of the initial incident or hazard event should not be used (as it sometimes is in the safety discipline). These ‘conditional likelihoods’ need to be factored into calculating the final likelihood of the effect occurring.

Estimating levels of risk requires assigning a magnitude or value to each of the outcomes identified. It may also be necessary to estimate multiple impacts. For example in addressing the risk to human health, effects might range from mild impairment, to death. Different sectors of the population might also need to be considered separately because of different risk factors (e.g. age, ethnicity, socio-economic factors etc).

In the same way that the likelihood must reflect the end of chain effects, the magnitude must be a measure of the endpoint (specified by the Act and the Methodology). The magnitude of the effect is not the same as the effect itself. As well as the measure of effect, a measure of exposure and measure of ecosystem and receptor characteristics may be required.

4.3 Quantitative and qualitative assessments

Estimates of magnitude and likelihood of effect may be qualitative or quantitative. Whether qualitative or quantitative approaches are used depends on the amount, type, and quality of the data available. Risks, costs, and benefits are two-dimensional, and in many cases, qualitative analysis is more useful than quantitative analysis because the information about the magnitude and the likelihood of the effect is preserved.

Quantitative assessment uses numerical values that have a direct physical relationship for both effects and likelihood. The quality and validity of the assessment is dependent on the availability of data, and on the accuracy and completeness of the numerical values and the methods used to derive the data (scientific experiments, models, extrapolation etc).

Consequences may be estimated by modelling the possible outcomes of an event or set of events, or by extrapolation from experimental studies or past data.

Likelihood measures may be either probabilities or frequencies depending on the type of data and the nature of the effect. Where frequencies are used the units applied need to be included as part of the measure of the risk. Probabilities are dimensionless.

Some of the estimates made and the data used in quantitative analyses will be imprecise, and sensitivity analysis should be carried out to test the effect of changes in values and limits. The accuracy of the measurements is also relevant.

The output from a quantitative assessment is a numerical value for a level of risk that can be compared with other similarly derived levels of risk.

Semi-quantitative assessment assigns values to qualitative scales. These values are representative numbers, often presented in orders of magnitude, such as powers of ten. They do not have a direct physical relationship to the likelihoods and magnitudes of effect that they represent.

Representative numbers are assigned to each of the magnitude and likelihood components, and in a similar way to quantitative risk assessment. The level of risk may be determined by multiplying the two assigned values.

The numbers assigned to each description do not have to bear an accurate relationship to the 'actual' magnitude or likelihood of consequences, provided that the system used for prioritising the risks matches the system chosen for assigning the numbers and combining them. The assigned numbers should not be interpreted as having any meaning other than in a comparative sense. Similar to qualitative analysis, semi-quantitative analysis is used to **prioritise** risks and benefits, and to decide which

ones need further analysis or control, and which ones do not need any further consideration.

The output from semi-quantitative analysis is a ranked list of risks or benefits.

A serious problem with semi-quantitative analysis is that information is lost when the assigned values for magnitude and likelihood are combined, by multiplying them together. This is of particular concern when the numbers assigned do not properly reflect the relativity between the descriptive categories.

Qualitative assessment uses words to describe the magnitude, or a measure of the severity of that effect, and the probability or likelihood of the effect occurring.

The descriptors used are unique to the particular application. Rather than trying to force the effects of a particular application to fit a generic description, it is more important to ensure that there is some comparability between the descriptions for each level for different applications. Where some groups of applications may be considered similar in nature then generic descriptions may be used for that group only. Chapter 4.4 looks at the development of qualitative descriptors in more detail and provides some generic examples that may be used as a starting point.

When there is a chain of consequences leading to the final effect, it may be difficult to combine the qualitative ‘consequential likelihoods’ and an overall judgement of likelihood may need to be made.

Qualitative assessments are used to prioritise risks and benefits to decide which ones need further attention, and which are negligible. As a result of qualitative assessment, in some circumstances the Authority may request the applicant to undertake a quantitative assessment, or additional sensitivity analysis.

Qualitative information for magnitude and likelihood of effect can be combined in a single two-dimensional table and used to allocate levels of risk or benefit, based on professional judgement. The output from this type of qualitative analysis is a series of ‘buckets’. In the case of adverse effects, risks that are in the lowest risk bucket may be deemed to be acceptable and may not need further consideration.

Another form of qualitative assessment is to specify a series of characteristics of a substance or organism and to assign a ranking to each of these. Indices are then calculated by either adding or multiplying the rankings for the allocated components. Weights can be applied also. This type of approach is often used for hazard assessment, but can be extended to risk assessment. Theoretically, it could be used for benefit analysis if deemed useful. In common with other qualitative techniques, these indices are relative indices and can only be used to rank or prioritise risks for further treatment.

4.4 Descriptors for likelihood, magnitude and risk/benefit

Experience to date has shown that while in some cases some quantitative data may be available for some effects associated with an application, the data necessary for a full quantitative risk analysis is rarely available. An appropriate form of assessment is qualitative analysis using the risk matrix approach or risk index approach. Risk indices

are useful for analysing pathways and deriving qualitative estimates of likelihood, and are therefore useful in combination with qualitative indices¹⁰.

Different types of applications involve different complexities and the risks and benefits are not necessarily the same. The use of similar sets of descriptors allows for comparisons between different types of effect¹¹. However, it is more important to ensure that the qualitative descriptors and the level of risk derived from them are appropriate to the application.

Qualitative matrices are used to prioritise risks (and benefits)¹², and to identify any risks that are unacceptable. The measure of the level of risk (combination of magnitude and likelihood) is specific to the application therefore measures of level of risk should not be compared between applications. However, the measures (descriptors) for different types of risk (human health, ecological etc) should be established so that they represent relative orders of magnitude.

Ideally, descriptors should be developed for each application. However, practically, most applications fall into broad categories. Therefore, standard descriptors can be developed for different groups of applications. There will be some applications that cannot be addressed in this manner, and for these, specific tables will need to be defined on a case-by-case basis.

The development of sets of descriptors for different types of application is ‘work in progress’. Chapters 4.4.1 and 4.4.2 describe how descriptors should be developed and provide some examples that the Agency will use as a starting point.

4.4.1 Development of scales for magnitude of effect

The magnitude of effect is described in terms of the element that might be affected. The qualitative descriptors for magnitude of effect are surrogate measures that should be used to gauge the end effect or the ‘what if’ element.

Tables 3 and 4 contain **generic descriptors** for magnitude of adverse and beneficial effect. These descriptors are examples only, and their generic nature means that it may be difficult to use them in some particular circumstances. They are included here simply to illustrate how qualitative tables may be used to represent levels of risk.

¹⁰ This does not imply the use of semi-quantitative analysis. It is simply a useful device to ensure that all aspects of the pathway are considered in assessing the likelihood of the effect being realised.

¹¹ Care must be taken when comparing qualitative assessments. While comparisons can be made across effects for a particular application, it is less valid to compare assessed effects between applications.

¹² AS/NZS 4360 Risk Management (the Australian and New Zealand Risk Management Standard), Basic Frameworks for Risk Management, NERAM (Network for Environmental Risk Assessment and Management, Canada), Zurich Hazard Analysis.

Table 3: Magnitude of adverse effect (risks and costs)

Descriptor	Examples of descriptions - ADVERSE
Minimal	<p>Mild reversible short term adverse health effects to individuals in highly localised area</p> <p>Highly localised and contained environmental impact, affecting a few (less than ten) individuals members of communities of flora or fauna, no discernible ecosystem impact</p> <p>Local/regional short-term adverse economic effects on small organisations (businesses, individuals), temporary job losses</p> <p>No social disruption</p>
Minor	<p>Mild reversible short term adverse health effects to identified and isolated groups</p> <p>Localised and contained reversible environmental impact, some local plant or animal communities temporarily damaged, no discernible ecosystem impact or species damage</p> <p>Regional adverse economic effects on small organisations (businesses, individuals) lasting less than six months, temporary job losses</p> <p>Potential social disruption (community placed on alert)</p>
Moderate	<p>Minor irreversible health effects to individuals and/or reversible medium term adverse health effects to larger (but surrounding) community (requiring hospitalisation)</p> <p>Measurable long term damage to local plant and animal communities, but no obvious spread beyond defined boundaries, medium term individual ecosystem damage, no species damage</p> <p>Medium term (one to five years) regional adverse economic effects with some national implications, medium term job losses</p> <p>Some social disruption (e.g. people delayed)</p>
Major	<p>Significant irreversible adverse health effects affecting individuals and requiring hospitalisation and/or reversible adverse health effects reaching beyond the immediate community</p> <p>Long term/irreversible damage to localised ecosystem but no species loss</p> <p>Measurable adverse effect on GDP, some long term (more than five years) job losses</p> <p>Social disruption to surrounding community, including some evacuations</p>
Massive	<p>Significant irreversible adverse health effects reaching beyond the immediate community and/or deaths</p> <p>Extensive irreversible ecosystem damage, including species loss</p> <p>Significant on-going adverse effect on GDP, long term job losses on a national basis</p> <p>Major social disruption with entire surrounding area evacuated and impacts on wider community</p>

The economic effects category has been given a surrogate magnitude. This is for demonstration as a means of illustrating the type of magnitudes that might be encountered.

Table 4: Magnitude of beneficial effect (benefits)

Descriptor	Examples of descriptions -BENEFICIAL
Minimal	<p>Mild short term positive health effects to individuals in highly localised area</p> <p>Highly localised and contained environmental impact, affecting a few (less than ten) individuals members of communities of flora or fauna, no discernible ecosystem impact</p> <p>Local/regional short-term beneficial economic effects on small organisations (businesses, individuals), temporary job creation</p> <p>No social effect</p>
Minor	<p>Mild short term beneficial health effects to identified and isolated groups</p> <p>Localised and contained beneficial environmental impact, no discernible ecosystem impact</p> <p>Regional beneficial economic effects on small organisations (businesses, individuals) lasting less than six months, temporary job creation</p> <p>Minor localised community benefit</p>
Moderate	<p>Minor health benefits to individuals and/or medium term health impacts on larger (but surrounding) community and health status groups</p> <p>Measurable benefit to localised plant and animal communities expected to pertain to medium term</p> <p>Medium term (one to five years) regional beneficial economic effects with some national implications, medium term job creation</p> <p>Local community and some individuals beyond immediate community receive social benefit</p>
Major	<p>Significant beneficial health effects to localised community and specific groups in wider community</p> <p>Long term benefit to localised ecosystem(s)</p> <p>Measurable beneficial effect on GDP, some long term (more than five years) job creation</p> <p>Substantial social benefit to surrounding community, and individuals in wider community.</p>
Massive	<p>Significant long term beneficial health effects to the wider community</p> <p>Long term, wide spread benefits to species and/or ecosystems</p> <p>Significant on-going effect beneficial on GDP, long term job creation on a national basis</p> <p>Major social benefit affecting wider community</p>

4.4.2 Development of scales for likelihood

Likelihood in this context applies to the **composite** likelihood of the end effect, and not either to the initiating event, or any one of the intermediary events. It includes:

- the concept of an initiating event (triggering the hazard), and
- the exposure pathway that links the source (hazard) and the area of impact (public health, environment, economy, or community).

Thus, the likelihood is **not** the likelihood of an organism escaping, or the frequency of accidents for trucks containing hazardous substances, but the likelihood of the **specified** adverse effect¹³ resulting from that initiating event. It will be a combination of the likelihood of the initiating event and several intermediary likelihoods¹⁴. The best way to determine the likelihood is to specify and analyse the complete pathway from source to impact.

Likelihood may be expressed as a frequency or a probability. While frequency is often expressed as a number of events within a given time period, it may also be expressed as the number of events per head of (exposed) population. As a probability, the likelihood is dimensionless and refers to the number of events of interest divided by the total number of events (range 0-1).

Table 5: Likelihood

Descriptor	Description
Highly improbable	Almost certainly not occurring but cannot be totally ruled out
Very unlikely	Considered only to occur in very unusual circumstances
Unlikely (occasional)	Could occur, but is not expected to occur under normal operating conditions
Likely	A good chance that it may occur under normal operating conditions.
Highly likely	Almost certain, or expected to occur if all conditions met

Table 5 provides an example of a set of generic likelihood descriptors for adverse and beneficial effect.

In most circumstances the likelihoods for adverse effects will fall into categories 1 through 4, while beneficial effects will be in categories 4 through 7. The table is not symmetrical. This is to allow for classification of very low probability adverse effects.

In practical terms, where the exposure pathway is complex, it may be conceptually difficult to condense all the information into a single likelihood. For any risk where the likelihood is other than 'highly improbable' or 'improbable', then an analysis of the

¹³ The specified effect refers to scenarios established in order to establish the representative risk, and may be as specific as x people suffering adverse health effects, or y% of a bird population being adversely affected. The risks included in the analysis may be those related to a single scenario, or may be defined as a combination of several scenarios.

¹⁴ Qualitative event tree analysis may be a useful way of ensuring that all aspects are included.

pathway should include identifying the ‘critical points’; the aspects that are the most vulnerable, and the elements where controls might be used to ‘cut’ the pathway.

4.4.3 Cut-off between magnitude and likelihood of adverse effect

Risk is measured in terms of likelihood of occurrence and magnitude of consequences. In environmental terms, risk should be thought of as the environmental consequences of a given severity, and the likelihood of that particular consequence occurring (usually within a specified time frame). The likelihood refers to the pathway between the source of risk and the area of impact and includes a measure of the degree of exposure.

When dealing with environmental risk, the ‘likelihood’ component of the risk definition applies specifically to the end-point environmental impact, and not the initiating event. For example, consider an application for the conditional release of a genetically modified organism; sugar beet. A defined risk would be the likelihood of the transfer of genetic material to other organic sugar beet crops leading to a defined level of ‘contamination’ of the crop. If the contamination were at a particular level then the crops would then need to be destroyed as they would not be able to be sold.

The likelihood includes the likelihood of pollen escape, the likelihood of reaching other (organic) crops, and the likelihood of expression in those other crops.

The magnitude is measured as the direct economic losses to individual farmers from loss of the crop, and in extreme circumstances may include the economic loss to the country from loss of non-genetically modified status (for sugar beet and possible more generally).

For hazardous substances, an example might be a risk to aquatic life from a toxic chemical entering a waterway as a result of a transport accident.

The likelihood includes the likelihood of an accident, the likelihood of the accident occurring near a waterway, the likelihood of the substance entering a waterway, and the likelihood of susceptible aquatic life being present.

The magnitude is measured in terms of the expected damage to the aquatic life if the chemical entered the waterway.

Care needs to be exercised where there is the remote possibility of extreme outcomes (such as loss of organic status). Under those circumstances, there is a tendency to focus only on the outcome and not to consider adequately the likelihood element. For example, the conclusion may be that the outcome is so extreme that the risk is not acceptable despite the extremely low likelihood. Situations of this type need to be tested by analysing the likelihood of less extreme outcomes. These may be analysed as separate risks.

4.4.4 Calculating the level of risk

Using these tables an additional two-way table representing a level of risk (combined likelihood and measure of effect) can be constructed.

In the example shown in Table 6, four levels of risk/benefit are allocated: A (negligible), B (low), C (medium), and D (high). These terms have been used to avoid confusion with the descriptions used for likelihood and magnitude, and to emphasise that the matrix is a device for determining which risks (benefits) require further analysis to determine their significance in the decision making process.

For negative effects, the levels are used to show how risks can be reduced by the application of additional controls. Where the table is used for positive effects it may also be possible for controls to be applied to ensure that a particular level of benefit is achieved, but this is not a common approach. The purpose of developing the tables for both risk and benefit is so that the risks and benefits can be compared.

Table 6 Calculating the level of risk (benefit)

	Magnitude of effect				
Likelihood	Minimal	Minor	Moderate	Major	Massive
Highly improbable	A	A	A	B	B
Very unlikely	A	A	B	B	C
Unlikely	A	B	B	C	C
Likely	B	B	C	C	D
Highly likely	B	C	C	D	D

The table presented here is symmetric around an axis running from highly improbable and minimal to massive and highly likely. However, this will not be the case for most applications because significant levels of risk are unlikely to be acceptable under any circumstances. That is, the top left hand corner of the table is of most practical interest. The degree of asymmetry will depend on the type of application.

The user of the risk levels (A to D) is useful at the level of analysis, but not for writing of decisions. In writing decisions it will usually be preferable, for readability reasons, to use descriptive terms with more explicit meaning such as those suggested above: A (negligible), B (low), C (medium), and D (high).

4.4.5 Impact of uncertainty

These tables do not directly reflect uncertainty. Uncertainty is taken into account in two ways. Firstly, when developing these tables a range of descriptors may be used. For example, a risk may be allocated a range of very unlikely-improbable, and minor-major. This would put the range of the risk as B through E.

Alternatively, the level of risk (or benefit) may be adjusted *after* it has been estimated, on the grounds of uncertainty. For example, a risk may be deemed to be low, but with high uncertainty. A practical application of a precautionary approach could consist of revising the level of risk to medium.

The way in which uncertainty is addressed, either during the allocation process, or after the estimation of the level of risk should be specified in each case.

The degree of uncertainty will also affect the Authority's approach to risk, that is, the degree to which the Authority will be more or less risk averse or risk taking. This is addressed in Chapter 6.

4.4.6 Risk and benefit

Qualitative risk assessment is not a decision making process in itself since the criteria for whether or not individual risks (or the balance of risks, costs and benefits) are deemed to be acceptable is part of risk management, and relies on external criteria (in this case specified in the Act and the Methodology). Approaches to weighing-up adverse and beneficial effects are discussed in Chapter 7.

However, a point of caution is noted. At some point, where risks are deemed to be unacceptable, no amount of benefit will be sufficient to allow an application to be approved. Therefore, the level of 'acceptability' is an important element to be considered in the assessment. For new organisms this is 'hard-wired' into the Act through section 30 (Minimum Standards). There is no equivalent for hazardous substances but the principle applies none the less.

4.5 Considering distribution of effects and equity

The Authority is required to consider those effects that relate to New Zealand.¹⁵ However, it should be noted that with increasing globalisation, at times it can be difficult to separate New Zealand interests from international interests.

A further complication is that in most cases the groups that receive the benefits will differ from the groups that bear the risks. Issues such as the distribution of effects and elements of equity need to be considered in the evaluation or weighing-up processes, however, when effects are being assessed these aspects should be identified and recorded.

Clause 13 (c) of the Methodology requires the Authority to take into account the distributional effects of the costs and benefits over time, space, and groups in the community.

The distribution over time reflects the timeframe of a project, for example the benefits accruing from a research programme involving GMOs are most likely to accrue at the end of the project, whereas the costs will accrue at the beginning, and risks will be distributed throughout, with greatest risks occurring earlier in the project. Longer timeframes may also be relevant, with risks, costs, and benefits having intergenerational

¹⁵ Clause 14 of the Methodology.

aspects such that benefits may accrue to current generations, with risks and costs being primarily born by future generations¹⁶. When distribution over time is being considered it will be useful to state the timeframe explicitly. In general terms new organism release applications will need to consider long timeframes (intergenerational aspects), and new organism containment applications may only need to consider the timeframe of the project, unless the potential (adverse) effects in the case of escape are sufficiently large that a longer timeframe is considered relevant. The timeframe for hazardous substance applications will also depend on the magnitude of potential (adverse) effects.

Spatial distribution may also be referred to as physical or geographical distribution. In the HSNO context spatial distribution is relevant to the release of a substance where the intended use is limited to particular areas, and to the release of an organism where the organism is expected to be limited in spread by climate, host species or other factors. The notion of conditional release depends entirely on restricted spatial distribution. For containment of a new organism the location of a containment facility may be used as a control, for example, a requirement may be for the removal of all host organisms or potentially adversely affected plants in the vicinity of a containment facility.

Distribution over groups in the community relates to spatial distribution in terms of physical location, as well as distribution over different socio-demographic groups, and groups defined by different susceptibilities such as a predisposition to certain diseases.

There are two key factors in considering the distribution of effects. The first of these is the distribution of risks and costs, and secondly there is the extent to which risks and costs are distributed differently to benefits. Both of these aspects relate to natural equity and environmental justice¹⁷.

Where risks and costs are distributed evenly over the timeframe of the project, all of New Zealand, and all groups in the community, the distribution of effects does not need to be considered further. Where the distribution is uneven, then the Authority may choose to be more risk averse (see chapter 6), depending on the relevance of the uneven distribution to the application and the purpose of the Act. The Authority may also choose to focus on those situations where unequal distribution of risk is most acute. If a reasonably equitable outcome is not achievable in those situations, this may influence the decision.

If the benefits and risks accrue to the same group, and occur within the same timeframe, then the distribution does not need to be considered further, and the weighing-up of adverse and beneficial effects can be undertaken within a simple linear framework.

However, where benefits accrue to one group or in one timeframe, and risks and costs are borne by a different group, or occur in a markedly different timeframe, then the Authority may choose to be more risk averse by giving greater weight to the adverse

¹⁶ This aspect is explicitly referred to in section 5(b) of the Act.

¹⁷ Environmental Justice (EJ) is an issue on the United States policy agenda with USEPAs' Office of Environmental Justice (1992) and Executive Order 12898 (1994) requiring federal agencies to include EJ in their decision making processes. The issues of risk that are deemed to be concomitant with claims of environmental injustice are categorised as human health, economic, environmental, and institutional risk, thus aligning with ERMA requirements for consideration.

effects. From an equity perspective, it is much more difficult to sustain a claim of an overall net benefit if those who enjoy the benefits are different to those who will bear the costs.

Where there is uncertainty as to whether, or to what extent future generations may bear the costs of allowing a benefit to be enjoyed by the current generation, it is possible that the uncertainty will overwhelm any apparent benefit to emerge from a risk (cost) benefit analysis, especially if the type or potential severity of the risk suggests that the Authority should act with a high degree of caution.

The crucial consideration is that in all circumstances where risks are deemed not to be negligible the distribution of risks, costs and benefits should be analysed in terms of time, space, and groups in the community, and the results of this analysis should be taken into consideration in the weighing-up process.

4.6 Impact of controls

The HSNO context requires risks, costs and benefits be assessed in the context of the proposed controls, and in the absence of controls. In the risk context, residual risk is the risk remaining when levels of risk are determined with controls in place. Evaluating the *effectiveness* of controls is also part of the assessment process.

The assessment of risks, costs and benefits with controls in place should not be entirely based on the assumption that the approval holder or others will adhere to the specified controls (where relevant). Controls may not be adhered to, not always deliberately. For example, it cannot be guaranteed that users of chemicals will diligently read the label. Deliberate unauthorised entry is a real possibility with field trials of genetically modified organisms.

At the same time, the practicality of the controls should be considered. Some reasons why controls might not be complied with include impracticality, problems with changing existing practices, and wilful non-compliance. While the last point cannot be addressed, the assessment should include consideration of whether the proposed controls are feasible to implement, and whether they are practical in terms of current best practice.

4.7 Comparative analysis

The Authority makes decisions on applications for new organisms and hazardous substances in the context of the existing situation in New Zealand. This means that assessments need to address the additional or incremental risks, costs, and benefits posed by the organism or substance.

Thus, the aim of assessing risks, costs and benefits is to identify and assess the changes that will result if an application is approved. This requires:

- establishing a baseline scenario of what will happen if the organism or substance is not approved
- identifying and assessing the risks, costs and benefits if the organism or substance is approved, and

- determining the difference between the two scenarios.

The baseline scenario will not be static; therefore, the first step consists of specifying an appropriate timeframe. For organisms in containment (including field trials) and conditional releases, the appropriate timeframe will be the proposed length of the project. For full releases, a suitable timeframe might be 25 years since this is an adequate length of time for effects to be realised. While in some case there might be an argument for a longer timeframe, this should be reviewed on a case-by-case basis. A timeframe for applications for release of hazardous substances will also need to be set on a case-by-case basis and may reflect the expected market hold for products of a similar nature. In most cases, the timeframe would be expected to be between five and ten years.

The degree to which the baseline scenario will be specified will depend on an initial judgement as to the significance of the application. As risks and benefits are identified and assessed it may be necessary to specify the baseline in more detail. In other cases, the baseline scenario may be judged unlikely to change over time, and therefore the risks and benefits of approving the organism or substance can be compared to a single point assessment of the current situation.

Where it is necessary to specify the baseline scenario and the approval scenario over a long timeframe (more than ten years), it may be necessary to look at several different scenarios in each case, or to undertake some sensitivity analysis.

Once the baseline scenario has been established, the risks and benefits associated with the baseline scenario and approval of the application can be determined. Finally, the difference between the two scenarios provides the changes in risk and benefits that can be expected to occur if the organisms or substance is approved.

4.8 Scenario analysis

The development of scenarios, or descriptive models of reality, is a common tool and is often used in conjunction with other approaches.

Scenario analysis can be used both for assessment of effects and for weighing-up of effects. In the assessment process, sets of scenarios reflecting best case, worst case and 'expected' case may be used as surrogate approaches for exposure analysis. In a similar manner, scenario analysis may be used to assist in weighing-up risks, costs and benefits. In general, terms, scenario analysis consists of defining a simplified 'model' of a real system, and using the model to describe what might happen. Often the defined 'scenarios' are representative of special sets of circumstances that the analyst wants to know more about.

Informal scenario analysis has been used by risk analysts in a number of different ways, including to gain information about exposure¹⁸, as a means of sensitivity analysis¹⁹ and to set boundaries. These informal applications have provided information for scoping

¹⁸ Scenario analysis is used to gain information about exposure by postulating exposure pathways from source to area of effect and making judgements about the feasibility of the pathway, and the exposed population (either people or ecosystems and components).

analyses. More recently, a more formal approach to scenario analysis in risk assessment and risk management has been adopted, in line with ‘futures’ analysis and specifically to analyse the future effect of policy changes.

In this latter context, scenario analysis¹⁹ is a tool used to help decision makers and stakeholders think through how a particular policy or activity will ‘perform’ under different plausible future situations (scenarios). Each scenario focuses on a plausible change in parameters, takes into account significant but predictable factors (e.g. use patterns), and then explores how ‘successful’ the policy (activity) would be in this new scenario. It effectively ‘pre-tests’ outcomes by using ‘what if’ questions based on model assumptions. In a futures ‘context’ this is considered preferable to the traditional approach of relying on high-medium-low forecasts that assume, through the use of historical data, that future events will likely continue to follow past trends.

The process of formal brainstorming requires a team of experts from different areas to work together to design the scenarios, to review the effects through short, medium and long-term, and to analyse the parameters. Scenario analysis helps decision makers to highlight and explore uncertainties, and most importantly to determine the parameters that will have the most effect on the postulated outcomes (see note on sensitivity analysis).

Since scenarios are only defined ‘slices’ of reality, it is important to make sure that account is taken of the likelihood of a particular outcome (scenario) occurring, i.e. to adopt a risk framework. For example, where best case, worst case and expected case scenarios are used some attempt should be made to qualify, or express the likelihood of each scenario occurring.

Two examples of where scenario analysis may be useful:

- where the distribution of adverse and beneficial effects varies over time, e.g. where benefits are strong and risks and costs weak in the short term, but in the long term the situation is reversed. In these circumstances, scenario analysis may be used either to look at time series, or to review particular ‘spots’ or cuts in time;
- in addressing the distribution of effects over different groups in the community, e.g. to look at the balance of adverse and beneficial effects for Maori and to compare this with other particular groups in the community, or the community as a whole.

In terms of risk analysis and weighing-up processes the main difficulties in using scenario analysis are associated with the availability of data, and the ability of the analysts and decision makers to be able to develop realistic scenarios (dependent on state of knowledge), are amenable to probing of possible outcomes.

The principal value of scenario analysis is the flexibility that it brings to the assessment of risks. Its weakness is that in circumstances where there is high uncertainty, and the

¹⁹ Source: World Bank documents, PSIA Users guide and Workshop

possible outcomes (and some of the key parameters) are not known, that the results may be unrealistic.

The dangers of using scenario analysis as a decision making tool are that the scenarios used may not have an adequate foundation, that data may be speculative, and that unrealistic results may not be recognised as such.

4.9 Special issues in considering benefits

The Methodology defines benefits and costs as the values of particular positive and adverse effects expressed in monetary or non-monetary terms. These definitions contrast with the definition of ‘risk’, which is in terms of the magnitude of an adverse effect and the probability of its occurrence.

Strictly speaking this implies that risk is two-dimensional (i.e. risk is comprised of a probability or likelihood and a magnitude) and benefits and costs are one-dimensional. The Act requires the Authority to weigh adverse and beneficial effects. In practical terms, it is obvious that beneficial effects arising from applications are not certain, and that they will also have a probability (likelihood) component as well as a magnitude component.

Therefore, in balancing adverse and beneficial effects in the language of the Methodology, the Authority is balancing risks and costs against benefits, where adverse and beneficial components are viewed as being two-dimensional. Thus, the evaluation or weighing-up of adverse and beneficial effects becomes a risk/benefit analysis in the broader sense of the word ‘analysis’.

Three particular issues arise in then considering the benefits side of the analysis, and these are explored further below:

- how wide a scope exists for considering matters that might be beneficial;
- how to deal with private versus public benefits; and
- the relevance of benefits in negligible risk situations.

4.9.1 Scope of acceptable benefits

Benefits can be considered in terms of all the possible effects that the Act requires to be considered, that is, beneficial effects on the natural environment, human health, the economy, people and communities, and Māori. Sections 5 and 6 of the Act are most relevant in this, although references in section 2 (the definition of environment) and in various sections in Part V are relevant as well.

It is especially important to look at section 6(e) because many of the benefits of commercial releases will be economic in character. The rationale for doing this is reinforced by the more general wording in both section 2 and section 5(b).

The reference to ‘and related ...’ in section 6(e) is also construed to bring in a range of other matters that are not directly economic in character but which have the potential to be so. These include benefits related to social and economic well-being such as substances that are easier to use (or apply) than existing substances, or biocontrol agents designed to assist local communities to manage environmental ‘nuisance’ problems. Scientific and research benefits may also be considered as covered by this reference.

Benefits must be related to the application being considered. While both direct and indirect benefits may be relevant to the consideration, how far indirect benefits will be considered will depend on the nature of the application.

For containment applications the benefits are often quite constrained. This applies to the development of GMOs, importation of an organism into containment, and to approvals for hazardous substances in containment. The benefits may often be confined to the information, or the scientific or research benefits that will be gained from undertaking the activity. It is difficult to measure these benefits on any practical scale, and where risks are non-negligible, significant evidence of such benefits may need to be provided. While it is not valid to include the benefits of anticipated later release of the organism or substance in the weighing-up process, there may be circumstances where the end-use may need to be considered as part of the decision making process. However, this should be accompanied by considerable caution as, at the research stage, end-use benefits are often very speculative.

With hazardous substances the benefits may be primarily related to substitution of one product for another with the new (proposed) product expected to be 'less risky' than the current product. The realisation of these benefits will depend on the market-share that the new product achieves, and it may be useful to consider and compare a range of scenarios in evaluating such benefits.

4.9.2 Public versus private benefit

Benefits and costs can be considered to have two components; private and public²⁰. Private benefits are those captured by individuals or individual organisations, while public benefits are those that accrue more widely to the community. Total benefits can be subdivided into private plus public benefits (private benefits plus public benefits equals total benefits), and similarly total costs can be divided into private plus public costs.

Clause 13(c) of the Methodology recognises that the distribution of effects is important (see also Chapter 4.5 of this document). It is thus legitimate to consider both private and public benefits, as this distinction is just one aspect of distributional impacts. Distributional issues are particularly important for economic effects, because the benefits (private benefits) to the applicant of an approval may be different from the wider public benefits. The public benefits themselves may fall unevenly.

Chapter 7.7 discusses the issues relating to private and public benefits and costs within the context of the application of cost-benefit analysis, and which benefits and costs are considered germane to the balancing of beneficial and adverse effects.

²⁰ Public benefits and costs are sometimes called 'external' or 'social'. In some literature, public benefit (cost) is defined as synonymous with total benefit (cost), but as used here, we are defining total benefits to be the combination of private benefits that accrue directly to the individual or firm conducting the activity, and public benefits which accrue to other people.

Public benefits include matters such as benefits to public health, the environment (ecological), communities and social groups, culture and the economy²¹.

Private benefits in the HSNO context include those benefits that accrue directly to the applicant, such as proprietary knowledge, company profits and elements of competitive advantage. Private benefits will most often be economic in character.

Benefits may also be presented in the form of reduced costs. As an example, a public environmental benefit might be claimed for a biocontrol agent in terms of the reduced use of a pesticide. In this instance a private economic benefit (to farmers) in the form of reduced cost of chemicals might also be claimed²². In these cases it is important to be clear about which benefits are considered admissible (see above). It is also important to ensure that ‘double counting’ does not occur. In terms of direct and indirect benefits, inclusion may be linked to issues such as the expected commercial life of the product, or the term of the project. For release of new organisms the timeframe may be very long, and hence indirect benefits may have greater relevance.

Applicants may or may not choose to detail the private benefits they expect to receive as a result of a successful application, or they may provide this information only under conditions of confidentiality. In most cases this is unlikely to be of concern since the Authority will assume that private benefits exist, and that private benefits exceed private costs. While some applicants may choose to submit an application for which the private economic costs exceed the private economic benefits (i.e. they expect to make a net loss), in order for them to submit the application there must be counterbalancing organisational benefits (e.g. goodwill). As noted in Chapter 7.7, the only circumstance where the applicant may be required to provide details of private net benefit is where public costs exceed public benefits.

4.9.3 Dealing with negligible risk applications

Where the risks of a substance or organism are judged to be negligible, and there are no external costs (i.e. the costs are all internalised by the applicant), then the existence of an application may be judged to be *prima facie* evidence of the existence of benefit (i.e. the applicant deems that their internal net benefit is positive). This does allow for an applicant to accept a net loss on a particular substance or organism, or the notion of a ‘loss leader’, however, the circumstance is very restricted since it only arises where risks are negligible and there are no external (public) costs.

However, the nature of the benefits should still be identified, even if there is no need to quantify them or judge their weight. This is a safeguard against situations where, although the risks are negligible, there are no identifiable benefits at all or possibly even disbenefits that the applicant has failed to identify.

²¹ Public economic benefits may include increased employment, increased GDP, and an increased knowledge base.

²² These types of benefits may get very complex and it is important to remember to adopt the national perspective. As noted the reduced cost of chemicals is a private benefit to farmers. In addition there will be associated indirect private costs to the pesticide manufacturer (but which might lead to indirect public costs in terms of the loss of employment).

5 Specific techniques

5.1 Health risk assessment

This Chapter provides a brief overview of the process used to assess risk to human health. For further information refer to the Technical Guide *Assessment of effects of hazardous substances and new organisms on human health*.

Human health risk assessment involves estimating the likelihood and the magnitude of the effect on public health from the hazardous substance or new organism. The risk assessment process is divided into four steps:

- 1. Hazard identification** is a component of risk identification, and is equivalent to determining the source of risk. It involves the identification of a substance as a source of potential harm to humans. It is based on the type and quality of data on humans and/or laboratory animals and *in vitro* systems, other information such as toxicokinetics and structure-activity relationship analysis, and the weight of evidence from all of these data sources. This requires examining the intrinsic properties of the substance that suggest that it is a source of potential harm to human health and safety.
- 2. Dose-response assessment** addresses the issue of how health effects vary with the level of exposure and determines the amount of the substance that causes adverse effects. It uses information on the effects associated with various levels of exposure (or dose) from experimental (toxicological) and epidemiological studies and information on ‘real world’ exposure to develop estimates of the likelihood of effects in potentially exposed populations. Dose-response relationships are measures of the amount of effect induced by different concentrations or exposures to the hazard.
- 3. Exposure assessment** is used to estimate the magnitude, duration, and frequency of exposure (to pollutants of concern) and to determine pathways of exposure and the number of people likely to be exposed. Exposures may be estimated from workplace data and lifestyle models. Different groups of individuals are likely to be affected differently, and commonly exposure is assessed for most ‘at risk’ groups such as pregnant women, small children and the elderly, as well as the ‘average’ person.
- 4. Risk characterisation** or risk evaluation integrates the information from the hazard identification, dose-response, and exposure assessment to estimate the risk associated with each exposure scenario, and thus calculate the level of risk. It describes risk in terms of the probability of its occurrence and the magnitude of the adverse effect.

Characterisation should address quantitative and qualitative features of the assessment and identify its important strengths and uncertainties, as well as an uncertainty range on the parameters.

The risk measures calculated are most often expressed as frequencies for a given time period or rates per head of population. Typical measures of risk might be:

- expected number of deaths
- expected number of injuries
- loss of life expectancy
- loss of quality of life
- working days lost.

Health risk assessment draws on the knowledge and methods of epidemiology, toxicology and exposure analysis. It aims to identify the adverse health effects that may be associated with exposure to a substance and to predict the likelihood that specific human populations will experience such effects at given exposure levels.

There is a large number of uncertainties and causes of variability in health risk assessment. Dose-response relationships are difficult to estimate, especially the extrapolation to low-dose exposures. Differentiating between acute and chronic exposure may not be possible, and the validity of extrapolating from animals to humans may be questionable.

The methods used for human health risk assessment are often divided into methods for estimating non-cancer risks and cancer risks. This derives from United States legislative requirements (the Delaney clause) which state that where cancer-causing substances are concerned there is no acceptable level of risk. For non-carcinogens, the key indicator of risk is the reference dose (RfD) or the daily dose of a substance likely to be without appreciable risk (acceptable daily intake, ADI). For carcinogens and other non threshold substances (where there is no evidence of a level below which no adverse effects can be detected) risk estimates concentrate on calculating loss of life expectancy, and expected number of *additional* deaths due to the substance. Recent changes to legislation, modifying the ‘zero risk’ assumption to ‘reasonable certainty of no harm’ mean that new approaches to estimating health risk will not differentiate as distinctly between carcinogens and non-carcinogens.

5.2 Ecological risk assessment

Ecological risk assessment²³ is the practice of determining the nature and likelihood of effects of human actions on animals, plants and the natural environment.

Ecological risk assessment requires making estimates of probability of harm to plant and animal life, and to ecosystem integrity. While human health risk assessment only addresses the impacts on one organism, ecological risk assessment must address numerous organisms and their interactions.

There will inevitably be considerable uncertainty both in terms of variability of data and lack of information. Many environmental risks fall into the low probability and high consequence category which means that they cannot easily be compared with other

²³ At present there is no published technical guide to ecological risk assessment, and the best reference is to the USEPA *Guidelines for Ecological Risk Assessment* (USEPA, 1998).

types of risk; and environmental risks may have long lead times between cause and effect with the possibility of irreversible outcomes.

The USEPA guidelines for ecological risk assessment (USEPA, 1998) are based on a refinement of the framework referred to above. This is a modification of the health risk assessment paradigm. The guidelines propose a three-step process of problem formulation, analysis and risk characterisation, where ‘analysis’ incorporates characterisation of exposure and characterisation of ecological effects.

5.3 Assessments involving cultural and ethical values

The assessment of cultural and ethical values can be separated into two aspects; assessment of Maori cultural and spiritual values as provided for in section 6(d) and section 8 of the Act, and the assessment of the general community values as provided for in sections 5(b) and 6(e) of the Act. The assessment of Maori cultural and spiritual values is being specifically addressed in the development of user guides and other specific documentation. This Chapter examines the broader context of the values and ethics²⁴ ascribed to the whole population.

While much of the language of the Act assumes the priority of scientific knowledge, social values and an acceptance or assumption of ethical or value judgements are also embedded in the language of the Act, through expressions such as ‘intrinsic value’, ‘relationships of Maori to their culture and traditions, economic and related benefits’, the ‘maintenance and enhancement of the capacity for people and communities to provide for their own economic, social and cultural wellbeing’, and the definition of environment itself. These matters are central to the Act in that they are referenced in the purpose and principles.

To some extent these matters can be described in scientific terms, but descriptions do not capture the social meaning given to the relationships that are there, or the values expressed through those relationships and in the social arrangements and traditions that sustain or change the significance of the relationships. Other forms of knowledge in addition to science are necessary to understand the values embedded in and transmitted through the social, economic and cultural dimensions of the environment, and how these things may be affected by or in turn affect a particular use of a technology. The key issue is how to relate these other forms of knowledge to scientific knowledge in the decision making process.

5.3.1 Interaction between scientific and non-scientific information

In developing processes for assessing information relating to cultural and ethical values, it is essential that stakeholders and interested parties trust the decision making process. While it may appear to be easier to assess science-based information, it is clear that more than scientific information needs to be considered in the assessment process. Therefore processes for confirming and incorporating non-scientific information need to be considered.

²⁴ ‘Ethics’ is defined here as the values held by individuals and collectives, and is deemed to incorporate the consideration of ethical and cultural issues, since both are concerned with values and beliefs. This is a broader term than that used by academia where ‘ethics’ is more narrowly defined as a sub-branch of philosophy.

In addition to these processes, there may also need to be an acknowledgement of more subtle mechanisms such as dynamics of conversations, and social judgements by and of participants in the conversations about each other. Acknowledgement of these issues assists in clarifying some of the underlying political issues inherent in such conversations, and making any trade-offs transparent to all parties.

5.3.2 Risk/benefit assessment and ethics

Ethical considerations in risk assessment are implicit in the choice of:

- what is measured
- the weight given to the magnitude of effect of different risks/benefits
- the weight given to probability of different risks/benefits
- the approach to uncertainty.

People engaging in a conversation about ethics in relation to consequences agree on the value of science. However, people may differ on what science is needed, how much certainty is required, and how to deal with uncertainty. These are matters of judgement, informed by a range of considerations that fall outside science. Assessments of consequences are thus influenced by the context of the size of the frame within which one operates; ranging from the immediate physical effects to the broader social and cultural impacts, and the wider social/political environment of the community.

There is also potential for disagreement about how to deal with consequences that are not amenable to scientific or empirical analysis, where issues of measurement arise. Judgements are also required when considering social risks of a technology for which there may for instance be a total lack of data on which to base risk assessment. For example, in the area of reproductive technology, when IVF surrogate motherhood became a possibility, there was initially no data about the effect of surrogacy on either the birth mother or the child, yet alone wider effects on methods of family formation, and judgements were required. While such judgements are informed by science, they are more social than scientific assessments.

These issues are best dealt with by making them explicit, by articulating the trade-offs that are available, those taken, and the reasons for those choices.

There may also be ethical positions that are based not only on assessments of consequences, but also based on other considerations. For example, a fundamental sense of what is right or appropriate, or a position or set of values that emerges out of a longer cultural view about what is the right way to conceptualise or frame an issue, or to deal with a set of responsibilities (whether individually or collectively). Many difficulties with biotechnologies are based on a sense of what are appropriate relationships, between humans (including across generations) and with the non-human world. What is 'right' is based not only on immediate or short terms risks, and on the particulars of a narrowly defined situation but also on a longer view, and on collective wisdom over time.

Sometimes these views are informed by consequences, but have developed into cultural or philosophical positions from which the response to the particular situation is derived (rather than the immediate response being from a narrow calculation of immediate risks/benefits).

Cultural or philosophical positions may take a longer view that is likely to recognise uncertainty, value humility, and does not expect or imagine that there is the possibility of absolute control (perhaps because the roots of these cultural and philosophical approaches pre-date the modern scientific period). There are also likely to be understandings of social justice and distribution of benefits/risks that are brought to decisions about biotechnology.

5.3.3 Practical approaches

It is apparent that forms of knowledge other than science require consideration, along with attention to the social distribution of power as expressed in the issues that are admitted for consideration, the framing that is granted power and influence, and the type of argument used. It is unlikely to be possible to find any one position on these issues from which other decisions can be derived. Instead it will be necessary to have continual engagement with and exploration of the multiple dimensions of the conversation and, if there is to be public confidence in the decisions, an explicit discussion of the issues and their impact on the decision making process.

Issues that need to be discussed in the public arena include:

- limitations of the science
- the position taken on uncertainty
- options for management of biological/physical risks
- which other forms of knowledge are granted legitimacy and on what basis
- the basis on which some voices granted authority and others not
- where and how do the ethical considerations impact on scientific decision making
- the options for response, and
- which option is chosen for what reasons.

Two primary approaches to addressing these issues and including consideration of cultural and ethical values in the decision making process are:

- an *ad hoc* approach based on judgement, and
- the establishment of a formal framework.

In the first instance the approach might be to look at a problem; if it seems like an ethical issue treat it as one, and allow the treatment to reflect the values and beliefs of those involved, and their knowledge of the values and beliefs of the communities they are involved with or know about. While this approach is simple and direct, the danger is that the results will inevitably reflect the views of the individual decision makers, and there is no reason to suppose that those views will necessarily be reflective of those of the community as a whole.

The second approach also requires judgements, but those judgements are made with attention to specified categories, or within a framework that defines what is to be considered and how it is to be considered. The benefits of this approach are that it imposes discipline on the process, and makes it more transparent and more explicable, thus addressing some of the issues of trust raised earlier.

The elements of such a structure need to address:

- principles or benchmarks²⁵ to help the process of analysis and decision
- the data or information required to apply these principles or benchmarks
- a format for integrating the results into the ‘effects based’ HSNO decision making framework.

While the longer-term goal is to develop such a framework, it is evident that in the shorter term a more pragmatic or *ad hoc* approach will need to be maintained. Careful tracking and analysis of past decisions will be an important input to the development of the framework.

5.4 Social impact assessment

Social impact assessment²⁶ is a well developed discipline. A common use of social impact assessment is to establish baseline scenarios against which social and community changes resulting from particular activities or projects can be measured. Application of social impact assessment requires an identifiable community of interest.

Specific relevant elements are:

- scoping of key issues (e.g. employment, training, host community perceptions of change, and wider environmental concerns)
- developing a profile of the host community including previous cycles of resource use and economic development, and social structure and demographics
- developing and assessing alternative scenarios in the context of a particular project
- establishing monitoring procedures to feedback into future similar activities.

In the HSNO context it is not clear how much the formal application of social assessment will play a significant role. In the hazardous substance area the scope is limited by the fact that substances are approved or declined, rather than particular uses or sources of supply of substances. These latter aspects are more likely to be addressed under the Resource Management Act. Experience with new organisms is too limited yet to give a clear indication. However, it is important to recognise that these tools exist and may provide information.

²⁵ The term ‘benchmarks’ is used to describe defined points of reference, or categories for consideration.

²⁶ ERMA New Zealand is preparing a Technical Guide to Social Assessment (incorporating social impact assessment) to be published in early 2004.

5.5 Economic assessment

Economic risks, costs and benefits are those that relate to the use of resources, and which affect the economic performance of the country. They include items such as increased productivity, changes in markets, changes in production costs, changes in employment etc.

Cost-benefit analysis (where risks and costs are considered as synonymous) is one tool that can be used for the assessment of economic effects, but it is most commonly used where all the economic effects can be quantified, or at least a feasible range can be placed on the parameters. In the HSNO context there may be few circumstances where this is possible. Therefore, assessing economic risks, costs and benefits will most likely be undertaken within the frameworks discussed in 4.3.

Cost-benefit analysis is a technique for evaluating the total social costs and total social benefits associated with an economic activity or project. Cost-benefit analysis (CBA) has been developed as a formal framework that is used to identify and analyse direct and indirect costs and benefits. When undertaking CBA the decision maker needs to establish the boundaries for the analysis, part of which requires determining from whose perspective the analysis will be done. Early analyses were concerned with the national interest, therefore costs and benefits to the nation were considered. As experience and techniques for measuring costs and benefits developed, regional analyses were undertaken. More recently, it has become common for CBA to be used to analyse particular projects and activities. This, however, highlights one of the key identified deficiencies of the application of CBA, that the group that receives the benefits may be quite different from the group that bears the costs (see 4.5).

Many 'goods' cannot easily be measured in the market place. Non-market valuation techniques can be used to impute prices. However, these techniques are expensive to apply require highly specialist application, and can produce suspect (non-verifiable) results.

General methodological issues associated with cost-benefit analysis include:

Valuation of 'intangibles'

These are things with no explicit monetary value, generally because they are not traded and hence have no price. Examples include pesticide residues, species at risk, and areas used for recreational activities. The two principal approaches to dealing with intangibles are to either put a monetary value on the intangibles in some way, or ascertain the value of the tangible outcomes and to compare these with the intangible outcomes and make a decision.

Valuation of future benefits and costs

This problem is usually partially addressed by a discount rate (future benefits are worth less than present benefits by a specified percentage), although there is still argument about what discount rate is appropriate. Any particular discount rate has implications for inter-generational equity. Moreover, it is not clear that future generations will have similar values to the next generation, and this a particular problem in cases where outcomes are not reversible. Finally, one generation (which gets the benefits) may not compensate the next generation (which suffers the future costs).

Distribution of both benefits and costs

As noted earlier, CBA, as generally applied, ignores the actual final distribution of costs and benefits, contenting itself with the knowledge that redistribution could have been made to ensure that no group was worse off after the decision than it had been before. Many decisions give benefits to one group while imposing costs on others. Where a project has benefits greater than costs, then in principle the beneficiaries are able to compensate the losers so that on balance everyone is as well off or better off than without the project. However, in the absence of regulatory or other intervention, compensation is unlikely to occur.

6 Approach to risk

For further information refer to Discussion Paper *Approach to Risk* (ER-OP-03-02 12/02)

6.1 Uncertainty, caution and precaution

In making decisions under the HSNO Act, the Authority is required to weigh up adverse and beneficial effects (or, to use the language of the Methodology, risks, costs and benefits²⁷. Many, if not most, effects that are required to be considered by the Authority are not certain for a variety of reasons and the quality of information may vary significantly between the alternative actions. The notion of decision making under uncertainty requires the Authority to consider the criteria it will apply in making decisions and its attitude to uncertainty. Decision-making may also be influenced by risk characteristics (other than the probability and magnitude of consequences) and therefore guidelines are necessary to make transparent the extent to which risk characteristics may make the Authority more or less risk averse.

The issues of how risk averse to be and that of dealing with uncertainties are quite different, although they might be dealt with in practical terms in similar ways. Thus it is possible to behave in a risk averse way, even if the risks are quite ‘certain’ – and vice versa. In decision making, it is thus important to be aware of both aspects, even if they are considered in a consolidated way.

Risk-based decision making is concerned with the decision maker deciding whether the estimated levels of risk are deemed ‘acceptable’²⁸ or not. The criteria that the decision maker uses to decide whether risks are acceptable or not reflect, amongst other things, the decision maker’s approach to risk. The context in which the decision is being made also determines acceptability. Decision makers are acting on behalf of the whole of society but must understand and take account of the factors that affect the attitudes towards risk of the different societal groups that they represent.

There are two common ways of looking at ‘approach to risk’.

In formal decision analysis, a decision maker may adopt an approach to risk based on the calculation of expected values and a weighing-up of risks, costs and benefits. This concept of an approach to risk depends on applying different criteria depending on the attitude of the decision maker. Different decision rules will select different optimal outcomes²⁹.

²⁷ The exception being rapid assessments where only adverse effects are considered.

²⁸ In some jurisdictions the concept of ‘tolerable risk’ is used in preference to ‘acceptable’ risk on the grounds that risks are not ‘acceptable’ but may be tolerated under certain circumstances or for a certain period of time with the expectation of particular counterbalancing benefits. In the ERMA context the phrase ‘acceptable risk’ is aligned with ‘tolerable risk’ since the decision making process requires weighing-up of risks and benefits.

²⁹ Types of decision rules include minimising the maximum loss, maximising the maximum benefit, and simple expected value.

This first course of action does not specifically consider uncertainty, and assumes that the information available to the decision maker about the magnitude and likelihood of effects is statistically sound. Uncertainty may be addressed by calculating standard deviations for the key parameters (where the major issue is sampling error), or in other ways constructing a range of values. These ranges may be applied to estimates of both magnitude and likelihood, and these may be combined, to estimate bounds on the level of risk.

A second way of looking at ‘approach to risk’ addresses uncertainty explicitly, and considers how the decision maker should address risk in the face of uncertainty. There are many circumstances, particularly in environmental decision making, where there may be very little information available, or the information may be recognised as being statistically unreliable. In these circumstances, the decision maker may choose to be cautious.

Both ways of looking at the approach to risk need to take account of the other factors influencing the decision, including:

- who is at risk and who bears the benefits
- the characteristics of the particular risks
- the administrative basis for the decision, and
- how the ‘acceptable level’ of risk is determined (criteria).

Section 7 of the Act, entitled ‘Precautionary Approach’, requires ‘all persons exercising functions, powers, and duties under this Act’... to ‘take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects’. Caution is defined in the dictionary³⁰ as ‘attention to safety, prudence, or carefulness’, while precaution is defined as ‘an action taken beforehand to avoid risk or ensure a good result’. The notion of precaution includes reference to actions taken beforehand and ‘risk’, while the definition of caution carries an ongoing imperative and refers to ‘safety’. The distinction between caution and precaution does not pertain within the HSNO context, as the Authority makes decisions at a point in time and cannot revisit that particular decision without recourse to reassessment of the organism or substance³¹.

The Methodology (ERMA, 1998) is more explicit about what to do when there is significant uncertainty. In particular Clause 29 states:

Where the Authority encounters scientific and technical uncertainty relating to the potential adverse effects of a substance or organism, or where there is disputed scientific or technical information the Authority:

- (a) *Shall determine the materiality and significance to the application of the uncertainty or dispute taking into account the extent of agreement on the scope and meaning of the scientific evidence; and*

³⁰ The Concise Oxford Dictionary, 8th Edition. © Oxford University Press.

³¹ The process for reassessment is such that it requires a new application and approval process.

- (b) *May, where the uncertainty or dispute is material or significant, facilitate discussion between the parties concerned to clarify the uncertainty or dispute.*

However, this does not give any guidance as to how the Authority will treat unresolved uncertainty within its decision making processes. Clause 33 states the factors associated with effects that will lead the Authority to be more or less ‘risk averse’:

- (a) Exposure to the risk is involuntary;
- (b) The risk will persist over time;
- (c) The risk is subject to uncontrollable spread and is likely to extend its effects beyond the immediate location of incidence;
- (d) The potential adverse effects are irreversible;
- (e) The risk is not known or understood by society and there is little experience or understanding of possible measures for managing the potential adverse effects.

The notion of ‘risk averseness’ most often applies to adverse effects and thus, if it is felt appropriate to be more ‘risk averse’, the result will be to increase the weight applied to adverse effects. However, where an application has benefits that are directed towards achieving the purpose of the Act by, for example, mitigating an environmental risk, the Authority may choose to place lesser weight on the adverse effects (i.e. be less ‘risk averse’) when weighing-up risks, costs and benefits.

Sub-clause 33(e) is interesting because it effectively introduces the notion of perceptions of ‘risk’ into the determination of risk averseness. Lack of understanding leading to heightened fears in the community, might well lead the Authority to be more risk averse. However, the level of risk is still important, e.g. if there is negligible risk then that will still be the case, even if a risk averse approach is taken.

The key aspects are that there can be uncertainty in all parameters associated with measuring and estimating effects, including magnitude and likelihood of effect, structural uncertainty relating to the models used for estimation, and uncertainty in terms of lack of knowledge of physical systems. However, there is also inherent variability (different from uncertainty) because of the probabilities associated with risk. Irrespective of uncertainty or statistical variability, a decision may also be made on whether to be more or less risk averse.

6.2 Practical approaches to addressing risk averseness

While it is possible to identify the risk characteristics or factors that might lead to risk averseness, it is more difficult to determine how these factors should be included in the decision making process, and to what extent they should influence decision making. The simplest approach is to apply explicit weights to the risks (or benefits) in the weighing-up process.

There is no evident theoretical basis for addressing the issue of determining appropriate weights. In the absence of any agreed information, there is thus no option but to deal with it empirically, most probably by collecting information on the ‘strength of feeling’

people have associated with the various factors and including this in the analysis. Very little work has been done on this, either overseas or in New Zealand.

In the absence of empirical data, the alternative is to rely on the informed judgement of the decision makers. Effectively this can be considered as a sample of the views of the wider population. However, the judgement should be made explicitly and each of the significant risks of an application should be evaluated against each of the factors.

The most practical way of including information of this nature in the decision making process is to apply a weight to the magnitude of the adverse effect in the weighing-up process. Such an approach must be consistent and transparent. Thus in circumstances where the Authority decides that a risk averse stance should be adopted, there should be a full discussion of the factors that led to that conclusion, and an indication of the degree of risk averseness adopted. Over time a scale of risk aversion may be developed.

The opposite concept to a 'risk averse' decision maker is a 'risk prone' decision maker (a risk taker). Since the purpose of the HSNO Act is to protect the environment and the health and safety of people it is not clear that there are any circumstances where the Authority should be a risk taker. The decision making process is a weighing-up of adverse and beneficial effects, thus allowing full consideration of benefits (where there may also be uncertainty).

6.3 Practical approaches to addressing uncertainty

Two situations can be distinguished in dealing with uncertainty:

- where there is some knowledge about the degree and type of uncertainty, and
- where there is little or no knowledge about the degree of uncertainty.

As a first step, where possible uncertainty should be analysed, or at the least described in terms of whether the uncertainty relates to the likelihood of occurrence or the magnitude of the effect (or both), and the source of the uncertainty (if known). In addition, the Authority should consider whether or not additional information might reduce uncertainty, and whether it is feasible and/or cost effective to obtain additional information. However, it is important not to fall into the trap of using the search for more information as a way of avoiding the need to deal with uncertainty. Some degree of uncertainty is unavoidable, and cost effective decision-making relies on the decision makers making a sound judgement on 'how much is enough'.

Once the impact of uncertainty has been established, the Authority should look at where the uncertainty exists, and determine whether the uncertainty is sufficiently significant to influence the decision on the application. Logically, if the uncertainty is not expected to affect the decision, then no further analysis is required. For example, if uncertainty mainly relates to risks that are not considered to be dominant, then there may be little merit in exploring the uncertainty too far.

If information on uncertainty bounds of the parameters is available, then it is good practice to start by looking at the boundary circumstances i.e. best case, worst case. However, the likelihood of best and worst case also has to be considered³². Worst-case scenarios can be particularly awkward because they may be limited only by the imagination of those doing the analysis. The test of ‘reasonableness’ must always apply.

If information on bounds is not available (usually the case for hypothetical or unknown uncertainties), then a judgement must be made. As indicated previously, the only guidance that can be given is that the judgement is reasonable (and consistent) given all of the circumstances.

A common fault in dealing with uncertainty is not to recognise the information actually available. This is particularly the case with decision making by ‘expert’ committees. The expertise of the Members should be drawn on fully, to give all available insights into the nature and extent of uncertainty.

Secondly, the Authority will determine whether it is feasible and cost effective to obtain additional information that might usefully reduce uncertainty. This may depend on the nature of the application.

Thirdly, the Authority will consider whether the decision can be framed in a way that reduces the **impact** of uncertainty. This is a very powerful issue for containment decisions, since containment may reduce residual risk to a negligible level despite uncertainty. However, it has force as well for hazardous substance releases because of the ability to set controls.

Finally, uncertainty must be taken into account in the making of a ‘yes/no’ decision on an application.

If information is available on uncertainty bounds, then the logical approach is to reflect uncertainty in the ‘values’ that are ascribed to risks and benefits in the weighing-up of costs, risks and benefits either by sensitivity analysis or by assigning explicit weights. This is no different in practical terms to allowing risk characteristics to influence the weighing process. However, it is important to consider carefully how uncertainty should be reflected, e.g. it may not be reasonable to use a worst-case scenario if the likelihood is very low or if the scenario is judged unrealistic.

If information is not available on uncertainty bounds, then the approach is the same as indicated above, i.e. an informed judgement must be made. However, at this final stage the judgement is not about the significance of the risk, it is a broader judgement about whether an application should be approved or declined, which may be influenced by the degree of uncertainty particularly in circumstances where the magnitude of the potential risk is very high.

³² Ideally a limited form of probabilistic risk analysis should be undertaken, but this requires more data than will normally be available.

7 Evaluating (weighing-up) beneficial and adverse effects

7.1 Introduction

The need to weigh up adverse and beneficial effects is fundamental to the Authority's decision-making process.

Most techniques available for weighing-up effects require judgement, and this judgement will be made easier if some of the risks, costs and benefits can be combined. Where effects can be measured in similar units and where there are suitable high-quality data available effects can be most readily combined. Sensitivity analysis can be used to show how variations in parameters affect the overall combination.

The most common approach to combining risks, costs and benefits that are all measured in similar units is to calculate them as expected values and adopt either an economic cost-benefit or a risk-benefit framework. As discussed below the two approaches are similar, except that risk-benefit analysis considers risks more explicitly. However, expected values calculated in dollar terms should only be used where there is a good understanding of the risk and the range of the parameters, and preferably, where the probabilities and the magnitudes of the consequences can also be calculated with reasonable certainty. There are very few circumstances where Authority decision making meets these requirements.

Often it is not possible to combine the risks, costs and benefits because either some or all of the data is qualitative, or the units are dissimilar. In these circumstances, other techniques such as identifying dominant effects, ranking and judgemental weighting are more useful or relevant.

The practicality of the controls (where relevant) will be addressed in weighing-up risks, costs and benefits, as well as any aspects of the controls that create concerns about whether or not they will be adhered to. The consequences of non-compliance will need to be considered if non-compliance is a factor.

7.2 Baseline analysis

A fundamental principle of the HSNO weighing-up process is that all effects (risks, costs and benefits) should be considered in the context of the existing baseline (see 4.7). Any form of risk-cost-benefit analysis is an evaluative or comparative tool. That is, the results of assessing risks, costs and benefits for one option are compared against an assessment for one or more alternative options.

In the case of HSNO decision making, the baseline against which the application should be considered is the *status quo* i.e. what would happen if the application were not approved. This does not mean that the baseline will be static over time nor that the current existing risks and benefits will remain the same over the foreseeable future. For example, the importation of a biocontrol agent may be proposed because current control measures are becoming increasingly less efficacious as pests adapt or develop resistance to current chemical controls. The baseline in this circumstance will need to reflect increasing risks and/or costs over time. Similarly, a new chemical may be promoted as expected to reduce use of other chemicals known to have different risks or

levels of risk. Other factors, such as societal pressures, may also be affecting the use of existing chemicals.

In most cases, the baseline will need to be projected over the estimated life of the project³³. This will mean postulating scenarios for what is expected to happen if the application is approved and what is expected to happen if the application is declined (see also 7.6). The weighing-up process will therefore not address absolute risks, costs and benefits, but the marginal effects. The risks, costs and benefits are therefore represented by the difference between the two scenarios.

Where possible the baseline should be described in detail, so that it is clear that all risks, costs and benefits associated with the application have been assessed with respect to the same baseline.

7.3 Ranking and grouping of effects

Qualitative effects may be compared by ranking adverse and beneficial effects separately, and listing them in two side-by-side columns. There are various ways of undertaking the comparison, one of which is shown in Table 7, where the effects are ranked such that $A1 > A2 > A3$ etc and $B1 > B2 > B3$

Table 7: Qualitative balancing of adverse and beneficial effects

Adverse effects	Beneficial effects
A1	B1
A2	B2
A3	B3
A4	
A5	
A6	

In this simple example, there are six adverse effects and three beneficial effects, and the test is that beneficial effects must outweigh adverse effects.

- | | | |
|--------|--------------------------------------|---|
| Step 1 | compare A1 and B1 | $\Rightarrow B1 > A1$ |
| Step 2 | compare A1+A2 with B1 | $\Rightarrow B1 > A1+A2$ |
| Step 3 | compare A1+A2+A3 with B1 | $\Rightarrow B1 < A1+A2+A3$ |
| Step 4 | compare A1+A2+A3 with B1+B2 | $\Rightarrow B1+B2 > A1+A2+A3$ |
| Step 5 | compare A1+A2+A3+A4 with B1+B2 | $\Rightarrow B1+B2 > A1+A2+A3+A4$ |
| Step 6 | compare A1+A2+A3+A4+A5 with B1+B2 | $\Rightarrow B1+B2 > A1+A2+A3+A4+A5$ |
| Step 7 | compare A1+A2+A3+A4+A5+A6 with B1+B2 | $\Rightarrow B1+B2 > A1+A2+A3+A4+A5+A6$ |

³³ The 'life of the project' will differ according to different types of application. In the case of an application for an organism in containment, the project can be clearly defined. For a hazardous substance, the 'life of the project' might be set arbitrarily at say 10 years, or alternatively relate to the time before another similar product might be expected to come to market.

The line under A6 and B2 indicates that $B1+B2 > A1+A2+A3+A4+A5+A6$, hence positive effects outweigh negative effects (noting that not all of the benefits need to be considered).

In the HSNO context effects may be grouped into environmental (ecological), human health, social, cultural and economic groupings. Depending on the number of effects identified and assessed as requiring consideration in the decision making process, the technique can either be applied to all effects combined, or firstly within the grouping and then across groupings.

The comparison, or weighing-up, process requires the decision maker to understand the nature of the risks, costs and benefits, and to be able to make judgements about their relative sizes. It also requires the decision maker to be able to estimate the sum of adverse and beneficial effects. The process requires some experience, but is a useful way of formally presenting a judgemental process. It can also be used to identify where additional analysis of the magnitude and likelihood of effects is required either to allow effective prioritisation, or to assist in determining the relative sizes of adverse and beneficial effects.

7.4 Dominant effects

The notion of dominant effects is linked to ranking of risks, costs and benefits (7.3) and can be used when it is clear that one or more effects effectively dominate all other effects. In this case, a simple comparison of the dominant adverse and beneficial effects may be sufficient to weigh up the risks, costs and benefits.

The first step in this process will be the same ranking process as applied in 7.3. Consider Table 8. If A1 and A2 are known to be much greater than A3 (and thus A4-A6), and B1 is known to be much greater than B2, then the weighing-up process is limited to comparing A1+A2 and B1.

Table 8: Dominant effects

Adverse effects	Beneficial effects
A1	B1
A2	B2
A3	B3
A4	
A5	
A6	

The essential aspect of this type of approach is determining the meaning of ‘much greater’ so that cut-off points can be determined. A useful ‘rule of thumb’ might be that where effect X(n) is believed to be more than five times greater than the next largest, i.e. X(n+1). However, problems may still arise where there is a large cluster of small adverse effects (e.g. A3, A4, A5, A6) all approximately the same size that together might combine to be significant. In these circumstances, judgement will be required.

The dominant effects approach is only useful when the number of effects entering on each side of the weighing-up process can be reduced to at most three (preferably one or two), and where it can be shown that the ‘discarded’ effects are sufficiently small as to have very little impact on decision making.

This approach can be applied sequentially to groups of effects (environmental, human health etc); especially in circumstances where one positive and one negative effect dominate each group.

7.5 Additivity of effects

In cases where common measures are possible (for example dollars), it is self-evident that effects may be additive.

Additivity also needs to be considered, where there are no common units, albeit with some caution. Thus, if a decision is characterised by a large number of risks that are each “very low” the question needs to be asked if they necessarily outweighed by one benefit which is characterised as ‘low’. Where circumstances warrant, it is prudent to consider specifically that issue.

7.6 Weighting techniques

One of the issues with weighing-up adverse and beneficial effects (i.e. risks, costs and benefits) relates to the different nature of the effects, i.e. environmental, human health, social, cultural and economic. Even where it may be possible to aggregate all effects using a common measure or unit (such as within cost-benefit analysis), for reasons such as those discussed in the section on ‘approach to risk’ (Chapter 6) it may be considered desirable or prudent to apply different weights to different types of effects.

Weighting techniques can be used in conjunction with cost-benefit analysis and decision analysis. Some quantitative applications separate effects into risks, costs and benefits, such that effects are given an additional weighting (over and above the likelihood weighting) according to particular rules set by the decision maker. This approach is most effective where quantitative data is available.

Variable weights may be applied to:

- different individual effects
- different groups of effects.

For the purposes of this discussion, all effects are considered to have a normal weighting of one (unity). A weight of less than one indicates that the effect is considered to have less importance, while a weight of greater than one implies greater importance.

7.6.1 Individual effects

The most common circumstance where different weights might be applied to different individual adverse effects is associated with ‘approach to risk’ (Chapter 6). As noted in 6.2, the concept of a risk prone decision maker (risk taker) is not consistent with the

Purpose of the Act, therefore there are no foreseeable circumstances where an adverse effect would be given a reduced weighting.

The effect of increasing the weight of an individual effect is to make it more important, either positively or negatively, in the balancing process. Clearly, any weighting should be explicit and justified, and should be done before any process such as ranking or determining of dominant effects is undertaken.

During the assessment process, each effect is analysed and ‘measured’, and for adverse effects, the characteristics referred to in Clause 33 of the Methodology are reviewed. Where for an individual adverse effect the Authority determines that it wishes to be risk averse, then it may choose to reflect this stance by increasing the weight on this effect to greater than one. In practical terms, it is unlikely that this will be a mathematical process. It is more likely that the Authority will simply ‘flag’ this effect and consider this during weighing-up.

For example, consider the terminology of Tables 7 and 8. Adverse effects are initially ranked without weighting. However, if the characteristics of A4 require the decision maker to be risk averse then the weight may be increased to 1.5. It is then determined that A4 is greater than A3.

A similar approach may be applied to beneficial effects, although this will generally be to reflect uncertainty rather than risk averseness. It is, for example, not unusual for estimates of benefits to be over-optimistic. One circumstance where the Authority may decide to apply a lesser weight to a beneficial effect may be where the timeframe is such that the benefit may be deemed speculative (over and above the likelihood of realisation that will already have been applied). One circumstance where a benefit might be given a weighting greater than one is where the benefit applies to a sector of the community with particular vulnerability, or an ecological community deemed particularly worthy of protection.

7.6.2 Groups of effects

In some circumstances, the Authority may decide to apply variable weights to groups of effects. For example, human health effects may be deemed to be of more importance than environmental effects. This can be viewed as a special case of differential weighting of individual effects, where all (adverse, beneficial or both) effects in a particular group are given the same amended weighting, or where the net effect only is weighted. Since for most Authority decisions it is difficult to aggregate effects across types meaningfully, the former approach will be the most commonly adopted.

Justification for differential weighting of different types of effect might be associated with exposure or use. For example, consider an application for a hazardous substance for release where the substance has both adverse environmental and human health effects, but is expected to be used in a limited environment where people (workers) are exposed, but the ecosystem components of the environment are not.

This example is to some extent speculative, since in most cases the need for weighting should be countered by the estimation or assessment of the effect itself. A more realistic example relates to cultural and social effects where risks, costs, or benefits are

expected to have more importance for one sector of the community over another, and where (for one reason or another) the social and cultural effects are deemed to be of more importance than environmental or human health effects.

7.7 Scenario analysis

Scenario analysis has been discussed previously in Chapter 4. In 4.8 it was noted that scenario analysis can be used either for assessing risks, costs and benefits or in decision processes. It was pointed out that when using scenario analysis as a decision tool care needs to be taken to ensure that the assumptions and their effect on the results are well understood.

7.8 Decision analysis and economic tools

Cost-benefit analysis is an economic device used to weigh up costs and benefits. An important aspect of the weighing-up of costs and benefits is that assessments must be undertaken within a positive rather than normative framework, in other words, under assumptions about what is likely to happen, and not under scenarios reflecting what should happen.

Costs and benefits may be quantitative or qualitative. Where costs and benefits are mixed (i.e. include both quantitative and qualitative), it is useful to present quantitative costs and benefits combined as a net benefit (cost), and to present qualitative costs and benefits in the form of a qualitative analysis to be considered along with the quantitative information.

As discussed in 4.8.2, costs and benefits have two components – private and public³⁴. Where public costs are negligible or where public benefits exceed public costs, there is no need to consider the size of private benefits and costs. However, where public costs are not negligible, and where public benefits are less than public costs, the applicant may be required to indicate the size of the expected net private benefit.

It can be assumed that when an application is lodged, the applicant judges that the expected present value of the time profile of private benefits will exceed the present value of the time profile of private costs. Therefore, private benefits will always exceed private costs.

Thus, where public costs are deemed to be negligible it can be generally assumed that since net private benefit is positive, then total benefits (public and private) will exceed total costs (private and public).

However, where there are ‘significant’ levels of public costs, then the net private benefit needs to be compared with net public benefit.

³⁴ Public costs are sometimes called ‘external’ or ‘social’. In some literature, public cost is defined as synonymous with total cost, but as used here, we are defining total costs to be the combination of private costs that fall directly on the individual or firm conducting the activity, and public costs which fall on other people.

Total net benefit can be positive in two ways.

1. If public benefits exceed public costs, then total net benefit must be positive.
2. If public benefits are less than public costs, then the excess private benefit over private cost must be greater than the excess of public cost over public benefit.

Thus the only circumstance where the applicant may be required to provide details of private net benefit are where public costs exceed public benefits.

7.9 Benchmark risks

The purpose of the development of benchmark risks is to provide a ‘scale’ of risk rather than unitary measurements of risk. Risks may be measured in many different units, but the goal of ‘benchmarking’ is to have a common scale on which risks may be placed. Risks will have measurements in terms of probability and magnitude. A major difficulty with this type of benchmarking is that a general consequence scale has to be developed. Usually this is measured in terms of measures like ‘days of life lost’, and benchmarking tends to be limited to human health risk. Obviously similar benchmarks could be established for ecological, and social and cultural risks, but the problems of comparing or aggregating across risk types still arises. Developing benchmarks is very expensive and time consuming, and requires large quantities of high quality data. Over time, the Authority may develop data sets for similar groups of applications that may be amenable to benchmarking.

The intention of benchmarking is to remove value judgements from assessing risks and making comparisons with other risks. However, modelling assumptions and changing societal aspirations mean that benchmarking does require judgements, which reduces its utility as an objective tool.

7.10 Negligible risks

Clauses 26 and 27 of the Methodology differentiate between the balancing processes required when all risks are deemed as negligible. When all risks are deemed negligible, then the Authority will weigh up the costs and benefits associated with the application. A special case is where all risks are negligible and there are no costs to third parties (see 7.7). In this circumstance, the fact that the applicant is making an application will be generally accepted as evidence of benefit, and the Authority will not undertake a risk-cost-benefit analysis³⁵.

Where risks are not deemed negligible, the Authority will weigh up risks, costs and benefits.

³⁵ Sometimes referred to as risk-benefit balancing or social cost-benefit analysis.

Appendix A Glossary of terms

The terminology used in this document is based on the Environmental Risk Management Authority Methodology (Order-in-Council) (ERMA, 1998), the Australian and New Zealand *Risk Management* Standard AS/NZS 4360: 1999 (AS/NZS, 1999), and the Standards handbook *Environmental Risk Management: Principles and Process* AS/NZS HB203: 2000 (AS/NZS, 2000).

Definitions from the Methodology:

Act means the Hazardous Substances and New Organisms Act 1996.

Application means an application lodged under Part V of the Act.

Assessment means a process of identifying and assessing risks, costs and benefits associated with the introduction of hazardous substances or new organisms in the context of applications made under Part V of the Act.

Benefit means the value of a particular positive effect expressed in monetary or non-monetary terms.

Cost means the value of a particular adverse effect expressed in monetary or non-monetary terms.

Evaluation means the evaluation by the Authority of the combined assessments of risks, costs and benefits associated with applications made under Part V of the Act for the purposes of deciding whether the application should be approved, approved with conditions, or declined.

Risk means the combination of the magnitude of an adverse effect and the probability of its occurrence.

Definition from the HSNO Act 1996:

Effects include

- (a) Any potential or probable effect; and
- (b) Any positive or adverse effect; and
- (c) Any temporary or permanent effect; and
- (d) Any past, present, or future effects; and
- (e) Any acute or chronic effect; and
- (f) Any cumulative effect which arises over time or in combination with other effects.

Other definitions:

Frequency is the measure of the rate of occurrence of an event expressed as the number of occurrences of an event in a given time. By definition, frequency is a numerical measure and can be used in quantitative risk approaches. Frequency can also be expressed in other suitable quantitative measures, such as per million units, per head of population, and per thousand births (AS/NZS 1999).

Hazard is a source of potential harm or a situation with a potential to cause loss (AS/NZS, 1999).

Likelihood is used as a qualitative description of probability or frequency, in relation to how likely it is that something will occur. Likelihood is used in qualitative risk approaches (AS/NZS 1999).

Probability is the chance of a specific event or outcome, measured by the ratio of specific events or outcomes to the total number of possible events or outcomes. Probability is expressed as a number between 0 and 1, with 0 indicating an impossible event or outcome and 1 indicating an event or outcome that is certain. By definition, probability is a numerical measure and can be used in quantitative risk approaches (AS/NZS 1999).

Appendix B Common techniques for identifying and assessing risks, costs and benefits

Brainstorming and common sense assessment

Brainstorming is a popular decision making technique that may be formal or informal. It involves a group of decision makers discussing the problem together. The purpose of a formal brainstorming session may be to develop the objectives and criteria for a decision, or it may be to choose directly an option.

Brainstorming works best if the two processes of setting criteria (context) and making the decision (process) are separated, and if the decision makers represent a wide range of interests and knowledge.

Formal brainstorming occurs when a meeting is held specifically for that purpose. Informal brainstorming is less structured.

For risk identification, a mixture of formal and informal brainstorming may be used, but the results of the processes should be documented. The composition of the group involved is important and in the context of the HSNO Act should include people involved at all stages of the process or activity.

Checklists

Checklists are most commonly used when the situation in which risks are being identified is similar to situations that are addressed on a regular basis. Checklists may be used to examine common sources of risk and common elements at risk. An applicant may choose to develop a checklist based on elements at risk as detailed in the Methodology.

Databases of incidents

Databases may be public or private.

Epidemiological surveys

Epidemiology studies the distribution of disease in human populations and the factors influencing that spread. It is concerned with groups of people rather than individuals. Epidemiological studies may be descriptive or analytical. While epidemiological studies are mainly used to assess risks, in some cases they may be used to scope cause-effect relationships and so help to identify risks.

Flow charting, systems analysis

Flow-charting and systems analysis may be seen as analytical approaches similar to decision analysis. In all cases, the essential element is a systematic approach to looking at all possible actions and outcomes.

Interview/focus group discussion, consultation

Consultation processes may be used to help identify effects on particular societal or cultural groups.

Life Cycle assessment

Life Cycle Assessment (LCA) is used as a tool to assess the environmental impacts of a product, process or activity throughout its life cycle; from the extraction of raw materials through to processing, transport, use and disposal. In its early days it was primarily used for product comparisons, for example to compare the environmental impacts of disposable and reusable products. Today its applications include government policy, strategic planning, marketing, consumer education, process improvement and product design.

Life Cycle Assessments involve cradle-to-grave analyses of production systems and provide comprehensive evaluations of all upstream and downstream energy inputs and multimedia environmental emissions. As an approach to risk identification LCA is used to mean a systematic approach to determining what might happen and how at all stages of a product's lifecycle or project length.

Past agency experience (including analogy to known cases)

These methods all rely on past experience of similar situations. The important aspect of any comparative approach to risk identification is that the situations or activities being compared must be similar. If these approaches are used then the similarity with past cases needs to be clearly established, particularly if this is the sole method used. With this caveat, past experience is a very powerful tool for addressing many HSNO applications.

Reported overseas experience

Reported overseas experience can be used to supplement other risk identification processes in the same way as past agency experience. Once again, it is important to ensure that comparisons are made between 'like' substances, organisms and/or activities.

Safety audits or physical inspections

Safety audits and physical inspections of existing activities or relating to existing substances and organisms may be used to identify risks. Information from MAF audits may be used to identify risks.

Scenario analysis, decision trees (including fault trees and event trees)

Scenario analysis is used where the range of possibilities may be very extensive. A set of representative situations that cover a variety of outcomes from best to worst case can be postulated and analysed using different modelling and decision analysis techniques.

The scenarios need to be carefully chosen so that all possibilities are covered.

Formal brainstorming or Delphi might be a useful preliminary step to scenario analysis.

Fault tree and event tree analyses are particular decision analysis techniques used to examine scenarios.

Fault tree analysis

Fault tree analysis is a systems engineering method for representing the logical combinations of various system states and possible causes that can contribute to a specified event (called the top event). The top event is the adverse consequence. Fault tree analysis works backwards to determine the different ways in which the adverse consequence can occur, or the sequence of events that is required.

Event tree analysis

Event tree analysis is a technique that describes the possible range and sequence of the outcomes that may arise from an initiating event. The initiating event may be a minor irregularity that as a result of a subsequent chain of events leads (forwards) to an adverse consequence.

It is often useful to apply both techniques.

SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis

SWOT analysis is traditionally used as a positioning or marketing tool, and consists of a systematic approach to identifying the strengths and weaknesses, and of examining the opportunities and threats associated with the proposed activity.

Its use for risk identification is simply to provide a structured framework to the identification process. The value of SWOT analysis depends on developing the appropriate questions to be answered in each category. It is also valuable when used as a role play with different people adopting different perspectives.

Toxicology studies

Toxicological studies use animal studies to explore effects of chemicals in humans. Animal experiments resemble epidemiological studies insofar as they are concerned with the effects of different levels of exposure to a suspect agent. However, toxicological experiments can be better controlled in terms of homogeneity of the subjects and the number of subjects. The difficulties arise in extrapolating from animal populations to human populations.

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