ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

Identifying Risks

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 will be authored by a member of staff, but in other cases, there may be an external author.

This guide will be updated from time to time and is relevant for applications to:

- import or manufacture a hazardous substance
- import or manufacture a hazardous substance in containment
- import, field test in containment, or release from containment a new organism (including genetically modified organisms) (GMOs)
- import or develop a new organism (including GMOs) in containment
- reassess an approved hazardous substance.

Acknowledgement

Some of the information in this guide is based on the Standards Australia and Standards New Zealand Environmental Risk Management Handbook (in preparation), and the Guidelines for Managing Risk in the Australian and New Zealand Public Sector (Standards Australia and Standards New Zealand, 1999).

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INTRODUCTION

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
- Maori values
- economic benefits
- international obligations.
- the reasonably foreseeable needs of future generations.

In addition, 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 is risk identification?

Identifying risks is a critical step in risk management. If risks are not identified, they cannot be assessed or managed.

Risks arise because of interactions between people, their activities, and the general social and physical environment. Comprehensive risk identification requires a combination of lateral thinking and a rigorous structured analysis of the organism or substance. A range of experience and understanding is important and in many cases, risks can be best identified by a group rather than an individual.

Risks 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 HSNO Act and the methodology. Establishing the context is an important first step in identifying risks. Once the risks have been identified, they can be assessed or analysed.

Risk identification and risk assessment are closely linked and so this guide includes an overview of the requirements of risk assessment. Risk assessment is covered in more detail in other ERMA New Zealand technical guides.

Key terms

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

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

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

Risk identification is the process used to define potential events by determining what can happen, why and how (ISO, 1998)[1]

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 New Zealand, 1998)[2].

Effects are defined outcomes (ERMA New Zealand, 1998) and include potential or probable, positive or adverse, past, present or future, acute or chronic, and cumulative effects (Section 2, HSNO Act 1996).

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[1] Notes from the ISO definition below are not necessarily relevant in this context.

Note 1. Risk identification is often referred to as hazard identification in a [health and] safety context

Note 2. Events may have either positive or negative consequences.

Note 3. Risk identification may also include information to indicate relevance, such as likelihood, consequences, stakeholder concerns, etc.

In this guide 'risk' and 'hazard' are considered to be different as defined above, and hazard identification is seen as a part of risk identification.

[2] **Risk assessment** in the ERMA New Zealand context is therefore equivalent to the process of **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).

Overview of contents

Section 2: Risk management

This section is an overview of the risk management process and where risk identification fits within it. It emphasises the importance of risk identification and the necessary links with other parts of the process.

Section 3: Specifying or establishing the context

This section stresses the importance of the context in the process of risk identification. There are three aspects to establishing the context for risk management: the organisational context defined by the Methodology and the HSNO Act; the strategic context relating to the objectives of the applicant; and the risk management context relating to the application itself and the particular new organism or hazardous substance.

Section 4: Identifying risks

This is the main section and is a guide to how risks may be identified, what should be in a formal risk identification, and the criteria for evaluating risk identification.

Section 5: Assessing risks

Risk identification and risk assessment are closely linked and so this guide has an overview of the requirements of risk assessment. Risk assessment is covered in more detail in another ERMA New Zealand technical guide.

Appendix A is an example of a risk register showing risks identified. It has been adapted from AS/NZS 4360: Risk management.

Appendix B shows the differences between qualitative, quantitative and semi-quantitative risk assessment. It is also derived from AS/NZS 4360. During the risk identification stage, approaches to the subsequent risk assessment should be considered.

Appendix C has brief descriptions of particular techniques used to identify risks.

Appendix D is a set of risk identification guidelines or templates for identifying risks associated with applications for new organisms. Four templates are provided:

- new organisms in containment
- new organisms for release
- genetically modified organisms in containment
- genetically modified organisms for release.

Templates for hazardous substances have not yet been included. A user guide for the application forms will have more information.

Appendix E has more specific examples of the type of information that might be required.

RISK MANAGEMENT

The risk management process is defined in the Australian and New Zealand Standard (AS/NZS 4360: Risk Management) as: 'the systematic application of management policies, procedures and practices to the tasks of establishing the context, identifying, analysing, evaluating, treating, monitoring and communicating risk'. This is an ongoing process with frequent interaction between the steps.

Figure 3.1 from the revised standard is reproduced below. ***Risk assessment*** as used in the Methodology is equivalent to the step 'analyse risks'.

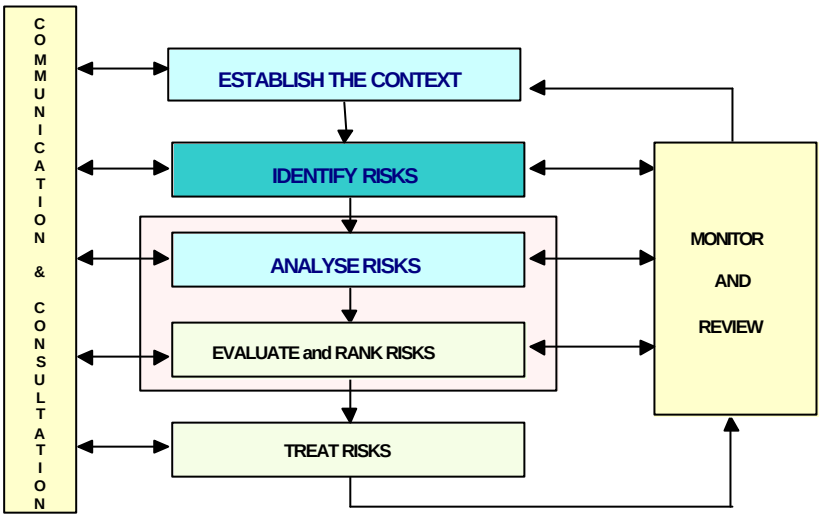

Figure 1: Risk management process

Identifying risks is a critical step in risk management. If risks are not identified, they cannot be assessed or managed. The methods used to assess or analyse risks vary according to the types of risk (source and consequence), but the general processes of risk identification and hazard identification are common to all types of risk.

Before identifying risks, the context must be established. Context includes the organisation context, the strategic context, and the risk management context.

The risk management and strategic contexts are important because context determines what types of risks will be considered. Identifying risks is not a stand-alone exercise. Risks arise because of interactions between people, their activities, and the general social and physical environment.

SPECIFYING OR ESTABLISHING THE CONTEXT

Establishing the context is an important first step in identifying risks. It is similar to the problem definition step in formal systems analysis (Wagner, 1969) and means establishing responsibilities, and setting scope and boundaries for identifying risks.

In particular, it 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, how the substance or organisms will be contained)
- 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).

There are three components of context within the risk management process: the organisational context, the strategic context, and the risk management context.

> The **organisational context** is provided by the Methodology and the HSNO Act. Specifically, the application forms provide the framework for ensuring that the applicant operates within the required organisational context.
>
> 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)[3].
>
> The **risk management context** relates to the particular new organism or hazardous substance that the application is for. 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 release.

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

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[3] Identifying stakeholders and interested parties is important. For applications where there is likely to be a significant public interest, applicants may choose to identify possible submitters and enter discussions with stakeholders at an early stage with a view to resolving conflict.

The following list of questions has been drafted as a prompt to help reviewers and applicants decide whether the context for identifying and assessing risks has been adequately addressed, and whether there is sufficient background information to show that the context has been appropriately scoped.

Questions

- What are the major outcomes expected? What might happen and how?
- Is it possible to estimate dollar values for the outcomes? Is it possible to measure the outcomes in other units?
- What are the major threats and opportunities the application presents?
- What are its strengths and weaknesses? Who are the stakeholders and interested parties? Can they be involved in the risk identification process? Can they be engaged at an early stage?
- Are there any significant factors in the applicant's internal and external environment that might affect the outcomes? (consider the broader context of the application and any geographical, economic, political, environmental, social and technological factors that might influence outcomes)
- What are the most appropriate risk criteria (derived from Sections 5, 6, & 8 of the HSNO Act)? Are these criteria measurable? If not, are there any appropriate surrogate measures?
- How much is known about the science of the application – is there uncertainty about the science relating to the risks, costs and benefits?
- What is the best way of structuring the risk identification task?
- What types of tools are available for identifying risks?

These questions will also be useful for identifying costs and benefits.

IDENTIFYING RISKS

Overview

Identifying risk is a systematic analysis of all the possible impacts of the substance or organism on the natural environment (ecosystems), people, and communities. In the context of the HSNO Act and the Methodology, risk identification must consider all possible impacts of the substance or organism on the natural environment, people and communities. This means considering the sources or origins of the risk and the individuals or population at risk, as well as defining the conditions of exposure to the hazard. Pathways between the sources of risk and the elements at risk should be identified[4]. In some cases, risk identification is separated into two steps reflecting cause and effect, namely hazard identification and identification of consequences (Ministry for the Environment, 1995).

The widest possible range of risks must be identified and applicants will be encouraged to demonstrate that they have conscientiously considered obvious and non-obvious risks. Risks that are not under the control of the applicant should also be included.

Applicants should state the method used to identify risks, including the identification **of sources of risk** and **elements at risk** (impact), and present the material in a systematic format.

For containment applications, control measures (physical and procedural) may significantly reduce the likelihood or the consequences of adverse effects. A common way of doing this is to specify measures that restrict the exposure pathways. However, the impact of the consequences of the breakdown of these controls or barriers must be well understood. Therefore, when identifying risks applicants should consider and identify risks both with the proposed controls in place, and in the absence of controls.

In many circumstances, there may be considerable uncertainty associated with the set of possible outcomes. The objective of the risk identification therefore must be to examine carefully all possibilities of harm regardless of the likelihood of occurrence.

The Environmental Risk Management Handbook (AS/NZS, 1999b) notes that examples of common approaches to identifying risks fall broadly into four categories:

Comparative methods

Examples of comparative methods include reviewing historical data and previous experience, and developing checklists. Information may be obtained from other countries' experience, and from a comparison with substances and organisms with similar characteristics.

Structured methods that raise a series of 'what if' questions

An example of this type of approach is HAZOP analysis (Hazards and Operability Analysis) which is widely used and recognised as a preferred approach to analysing process hazards by the chemical process industries. HAZOP analysis is the process of systematically identifying every conceivable deviation from the design intent, all possible abnormal causes, and adverse hazardous consequences that can happen in a chemical plant. Versions of HAZOP can also be used in

[4] If there are no exposure pathways then the hazard cannot give rise to a risk. Controls may concentrate on eliminating particular pathways (e.g. preventing GM crops from flowering and producing pollen). Applications to release a new organisms will not have controls and therefore all pathways are feasible.

environmental risk analysis and are highly amenable to containment applications. HACCP (Hazard Analysis Critical Control Point) is another systems based technique used in the food industry that links hazards to critical parts of a typical production system.

Inductive reasoning techniques

Techniques such as event trees and fault trees are commonly used to identify risk (as well as to assess risk). These are scenario approaches to risk identification since although the object is to examine all possibilities, in practice it is likely that some options will be either overlooked or ignored. Although not perfect, they provide careful systematic approaches, which can be easily applied to a variety of situations.

Other techniques that can be applied to specific problems

Specific techniques may include brainstorming, Delphi techniques and custom modelling. Brainstorming can be particularly important in situations where little is known about the significance of risks (see Appendix C). It should be used systematically, and involve a number of people with varying knowledge and expertise.

Risks are identified within the context established in the first step of the risk management process. If the context is not specified comprehensively or correctly, the risks may not be properly identified. The methods used to identify risks, as well as the risks identified, should be recorded in a **risk register** (see Appendix A). Where risks have been discarded as not requiring further analysis, they should be documented along (where practical) with the reasons why they do not need further analysis.

Appendix D contains a set of guidelines or templates for new organisms, and Appendix E includes some examples of more specific questions for particular applications.

Risk identification process

Risk identification involves examining all sources of risk and areas of impact.

Each source of risk must be identified so that the analysis can consider the contribution each makes to the likelihood and the consequences of the risk (the adverse effect). Risk assessment may concentrate on one or many possible areas of impact, but risk identification should address all sources and possible areas of impact.

Meaningful and reliable information is important in identifying risks and in understanding the source and the areas of impact. Since risk identification is frequently done with risk assessment, in its preliminary stages it may not always be possible to have the best or complete information. A ‘first pass’ will identify where there are information gaps that may need to be filled in if there is evidence that risks may exist. However, it should be as relevant, comprehensive, accurate and timely as resources will permit.

People doing the risk identification must understand:

- the policies and procedures of the applicant organisation
- the requirements of the HSNO Act and the Methodology
- the science of the application
- any intended controls.

Very few people may understand all of these elements and a group may need to be formed to identify the risks.

Possible sources of risk (this is not an exhaustive list)

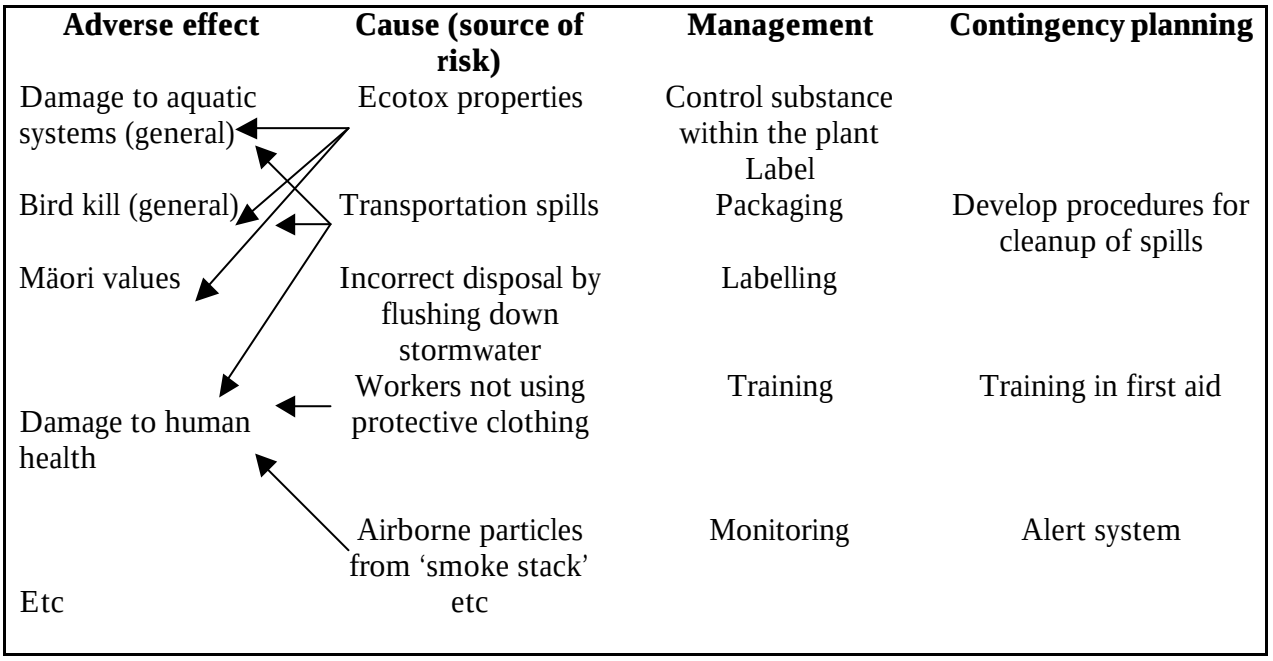
- the nature of the science or technology (whether the processes and/or the outcomes are well-known)
- human behaviour (affecting management or containment procedures)
- socio-economic issues
- political and legal issues
- commercial and legal relationships
- financial or market aspects
- management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

Possible areas of risk effect (from the HSNO Act and Methodology)

- ecosystems
- people
- public health
- community and culture
- performance: how well the activity is performed
- timeliness.

Identifying risk means generating a complete list of events that might be associated with the activity posed by the application (brainstorming, Delphi, checklists etc), and identifying possible causes and scenarios ('what if' analysis, decision trees etc).

The figure below shows a typical (simplified) relationship between source and impact, for a hypothetical substance. The primary source of risk is that it is toxic to fish and birdlife.



Common ways to identify risks

- personal or past agency experience
- common sense assessment
- local or overseas experience
- brainstorming
- analogy to known cases
- history, failure analysis
- Delphi technique
- consultation, interview/focus group discussion (stakeholder consultation)
- checklists
- safety audits or physical inspections
- scenario analysis, decision trees (including fault trees and event trees)
- epidemiological surveys
- experiments and tests of product performance
- strengths, weaknesses, opportunities and threats (SWOT) analysis
- flow charting, systems analysis, systems engineering techniques
- databases of incidents
- HAZOP studies.

Source: AS/NZS 1999b, AS/NZS 1999c.

Not all the techniques listed can be used universally and their suitability for any given circumstance will be a matter of expert judgement. Appendix C has a brief description of these approaches.

Key questions

- When, where, why, how are the adverse effects likely to occur, and who might be involved?
- What is the nature of the adverse effect?
- What is the source of each risk?
- What are the consequences of each risk?
- What are the exposure pathways?
- What is the potential cost of each risk (and what units can it be measured in)?
- What are the controls that are proposed for mitigating the risks?
- What are the accountability mechanisms - internal and external?
- Is there a need for research into specific risks? If so, what is the scope of this research, and what resources might be needed to carry it out?
- How reliable is the information on hand?
- What are the stakeholders' expectations? Are these relevant?

The identified risks should be documented as part of the application. The methods used to identify risks should also be noted (along with any verification). In cases where risks are deemed too small to need further consideration, they should be documented in case changes in circumstance affect their significance or contribution to overall risk.

The Authority may request further information and evidence of a full documentation of risks.

At the very least, a register should be maintained containing the name of the risk, a descriptive summary, its source and its consequence, and any known control methods. Appendix A has an example of a risk register.

Example: Application to import and release a new type of fruit tree[5].

Possible sources of risk:

- The tree may spread rapidly and be an aggressive competitor.
- The leaves of the tree may be poisonous to some insects, birds or animals.
- The tree may be known to be susceptible to particular disease or pest infestations.

[5] Establishment of the context will include consideration of whether the tree is a new organism or not.

Possible consequences:

- The tree may infest roadsides and fringes of waterways (cf. apples and plums).
- Insects required for pollination of other fruit trees may be affected.
- Ecosystems may be adversely affected through grasses being unable to grow under the trees.
- Other species may be affected through the tree being a host for disease or pests.

Since the application is for release there will not be any controls on the activity. Therefore, there will be a direct link between sources of risk and areas of impact. However, natural barriers may restrict the exposure pathways, for example, climate may restrict geographical spread, or the presence of native or naturalised species may inhibit growth.

Containment and controls

Risk identification should address risks with and without controls. Containment applications specify containment and controls designed to minimise the likelihood of escape or adverse effects, or to mitigate the consequences of the risks[6]. As part of the risk assessment process, applicants should identify both the likelihood of containment being breached or controls not being adhered to, and the magnitude of the consequences of the adverse effects if this happens.

Questions

- What could happen if containment is breached?
- What could happen if the controls are not adhered to?
- Are there any backup systems in place?
- What sort of backup systems would be useful, and would they be cost-effective?

Example: **Application to develop a new herbicide in containment**

Possible sources of risk:

- The conditions placed on testing may be difficult to implement or not feasible in practice.
- The herbicide may be easily airborne.
- The effect on non-target species may not be known.
- Access to the testing area maybe difficult to control.

[6] In addition to containment provisions proposed by the applicant the Authority will specify controls based on the 3rd Schedule (new organisms) or the properties of the substance.

Possible consequences:

- People working in the containment area may not use the required protective clothing.
- The herbicide may escape to the general environment and damage nearby crops.

Evaluating the quality of the risk identification

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 identifying risks. The following questions should be asked

Questions

- Has a systematic approach to identifying risks been demonstrated and documented?
- Has the applicant stated clearly what approach was used, and why?
- Is the context in which risks have been identified clear?
- Is the context consistent with the requirements of the Act and the Methodology?
- Does the identification consider 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?
- Have all obvious sources of risk (and stressors) been considered?
- Have all targets (receptors) been considered?
- Have the possible consequences been widely scoped?
- Have all pathways been considered?
- Has the applicant included in the documentation risks or sources of risk that have been considered and discounted?

ASSESSING RISK

Overview

Risk is assessed by combining estimates of likelihood and consequence[7]. Risk assessment (or risk analysis) is often considered together with risk identification[8], and informal risk assessment may be done during the risk identification to determine whether a further (full) analysis of risks is required.

Risk estimates used for assessment or analysis may be qualitative or quantitative. The methods used to estimate the risks should be specified, and if required, be able to be justified by reference to common practice, accepted science, or use in other jurisdictions.

Risk assessments should take account of the scope for managing risks through controls (and modifications of controls) specified in the HSNO Act and the regulations under the Act.

The degree of accuracy of the estimates should reflect the level of risk posed.

Both the magnitude and probability of the adverse effect need to be described for a risk to be properly assessed. In some cases, the likelihood or probability may depend on a complex pathway between the source of the risk and the adverse effect. In these cases a probability analysis, such as those used in fault trees and event trees, may be used to calculate probabilities.

Risks should be assessed in terms of the relevant characteristics identified in the Methodology and an assessment made of the degree to which that characteristic is present. (It may be convenient to use a scale of 1 to 5, with 1 for not applicable and 5 completely applicable.)

The Methodology states that the risk characteristics considered should at least include the:

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

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. This section concentrates on some of the generic elements of risk assessment that are linked directly to risk identification.

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[7] The third step in the risk management process is risk analysis, or using the ERMA New Zealand Methodology terminology, risk assessment.

[8] The standard approach to health risk assessment explicitly includes hazard identification as part of the assessment. Process. Risk identification as discussed here becomes a scoping process undertaken before the formal integrated identification and assessment.

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 entitled "Assessment of Effects of Hazardous Substances and New Organisms on Human Health".)

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. Under the HSNO process the Authority will establish acceptable levels of risk based on a risk-cost-benefit analysis.

Ecological risk assessment

Ecological risk assessment methods and eco-toxicological 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.

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

Risk assessment process

A preliminary study of sources of risk and consequences will have been done as part of the risk identification step. The risk assessment needs to address some (but not all) of these in more detail.

At the least, reference should be made to:

- scoping (defining the boundaries of the analysis and determining whether it should be quantitative or qualitative)
- scenario construction (detailing the concerns)
- stakeholder identification
- identifying stressors
- identifying targets or receptors under threat
- defining exposure pathways.

The choice of quantitative or qualitative analysis will depend on:

- the type, quantity and quality of the data available
- the estimated severity of the risk
- known variability
- the degree of uncertainty
- the purpose of the application.

Where quantitative analysis is not possible (or appropriate), the use of a risk matrix (see AS/NZS 4360 Appendices) based on the use of some qualitative (or adjudged) measures of likelihood and consequence may be used.

Qualitative analysis uses word form or descriptive scales to describe the likelihood of each event arising and its consequences. These scales can be adapted or adjusted to suit the circumstances and different descriptions may be used for different risks. Typically, qualitative methods involve the use of sampling of expert opinion, or professional judgement.

Appendix B describes the differences between quantitative, qualitative and semi-quantitative risk assessment methods.

DOCUMENTING RISK IDENTIFICATION

A completed application form is the base documentation used to demonstrate that the risk identification and assessment has been done. However, when an applicant submits an application, they will have made judgements about how much information to submit, and in what form. Often the applicant will consult with ERMA New Zealand before lodging their application.

The Authority may request additional information from the applicant to verify that a thorough and systematic approach has been followed.

Reviewers will be looking for information about the process used to identify risks, and the reasons why that process was used. The context within which the applicant has identified risks will be relevant. In some cases, the reviewer may decide that the context (which may be addressed either implicitly or explicitly) is too narrow, and that as a result the risk identification is inadequate.

The adequacy of the risk identification will, to a significant extent, be determined by an examination of the documentation.

This should include:

- the approach used to identify risks
- the reasons why that approach was used
- a description of the process followed
- a list of all the risks identified with information about source and impact
- a list of risks deemed significant enough to require further analysis[9]
- the current controls on all of the risks
- the feasibility of the controls (possibly including some sensitivity analysis)
- the possible outcomes if the controls are breached, including some preliminary contingency planning.

While not strictly part of identifying risks, where the applicant has used modelling approaches to develop levels of risks (systems models or simulation models) , the documentation should include details of:

- the assumptions and approximations made
- the sources of data
- the modelling processes used
- any uncertainties in data and in the results of analysis
- the procedures to be used for the validation of data or outcomes.

[9] Applicants may wish to detail why other risks are been deemed insignificant.

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APPENDIX A SAMPLE RISK REGISTER

Adapted from AS/NZS 4360: Risk management (1999).

For each risk identified, a risk register records

- source
- nature
- existing controls
- likelihood and consequences
- initial rating
- sensitivity to external/internal factors.

RISK REGISTER

Organism or substance

Purpose of application

Date
Compiled by

Reference / description	The risk What can happen and how can it happen? (source)		Order of magnitude of the consequences	Existing / proposed controls	Vulnerability / sensitivity / effectiveness of controls	Comment
	Likelihood level	Consequences				

APPENDIX B RISK ASSESSMENT METHODS

There are three main categories of risk assessment methods that can be used to determine the level of risk: qualitative, semi-quantitative, and quantitative. If the information is available numerically then a mathematical process may be used.

The approach most readily used tends to be qualitative. The process should be carefully structured to use judgement consistently and in the best possible way, with explicit scales for likelihood and consequences. The level of risk is determined from the relationship between likelihood and consequence, which is usually set out in a table. Applicants should construct these mapping tables taking into account their knowledge of the system and appropriate risk criteria.

Qualitative analysis
Qualitative analysis is used where the level of risk does not justify the time and resources needed to do a numerical analysis, where the numerical data are inadequate for a more quantitative analysis, or to perform an initial screening of risks prior to further, more detailed analysis.

The value of qualitative analysis is enhanced when the determination of risk is shared across a range of people with varying backgrounds and interests. One person's view may be different from another's and the contribution of many ideas may improve the usefulness of the outcome.

Semi-quantitative analysis
A semi-quantitative approach allocates numbers to qualitative word rankings such as high, medium and low, or to more detailed descriptions for likelihood and consequence. These rankings are shown against an appropriate numerical scale for calculating the level of risk.

Information can then be processed for analysis using arithmetic methods.

It is important not to interpret the results of semi-quantitative analysis quantitatively. Numbers should not be used to give an appearance of precision that does not exist.

Quantitative analysis
Quantitative analysis can be used where the likelihood of occurrence and the consequences can be quantified numerically, either directly or through systems modelling.

Sophisticated quantitative techniques often require considerable assumptions to be made, and these need to be kept in mind.

APPENDIX C RISK IDENTIFICATION TECHNIQUES

This guide refers to a list of common risk identification techniques. Some of these, for which there may not be a common understanding, are briefly described here.

Brainstorming
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 directly choose 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.

Analogy to known cases, history, and failure analysis
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 a strong case must be made to demonstrate the similarity, particularly if this is the sole method used.

Delphi technique
The Delphi procedure was developed by the Rand Corporation in 1964 to forecast time-related future events. The process is used to make decisions about a scenario by testing the opinions of a panel of members. The formal process is characterised by three features that distinguish it from other consensus-achieving group forecasts:

- the group members do not in general know each other and represent a cross-section of expertise within the forecast area
- members are informed of current consensus but not 'harassed' by arguments
- majority and minority opinions can be maintained.

The term 'Delphi' has been used loosely in a number of areas. It is used to refer to a situation where a number of experts are consulted independently. Computer programmes that apply the Delphi approach have been developed. These systems rely on the expertise of the panel and use statistical scoring systems to provide feedback to participants to indicate how close they are getting to consensus.

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.

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.

Scenario analysis, 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 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 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.

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.

Databases of incidents
Databases may be public or private.

HAZOP studies
HAZOP studies are described on page 10.

APPENDIX D RISK IDENTIFICATION GUIDELINES/TEMPLATES

Introduction

These guidelines or templates provide guidance for identifying risks associated with applications for new organisms.

The organisms include:

- crops (food, fodder, fibre etc)
- other plants
- animals
- birds
- fish
- invertebrates[10]
- parasites or biological controls
- fungi
- micro-organisms.

The guidelines are a series of questions that should be considered. Depending on the type of organism not all the questions will be relevant. They are also not exclusive and applicants should demonstrate that any other relevant matters have been considered and addressed.

Context

The applicant is expected to establish the context of the application by providing full information about the organism itself, why the application has been made, what the general costs and benefits are, and where they will accrue. Information from local and overseas trials, if applicable, will be part of the context.

The contextual information will help with examining sources of risk. General information required for the context includes the:

- purpose of the application – what are the general benefits or advantages of the organism?
- characteristics or attributes of the organism
    - origin, survival range, and what limits the survival range (temperature, growing season, habitat, rainfall etc)
    - information about food
    - whether the organism has been present in containment in New Zealand
    - closest relatives in New Zealand
    - predators
    - hosts and host specificity
    - method of reproduction. Ease/difficulty of reproduction
    - size and habits (domesticated etc).

There is an extended list of characteristics or attributes in Annex A.

[10] "Invertebrates" covers all insects including thrips and butterflies, as well as worms, spiders, mites, ticks, crustacea etc.

Applications for **release** require comprehensive information about survival range, relatives and characteristics etc, whereas for **containment** and field trial applications, less comprehensive or 'best available information' may be sufficient[11].

In establishing the context, the applicant should consider the minimum standards as specified in Section 36 of the HSNO Act which require the Authority to decline the application if the new organism is likely to cause:

- any significant displacement of any native species within its natural habitat
- any significant deterioration of natural habitats
- any significant adverse effects on human health and safety
- any significant adverse effect to New Zealand's inherent genetic diversity
- disease, or be parasitic, or become a vector for human, animal, or plant disease, unless the purpose of that importation or release is to import or release an organism to cause disease, be a parasite, or a vector for disease.

In addition the applicant should consider:

- the ability of the organism to establish an undesirable self-sustaining population
- the ease with which the organism could be eradicated if it established an undesirable self-sustaining population.

Risk identification

Identifying risks requires examining the sources of risk and the areas of impact (elements at risk).

The applicant will need to have regard to the principles and matters relevant to the purpose of the HSNO Act (Sections 5 & 6).

These principles are:

- the safeguarding of the life-supporting capacity of air, water, soil, and ecosystems
- 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.

The matters to be taken into account are:

- the sustainability of all native and valued introduced flora and fauna
- the intrinsic value of ecosystems
- public health
- the relationship of Mäori 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.

[11] Section 7 of the HSNO Act requires the Authority to take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.

Non genetically modified new organism in containment

Sources of risk – primary stressors
In all cases the primary source of risk or the primary stressor will be the organism that is the subject of the application.

Primary sources of risk	• organism habits and nature • escape from containment.

Secondary sources of risk derive from primary sources of risk. The following questions can be used to help identify secondary sources of risk (generally associated with escape of the organism from containment).

Secondary (consequential) sources of risk	**Questions**
	• What are its closest relatives present in New Zealand? • What is the method of reproduction/propagation? Are other organisms involved? • Will it displace another species? • Is it known to be toxic? • What does it eat? • Is it likely to become the prey of existing species?

In making decisions on applications for containment, the Authority is required to take into account the beneficial effects of having the organism in containment, the adverse effects should the organism escape from containment, and the ability of the organism to escape.

Areas of impact
Areas of impact are the areas or elements at risk. These are defined above by the principles and matters to be taken into account in making decisions under the HSNO Act.

In the case of applications for containment there are two aspects to each of these areas of impact:
- the effects associated with the organism in containment
- the effects if the organism were to escape.

The following questions should be asked for each circumstance.[12]

Note that information based on common best practice may be adequate whereas applications for release require stronger evidence.

Issue	Questions
Ability to escape from containment	• How could the organism escape from containment - under normal operating conditions? - as a result of abnormal conditions resulting from natural hazards? - through sabotage?

Effects or consequences	Questions
Public Health	• Is the organism known to have any adverse effects on human health, or to carry any organisms that may affect human health? What are these effects? • What testing has been done to support any assertions regarding effects on human health? • Have short term (acute) and long term (chronic and cumulative) effects been considered? • Will any products of the organism enter the food chain? If so, have these products been approved as a food in New Zealand? Overseas?
Exposure[13] (potential contact)	• How will people come in contact with the organism or its products? • Who will come in contact with the organism? Is contact restricted within the containment facility?

Life supporting capacity of air, water, soil and ecosystems (including risks to flora, fauna and ecosystems)	• Is it likely to affect any biodiversity values? • Is it known to have any adverse effect on any other species? • Where does it originate? Has it been introduced to other countries? If so, what impacts were noted, and is this relevant to New Zealand? • Which species has it been tested on? What tests were conducted? • What are its feeding habits?
Life supporting capacity of	

[12] In some aspects the risk identification is more complex for containment applications than for release applications since the two aspects of effects in containment and effects if the organism escapes have to be considered. However, the data requirements (quantity and quality) may be less since more uncertainty may be tolerated on the grounds that good containment should mean that escape is unlikely.

[13] Identifying risks requires looking at possible exposures and links between cause and effect. Risk assessment or risk analysis will address the likelihood of the exposure occurring or the risk eventuating. If there is no exposure the hazard cannot eventuate and there is no risk.

air, water, soil and ecosystems (including risks to flora, fauna and ecosystems)	• What is its preferred habitat? Has it been found in any other habitat? • Is it likely to be localised or widespread? • Is it likely to have any adverse effect on pasture? Forest? Grasslands? Other ecosystems? • In the case of a parasite or biological control what is the host range? Is it host specific? What evidence is there to support this?
Exposure (potential interaction) (see also secondary sources)	• How does it reproduce, and what factors affect reproduction? What evidence is there regarding hybridisation? • What are the closest relatives present in New Zealand? • Are there any known mutations? – cross-species reproduction?

Economic activity	• What are the likely positive effects? (potential benefits) • What are the likely negative effects? (potential costs) • What effect is the application likely to have on the international expectations and perceptions of New Zealand agriculture, or New Zealand's 'clean green' image? • What are the likely impacts on employment?

Mäori values	• Will the application have any effects that may impact on the list of issues attached as Annex B

Future generations	• Will the application have any effects that may impact on the ability of future generations to make choices? • Are the effects of the organism reversible?

Capacity of people and communities to provide for their own economic, social, and cultural wellbeing	• Will the organism have any impacts on people or communities that might affect their ability to provide for their own economic, social, and cultural wellbeing? • Will the application affect individual or community choice?

Non genetically modified new organism for release

Sources of risk – primary stressors
The primary source of risk or the primary stressor will in all cases be the organism that is the subject of the application. The activity (release) will also be a primary source.

Primary sources of risk	• organism habits and nature • release of the organism.

Secondary sources of risk derive from primary sources of risk. The following questions can be used to help identify secondary sources of risk.

Secondary (consequential) sources of risk	**Questions**
	• What are its closest relatives present in New Zealand? • What is the method of reproduction/propagation? Are other organisms involved? • Will it displace another species? • Is it known to be toxic? • What does it eat? • Is it likely to become the prey of existing species?

Areas of impact
Areas of impact are the areas or elements at risk. These are defined above by the principles and matters to be taken into account in making decisions under the HSNO Act.

Effects or consequences	**Questions**
Public health	• Is the organism known to have any adverse effects on human health, or to carry any organisms that may affect human health? What are these effects? • What testing has been done to support any assertions regarding effects on human health? • Have short term (acute) and long term (chronic and cumulative) effects been considered? • Will any products of the organism enter the food chain? If so, have these products been approved as a food in New Zealand? Overseas?
Exposure[14] (potential contact)	• How will people come in contact with the organism or its products? • Who will come in contact with the organism?

[14] Identifying risks requires looking at possible exposures and links between cause and effect. Risk assessment or risk analysis will address the likelihood of the exposure occurring or the risk eventuating. If there is no exposure the hazard cannot give rise to risk.

Life supporting capacity of air, water, soil and ecosystems (including risks to flora, fauna and ecosystems)	• Is it likely to affect any biodiversity values? • Is it known to have any adverse effect on any other species? • Where does it originate? Has it been introduced to other countries? If so, what impacts were noted, and is this relevant to New Zealand? • Which species has it been tested on? What tests were conducted? • What are its feeding habits? • What is its preferred habitat? Has it been found in any other habitat? • Is it likely to be localised or widespread? • Is it likely to have any adverse effect on pasture? Forest? Grasslands? Other ecosystems? • In the case of a parasite or biological control what is the host range? Is it host specific? What evidence is there to support this?
Exposure (potential interaction) (see also secondary sources)	• How does it reproduce, and what factors affect reproduction? What evidence is there regarding hybridisation? • What are the closest relatives present in New Zealand? • Are there any known mutations? – cross-species reproduction?

Economic activity	• Is the release likely to have any effects on other organisms used for similar purposes? • What are the likely positive effects? (potential benefits) • What are the likely negative effects? (potential costs) • What effect is the release likely to have on the international expectations and perceptions of New Zealand agriculture, or New Zealand's 'clean green' image? • What are the likely impacts on employment?

Mäori values	• Will the release have any effects that may impact on the list of issues attached as Annex B?

Future generations	• Will the release have any effects that may impact on the ability of future generations to make choices? • Are the effects of the release reversible?

Capacity of people and communities to provide for their own economic, social, and cultural wellbeing	• Will the release have any impacts on people or communities that might affect their ability to provide for their own economic, social and cultural wellbeing? • Will the release affect individual or community choice?

Genetically modified new organism in containment

Sources of risk – primary stressors

In all cases the primary source of risk or the primary stressor will be the organism that is the subject of the application.

Primary sources of risk	• organism habits and nature • escape from containment.

Secondary sources of risk derive from primary sources of risk. The following questions can be used to help identify secondary sources of risk (generally associated with escape of the organism from containment).

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Secondary (consequential) sources of risk	**Questions to be asked**
	• What is the origin of the gene? • Where is the gene expressed? • What is the function of the gene(s)? • How stable is the construct? Are there any known mutations? • Is the unmodified organism present in New Zealand, if not, what are the closest relatives present. • What is the method of reproduction/propagation? Are other organisms involved? • Will it displace another species? • Is it known to be toxic? • What does it eat? • Is it likely to become the prey of existing species?

In making decisions on applications for containment, the Authority is required to take into account the beneficial effects of having the organism in containment, the adverse effects should the organism escape from containment, and the ability of the organism to escape.

Areas of impact

Areas of impact are the areas or elements at risk. These are defined above by the principles and matters to be taken into account in making decisions under the HSNO Act.

In the case of applications for containment there are two aspects to each of these areas of impact:

- the effects associated with the organism in containment
- the effects if the organism were to escape.

The following questions should be asked for each circumstance.[15]

Note previous reminder that information based on common best practice may be adequate whereas applications for release require stronger evidence.

Issue	Questions
Ability to escape from containment	• How could the organism escape from containment - under normal operating conditions? - as a result of abnormal conditions resulting from natural hazards? - through sabotage?

Effects or consequences	Questions
Public health	• Is the organism known to have any adverse effects on human health, or to carry any organisms that may affect human health? What are these effects? • What testing has been done to support any assertions regarding effects on human health? • Have short term (acute) and long term (chronic and cumulative) effects been considered? • Will any products of the organism enter the food chain? If so, have these products been approved as a food in New Zealand? Overseas?
Exposure[16] (potential contact)	• How will people come in contact with the organism or its products? • Who will come in contact with the organism? Is contact restricted within the containment facility.

Life supporting capacity of air, water, soil and ecosystems (including risks to flora, fauna and ecosystems)	• Is it likely to affect any biodiversity values? • Is it known to have any adverse effect on any other species? • Where does it originate? Has it been introduced to other countries? If so, what impacts were noted, and is this relevant to New Zealand? • Which species has it been tested on? What tests were conducted? • What are its feeding habits?

[15] In some aspects the risk identification is more complex for containment applications than for release applications since the two aspects of effects in containment and effects if the organism escapes have to be considered. However, the data requirements (quantity and quality) may be less since more uncertainty may be tolerated on the grounds that good containment should mean that escape is unlikely.

[16] Identifying risks requires looking at possible exposures and links between cause and effect. Risk assessment or risk analysis will address the likelihood of the exposure occurring or the risk eventuating. If there is no exposure the hazard cannot give rise to risk.

Life supporting capacity of air, water, soil and ecosystems (including risks to flora, fauna and ecosystems)	• What is its preferred habitat? Has it been found in any other habitat? • Is it likely to be localised or widespread? • Is it likely to have any adverse effect on pasture? Forest? Grasslands? Other ecosystems? • In the case of a parasite or biological control what is the host range? Is it host specific? What evidence is there to support this?
Exposure (potential interaction) (see also secondary sources)	• How can the genetically modified material be transferred to other organisms? • How does it reproduce, and what factors affect reproduction? What evidence is there regarding hybridisation? • What are the closest relatives present in New Zealand? • Are there any known mutations? – cross-species reproduction?

Economic activity	• What are the likely positive effects? (potential benefits) • What are the likely negative effects? (potential costs) • What effect is the application likely to have on the international expectations and perceptions of New Zealand agriculture, or New Zealand's 'clean green' image? • What are the likely impacts on employment?

Mäori values	• Will the application have any effects that may impact on the list of issues attached as Annex B?

Future generations	• Will the application have any effects that may impact on the ability of future generations to make choices? • Are the effects of the organism reversible?

Capacity of people and communities to provide for their own economic, social, and cultural wellbeing	• Will the organism have any impacts on people or communities that might affect their ability to provide for their own economic, social and cultural wellbeing? • Will the application affect individual or community choice?

For field trials, some additional risks maybe identified, since it is more difficult to contain genetic material in a field trial than it is in normal containment facility such as a greenhouse or animal house.

Additional exposure pathways will need to be considered, and the possibility of sabotage should be addressed.

For crops, temporal separation as well as physical separation should be considered.

Genetically modified new organism for release

Sources of risk – primary stressors

The primary source of risk or the primary stressor will in all cases be the organism that is the subject of the application. The activity (release) will also be a primary source.

Primary sources of risk	• organism habits and nature • release of the organism.

Secondary sources of risk derive from primary sources of risk. The following questions can be used to help identify secondary sources of risk.

Secondary (consequential) sources of risk	**Questions** • What is the origin of the gene? • Where is the gene expressed? • What is the function of the gene(s)? • How stable is the construct? Are there any known mutations? • Is the unmodified organism present in New Zealand, if not, what are the closest relatives present? • What is the method of reproduction/propagation? Are other organisms involved? • Will it displace another species? • Is it known to be toxic? • What does it eat? • Is it likely to become the prey of existing species?

Areas of impact

Areas of impact are the areas or elements at risk. These are defined above by the principles and matters to be taken into account in making decisions under the HSNO Act.

Effects or consequences	**Questions**
Public health	• Is the organism known to have any adverse effects on human health, or to carry any organisms that may affect human health? What are these effects? • What testing has been done to support any assertions regarding effects on human health? • Have short term (acute) and long term (chronic and cumulative) effects been considered? • Will any products of the organism enter the food chain? If so, have these products been approved as a food in New Zealand? Overseas?

Exposure[17] (potential contact)	• How will people come in contact with the organism or its products? • Who will come in contact with the organism?

Life supporting capacity of air, water, soil and ecosystems (including risks to flora, fauna and ecosystems)	• Is it likely to affect any biodiversity values? • Is it known to have any adverse effect on any other species? • Where does it originate? Has it been introduced to other countries? If so, what impacts were noted, and is this relevant to New Zealand? • Which species has it been tested on? What tests were conducted? • What are its feeding habits? • What is its preferred habitat? Has it been found in any other habitat? • Is it likely to be localised or widespread? • Is it likely to have any adverse effect on pasture? Forest? Grasslands? Other ecosystems? • In the case of a parasite or biological control what is the host range? Is it host specific? What evidence is there to support this?
Exposure (potential interaction) (see also secondary sources)	• How can the genetically modified material be transferred to other organisms? • How does it reproduce, and what factors affect reproduction? What evidence is there regarding hybridisation? • What are the closest relatives present in New Zealand? • Are there any known mutations? – cross-species reproduction?

Economic activity	• Is the release likely to have any effects on other organisms used for similar purposes? • What are the likely positive effects? (potential benefits) • What are the likely negative effects? (potential costs) • What effect is the release likely to have on the international expectations and perceptions of New Zealand agriculture, or New Zealand's 'clean green' image? • What are the likely impacts on employment?

[17] Identifying risks requires looking at possible exposures and links between cause and effect. Risk assessment or risk analysis will address the likelihood of the exposure occurring or the risk eventuating. If there is no exposure the hazard cannot give rise to risk.

Future generations	• Will the release have any effects that may impact on the ability of future generations to make choices? • Are the effects of the release reversible?

Capacity of people and communities to provide for their own economic, social, and cultural wellbeing	• Will the release have any impacts on people or communities that might affect their ability to provide for their own economic, social and cultural wellbeing? • Will the release affect individual or community choice?

Annex A

Information relevant to the determination of the characteristics or attributes of an organism

- taxonomic classification of the organism including reference to common names and history of any recorded name change

- general information on attributes and characteristics of the family and genus of the proposed organism

- information on the biology and lifecycle of the organism including for example its physical (morphological appearance, size, sexual dimorphism etc), anatomical (venomous etc), behavioural (habitat requirements), reproductive (number of eggs, young, generations), longevity, and predator/prey characteristics

- natural distribution of the organism, eg, montane tropical, sub tropical, cool temperate, warm temperate etc

- habitat requirements including specific habitat requirements, eg, terrestrial, aquatic, pasture, forest, scrub, mountain, arable land, waste land etc

- basic description of the structure of the organism, eg, leave, fruit, flowers and branches of plants, and morphology, sexual dimorphism, height, length, weight, and size of animals

- life history and life cycle information eg, mode of reproduction, longevity and mechanism of seed dispersal in plants and seasonal pattern of reproduction in animals

- affinities with New Zealand biota in terms of its potential to interact and form associations with the organisms already present in New Zealand and its ability to produce crossbreeds

- factors that might limit the organism's distribution, eg, altitude, temperature, humidity, wind resistance, rainfall, food supply, soil type, water quality etc

- competitors and predators in management and natural environments

- special characteristics and behavioural patterns, eg, weedy potential, toxicity, venomous nature, spines, feeding patterns, aggressive behaviour, offensive odour etc

- potential uses, eg, increased productivity, greater use potential, value as food/product/herb/medicinal/ornamental/forage etc.

Annex B

Issues of potential significance to Mäori

Outlined below are matters that are likely to be of potential significance to Mäori. The Authority, in its decision-making, will consider the impact an application has on the issues listed below.

Potential issues of significance in relation to Treaty outcomes

- the relevance to unresolved Treaty claims to the Waitangi Tribunal
- the continued ability of Mäori to exert their developmental right as implied by the Treaty, where these are recognised by the Waitangi Tribunal.

Potential issues of significance in relation to environmental outcomes

- the continued and improved availability, quantity and quality of traditional food resources (mähinga kai)
- the continued availability, quantity and quality of traditional Mäori natural resources
- the retention of New Zealand's diverse range of indigenous flora and fauna
- the protection of indigenous flora and fauna valued by Mäori
- the purity of water (inland, coastal and offshore) and the need to retain and extend its productive and life-sustaining capacity
- the purity of land and the need to retain and extend its productive and life-sustaining capacity
- the purity of air and the need to retain and extend its productive and life-sustaining capacity
- the purity of human health and wellbeing
- the restoration and retention of natural habitats.

Potential issues of significance in relation to cultural outcomes

- the recognition and protection of Mäori cultural, spiritual, ethical, or socio-economic values
- the protection of the mauri of peoples
- the preservation and maintenance of traditional Mäori knowledge by Mäori

- the maintenance, expression and control by Mäori of their traditional practices eg kaitiakitanga, tapu, and rähui
- the protection of the mauri (spiritual integrity or life-force) of valued flora and fauna
- the protection of the mauri of land
- the protection of the mauri of waterways (inland, coastal and offshore)
- the protection of the mauri of air and other taonga.

Potential issues of significance in relation to health and well-being outcomes

- the protection of taha wairua: spirituality, balance with nature, protection of mauri
- the protection of taha whanaunga: responsibility to the collective, the capacity to belong, to care and to share
- the protection of taha hinengaro: mental health and well-being, the capacity to communicate, to think and to feel
- the protection of taha tinana: physical growth and development.

These attributes together comprise and express the holistic nature of hauora (Mäori health and wellbeing) and this model is also known as the Whare Tapawha (square house) Model of Mäori Health.

APPENDIX E EXAMPLES

Example 1 Application to release a new organism (biological control agent for gorse) from containment

The applicant is expected to establish the context of the application by providing full information about the organism itself and the purpose of the application. The results of trials conducted while the organism has been in containment will be part of the context.

The contextual information will provide assistance with examining sources of risk. It may include information addressing the following questions.

- What is the purpose of the application?
- What is the organism (how big is it, how long does it live, it is a vertebrate or invertebrate)?
- How does it attack gorse?
- What is its known survival range, and what limits the survival range?
- What is its lifecycle?
- What plants is it known to attack?
- What plants of similar species has it been tested on, and why were these plants selected?
- What plants of similar species has it *not* been tested on, and why not?
- Are there plants that it has been shown that it does not attack?
- Has any overseas testing been done?
- Are there any known predators?
- How does it propagate, and what factors affect propagation?
- How does it colonise?
- Does it have any pest characteristics, and if not, what evidence is there that it will not becomes a pest?
- Are there any known mutations?
- Does it have any biodiversity values or is it likely to affect any biodiversity values?
- Does it have any cultural value and will its release impact on any cultural values?
- Is there likely to be any public concern about release of the organism?
- What are the pathways by which it might affect other organisms??
- Is it known to have any adverse effect on insects?
- Is it known to be poisonous to any species?
- Is it known to have any adverse effect on humans?
- Is the organism well researched and understood, or are there significant uncertainties?

The applicant is required to specify an approach to identifying risk.

One suitable approach in this case might be to convene a panel of experts. The expertise and experience of those contributing should be documented, and the form of the panel[18] should be specified.

[18] This might take the form of a Delphi group where the experts are consulted independently, or it might consist of a group discussion.

By examining the answers to the questions posed above, and any additional questions that might be raised in the process sources of risk should be established.

Once the sources of risk have been established, then the consequences need to be addressed.

The areas of impact specified as relevant in the HSNO Act are:

- the life-supporting capacity of air, water, soil, and ecosystems
- 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
- the sustainability of all native and valued introduced flora and fauna
- the intrinsic value of ecosystems
- public health
- the relationship of Mäori 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.

Each of the sources identified should be examined to determine the possible effect on these areas of impact.

Reviewers will need to be convinced that a systematic approach has been taken to this analysis.

Example 2 Application to import a treatment for dust mite habitat to reduce populations

The contextual information will provide assistance with examining sources of risk. Some of the questions that should be addressed include the following.

- What is the purpose of the application?
- How is the substance defined?
- What is it used for?
- Is it an effective substance for its intended use?
- What types of habitat is it effective in?
- What types of habitat does it not work in (and why not)?
- What is its lifecycle? How long does it persist in the environment (water, soil, other hosts such as carpet)?
- If it breaks down, what is the nature of the components?
- What factors affect how long it persists in the environment?
- What are the pathways by which it could reach waterways?
- How does the substance behave in water?
- Is it readily airborne?
- What is the effect on animals or humans if inhaled?
- What are the disposal requirements?
- Has it been assessed in any overseas jurisdiction?
- What are the occupational exposure considerations?
- Does it have any general toxic properties?
- Does it have any ecotoxic properties?
- Is it know to affect anything other than dustmites? Does it affect any beneficial insects?
- Has it been tested on other organisms, which ones and why were they selected? Who did the testing, and what were the results?
- Are there any other organisms it *should* be tested on?
- Has any testing been done in New Zealand?
- Are there any synergistic or cumulative effects – have these been looked for?
- Does it need special handling? Eg, will it require childproof packing?
- Is there likely to be any public concern about its use?
- What are the pathways by which it might affect other organisms?
- Are there any measures that would increase safe use that are not normally implemented (possibly for cost reasons)?
- Can it be neutralised? Or can chemical effects be reversed?

The applicant is required to specify an approach to identifying risk.

Evidence to support the contention that a systematic approach has been taken to identifying risks might include copies of company checklists, incident reports, and other documentation associated with the production and use of the product.

In some cases the applicant may not be the manufacturer. Either the applicant will need to get data from the manufacturer or developer and undertake the risk identification and assessment themselves, or information from the manufacturer or developer will be required, including evidence that they have considered indirect and direct risks.

Example 3 Application to release a transgenic plant (general)

This example lists the types of questions that can be used to identify the sources of risk associated with the release of a genetically modified plant.

Sources of risk

- What is the purpose of the application? What problem is the transgenic plant designed to overcome? Is it intended that the organism should be grown as a seed crop, a food crop or fodder crop, or is it ornamental?
- Has it been tested previously overseas? Has overseas data been included?
- How important is the introduced trait? Is the novel property a priority?
- What are the differences between the GMO and the current non genetically modified version.
- Has the gene been introduced into other plants?
- Will the introduction of the GMO prejudice the use of the introduced gene in other crops?
- Are cultivars of the plant already in existence which carry other novel genes, which could impact upon the use of this GMO?
- Who is the owner of the gene? What intellectual property considerations apply? Who will own plant varieties that contain the gene?
- Is the GMO subject to any international controls?
- What is the geographical distribution of the plant? Is its management well understood in New Zealand?
- How will the GMO be integrated into the farm rotation? Prepare examples with options for several successive years.
- Will the introduction be sustainable over the long term?
- Will the transgene persist and if so, for how long?
- Is the seed viable (or sterile)?
- Will the presence of the GMO interfere with other plants?
- Is the gene intended to impact on insect populations? How?
- What are the likely effects on animals and birds?
- If the gene is designed to control pests, what total pest management programmes are currently place? Will the transgenic plant disrupt this program?
- How often will chemicals (fertilisers, pesticides, herbicides etc), be applied in conjunction with the GMO crop? Is this more or less than for a conventional crop?
- How does the plant propagate? What is known about the nature of the plant in terms of out-crossing?
- Is there any evidence about whether the GMO may pose a threat as a weed in the environment? If it does, will it be a greater threat than normally bred or current varieties?
- Are any plant residues from the GMO likely to remain in soil? If so, are they likely to pose any hazard? Do plant residues decay in a similar manner to normally bred varieties?

Plants modified for herbicide resistance

- Are there any known phytotoxic effects from use of the herbicides?
- Are the common weeds, given their history and biology, likely to develop resistance to the herbicide used in the transgenic crop? What is known about resistance?
- Have any discussions occurred with representatives of other industries that might be affected by the release of the GMO?

- Will the use of the transgenic crop lead to greater use of herbicides?
- Will the use of the transgenic crop lead to use of more or less benign herbicides?
- Will the transgenic crop change the range of herbicides that can be used?

Plants modified for insect resistance

- Has the target pest evolved resistance to pesticides (in the target crop or any other crops)?
- Has the new gene already been introduced into other crops? If so, what relevant information is available?
- Does the target pest occur on other crops in which the new gene is also deployed?
- Is the transgenic crop likely to come into contact with other crops in which the same trait is deployed?
- Have any tests been done to look for evidence of the emergence of resistance in insects?

Where the genetic modification is for other purposes, then other specific questions will be required.