ENVIRONMENTAL RISK MANAGEMENT
NGĀ KAIWHAKATŪPATO WHAKARARU

Preparing information on

RISKS, COSTS AND BENEFITS

for applications under the Hazardous Substances and New Organisms Act 1996

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Preface

This guide is part of a series of technical guides produced by ERMA New Zealand to help people involved with the HSNO Act. It will be particularly helpful for those people who are reviewing applications (and that is the way it has been written), but it may also be useful for applicants and those people interested in HSNO related risks more generally. People with a less technical interest in HSNO are advised to start with the other series of documents we publish, especially:

- the quick guides (aimed at a very general audience or for those making a first acquaintance with HSNO);
- the user guides (aimed at those directly involved with HSNO but not a great degree of technical detail).

Publications in this technical series are not formally endorsed by ERMA New Zealand. They are intended to provide a technical point of reference. Most of the documents are authored by a member of staff, but in other cases, there may be an external author.

This guide overviews the process of identifying and assessing HSNO risks, costs and benefits. It is potentially relevant to all applications made under Part V of the HSNO Act. The information in this guide has been consolidated from the first set of Protocols issued by the Authority, now obsolete. Protocols are formal documents that have the approval of the Authority. In this instance it was decided that the material did not warrant this status because it had not yet been 'proved' in a wide range of circumstances. However, ERMA New Zealand is sufficiently confident of the material to make it available as a technical guide.

Existing worldwide knowledge of risk identification and assessment is more based on experience with hazardous substances than with new organisms. This is reflected in the content of this guide. For example there is emphasis on the 'magnitude vs probability' paradigm that is standard in the risk analysis profession and very applicable to hazardous substances. It is also readily applicable to organisms in containment where the dominant issue tends to be probability of escape and the consequences if escape occurs.

The conventional paradigm is less applicable to the release of new organisms because release is concerned with the behaviour of biological and ecological systems over unlimited periods of time. Biological and ecological systems are dynamic, self-managing to a degree, evolutionary in character and non-linear in behaviour. A paradigm based on as simplistic a notion as assessing probability and consequences for separately identified risks is thus unlikely to capture the nuances of good decision making. However, the simplistic paradigm is all that we currently have and the challenge for ERMA New Zealand is to develop a better approach. Much of that development will occur through 'doing and learning' ie dealing with real issues in applications as they occur and translating the solutions into a wider developmental framework.

I hope that the results of the developmental framework will appear in future revisions of this technical guide.

Bas Walker
Chief Executive

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Introduction

Purpose of this guide

This document provides a practical guide to the conduct of risk-cost-benefit analysis. It has been written primarily to assist ERMA New Zealand analysts in evaluating information contained in applications received by the Authority.

However, it is also anticipated that the guide will be of interest to potential applicants (insofar as it indicates how their risk-cost-benefit information is likely to be treated) and to those with a technical interest in risk-cost-benefit analysis generally.

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.

To do this, the Act requires the Authority to consider a number of matters in its decision-making, including:

- the sustainability of flora and fauna
- the intrinsic value of ecosystems
- public health
- Māori values
- economic benefits
- international obligations
- the reasonably foreseeable needs of future generations.

In addition, the specification in the Act of the principles relevant to the purpose of the Act oblige the Authority to recognise and provide for the following:

- safeguarding the life supporting capacity of air, water, soil, and ecosystems
- maintaining and enhancing the capacity of people and communities to provide for their own economic, social, and cultural well-being.

The Authority must also take into account the principles of the Treaty of Waitangi and the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.

What are risks, costs and benefits?

As required by the Act, the Authority has established a methodology (referred to as the *Methodology*) for making decisions under Part V, including provision for an assessment of monetary and non-monetary costs and benefits. A key part of the *Methodology* concentrates on the evaluation of risks, costs and benefits. [The *Methodology* has been entered as an Order-in-Council (ERMA, 1998a). The *Annotated Methodology* (ERMA, 1998b) provides additional information about the way in which the Authority will make decisions.]

Environmental and public risks arise because of the interaction between people, their activities and the general social and physical environment. Costs and benefits are the values that can be placed on particular effects that arise as a result of these interactions. Risks, costs and benefits are closely linked, and are defined in the context of the type of substance or organism, the purpose of the application and the requirements of the HSNO Act and the *Methodology*.

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

Key terms

The terminology used in this document is based on the Environmental Risk Management Authority *Methodology* (Order-in-Council)(ERMA, 1998a), the *Annotated Methodology*, (ERMA, 1998b), the current Working Draft of the ISO/TMB WG on *Risk Management Terminology* N12 (ISO 1998), the Australian and New Zealand *Risk Management* Standard (AS/NZS 4360: 1999), and the Australian and New Zealand *Environmental Risk Management Guide* (in press).

Risk means the combination of the magnitude of an adverse effect and the probability of its occurrence (ERMA, 1998a).

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

Risk identification is the process of determining what can happen, why and how (AS/NZS, 1999a). It is used to define potential outcomes.

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 (ERMA 1998a)[1].

Probability, Frequency, Likelihood

> **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 1999b).
>
> **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

[1] **Risk assessment** in the ERMA context is therefore equivalent to **risk analysis** as defined by the ISO working group.

Risk analysis *is the systematic use of available information to estimate the likelihood and consequences of risks and their components*
Note 1. The purpose of risk analysis is to provide a basis for risk evaluation, treatment, and acceptability.
Note 2. Information can include historical data, theoretical analysis and empirical analysis (ISO 1998).

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 1999b).

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 1999b).

Effects are defined outcomes (ERMA, 1998a) and include potential or probable, positive or adverse, past, present or future, acute or chronic, and cumulative effects (section 2, HSNO Act).

Benefit means the value of a particular positive effect expressed in monetary or non-monetary terms (ERMA 1998a & b).

Cost means the value of a particular adverse effect expressed in monetary or non-monetary terms (ERMA 1998a & b).

Attitude to risk is how the Authority will value uncertain outcomes viz-a-viz certain outcomes, for different risk types and characteristics (ERMA, 1998b).

Degree of caution is how conservative the Authority will be in the assumptions it uses in its analysis and determinations (ERMA 1998b).

Negligible risks are risks which are of such little significance in terms of their likelihood and effect that they do not require active management and/or after the application of risk management do not need to be justified by counterbalancing benefits (ERMA, 1998b).

Unacceptable risks are risks of a type or level which the Authority will not accept irrespective of any benefits that might accrue after taking account of the scope for risk management (ERMA, 1998b).

Overview of Contents

The guide is organised into five main sections, along with a number of appendices, as follows:

Section 1: The Decision Process

This section provides an overview of the Authority's decision processes under Part V of the HSNO Act. It highlights the key factors relating to the evaluation of risks, costs and benefits from the *Methodology* and outlines some of the tools that the Authority will apply.

Section 2: Identifying Risks, Costs and Benefits

Section 2 is a guide to identifying risks, costs and benefits. Note that risk identification is covered in more detail in another ERMA New Zealand technical guide, *Identifying Risks*.

Section 3: Assessing Risks

Risks may be assessed either quantitatively or qualitatively. This section discusses the general approaches that are used and some of the specific methods.

Section 4: Assessing Costs and Benefits

Section 4 examines the assessment of costs and benefits in general terms, and introduces some of the concepts and tools of cost-benefit analysis.

Section 5: Combined Consideration of Risks, Costs and Benefits

This last section discusses ways of presenting information on risks, costs and benefits so that they can be considered together. It includes advice on ways to combine the data.

Appendix A is an example of a modified risk register. A more comprehensive risk register is shown as Appendix A to the companion technical guide *Identifying Risks*.

Appendix B shows the areas of effect to be taken into account when identifying and assessing risk, specified in the *Methodology*.

Appendix C outlines the processes used for human health risk assessment and ecological risk assessment.

Appendix D is adapted from the Australian and New Zealand *Risk Management* Standard and gives an example of an approach to qualitative assessment of risk.

Appendix E is a worked example showing the analysis of cost and benefit streams.

Appendix F provides a sample template for the summary presentation of risks, costs and benefits.

Section 1
The Decision Process

Overview

Under the HSNO Act, the Environmental Risk Management Authority (the Authority) is empowered to approve or decline applications to import, develop, field test, or release a new organism or to import or manufacture a hazardous substance.

The decision process followed by the Authority is specified in the *Methodology* (ERMA 1998a), and elaborated in the *Annotated Methodology* (ERMA, 1998b). The essence of this process is that the Authority will make decisions on whether or not to approve applications for hazardous substances and new organisms based on an evaluation of the risks, costs, and benefits associated with the application. It notes that 'the Authority, its Chief Executive, its staff, and any appointed expert shall use recognised risk identification, assessment, evaluation, and management techniques'.

The *Methodology* and the protocols issued by the Authority provide guidance as to how it will reach its decision on the application before it, given the identification and assessment of all relevant risks, costs and benefits.

Note in particular however, that it is the applicant's task to identify and assess risks, costs and benefits. The role of ERMA New Zealand staff is thus primarily one of review.

The *Methodology*

Section 12 of the *Methodology* states that:

> *In evaluating assessments of risks associated with an application the Authority shall take into account:*
>
> *(a) the nature of the adverse effects*
>
> *(b) the probability of occurrence and the magnitude of each adverse effect*
>
> *(c) the risk assessed as a combination of the magnitude of the adverse effect and the probability of its occurrence*
>
> *(d) the options and proposals for managing the risks identified*
>
> *(e) the uncertainty bounds on the information contained in the assessment expressed quantitatively where possible but otherwise through narrative statements.*

In addition, section 13 states that:

> *In evaluating assessments of costs and benefits associated with an application the Authority shall take into account:*
>
> *(a) the costs and benefits associated with the application and whether they are monetary or non-monetary*
>
> *(b) the magnitude or expected value of the costs and benefits and the uncertainty bounds on the expected value*
>
> *(c) distributional effects over time, space, and groups in the community.*

Relevant costs and benefits (section 14) are those that pertain to New Zealand, and which would arise if an application were approved.

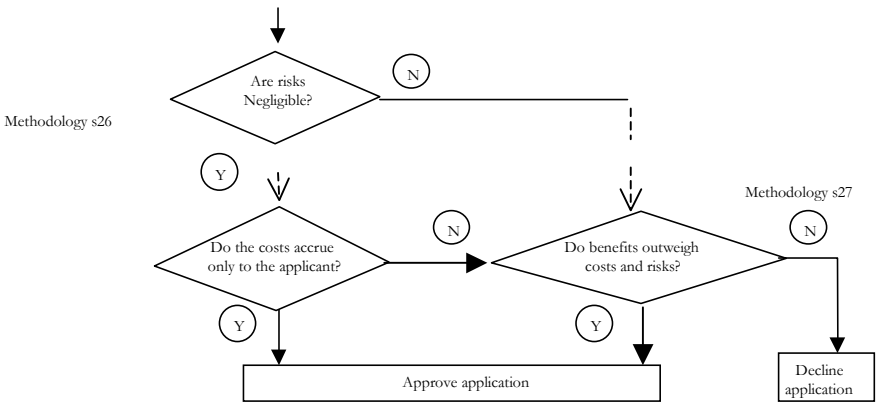
As addressed in the *Annotated Methodology* (8.4.3) the Authority will use the information provided by applicants to decide whether risks are:

- negligible (taking into account the scope for management)
- potentially tolerable (taking into account the scope for management), or
- unable to be categorised because of lack of information.

If the risks associated with an application are deemed to be 'negligible'[2], then under Clause 26 of the *Methodology*, the Authority may approve the application if it is evident that benefits outweigh costs where costs and benefits are assessed from a national perspective (Clause 14).

However, if some of the risks are not negligible then under Clause 27, risks and costs must be balanced against benefits.

Protocol 2, series 2, *Decision Paths* (ERMA, 1999c) lays out the decision paths to be followed for different types of application. The following figure shows a generalised version of this process.



Note that, where risks are negligible and the costs accrue only to the applicant, no explicit cost benefit analysis is required. In effect, the Authority takes the act of making an application as evidence that the benefits outweigh the costs.

Tools

The Authority's decision process is based on a process of risk management. Risk assessment (analysis) and cost-benefit analysis are two of the tools that may be applied within the decision-making framework.

Applicants are asked to identify and assess the **effects** of the application, where these effects include risks, costs and benefits. Risk assessment and cost-benefit analysis are common

[2] The test for negligible risk requires that all the individual risks be negligible, and also that the cumulative risk be negligible.

assessment tools that may be used either descriptively or analytically. Once the effects have been identified, applicants may want to consider the significance of the application (reflected by the magnitude of the effects) before deciding whether to undertake formal risk assessment, or cost-benefit analysis. Other factors that may affect the way the applicant decides to present the information are the distribution of effects (geographically, socially, and over time), and whether the effects are chronic or acute. Effects that are irreversible may need more careful analysis.

Section 2
Identifying Risks, Costs and Benefits

Overview

It is the responsibility of the applicant to provide evidence that they have taken a structured and systematic approach to identifying the risks, costs and benefits associated with their application.

The type of information that the Authority will require applicants to provide is described in the *Methodology*, the Application Forms and in the Regulations prescribing additional information to be provided in an application.

In addition ERMA New Zealand has published a technical guide *Identifying Risks* (ERMA New Zealand, 1999) which includes a series of templates providing guidance.

Specifying the baseline

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 need to compared against an assessment for one or more alternative options. In the case of HSNO decision making, the baseline should be considered to be the status quo ie what would happen if the application was declined and thus nothing changed.

Note that an applicant should not assume the baseline to be static over time. In most cases the baseline will need to be projected over the estimated life of the project. This will mean postulating a scenario for what is expected to happen if the application is declined. For example, consider an application to import a new agricultural chemical to replace one that is becoming less effective. The baseline projection should take account of the fact that more of the original chemical will be required over time, thus increasing the cost of maintaining the current position.

Adequacy of Information

Clause 8 of the *Methodology* states that:

> *The information used by the Authority in considering an application shall be that which is relevant and appropriate in the context of the scale and significance of the risks, costs and benefits associated with the substance or organism.*

Thus, applicants should seek to provide information which is significant to the proper consideration of the application; ie information which is 'necessary and sufficient' for decision-making.

In practice, defining the bounds between 'too much' and 'too little' information may require case-by-case discussion between applicants and ERMA New Zealand staff.

Identifying Risks

The objective of risk identification is to adopt a systematic, transparent approach to the process of identifying risks, and thus to minimise the impact of 'unknown' risk.

A comprehensive discussion of how to identify risks (including templates for particular applications) is presented in the technical guide *Identifying Risks*.

Applicants are expected to identify all reasonably foreseeable risks to the environment and the health and safety of people and communities. Applicants should also address the matters relevant to the purpose of the Act identified in section 6 of the HSNO Act.

Applicants should state the method used to identify risks, including the identification of both sources of risk and elements at risk (impact). The material on identification of risk should be presented in a systematic format. One acceptable format is set out in Appendix A (see Appendix A of the technical guide *Identifying Risks* for a more comprehensive version).

If the application is for a substance or organism in containment, then the focus should be on the residual risk, or the risk with controls in place. However, the risk of escape or failure of the controls should be considered and the effects if this did occur.

Approach

Risks are composed of two main elements; an identified adverse effect, and the likelihood (probability) of that adverse effect occurring.

Risk identification is about identifying what can happen, and how and why events might occur, through a systematic analysis of all aspects of activities or projects and their possible consequences, including their effects on the natural environment (ecosystems), individuals, and communities.

It requires analysis of all the possible impacts of the substance or organism on the natural environment (ecosystems), people, and communities.

There are two aspects to risk identification:

- identifying the source of the risk (the hazard), and
- identifying the elements at risk.

For substances the 'hazard' is identified by the properties of the substance, which determine its classification. Applicants will use scientific testing to determine the classification of the substance. Similarly for organisms, it is the organism and its characteristics that comprise the hazard or the source of risk.

Hazards are intrinsic properties. In addition to identifying sources of risk and elements at risk, the conditions of exposure (or exposure pathways) should be defined. A hazard cannot become

a risk unless there is a feasible exposure pathway between the hazard and the area of impact. In HSNO terms, it is the **activity** that provides the pathway between **cause** and **effect**.

Therefore, when identifying environmental risks, the focus should be on the individuals, population or elements at risk, what might happen to them, and any other factors that might affect their exposure to a hazard and their vulnerability.

One source of risk can have multiple (adverse) effects, several sources of risk may result in the same impact or effect, and multiple sources may have multiple impacts.

It is often useful to work from both ends, that is:

- start with source of risk, and look for adverse effects (event trees), and
- look at possible adverse effects and work backwards to find their possible source (fault trees).

The 'effects based' nature of the HSNO Act reflects the 'backwards' approach. However, often it is easier to begin by looking at the trigger event or what might happen (forwards approach), thus allowing for some events to be eliminated from further consideration.

Look for:

- very long term impacts,
- acute and chronic impacts, and
- cumulative and synergistic impacts.

Common approaches to identifying risks are:

- interview/focus group discussion, personal or past agency experience, consultation
- audits or physical inspections
- brainstorming
- local or overseas experience, history, failure analysis
- scenario analysis, and 'what if' analysis
- flow charting, systems analysis, systems engineering techniques, fault trees and event trees, HAZOP studies
- life cycle assessment (LCA)
- databases of incidents
- use of standard checksheets.

The two techniques which have been used by ERMA New Zealand in dealing with new organism applications (we have no experience yet with hazardous substances) are:

- brainstorming, and
- use of checksheets based on prior experience (this technique is very useful because applications commonly fall into groups which raise very similar issues eg all field trials of GM crops will raise the issue of risks from cross pollination).

Identifying costs and benefits

The objective is to identify all aspects of the costs and benefits associated with the application including all reasonably foreseeable direct and indirect, monetary and non-monetary costs and benefits, and where and when these costs and benefits accrue.

In identifying costs and benefits, applicants should consider:

- the nature of the costs and benefits (ie whether they are monetary or non-monetary)
- whether the costs and benefits are direct or indirect
- the timing of costs and benefits
- the individuals, organisations or communities that will receive the benefits, and
- the individuals, organisations or communities that will bear the costs.

Monetary costs and benefits are costs and benefits that are determined (valued) in the market place. Non-monetary costs and benefits are beneficial or adverse effects that are not subject to market valuations (and thus do not attract a price or dollar value).

Direct costs and benefits are those that flow immediately from the proposal.

Direct monetary costs are the quantifiable costs of undertaking the activity, for example the cost of:

- importing the organism
- undertaking the field trial
- importing the substance
- manufacturing and distributing the substance.

As part of identifying direct monetary costs consider:

(0) initial costs including:
- plant and machinery
- buildings and infrastructure
- legal and other infrastructure
- training and associated start-up costs
- computer systems
- product research and development
- surplus and waste management.

(0) recurring costs including:
- staff costs or time
- raw material costs and other consumables
- waste treatment and disposal
- maintenance
- testing and monitoring
- marketing, licensing etc.

Direct monetary benefits are the revenues that the applicant will receive as a result of the application. Applicants may choose to combine benefits and costs and present them as 'net benefit'.

Note that the stream of costs and benefits over time may vary. For example, consider the manufacture of a new household cleaning product. The major cost will be borne in the first year, with plant construction, staff training, impact marketing etc, with costs reducing in subsequent years. Benefits (revenues) will be low in the first two to three years, with full returns not realised until year six.

It is expected that applicants will estimate direct monetary costs and benefits in dollar terms, and provide information about their distribution (in time and space).

Direct non-monetary costs and benefits might include effects on the profile or reputation of the applicant organisation (which may have flow-on indirect monetary costs and benefits). There may also be direct health or environmental effects that are either difficult to quantify in dollars, or which the applicant does not believe it is necessary to quantify the effect in dollars. Improved staff expertise and new scientific knowledge through research are examples of direct non-monetary benefits.

Where non-monetary costs and benefits are involved, the Authority will generally be satisfied with qualitative estimates indicating relative size or impact. The application of non-market valuation techniques will not normally be required.

Indirect costs and benefits are those that flow as a consequence of the direct impacts. They may be monetary or non-monetary, and either quantifiable or non-quantifiable. To identify indirect costs and benefits look beyond the immediate purpose of the application to see where secondary effects may occur.

Example

The benefit of a new herbicide might accrue **directly** to the importer, and **indirectly** to a farmer using it and subsequently (through higher farm incomes) to the businesses in farming communities. On the cost side, downstream health impacts might be associated with the herbicide as an indirect cost if, for example, the maximum residue levels are exceeded.

Identifying **indirect costs and benefits** requires a careful systematic analysis of the life cycle of the organism or substance and its possible effects, including health effects, environmental (ecological) effects, and social, cultural effects. Tools used for risk identification such as scenario analysis and life cycle analysis may be particularly useful for looking for indirect costs and benefits.

There may also be **uncertainty** about the realisation of the postulated costs and benefits. For example, the benefits from a particular research project may not be known until the project is completed. **Potential costs** can be accounted for as risks. **Potential benefits** should be listed as benefits, but must be qualified so that it is clear as to the degree of certainty that these benefits

will be realised. Applicants should be realistic about potential benefits, and look at time frames for them to be realised.

In many ways, identifying costs and benefits is similar to identifying risks. Specifically, brainstorming, scenario analysis, life cycle assessment may also provide information about costs and benefits.

The following list of questions can be used by applicants and by reviewers as a check to ensure that a systematic process has been used to identify costs and benefits.

Questions

- Have all start-up and running costs been identified?
- Have secondary or indirect costs been considered?
- Are there any identified potential costs (that should be entered as risks)?
- What are the monetary benefits that will accrue if the application is approved?
- Are there any non-monetary benefits?
- Are indirect benefits identified realistic?
- Have potential benefits been identified realistically?
- How are the costs distributed (in time and space)?
- How are the benefits distributed (in time and space)?
- Is there a significant imbalance in the distribution of costs and benefits?

Section 3
Assessing Risks

Risk assessment

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.

Risks are **assessed** by combining the magnitude of the possible effects and estimates of the likelihood. For each risk, the combination of the effect (consequences) and likelihood determines the **level** of that risk.

The level of each identified risk is estimated by examining the severity of the potential effects (measure of severity of environmental impact), and the likelihood (frequency or probability) that those consequences will occur. These may be estimated quantitatively or qualitatively. The two measures are then combined.

While risk is estimated or assessed in terms of likelihood and severity, in most cases there are a number of additional factors that need to be taken into account in making decisions based on risk.

The *Methodology* requires that the following characteristics of the identified and assessed risks be considered:

- the degree to which exposure is involuntary
- the extent to which the risk will persist over time
- the extent to which the risk is subject to uncontrollable spread and is likely to extend its effects beyond the immediate location of incidence
- the extent to which the potential adverse effects are irreversible, and
- the extent to which the risk is not known or understood by society and whether there is a lack of experience in managing the potential adverse effects.

These characteristics will be used to decide how cautious the Authority will be in evaluating the risks. In addition, the *Methodology* notes that the Authority will be more cautious and risk averse with respect to some specific types of risk, which include but may not be limited to:

- risks to human health or well-being, including the human foetus
- risks to the survival of native species, or their habitats.

Thus as well as assessing risks applicants will be expected to provide contextual information about the risks that the Authority can use in evaluating the risks, costs and benefits.

Often a chain of events each with an associated likelihood or probability leads to a final environmental impact. 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.

Example

Consider the risk of an insect imported into containment for experimental purposes significantly displacing a native species.

The chain of events required for this to occur is:

- escape from containment
- survival (climate and initial survival)
- identification of a native species host
- selection of that native species as a preferred host
- significant displacement.

Each of these events has a likelihood attached to it. The likelihood of the insect significantly displacing a native species is a combination of all of these 'conditional likelihoods'.

Similarly, consider a volatile chemical with toxic properties.

A chain of events leading to a risk might be:

- a transport accident leading to spillage
- fumes reach residential area
- people affected by fumes.

Estimating levels of risk requires assigning a magnitude or value to each of the outcomes identified. It may 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 need to be considered separately also because of different risk factors (eg age, ethnicity, socio-economic factors etc).

In the same way that the **likelihood** must reflect the end of chain effects, the **magnitude** must reflect the endpoint (specified by the Act, the *Methodology*, and listed in Appendix B). The magnitude of the effect is not the same as the effect itself. If the adverse effect is that a certain quantity of chemical escapes into a stream, then the *assessment* endpoint will be degradation of that ecosystem, and the *measure of effect*[3] selected, or the surrogate measure of that degradation might be the expected number of fish killed.

As well as the measure of effect, a measure of exposure and measure of ecosystem and receptor characteristics may be required.

[3] Sometimes called the measurement endpoint.

Examples of different ways of measuring magnitude of effects on human health include:

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

A more specific measurement might be a recorded increase in the number of hospital admissions for asthma.

It is usually more difficult to measure effects on ecosystems, flora and fauna because of a lack of historical data, and because it may not be possible to conduct scientific experiments to determine the impact. In tests for ecotoxicity, indicator species are often used, and the data is extrapolated to other species.

Appendix C provides an overview of the approach used to estimate parameters for human health risk and ecological risk, for specific situations and activities. The remainder of this section looks at ways that applicants can combine this information to assess the level of risk.

Quantitative and qualitative assessments

Likelihood and magnitude of effect estimates may be qualitative or quantitative. Whether qualitative or quantitative approaches are used depends on the amount, type, and quality of the data available.

Risk is two-dimensional, and in many cases qualitative analysis is more useful than quantitative analysis because the information about the likelihood and the effect is preserved.

Qualitative assessment

Qualitative assessments use words to describe the probability or likelihood of the adverse effect occurring and the magnitude, or a measure of the severity of that adverse effect.

The two following tables show examples for qualitative descriptions of likelihood and magnitude of effect. See also Appendix D.

Descriptor	Description
Very unlikely	Not impossible, but only occurring in exceptional circumstances
Unlikely	Could occur, but is not expected to occur under normal conditions
50% likelihood	Equally unlikely/likely, mean chance
Likely	Will probably occur at some time
Very likely (almost certain)	Is expected to occur

Descriptor	Sample detailed description
Minimal	Mild reversible adverse effect on health affecting 1-2 people (eg minor skin damage), highly localised and contained environmental impact (eg spillage on to soil, but not reaching waterway)
Minor	Up to 10 people suffer mild reversible adverse health effects, localised and contained environmental impact (eg reaches small waterway, but able to be cleaned up)
Moderate	More than 10 people suffer reversible adverse health effects, measurable damage to an aquatic ecosystem (such as a small stream or lake)
Major	Significant irreversible adverse health effects affecting up to 10 people and/or more than 10 people suffer serious reversible adverse health effects, irreversible damage to localised ecosystem but no species loss
Massive	Significant irreversible adverse health effects to more than 10 people extensive irreversible environmental effects, including species loss

It is important to remember that the 'description' column is unique to the application.

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

Example

The risk of RCD severely reducing or destroying the black stilt population in the Mackenzie country could therefore be described as follows.

Likelihood = likelihood of RCD severely reducing rabbit population (high) times likelihood of predators switching prey to birds (medium) times vulnerability of black stilt (medium)

Combining these descriptive likelihoods requires judgement based on experience.

In this case it is reasonably easy to conclude that the likelihood is medium to high.

In other cases where there is a long chain of consequential likelihoods that range from low to high, the decision may be more difficult.

Qualitative assessment is useful for deciding which risks need further attention, and which risks are negligible. It is sometimes used as a screening tool. In some circumstances the Authority request the applicant to undertake more quantitative assessment, or additional sensitivity analysis.

As shown in Appendix D, qualitative information for likelihood and magnitude of effect can be combined in a single two-dimensional table and used to allocate levels of risk, based on professional judgement. The output from this type of qualitative analysis is a series of '**buckets**' or **groups of risk**. Risks that are in the lowest risk bucket may not need further consideration, that is, they may be accepted.

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. In common with other qualitative techniques, these indices are relative indices and can only be used to rank or prioritise risks for further treatment.

Semi-quantitative assessment

Semi-quantitative assessment assigns values to qualitative scales. The following table provides an example of a likelihood scale.

Descriptor	**Assigned value**
Highly unlikely	0.000001
Unlikely	0.0001
Possible	0.001
Likely	0.1
Extremely Likely	0.9

Representative numbers for consequence or magnitude of effect (usually nominal dollars) can also be assigned in a similar manner.

The level of risk is determined by multiplying the two assigned values for likelihood and consequence together.

Semi-quantitative analysis does not produce quantitative estimates of risk. 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. Similarly to qualitative analysis, semi-quantitative analysis is used to **prioritise** risks, 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.

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

Quantitative assessment

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.

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.

Dealing with uncertainties

Uncertainty exists where the possible outcomes of a system of activity are not well known, or cannot be assigned probabilistic values.

Human health and ecological risk assessment risk often produce results with a high degree of uncertainty and variability.

Reasons for this are:

- the complexity of the system, and the difficulty in identifying effects, and interrelationship between effects
- difficulty in making measurements
- natural variability
- time scale of effects.

Uncertainty refers to situations where there is a:

- lack of accuracy in measurement or estimation of likelihood or effects (sampling error or measurement uncertainty)
- lack of knowledge about what might happen as the result of an action (outcomes)
- lack of knowledge about the likelihood of the outcomes.

An important factor in uncertainty is also the reliability of the information. Important questions include the following:

- Is the source of the information free of bias?
- Was the information generated in a competent way eg using statistically reliable techniques?
- Has the work been peer reviewed ie is there any independent confirmation of the information?

Uncertainty can sometimes be reduced by further information, although this is not always worthwhile; the cost of obtaining more information should not exceed the value added by that information.

Variability differs from uncertainty. It arises from differences in the nature and extent of exposure and variations in susceptibility (heterogeneity). Sometimes probability or frequency

distributions can be used to analyse variability. More often, sensitivity analysis can put bounds around the impact of variability.

In some circumstances there may be **unknown** or **unsuspected** risk. Good risk identification can help reduce unknown risk.

Evaluation

In evaluating applications ERMA New Zealand staff and external reviewers will want to be assured that the applicant has adopted a thorough and systematic approach to assessing risks.

The following questions are suggested as a final checklist for ERMA staff and external reviewers.

Questions

- Is the context in which risks have been assessed clear?
- Is the context consistent with the requirements of the Act and the *Methodology*?
- If an assessment has not been done, is there a clear statement as to why not?
- What type of method has been used to assess the risks; quantitative, semi-quantitative, qualitative? Are there reasons given as to why this approach has been chosen?
- Has the applicant stated clearly what approach was used, and why?
- Is the approach selected appropriate given the type and quality of data supplied or available, and the level of risk?
- Have the identified risks been grouped into risks to human health, risks to ecological health, social and cultural risks, and economic risks? Can the risks be easily ranked within each of these groups?
- Can some of the risks be treated as negligible and what is the justification for this?
- How much quantitative data is available, and how reliable is it? Is it adequate for a quantitative assessment?
- Has each non-negligible risk been assessed in terms of likelihood and magnitude of the effects?
- Does the assessment address the adverse effects or consequences if the organism or substance breaches the containment provisions, or if the controls are not adhered to?
- Are ways in which containment could be breached considered and assessed?
- Are reasons why controls might not be adhered to considered and assessed?
- Has the applicant paid sufficient attention to uncertainty and how credible are their statements in that respect?
- Has variability in the populations potentially affected been addressed?
- Has the possibility of interaction between chemicals and their effects, and multiple exposure pathways and multiple health and ecosystem effects been considered?

Section 4
Assessing Costs and Benefits

Principles of cost-benefit analysis

The aim of cost-benefit analysis (CBA) is the **comparison** of the costs and benefits of a proposal. Such comparison is readily performed when all costs and benefits can be quantified in dollars, but this is usually not the case when viewing a project from a societal perspective.

The HSNO context requires applicants to address the **additional** or **incremental** costs and benefits associated with an application. Thus, the aim of assessing costs and benefits is to calculate the value of changes that will result if an application is approved. The types of changes that are relevant include:

- dollar costs associated with the application
- dollar benefits – often cost savings - associated with the application
- monetary costs and benefits that are difficult or impossible to quantify in dollars, including downstream effects and external effects (ie social costs and benefits)
- human health effects (may be positive or negative) including acute and chronic
- environmental effects (positive or negative)
- cultural impacts (positive or negative)
- community impacts (positive or negative)

As noted above the identification and valuation of costs and benefits should be considered against a **baseline scenario** of what is most likely to happen if the application is declined. **All** costs and benefits should therefore be estimated as incremental changes using that baseline for comparison. In most cases the baseline for costs and benefits can be expected to change over time.

Example

The baseline scenario for an application to release a biocontrol agent would consider the on-going efficacy of current controls. If current chemical controls are expected to become less effective over time then the baseline control costs will increase over time, as more chemical is required.

In contrast, consider an application for a new pesticide designed to control a pest that currently there is no ability to control. In this case, the costs and benefits for the baseline scenario will be zero.

When costs and benefits are not quantifiable in dollars, quantification in other units is still helpful.

The mechanics of cost-benefit analysis

Monetary costs and benefits are those costs and benefits that are determined (valued) in the market place. Direct costs and benefits are those that flow immediately from the proposal. They include capital and operating costs (running costs and labour costs).

There are two common ways of entering capital costs; either as a lump sum, or spread over the life of the project. However, these do not represent the true cost since neither includes the opportunity cost of capital. The preferred measure of economic impact is therefore the opportunity cost of the resources used, or the benefit foregone as a result of undertaking the activity.

Th most practical way of entering capital costs is for the applicant to assume that all capital will be borrowed, and to enter the cost of borrowing at appropriate interest rates (remembering that capital investment may occur at different stages in a project).

Example

Consider an application to manufacture a substance that needs additional plant capacity with an estimated cost of $20,000. Current borrowing rates are 8%, and it is estimated that the substance will be required for ten years. The direct monetary cost of capital is $1,600 per year.

Since only **additional** costs are relevant, any previous capital investment must be considered as a sunk cost, and not included as cost to the project/application.

Variable costs including wages, maintenance, and general day-to-day running costs should be included as direct costs.

Example

An application to field test genetically modified pigs in an existing piggery should not include the cost of building the piggery. However, a rental, or depreciation cost could be included.

Running costs would include:

- wages for scientists and animal handlers for time allocated to the project
- veterinary expenses
- purchase cost of breeding stock
- disposal costs
- electricity and water costs.

Direct monetary benefit is revenue received.

Costs and benefits will occur at different times over the life of a project. Where possible, applicants should forecast these monetary costs and benefits for the full expected life of the

project, and may choose to combine these as net benefit. This is particularly pertinent for economic or monetary costs and benefits.

The following example shows a project with a ten year planning horizon, where capital or fixed costs have been allocated at $1,600 per year over the life of the project. This example assumes that this is a new activity that does not replace any other activities, therefore the baseline scenario is zero-rated.

At face value the **net benefit** for the project is $134,000. However, most of the costs occur in the first three years, while benefits do not start until year 4, and are most significant at the end of the project. Therefore, discounted cash flows for costs and benefits, and the **Net Present Value** (NPV = total discounted benefits – total discounted costs) have been calculated.

Example

	YEAR										Totals
$,000	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	
Fixed costs	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	
Variable costs	100.0	30.0	20.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	
Total undiscounted COST	101.6	31.6	21.6	11.6	11.6	11.6	11.6	11.6	11.6	11.6	
Total discounted (10%) COST (rounded)	**92.4**	**26.1**	**16.2**	**7.99**	**7.2**	**6.6**	**6.0**	**5.4**	**4.9**	**4.5**	**177.14**
Total undiscounted BENEFIT	0	0	0	20.0	30.0	40.0	50.0	70.0	80.0	80.0	
Total discounted (10%) BENEFITS (rounded)	**0**	**0**	**0**	**13.7**	**18.6**	**22.6**	**25.7**	**32.7**	**33.9**	**30.8**	**177.95**
Net Present Value (NPV)											**0.81**

The NPV is a discounted cash flow associated with a project adjusted to allow for the timing of the cash flow and the potential interest on funds. For example, if an investor invested $100 at 10%, with compound interest, it would accumulate to $110 at the end of the year 1 and $121 at the end of year 2. Reversing the logic, $110 receivable after 1 year or $121 receivable after 2 years would be considered to have a present value of $100.

For this example, the NPV, calculated using a 10% discount rate is **$814**. If the discount rate is 8%, the NPV is $18,138, while with a 12% discount rate it is -$13,467. The choice of the discount rate can have a significant effect on the calculated NPV.

The NPV is used in cost-benefit analysis (CBA) as a way of comparing different options. In this example, as for most applications to ERMA, the alternative option is the baseline scenario. As

shown, sensitivity analysis where the discount rate (and where appropriate, the life of the project) are varied is very important because small changes can affect the economic viability. In addition, in most cases there will also be uncertainty or variability associated with the costs and benefits streams. Therefore sensitivity analysis should address parameters such as the expected efficacy (where relevant), costs and prices.

Non-monetary costs and benefits are those beneficial or adverse effects that are not subject to market valuations (and thus do not attract a price). Examples of non-monetary costs include human health effects, ecological effects, and effects on local communities such as loss of amenity. In addition there may be scientific benefits, social benefits, and ecosystem benefits.

Human health benefits will be picked up as monetary benefits (revenue) because people will buy the product if they believe that there are health benefits to be gained. Alternatively, aspects such as reduced anxiety of workers because of reduced toxicity can be addressed as social benefits[4].

Scientific benefit might be expressed as upskilling and training of researchers or expected number of peer reviewed scientific papers. Value can be demonstrated by peer review and referees reports, or reference to the current literature.

Social benefits may be linked to improvements in the health and well being of communities.

Ecosystem benefits are most likely to be in the form of reduced environmental damage, and might include reduced residue levels in soil, less damage to fish and aquatic systems from reduced toxicity, etc.

Non-monetary costs and benefits can be expressed as willingness-to-pay (WTP) for the specific product, or willingness-to-accept (WTA) compensation. Willingness-to-pay is the maximum amount an individual is prepared to pay to acquire a given benefit, while WTA is the amount of compensation that an individual expects to receive in order to forgo the benefit.

Where applicants are providing non-market valuations of costs and benefits they should ensure that:

- these derive from existing credible non-market valuations for the non-monetary costs and benefits, and
- the methods used for the valuation of the particular costs and benefits under consideration are commonly accepted.

In many cases applicants will only be able to provide qualitative estimates of non-monetary costs and benefits such as 'small', 'moderate' and 'large'. These types of estimates should be qualified by a description or scenario, and where possible, compared with other aspects of the application.

[4] Improved **health** of workers would be captured as a direct monetary benefit through reduced sick days.

Example

A new agricultural chemical may be expected to reduce ecosystem effects by a 'moderate' amount. While there is little quantitative data, it is known that the chemical does kill birds. Tests and toxicity data show that the new chemical will still be toxic to birds, but that the kill is expected to be about half the current rate.

An additional non-monetary cost linked to this new chemical is that it is a skin irritant, and that workers will therefore need to be more careful about protective clothing. This cost is considered to be 'small'.

Indirect costs and benefits are those that flow as a consequence of the direct impacts. They are sometimes called secondary costs and benefits. In practice, it is often difficult to value indirect costs and benefits in monetary terms. The Authority will not consider dollar value estimates of indirect costs and benefits unless their size is such that it is pivotal to the decision-making. Thus, where they are expected to be large then applicants should attempt to assign dollar values, but where they are expected to be small, qualitative descriptions should be given.

As noted previously there may be potential costs and benefits associated with an application. In the HSNO context potential costs should be listed as risks. Potential benefits should be listed as benefits, but should be qualified so that it is clear as to the degree of certainty that these benefits will be realised. This may be done using sensitivity analysis.

Typical areas where potential benefits may be identified are:

- potential health benefits, where clinical trials to demonstrate efficacy of a product have not yet been completed, and
- potential commercial benefits where an application is for research or product testing the result of which will be used to decide whether to proceed with commercialisation of a product.

Example

Consider an application to conduct a field trial with potential scientific and health benefits. The main benefit will accrue to the scientists directly involved. Other benefits may accrue to the wider scientific community.

The benefits to the scientists directly involved will accrue during the course of the project. Any wider benefit to science will occur when the results are published. Health benefits may be delayed for many years until testing is completed and may be coupled with a new suite of co-commitant costs. They are unlikely to figure significantly in the decision-making – especially if a new approval (eg release) would be required before the benefits are realised.

A critical factor in terms of whether the health benefits are realised may be a requirement to conduct clinical trials, after the field trial has been completed.

Where potential benefits are identified and assessed, in addition to how likely the benefit is to be realised, the applicant should consider carefully **who** will receive the benefit, **when** the benefit is likely to be realised, and **what** the critical factors are that will affect whether it is realised.

Uncertainty issues

Estimates of costs and benefits should include indications of the confidence levels pertaining to the estimate, and all assumptions made in the estimation.

As noted, sensitivity analysis should be undertaken for variables likely to affect the overall balance of costs and benefits (see later section on combining risks, costs and benefits). Where variable controls are likely to be applied, it may be appropriate to undertake sensitivity analysis for various levels of control.

Evaluation

In reviewing applications, ERMA New Zealand staff and external reviewers will want to be assured that the applicant has adopted a thorough and systematic approach to assessing costs and benefits. The following questions should be asked.

Questions

- Has the applicant assessed all the identified direct costs associated with the application (ie capital costs, labour costs, and running costs)? Are these estimates realistic?
- Has the applicant assessed all the identified direct benefits accruing? Is this assessment realistic given current knowledge? Are the assumptions valid?
- Have any direct non-monetary costs been assessed?
- Have any direct non-monetary benefits been assessed? Is the assessment realistic and is there credible evidence to back up this assessment?
- If human health benefits are included, is there any danger of double counting? What evidence is there of the likelihood of these benefits being realised?
- Are there any relevant indirect or secondary costs and benefits flowing from this application? Is an assessment necessary?
- Has the applicant indicated how likely it is that the proposed benefits will eventuate?
- Where the main benefit is scientific benefit, can an evaluation of the value of the research be made?

Appendix E contains an example of the assessment of costs and benefits.

Section 5
Combined Consideration of Risks, Costs and Benefits

Risk-cost-benefit analysis

Fundamental to the ERMA decision-making process as detailed in the *Methodology* is the need to balance **risks and costs** against **benefits** (see the generic decision path in Section 1). In summary, if risks are negligible and there are no costs to third parties, then the fact that the applicant is making an application will be accepted as evidence of benefit, and the Authority will not undertake a risk-cost-benefit analysis[5]. In all other circumstances the Authority will balance risks and costs against benefits.

Risk-cost-benefit analysis is not a precise science and requires judgement. This judgement will be made easier if some of the risks, costs, and benefits can be combined.

From the applicants perspective it will be important to make sure that data is presented clearly, that where data has been combined, there is good justification for the combination process, and sensitivity analysis has been used to show how variations in parameters affect the overall combination.

There are a number of ways in which risks, costs and benefits may be combined to simplify the analysis:

- risks may be calculated as expected values and included within economic cost-benefit analysis as costs
- monetary costs and benefits may be combined using economic cost-benefit analysis.

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 be calculated with reasonable certainty. Where there is high uncertainty, sensitivity analysis should be provided.

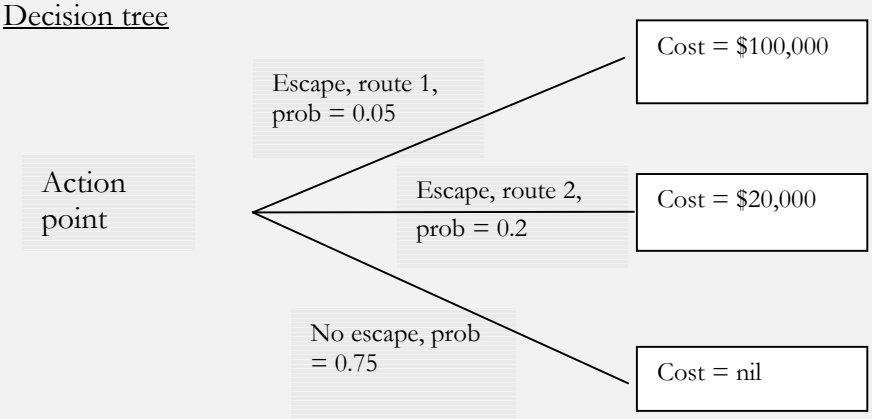
Referring to the example on the next page, if the probability of escape by route 1 were in fact in the range 0.01 to 0.10, and the probability of escape by route 2 ranged from 10% to 40%, then the range for the expected value would be $3,000-$18,000. Uncertainty in the estimate of the magnitude of the consequence (the 'cost') would increase this range.

[5] Sometimes referred to as risk-benefit balancing or social cost-benefit analysis.

Example

Consider a field trial, where there are two ways in which the organism could escape (route 1 and route 2), with different costs of clean up or remediation. Over the life of the project, there is an estimated 5% chance of escape by route 1, and the cost of remediation is estimated as $100,000. There is a 20% chance of escape by route 2, with a cost of $20,000.

Decision tree



The expected value is 0.05 x $100,000 + 0.2 x $20,000 + 0.75 x 0 = $9,000

Expected values can be incorporated directly into an economic cost-benefit analysis.

Valuation of risks, costs, and benefits is thus an important aspect of risk-cost-benefit analysis. The common ways of valuing effects on human health and environment are:

- conventional market price or effects on production
- household production function approaches (including variants such as the 'travel cost' method)
- hedonic pricing, and
- experimental markets (including contingent valuation methods).

Applicants should seek to value as many costs and benefits as possible in monetary terms. However, the application of non-market valuation approaches requires considerable expertise. It is not anticipated that non-market valuations will be used very often.

As indicated in the section on assessing costs and benefits, economic cost-benefit analysis can be used to combine monetary costs and benefits, and to calculate a **net benefit**. Appendix E gives an example of how this might be applied.

Distributional considerations will be important to the Authority not only for reasons related to fairness but also in forming a view of just how robust any claim of an overall net benefit might be. 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. As discussed earlier it will be important to

specify the timing of costs and benefits. In addition, applicants should clearly specify the geographical and social distribution of costs and benefits.

In many cases it will not be possible to estimate monetary expected values for all risks, and there may also be costs and benefits that can not be quantified in monetary terms. In these cases, information should be grouped, and where possible ranked from greatest to least.

It should be possible to group non-monetary risks, costs and benefits into the following categories, effects on:

- human health and safety
- the natural environment
- the social and cultural environment
- economic well being.

Other particular effects such as scientific benefits may require separate consideration.

Applicants should provide sufficient detail to allow risks, costs and benefits within each category to be ranked, and for ERMA to make a determination as to whether one effect dominates all others in the category. In some cases cumulative risk or synergistic risk may be an issue, and should be identified.

The balancing act

Balancing risks, costs and benefits will be a judgement based on types of effect, level of effect, distributional considerations (timing and spread), and a determination as to the likelihood of the effect being realised (including consideration of variability and uncertainty). Other factors that will be taken into account include voluntary or involuntary exposure, permanence of effect (irreversibility), and scientific and community understanding.

For containment applications (including field trials) it may be possible to reduce all risks to a negligible level by imposing stricter control, thus reducing the decision to comparing costs against benefits. The cost-effectiveness of reducing risks will need to be considered.

Example

Consider an application for a field trial for genetically modified barley. The application includes provision for bird netting. There is considered to be a risk of pollen escape from bees. This risk can be reduced to a negligible level by requiring the crop to be fully tented. The cost of tenting (as opposed to netting) may reduce the level of benefits from the trial so that it is no longer cost effective (to the applicant).

Controls cannot be applied to release applications, therefore risks cannot be reduced.

Appendix F provides an example of a template for use in the summary presentation of risks, costs and benefits. More detailed information will be needed to support this summary including details of variations in effects over time and sensitivity analysis.

The following questions are suggested as a partial checklist.

Questions

- Have any risks been calculated as expected values and included as costs? Are the assumptions made adequately justified?
- Have costs and benefits been combined as net benefit? Have time sequences for cost and benefit streams been included? If not, is there any justification for why these are not required?
- Is there evidence of sensitivity analysis for costs and benefits? Has the sensitivity analysis taken account of the worst case and the best case scenarios (particularly in calculating a net benefit)? Have Net Present Values been calculated? If so, are the time frame and discount rate appropriate?
- Have risks that have not been calculated as expected values been grouped and ranked? Is the ranking justified/valid?
- Have non-monetary costs and benefits been adequately justified. What certainty is there that they will be realised? Have they been grouped and ranked?
- Has attention been paid to areas where there may be expected to be cumulative risk?
- Have acute and chronic risks been addressed, and has consideration been given to risks that may have a long-term (or delayed) impact?

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Appendix A: Identification of Risks

Brief 'name' of risk	Source of risk	Elements at risk	Method used to identify risk	Is risk subjected to a full assessment? If **yes**, note cross-reference to summary of assessments If **no**, briefly explain why risk is considered to be insignificant

Appendix B: Areas of effect from the *Methodology*

Sections 9,10,11 of the *Methodology* (ERMA 1998a) notes that the Authority will take into account risks, costs and benefits relating to the safeguarding of the life supporting capacity of:

- air
- water
- soil, and
- ecosystems.

More specifically the Authority will consider risks, costs and benefits relating to:

- the sustainability of all native and valued introduced flora and fauna
- the intrinsic value of ecosystems
- public health
- the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga
- the economic and related benefits to be derived from the use of a particular hazardous substance or new organism
- New Zealand's international obligations
- (for a hazardous substance) the likely effects of the substance not being introduced.

For every application relating to a new organism the Authority shall in addition evaluate the information provided on the risks, costs, benefits, and any other impacts, which relate to:

- significant displacement of any native species within its natural habitat
- significant deterioration of natural habitats
- significant adverse effects on human health and safety
- significant adverse effects on New Zealand's inherent genetic diversity
- the ability of the organism to establish an undesirable self-sustaining population anywhere in New Zealand
- the ease with which the organism could be eradicated if it established an undesirable self-sustaining population
- the ability to cause disease, be parasitic, or become a vector for human disease, animal disease or plant disease.

For applications relating to a hazardous substance, the Authority shall in addition evaluate information that addresses the effects of the substance through its life cycle and the risks, costs, and benefits flowing from the following characteristics associated with the substance:

- explosiveness
- flammability
- capacity to oxidise
- corrosiveness
- toxicity (including chronic toxicity)
- ecotoxicity with or without bio-accumulation
- any one or more of the above properties generated when the substance comes into contact with air or water.

Appendix C: Risk assessment methods

Risk assessment methods vary according to the types of risks being assessed. This guide does not include detailed discussion of the specific methods used for risk assessment, since some of these are the subject of separate technical guides.

Typical technical methods for risk assessment include various forms of statistical analysis, fault tree and event tree analysis, and extrapolation. There may be some overlap between methods used to identify risk, and those used to assess risk.

Technical risk assessment concentrates on estimating the likelihood of (adverse) events occurring and the magnitude of the consequences if the event does occur. Likelihood and magnitude are calculated separately and then combined in different ways depending on whether the measured information is qualitative or quantitative.

Risks to human health

Risks to human health use human health risk assessment methods and epidemiological and toxicological studies. (More detailed information on this subject is contained in a separate technical guide *Assessment of Effects of Hazardous Substances and New Organisms on Human Health*, ERMA, 1999b.)

Health risk assessment generally follows a four-step process (National Research Council 1983):

- hazard identification
- establishment of dose-response relationships using laboratory experiments or epidemiological studies
- exposure assessment including pathway analysis
- risk characterisation, or the combining of information to estimate the risk associated with each exposure scenario.

Typically, the risk estimates obtained are then compared against standard levels of acceptable risks set by regulation or common practice. These tend to be measures such as increased numbers of cancers, reduced life expectancy, and expected number of deaths.

Ecological risk assessment

Ecological risk assessment methods and ecotoxicological studies are used to assess risks to ecosystems. (A separate technical guide on ecological risk assessment is being prepared.)

Ecological risk assessment requires estimates of probability of harm to plant and animal life, and to ecosystem integrity. Ecological risk assessment has three phases (USEPA, 1998):

- problem formulation (risk or hazard identification)
- analysis (including receptor identification, exposure assessment, and toxicity assessment)
- risk characterisation.

The relationship between these steps in shown in Figure 1.

Ecological risk assessment requires the specification of a relationship between stressors (physical, chemical or biological entities that induce adverse response) and receptors (ecological entities exposed to the stressors). Risk estimates are derived and measured against ecological endpoints.

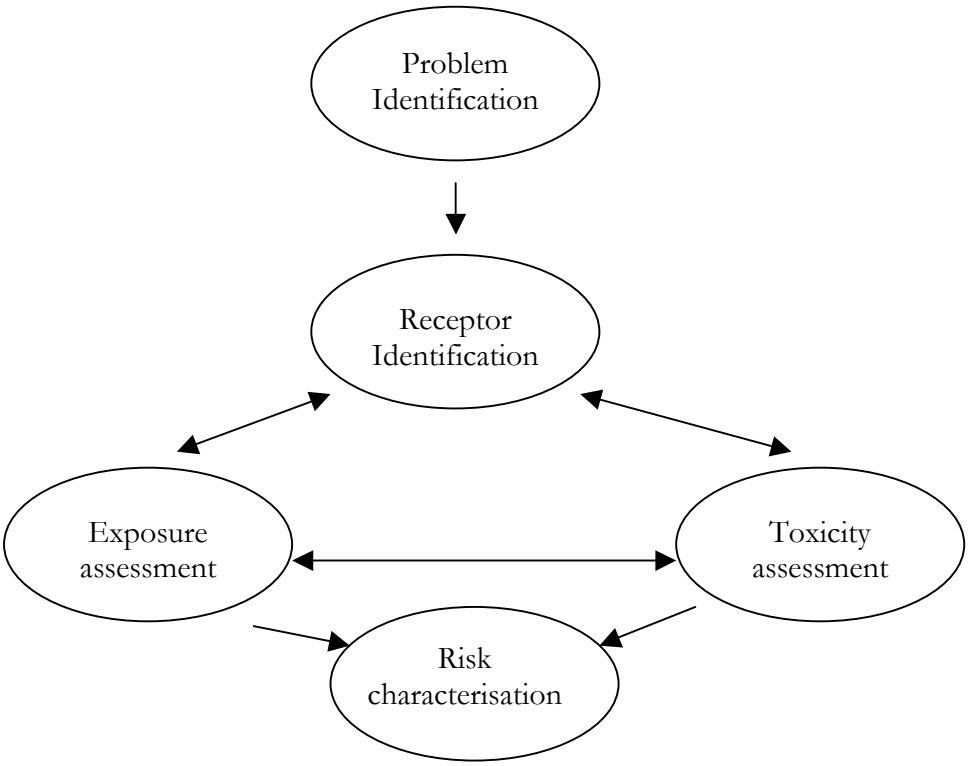


Figure 1: Components of an ecological risk assessment (source: Vic EPA, 1997)

Appendix D: Qualitative Assessment

Adapted from Australian and New Zealand *Risk Management AS/NZS 4360:1999*

These are **examples only**, and descriptors should be derived for each individual case. The number of categories in each case will vary and should be suitable for the particular application. In particular the number of **levels of risk** should reflect the quality of the information.

Qualitative assessments use words to describe the probability or likelihood of the adverse effect occurring and the magnitude, or a measure of the severity of that adverse effect. These are combined to form a qualitative estimate of the level of risk. Three sets of word scales are used.

Qualitative measures of likelihood

Level	Descriptor	Description
A	Very unlikely	Not impossible, but only occurring in exceptional circumstances
B	Unlikely	Could occur, but is not expected to occur under normal conditions
C	50% likelihood	Equally unlikely/likely, mean chance
D	Likely	Will probably occur at some time
E	Very likely (almost certain)	Is expected to occur

Qualitative measures of consequence or impact

Level	Descriptor	Example detail description
1	Minimal	Mild reversible adverse effect on health affecting 1-2 people (eg minor skin damage), highly localised and contained environmental impact (eg spillage on to soil, but not reaching waterway)
2	Minor	Up to 10 people suffer mild reversible adverse health effects, localised and contained environmental impact (eg reaches small waterway, but able to be cleaned up)
3	Moderate	More than 10 people suffer reversible adverse health effects, measurable damage to an aquatic ecosystem (such as a small stream or lake)
4	Major	Significant irreversible adverse health effects affecting up to 10 people and/or more than 10 people suffer serious reversible adverse health effects, irreversible damage to localised ecosystem but no species loss
5	Massive	Significant irreversible adverse health effects to more than 10 people extensive irreversible environmental effects, including species loss

Measures used should reflect the needs and nature of the organisation and activity under study.

Using these two tables, an additional two-way table representing a level of risk (combined likelihood and measure of effect) can be constructed. This table is specific to the particular situation or activity and can be used to rank and group the risks.

Qualitative risk analysis matrix: level of risk

	Consequence				
	Minimal	*Minor*	*Moderate*	*Major*	*Massive*
Likelihood	1	2	3	4	5
A (very unlikely)	I	I	M	H	H
B (unlikely)	L	L	M	H	E
C (moderate)	L	M	H	E	E
D (likely)	M	H	H	E	E
E (very likely)	H	H	E	E	E

I=Insignificant risk M = Moderate risk E = Extreme risk

L = Low risk H = High risk

This table is deliberately asymmetric. Greater weight has been given to the magnitude of effect component because of the uncertainty as to what might happen, and the potential for irreversible outcomes. In different circumstances other rules may be used.

Appendix E: Example of Assessment of Costs and Benefits

New organism release, biocontrol agent

Application to release a new organism as a biocontrol agent. The organism is a parasitoid that 'infects' a mite that affects citrus crops, and which is expensive to control by chemical means. While there is no evidence that current methods of control are becoming any less effective, there is some concern that within five years growers will have to stop using the current chemical control because of international pressures. There are other chemicals available, but they are less effective, and even more expensive.

Five years ago a study showed that uncontrolled orchards lost 30% of their crop to the mite.

Overseas experience (evidence provided) shows that in Australia, four years after release, the parasitoid was established in 60% of the crop (year 1: 10%, year 2: 25%, year 3: 50%). It was also estimated that by year 4, 50% of mites had been destroyed. These numbers were based on the results from a simulation model that used data from 10 test orchards. There has been limited verification of the model (in two other orchards).

The mite is also established in Japan and California, but there is no numerical data available (verbal reports from orchardists indicate that they believe it is successful).

Table E1: Direct monetary costs $m

	Year 1	Year 2	Year 3	Year 4	Year 5	Uncertainty / variability	Costs borne by
Rearing, distribution and establishment	0.1	0.05	0.2	0	0	+/- 10%	Applicant/ Growers

Table E2: Direct monetary benefits $m

	Year 1	Year 2	Year 3	Year 4	Year 5	Uncertainty / variability	Benefits to
Increased production	1.3	5.2	17.3	17.3	17.3	+/- 20%	Applicant/ Growers
Reduced pesticide costs	0	1.0	2.0	3.2	3.9	+/- 20%	Applicant/ Growers
TOTAL	1.3	6.2	19.3	20.5	21.2		

Basis for figures: 10,000 ha producing 5 tonnes/ha and $500/tonne (base figures). In year 1, the model predicts an increase of 5% (ie from $2.5m to $2.6m), in year 2 a further 15%, and in year 3, 40% - this increase is expected to continue to rise, but for the purposes of this analysis it is kept as constant.

Pesticide costs for the current year are estimated as $500 per ha (total $5m). Pesticide use is expected to be at the current level for the first year, to reduce by 20% in the second year, by a further 25% in the third year, and 40% in years 4 and 5, levelling off at about 20% of current usage (remember that a replacement needs to be found anyway).

A survey of orchardists and Accident Compensation Commission data show that on average 400 man days per year are lost to illness related to spraying (all chemicals). It is estimated that 5% are due to the chemical used to control the mite, that is 20 days. It is assumed that the reduction of sick days builds up slowly from 0 to 20 days over a five-year period (0, 3, 7, 13, 20). Table E3 shows the monetary valuation of this indirect benefit.

Table E3: Indirect monetary benefits $m

	Year 1	Year 2	Year 3	Year 4	Year 5	Uncertainty / variability	Benefits to
Reduced sick days	0.0035	0.0035	0.0035	0.0035	0.0035	+/- 30%	Applicant/ Growers

Using these costs and benefits, and assuming that they stabilise after five years, the Net Present Value (NPV) for a 20-year planning horizon can be calculated. The following table shows the variation in the NPV where three scenarios are given, where the 'low' and 'high' scenarios are calculated using the variability estimates given for costs and benefits. Three discount rates are used.

Table E4: NPV

NPV $m	Low	Mean	High
Discount rates			
5%	183.27	229.13	274.99
10%	118.22	147.82	177.42
15%	81.69	102.15	122.60
% difference from central (147.82)			
	-24.0	-55.0	-86.0
	20.0	0.0	-20.0
	44.7	30.9	17.1

Benefits not able to be measured in dollar terms are identified as:

- improved integrated fruit production
- decreased insecticide resistance, lower environmental pollution, increased overseas consumer confidence in NZ 'clean green' image
- significantly increased opportunities for organic production
- less chance of spray drift affecting neighbouring properties.

Indirect benefits:

- Economic benefit of improved industry returns.

Alternative scenario

If the parasitoid is not released, then the direct costs of mite control will increase slightly from the current baseline of $5m/year for five years (10% per year – as slight resistance develops), then significantly (ie by 50%) as the current chemical is replaced. It is expected that the chemical will be discontinued in five year's time, but external pressures may mean that it is still available for a further five years. No estimate of the likelihood of it being phased out in five years is available, a 'guestimate' suggests 60-70% chance. The alternative (baseline scenario) therefore postulates that the current chemical is phased out at year 8. Pesticide costs increase by 50% and this is maintained for the 20-year period.

Table E5: Pesticide costs (alternative scenario) $m

YEAR	1	2	3	4	5	6	7	8	9	10
Mite control	5.00	5.25	5.51	5.79	6.06	6.38	6.70	10.05	10.05	10.05

If these costs are substituted for the reduced pesticide costs in Table E2, then Table E2 can be rewritten as:

Table E6: Revised Total Monetary Benefits $m

YEAR	1	2	3	4	5	6	7	8	9	10
Increased production	1.3	5.2	17.3	17.3	17.3	17.3	17.3	17.3	17.3	17.3
Reduced pesticide costs	0	1.3	2.5	4.0	5.0	5.3	5.6	9.0	9.0	9.0
TOTAL	1.3	6.5	19.8	21.3	22.3	22.6	22.9	26.3	26.3	26.3

This represents a comparison with a baseline scenario.

The revised NPV for a 20-year planning horizon and 10% discount rate (mean scenario) is $170m (increased from $148m).

Appendix F: Template for the Summary Presentation of Risks, Costs and Benefits

Beneficial Effects						
	Name of effect (or other identifier)	**Best estimate**	**Uncertainty range**	**Spatial distribution**	**Temporal distribution**	**Who benefits?**
Direct Monetary Benefits						
Sub-total						
Direct Non-Monetary Benefits						
Indirect Benefits						
Adverse Effects						
	Name of effect (or other identifier)	**Best estimate**	**Uncertainty range**	**Distribution in space**	**Distribution over time**	**Who bears the cost?**
Direct Monetary Costs						
Sub-total						
Direct Non-Monetary Costs						
Indirect Costs						
Risks						

Impact of Risk Management (risks only)

Name of risk (cross reference from above)	**Is risk management applicable? (yes/no)**	**To what degree can the risk be reduced by risk management?**	**Method of risk management**
		(cross reference across columns) →	

Notes:

1. 'Best estimate' should be expressed in $NZ dollar terms for the direct monetary costs and benefits category but may be expressed in qualitative terms with respect to the other categories. The best estimate of any risks should include an estimate of the likelihood of occurrence and the magnitude of the possible adverse effect.
2. Uncertainty estimates may be expressed in either quantitative or qualitative form.