

ANNOTATED METHODOLOGY

*for the consideration of applications for hazardous substances
and new organisms under the HSNO Act 1996*

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY



NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

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August 1998

Prepared by the Environmental Risk Management Authority of New Zealand

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PREFACE

The purpose of the Hazardous Substances and New Organisms Act 1996 (the Act) is to protect the environment in New Zealand and the health and safety of the New Zealand people and their communities, by preventing or managing the adverse effects of hazardous substances and new organisms. To this end the Act has established the Environmental Risk Management Authority (the Authority). The primary function of the Authority under Part V of the Act is to decide whether hazardous substances and new organisms should be introduced to New Zealand, and if so under what conditions. In carrying out this function the Authority will act as an independent decision-making body, though it will work closely with other agencies responsible for related approvals.

In making decisions under Part V of the Act, the Authority is required to act in accordance with a prescribed methodology which is established by Order-in-Council. Section 9 of the Act requires the Authority to develop a draft of the methodology for the consideration of the Minister for the Environment.

A comprehensive proposal for this methodology was prepared by the Authority in 1997, after extensive consultation with stakeholders. The proposal was publicly released in January 1998. However, the process of translating the proposed methodology into an Order-in-Council required a significant degree of editing. This was to accommodate legal advice on what could be included in the Order-in-Council. Much of this related to the status of the Order as an “instruction from Government”, and statutory limitations on the degree to which the Authority could be so instructed. Section 17 of the Act specifically prevents the Government from issuing any policy directions as to the exercise by the Authority of its decision-making power under Part V of the Act. As delegated legislation it was important that the methodology did not seek to override any provisions of the Act.

The Methodology Order itself is available from other sources e.g. Bennetts Government Bookshop, as a self contained document. Its formal title is “Hazardous Substances and New Organisms (Methodology) Order 1998”.

This publication is in annotated form. It contains material from the Methodology Order which is picked out separately throughout the text. These extracts use the same numbering as the Methodology Order, for ease of cross-reference but also set out additional explanatory notes. These notes are drawn from the proposed methodology issued in January 1998. The framework used in the January document has been retained. The annotations give a more comprehensive picture of the methodological framework which the Authority will use, and also help in establishing the links between the Authority’s proposals and the Methodology Order.

It is emphasised however that only the material in the Methodology Order comprises the methodology referred to in the Act.

I. INTRODUCTION

The annotated methodology assumes that a valid application for an approval under Part V of the Act has been made. An application is required for all new organisms, including genetically modified organisms (GMOs), and for hazardous substances as defined in the Act, and which are not exempt under the thresholds established in regulations introduced under the Act.

The purpose of the annotated methodology and its protocols is to describe how the Authority will approach its decision-making responsibilities. The annotated methodology provides guidance on how the Authority will evaluate risks and monetary and non-monetary costs and benefits, and how the Authority will operate. The annotated methodology notes that in evaluating risks the Authority takes account of the ability to manage those risks. Evaluation by the Authority will be based on risk assessments provided by the applicant and others, and on other information provided to the Authority.

Many of the decisions which confront the Authority will, by their nature, be complex and cannot be reduced to simple decision-making formulae. For this reason the annotated methodology provides a framework for the process, but does not attempt to set out a detailed decision-making code. The annotated methodology provides for the Authority to exercise a degree of flexibility in its approach, amongst other things to reflect the level of complexity or significance of individual applications, while remaining faithful to the requirements of the Act. It is expected that the majority of applications will be processed 'routinely' by the Authority without the need to call on every element of the annotated methodology.

More generally, the annotated methodology reflects a premise that, while there may be substances and organisms whose risks are clearly incapable of being satisfactorily managed, and which should not therefore be introduced into New Zealand, with most applications the issue is likely to be establishing conditions for effectively managing the risks of the substance or organism concerned, so that the environment and health and safety of New Zealand people can be protected, as required by the Act.

The annotated methodology covers (among other things) the assessment and evaluation of risks, costs and benefits, most often in the face of uncertainty. These and related terms are used throughout the body of the methodology. The terms risk, cost and benefit have been given particular meanings which enable the methodology to best express the intentions of the Act. These and other selected definitions are given in Chapter 2. Further key definitions and interpretations are provided in supporting protocols as indicated in section 3.1 below. However, unless otherwise stated, terms have the same meaning as set out in section 2 of the Act.

2. DEFINITIONS

Definitions set out in the Methodology Order are as follows:

“Act” means the Hazardous Substances and New Organisms Act 1996:

“Application” means an application lodged under Part V of the Act:

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

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

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

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

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

Hazardous Substances and New Organisms (Methodology) Order 1998.

Other important definitions are:

Attitude to risk: How the Authority will value uncertain outcomes viz-a-viz certain outcomes, for different risk types and characteristics.

Degree of caution: How conservative the Authority will be in the assumptions it uses in its analysis and determinations.

Effect (or consequence): A defined outcome of the import or manufacture of a hazardous substance, or the import, development, field testing or release of a new organism.

Event: An incident or situation which occurs in a particular place during a particular interval of time.

Frequency: The number of occurrences of an event in a given time.

Hazard: A source of potential harm or a situation with a potential for harm.

Negligible risks: 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 can be justified by very small levels of benefits.

Probability: The likelihood of occurrence. Probabilities may be applied to effects or events.

Submitter: Person who makes a submission on publicly notified applications.

Risk management: Steps taken to reduce the probability of occurrence or the magnitude of the effects of a risk, or both.

Sensitivity analysis: The examination of how the results of a calculation or model vary as individual assumptions are changed.

Unacceptable risks: Risks of a type or level which the Authority will not accept, after taking account of the scope for risk management, irrespective of any benefits that might accrue.

3. STRUCTURE AND ON-GOING DEVELOPMENT OF THE DECISION-MAKING FRAMEWORK

3.1 THE DECISION-MAKING FRAMEWORK

The framework which guides decision-making by the Authority under Part V of the Act consists of:

- The Act.
- The broad statements of principle, policy and process set out in the Methodology Order.
- Supporting material issued by the Authority from time to time that describes in more detail how the Authority will go about considering applications and the information applicants may need to provide. Some of this supporting material is contained in the present document, but most will be contained in a set of protocols.

3.2 PROCEDURES FOR ESTABLISHING AND VARYING ELEMENTS OF THE DECISION-MAKING FRAMEWORK

Separate processes apply to the establishment and amendment of the Methodology Order and to the supporting protocols. The Order can only be changed by the Government and in accordance with the processes established in Section 9 of the Act.

In the case of protocols the Authority will:

- Issue draft documents from time to time covering matters determined by the Authority to be significant to the decision-making process, and provide an opportunity for public comment on the draft documents.
- Issue the protocols in final form and apply them to applications received after the date of issue.

4. ROLES AND RESPONSIBILITIES

A. ENVIRONMENTAL RISK MANAGEMENT AUTHORITY

1. **The Authority, or any Committee appointed under clause 43 of the First Schedule of the Act, and responsible for making decisions under Part V of the Act, must consistently apply this methodology when making decisions.**

Hazardous Substances and New Organisms (Methodology) Order 1998.

The Authority will also:

- apply the Methodology Order and other elements of the annotated methodology through a transparent process.
- make evaluations based on risk assessments from applicants and others.
- monitor its own decisions and the effectiveness of the annotated methodology, in order to improve its effectiveness in meeting the purpose of the Act.

B. NGĀ KAIHAUTU TIKANGA TAIAO

6. **The Authority may appoint advisory committees in accordance with clause 42 of the First Schedule of the Act to advise it on any matter relating to its responsibilities under Part V of the Act and in particular, the Authority may appoint a committee to be known as Ngā Kaihautu Tikanga Taiao to advise it on issues that may arise in taking into account the matters referred to in sections 6(d) and 8 of the Act.**

Hazardous Substances and New Organisms (Methodology) Order 1998.

The role of Ngā Kaihautu Tikanga Taiao is to provide advice on the Authority's decision-making process from a Māori perspective. In doing this Ngā Kaihautu Tikanga Taiao will especially consider:

- application of the Principles of the Treaty of Waitangi (Te Tiriti o Waitangi).
- adverse effects and risks of concern to Māori, and Māori approaches to risk.
- the extent to which applications adequately address issues of concern to Māori.

C. APPLICANTS

In making applications, applicants will be responsible for:

- providing necessary and sufficient information (including a risk assessment for the adverse effects which could follow from the introduction of a hazardous substance or new organism) so as to enable the Authority to make its decisions in accordance with the Act and the Methodology Order.
- providing valid applications in the form prescribed, including unequivocal identification of the hazardous substance or new organism that is the subject of the application.
- providing a summary of information, including risk assessments and estimated costs and benefits, for public release which has sufficient detail so that it is clear what the application is for and what effects the hazardous substance or new organism might have.
- providing further information at the Authority's request.

D. SUBMITTERS

- People making submissions on publicly notified applications have a responsibility to provide relevant information and a clear expression of their views on applications and their attitude to the risks posed.
- Where scientific evidence or uncertainty is at issue, the submissions should indicate the scientific basis for any challenge to the information contained in the application.

E. CHIEF EXECUTIVE AND STAFF OF THE AUTHORITY

- (1) The Authority must ensure that its chief executive and staff provide administrative, scientific, and technical support to the Authority in its functions, including the application of controls under Part V of the Act.***
 - (2) In relation to applications and decision-making, the Authority -***
 - (a) Must inform applicants (as far as practicable) of the provisions of the Act and this methodology and, where relevant, of the need to obtain approvals under other enactments:***
 - (b) Must arrange any statutory processes, including the notification of applications and the holding of hearings:***
 - (c) Must review and verify information contained in applications and submissions from the public or, where appropriate, engage expert bodies to conduct the review and verification or, to provide additional information so that the Authority may be expertly informed for the purposes of decision making:***
 - (d) May facilitate consultation and pre-hearing meetings between applicants and persons who make submissions opposing the application, where these are requested by the applicant and may assist in the early clarification of areas of technical or scientific disputes:***
 - (e) Must co-operate with other bodies (for example, government departments, Crown entities, and local bodies), in particular, when a hazardous substance or new organism also requires approvals under other enactments:***
 - (f) May assist applicants to decide on the extent of relevant and appropriate information to be included in any application provided that no advice given by the staff of the Authority shall prevent the Authority from seeking further information in accordance with section 58 of the Act.***
 - (3) Where assistance is given by the staff of the Authority under subclause (2)(f), that assistance does not prevent the Authority from seeking further information in accordance with section 58 of the Act***
- (1) The Authority must -***
 - (a) Direct its chief executive to advise the Authority solely on the basis of an objective and expert review of the substance or organism in an application and the assessment of risks, costs, and benefits relating to that substance or organism.***

- (b) **Prohibit its chief executive from making personal submissions on an application:**
- (c) **Direct its chief executive to issue a direction to the staff of the Authority-**
 - (i) **To advise the Authority solely on the basis of an objective and expert review of the substance or organism in an application and the assessment of risks, costs, and benefits relating to that application:**
 - (ii) **To prohibit staff from making personal submissions on an application:**
- (2) **Subclause (1)(b) does not apply where its chief executive has requested the Authority to reassess a hazardous substance or new organism in containment in accordance with the provision of the Act**
- (4) (1) **The Authority may, from time to time, issue documents consistent with the Act and this methodology further explaining the role and functions of the chief executive and staff of the Authority.**
- (2) **Documents issued under this clause do not form part of the methodology.**

Hazardous Substances and New Organisms (Methodology) Order 1998.

F. GOVERNMENT DEPARTMENTS AND LOCAL BODIES

- 5. **When implementing section 58(1)(c) of the Act, the Authority must consult any government department where the application relates to the interests or expertise of that department.**

Hazardous Substances and New Organisms (Methodology) Order 1998.

Government departments and local bodies have a role in contributing to an efficient decision-making process, particularly where joint or complementary approvals are required (eg with respect to the Agricultural Compounds and Veterinary Medicines Act 1997, Biosecurity Act 1996, Food Act 1981, Medicines Act 1981, and the Resource Management Act 1991).

The Act requires that Government departments should be notified of certain types of application. The departments then have a responsibility to provide advice on government policies and commitments where these are relevant to decision-making by the Authority.

The Ministry for the Environment is responsible for administering the Act.

G. THE MINISTER FOR THE ENVIRONMENT

Under the Act, the Minister for the Environment is responsible for:

- appointing the Members of the Authority.
- calling in applications for Ministerial decision under section 68 of the Act.

5. GUIDING PRINCIPLES

The following guiding principles will be applied in the making of decisions. Many of these principles are laid down in the Act and in the Methodology Order. However, the Authority has developed additional principles to guide the decision-making process.

GUIDING PRINCIPLES SET DOWN IN THE HSNO ACT

21. Decisions by the Authority must be in accordance with the specific requirements of the Act and the regulations made under the Act.

Hazardous Substances and New Organisms (Methodology) Order 1998.

In detail the guiding principles which flow from this section of the Methodology Order are as follows:

- Determinations by the Authority shall be consistent with the purpose of the Act which 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. (Section 4).
- Determinations by the Authority will recognise and provide for the following principles relevant to the purpose of the Act:
 - (a) *the safeguarding of the life-supporting capacity of air, water, soil and ecosystems;*
 - (b) *the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural well-being and for the reasonably foreseeable needs of future generations.* (Section 5).

Determinations by the Authority shall take account of the following matters relevant to the purpose of the Act:

- (a) *the sustainability of all native and valued introduced flora and fauna;*
- (b) *the intrinsic value of ecosystems;*
- (c) *public health;*
- (d) *the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga;*
- (e) *the economic and related benefits to be derived from the use of a particular hazardous substance or new organism;*
- (f) *New Zealand's international obligations.* (Section 6).
- Determinations by the Authority shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects. (Section 7).
- Determinations by the Authority shall take into account the principles of the Treaty of Waitangi (*Te Tiriti o Waitangi*). (Section 8).
- In making determinations, the Authority shall consistently apply this Methodology. (Section 9(1)).

- Determinations made by the Authority will be in accordance with specific requirements laid down in the Act and its regulations including:
 - (a) Section 29, on determining applications for hazardous substances.
 - (b) Section 30, 31, and 32, on importing hazardous substances in containment.
 - (c) Section 33, on exemptions from provisions of the Act for small-scale chemistry.
 - (d) Sections 34, 35, 36, 37 and 38, on assessing new organisms for importation or release Section 39, relating to new organisms in containment Sections 47 and 48, on the use of hazardous substances and new organisms in emergencies.
 - (e) Section 50, on prohibited organisms.
 - (f) Section 51, on transshipment of substances and organisms.
 - (g) Sections 52 to 61, on assessment procedures including public notification, hearings and information requirements.
 - (h) Sections 62 and 63, on reassessment of substances and organisms.
 - (i) Sections 74 to 76, on hazard classification.
 - (j) Section 77, on controls.
 - (k) Section 87 to 96 on transferable permits and environmental user charges.

ADDITIONAL GUIDING PRINCIPLES

HOW THE AUTHORITY WILL OPERATE

- Applications to the Authority will be considered in accordance with the decision paths, published in protocols, as described in Chapter 3
- Determinations by the Authority will be made in the most straightforward and efficient way apparent to the Authority which enables the requirements of the Act to be met.
- The Authority will endeavour to have technical and scientific disputes resolved as early as possible by making its staff available, to a reasonable extent, for consultation with prospective applicants, applicants and submitters, and by facilitating meetings between interested parties, should the parties consider these to be helpful.
- The Authority will work with government departments and local bodies to promote co-operation and efficiency, particularly where parallel approvals are required.
- In considering applications, the Authority will consider input from Ngā Kaihautu Tikanga Taiao in relation to Section 6(d) and Section 8 of the Act and in recognising and providing for the maintenance and enhancement of the capacity of Māori to provide for their own cultural wellbeing.

DEALING WITH INFORMATION

- 8. The information used by the Authority when considering an application must be relevant and appropriate to the scale and significance of the risks, costs, and benefits associated with the substance or organism.**
- 15. When considering submissions made on publicly notified applications in accordance with section 54 of the Act, the Authority must have regard to any evidence in those submissions that is relevant to the assessment of the risks, costs, and benefits of introducing the substance or organism.**
- 16. When considering submissions addressing scientific evidence or uncertainty, the Authority must take account of the scientific basis or authority for the information contained in the submission.**
- 17. The chief executive of the Authority or the Authority may appoint experts to review the information contained in applications, including the risk assessments and proposals for risk management.**

Hazardous Substances and New Organisms (Methodology) Order 1998.

In addition:

- Information provided to the Authority which has been generated by other processes and agencies in New Zealand or overseas (including standards, approvals, registrations, assessments and other material) will be taken into account by the Authority, having regard to the quality of the information and to the extent that it reflects New Zealand circumstances and the requirements of the Act.
- The release and withholding of information is governed by the relevant provisions of the Act, and the Official Information Act. In some cases the Medicines Act, and Agricultural Compounds and Veterinary Medicines Act may also apply. Within these bounds the Authority shall require the release of sufficient information to enable submissions on publicly notified applications to be made on an informed basis and, more generally, for the Authority to be able to publicly explain the rationale for its decisions.

MAKING DETERMINATIONS

- 22. (1) The Authority must evaluate risks, costs, and, where applicable, benefits taking into account -**
 - (a) The nature and characteristics of the substance or organism; and**
 - (b) The applicant's assessments and, where applicable, proposals for the management of the risks concerned; and**
 - (c) Any submissions received; and**
 - (d) The reviews prepared by the chief executive or any expert appointed by the Authority of the chief executive.**
- (2) Subclause (1) does not limit any discretion that the Authority may have under the Act.**

23. **The Authority may, in accordance with section 58 of the Act, obtain further information in order to gain a sufficient understanding of the actual or potential effects caused by the substance or organism and the means of managing those effects.**
24. **The Authority, its chief executive, its staff, and any appointed expert must use recognised risk identification, assessment, evaluation, and management techniques.**
25. **(1) When evaluating risks, the Authority must begin with a consideration of the scientific evidence relating to the application, and take into account the degree of uncertainty attaching to that evidence.**
 - (2) Where evidence relating to an application refers to other values and matters relevant to Part II of the Act, including the relationship of Māori culture and traditions with their ancestral lands and taonga, the Authority must also consider the values and other matters in that evidence.**
26. **Taking into account the measures available (if any) for risk management, the Authority may approve an application where a substance or organism poses negligible risks to the environment and human health and safety if it is evident that the benefits associated with that substance or organism outweigh the costs.**
27. **(1) Where clause 26 does not apply, the Authority must take into account the extent to which the risks and any costs associated with that substance or organism may be outweighed by benefits.**
 - (2) Where an application is for a new organism and that organism causes any of the effects in section 36 of the Act, clause 26 and subclause (1) do not apply and the authority must decline the application.**
28. **(1) The Authority may, from time to time, issue explanatory material relating to the calculation of monetary and non-monetary costs and benefits.**
 - (2) Explanatory material issued under this clause does not form part of the methodology.**

Hazardous Substances and New Organisms (Methodology) Order 1998.

In addition:

- The Authority's approach to risk will reflect the nature and characteristics of the risks being considered, will build on past decisions and other sources of information, and will be applied consistently across applications.
- The Authority's decisions will, over time, form a body of precedent which will inform its future decisions.

6. DECISION PATHS

In accordance with the guiding principles, decisions made by the Authority will follow a path which ensures that all relevant considerations are applied and in the right order. Decision paths ensure consistency in the Authority's approach, to help build up a history of precedents and provide some certainty to applicants about how their applications will be treated. The appropriate decision path will also apply to decision-making under authority delegated in accordance with section 19(2) of the Act.

General decision paths will apply to each hazardous substance and new organism application. However, there will necessarily be departures from this sequence for particular types of decisions, to allow for specific requirements of the Act.

The decision paths present a schematic view of the Authority's consideration of applications. Nothing in these paths removes the obligation to comply with the individual provisions of the Act itself.

In all cases the sequence described in a decision path starts with the formal receipt of an application. It is assumed that informal processes prior to that point (eg discussions with staff) will have established whether an application is valid, eg to determine whether an organism is in fact a new organism and to determine which type of application should be made.

Decision paths for the various approval types identified in the Act are set out in a protocol which is separately available.

7. CONSIDERING MĀORI PERSPECTIVES

The Act requires all persons exercising functions and powers under the Act to take into account the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga (Section 6) and to take into account the principles of the Treaty of Waitangi (Te Tiriti o Waitangi) (Section 8). This chapter sets out provisions for obtaining information on Māori perspectives, and for the operation of Ngā Kaihautu Tikanga Taiao as a forum for input to decision-making.

7.1 OBTAINING INFORMATION ON MĀORI PERSPECTIVES

If Māori perspectives are significant to an application, then information will need to be obtained accordingly. If information is provided by consultation with Māori, then that consultation should be in accordance with Tikanga Māori. It should also be appropriate to the substance of the particular application. The Authority will, in partnership with Ngā Kaihautu, develop a protocol which sets out guidelines which meet these criteria. These guidelines will, in particular, suggest that applicants consult with appropriate representatives from the Māori community, or affected whanau, hapū or iwi, where the hazardous substance or new organism applied for has a localised impact.

The Authority will also:

- in consultation with Māori, develop a schedule of matters covered by Section 6(d) of the Act and known to be of concern to Māori which should receive specific attention by applicants, while at the same time recognising and providing for the different protocols and values between various hapū/tribal groupings.
- in conjunction with Ngā Kaihautu, develop a schedule of contact representatives for Iwi Authorities and for Māori groupings for the purposes of consultation with Māori.

7.2 ESTABLISHMENT OF NGĀ KAIHAUTU TIKANGA TAIAO

To assist the Authority to meet its obligations under the Act and as required by the Methodology Order, the Authority has appointed, under section 42 of the First Schedule to the Act, the advisory committee known as “Ngā Kaihautu Tikanga Taiao” to provide Māori input into the Authority’s consideration of applications.

Ngā Kaihautu Tikanga Taiao comprises persons with the expertise and experience to provide a broad Māori perspective on matters coming before the Authority.

Ngā Kaihautu Tikanga Taiao will provide input in the following areas:

- application of the principles of the Treaty of Waitangi.
- the approach of Māori to risks and risk aversion.
- specific risks of concern to Māori.
- appropriate consultative mechanisms with Māori where risks are identified.
- the extent to which the application satisfactorily addresses Māori perspectives.
- other advice on kaupapa Māori as required.

Ngā Kaihautu Tikanga Taiao will be able to co-opt members with specific expertise should this be required for providing input on particular applications. Ngā Kaihautu Tikanga Taiao will not represent specific iwi or hapū interests.

Ngā Kaihautu Tikanga Taiao will have a direct relationship with the Authority rather than with applicants.

To ensure there is an effective relationship between the Authority and Ngā Kaihautu Tikanga Taiao:

- The Chairperson of Ngā Kaihautu Tikanga Taiao may attend and participate in governance meetings of the Authority.
- Ngā Kaihautu Tikanga Taiao shall be invited to nominate persons to become members of committees established in accordance with Section 43 of the First Schedule of the Act to hear and determine applications, where this is appropriate to the applications under consideration.

8. HOW THE AUTHORITY WILL APPROACH KEY ISSUES

Chapter 5 of this document sets out the guiding principles for decision-making. This chapter focuses more on key issues. Further detail on the Authority's approach will be set out in protocols issued under Chapter 3 of this annotated methodology.

8.1 MANAGING INFORMATION

Certain guiding principles deal with the provision of information, its use in decision-making and its release. The principles are expanded below. Further elaboration will be provided through protocols if experience with the annotated methodology indicates to the Authority that there is a need to do so. Particular aspects are:

8.1.1 PROVISION OF INFORMATION

Chapter 4 of the annotated methodology states that the applicant has the initial responsibility for providing information. Information requirements will be prescribed in the regulations made under section 140 of the Act. Further details on how to meet these requirements will be made available by the Authority. For particular types of application the Authority may provide further advice on the extent of the information which is necessary to reach a decision.

The staff of the Authority will interact with prospective applicants to endeavour to ensure that the information provided is in accordance with the guiding principle, i.e. is that which is necessary and sufficient. No advice given by the staff of the Authority shall however prevent the Authority seeking additional information.

8.1.2 TREATMENT OF INFORMATION FROM OTHER PROCESSES AND AGENCIES

- 20. The Authority may, subject to section 55(4) to (6) of the Act, take into account information produced for or by other and agencies in New Zealand and overseas (including standards, approvals, registrations, assessments, and other material) after having regard to -**
- (a) The quality of the information (including the status of the relevant agency), the reliability and authority of the information, and the rigour and completeness of the decision-making where the information is in the form of an approval; and**
 - (b) The extent to which it relates to New Zealand circumstances and the requirements of the Act.**

Hazardous Substances and New Organisms (Methodology) Order 1998.

The Authority will treat the information associated with each application on its merits. As experience is gained, the Authority may issue a list of the names of other agencies and types of decision they generate, which provide useful information on effects. Such agencies may also be prescribed under regulations issued under Section 140 (k) of the Act.

8.1.3 RELEASE OF INFORMATION

The guiding principles set out the approach of the Authority in regard to the release of information. This is based on ensuring that applicants are informed, as early as possible, about the information that the Authority may decide should be released, either to enable public submissions to be made or to enable decisions to be publicly explained.

- (7) (1) Where applications are required to be publicly notified, the Authority must -**
 - (a) Summarise the application including assessments of risks, costs, and benefits, and include sufficient information to make clear the purpose of the application and the adverse effects of the hazardous substance or new organism, but exclude any information to which section 55(3) to (6) of the Act applies and any information withheld in accordance with the Official Information Act 1982; and**
 - (b) Before releasing the summary to any person, give it to the applicant; and**
 - (c) If the applicant does not withdraw the application, make the summary publicly available.**
- (2) The applicant, after receipt of the summary and consultation with the Authority may, if the information in the summary is unacceptable, withdraw the application (including all the information provided by the applicant).**

Hazardous Substances and New Organisms (Methodology) Order 1998.

Except as stated above and provided that the action is in accordance with the provisions of the Act and the Official Information Act, the Authority will treat as confidential, for as long a period as is specified by the applicant, all information provided by the applicant which the applicant classifies as commercially confidential.

The Authority or the Chief Executive may wish to release information from applicants to third parties for the purpose of providing expert advice for the consideration of an application. As provided for in the guiding principles, under these circumstances the Methodology Order provides that:

- 18. (1) The applicant must be informed of the Authority's intention to appoint an expert (but not the name of the intended expert) before the release of any information contained in the application to that expert and the Authority must take into account any comments by the applicant before proceeding to appoint an expert and release information.**
- (2) The applicant may withdraw the application at any time.**
- 19. Any expert appointed under clause 17 may be required by the Authority to appear at a hearing of the application concerned, to present any material provided by them, and be questioned on that material.**

Hazardous Substances and New Organisms (Methodology) Order 1998.

In due course and once experience is gained, the Authority may issue a list of individuals and/or organisations, together with their areas of expertise, whom the Authority may engage to provide expert advice.

8.2 DEALING WITH UNCERTAINTY

The Authority will usually have to deal with uncertainty in considering applications. It may be a feature of the scientific and technical information about the adverse effects of hazardous substances or new organisms, but may also be a feature of other types of information relevant to decision-making. Information may be uncertain because of the difficulties or limitations of measurement, disputed interpretations, or contradiction between one piece of information and another. Uncertainty may also arise from the source of the information. Some sources will be more certain (or reliable) than others. The same will be the case in characterising costs and benefits. There may also be uncertainty about the effectiveness of the management of risks.

In describing uncertainty, and including uncertainty in assessments and evaluations, the Authority will first deal with matters arising from scientific and technical uncertainty about adverse effects. The approach to be adopted is set out in the Methodology Order as follows.

- 29. Where the Authority encounters scientific and technical uncertainty relating to the potential adverse effects of a substance or organism, or where there is disputed scientific or technical information the Authority -**
 - (a) Must determine the materiality and significance to the application of the uncertainty or dispute taking into account the extent of agreement on the scope and meaning of the scientific evidence; and**
 - (b) May, where the uncertainty or dispute is material or significant, facilitate discussion between the parties concerned to clarify the uncertainty or dispute.**
- 30. Where any scientific or technical uncertainty or dispute is not resolved to the Authority's satisfaction during its consideration of the application, the Authority must take into account the need for caution in managing the adverse effects of the substance or (to the extent provided for under the Act) the organism concerned.**
- 31. Where the Authority considers that uncertainty arises from an absence of information, or inconclusive or contradictory information, or information from an unreliable source, the Authority may request the applicant to provide further information in accordance with section 58 of the Act and must take full account of any additional information provided.**
- 32. Where the Authority considers there is uncertainty in relation to costs, benefits, and risks (including, where applicable, the scope for managing those risks), the Authority must attempt to establish the range of uncertainty and must take into account the probability of the costs, benefits, and risks being either more or less than the levels presented in evidence.**

Hazardous Substances and New Organisms (Methodology) Order 1998.

Uncertainty will require the Authority to exercise judgement in making decisions, taking account of both the nature and extent of the uncertainty and the Authority's approach to the risks being considered. In doing so the Authority will take into account evidence on statistical probabilities, but may determine such evidence to be inconclusive. In all cases the Authority will ensure that the rationale for each of its decisions is documented.

8.3 THE APPROACH TO RISK

8.3.1 KEY RISK CONCEPTS

The annotated methodology requires that the Authority's approach to risk should be consistent from one application to another. The approach to risk can be described with respect to five key risk concepts. These are:

- *Unacceptable risks* - i.e. those risks which the Authority will not accept irrespective of any benefits that might accrue, after taking account of the scope for risk management
- *Risks which may or may not be tolerable* - i.e. those risks which may be accepted if they are justified by outweighing benefits, after taking account of the potential for management to reduce the magnitude or likelihood of any adverse effects
- *Negligible risks* - i.e. those risks which are of such little significance in terms of their likelihood and consequence that they do not require active management and/or do not need to be justified by counterbalancing benefits, after the application of risk management
- *Attitude to risk* - i.e. how the Authority will value uncertain outcomes viz-a-viz certain outcomes, for different risk types and characteristics
- *Degree of caution* - i.e. how conservative the Authority will be in the assumptions it uses in its analysis and determinations.

The first three of these concepts define three distinct zones of risk, as indicated in Figure 1. The boundaries between these zones are outlined in section 8.3.3 of this annotated methodology.

The last two concepts provide reference points for describing what will influence the Authority in establishing the boundary lines (unacceptable risks and negligible risks), and in evaluating risks which may or may not be tolerable.

"Attitude to risk" is a term which embodies the concepts of being "risk averse", "risk neutral" and "risk accepting" or "risk taking". For the purposes of the Act "attitude to risk" describes how the Authority will deal with relatively certain as against uncertain courses of action. The concept of "degree of caution" describes how the Authority's approach to dealing with uncertainty will vary under differing circumstances. The two concepts are linked. In situations where the Authority is inclined to be very "risk averse" it will also be very "cautious" in dealing with uncertainty.

The issue of the Authority's approach to risk is different from that of considering together risks, costs and benefits. If benefits exist to outweigh risks and costs, this may lead to an approval where otherwise an application would be declined. However, irrespective of the level of benefit, the Authority should be consistent in the approach it takes in its consideration of types of risk or risk characteristics.

8.3.2 KEY FACTORS AFFECTING THE APPROACH TO RISK

The Authority's approach to risk will be influenced by, amongst other things, the type and severity of the possible adverse effects flowing from an application and risk characteristics. In all cases however, the Authority's approach will incorporate explicit consideration of the measures available for risk management.

In particular the Methodology Order requires that:

- 33. When considering applications, the Authority must have regard to the extent to which the following risk characteristics exist:**
- (a) Exposure to the risk is involuntary:**
 - (b) The risk will persist over time:**
 - (c) The risk is subject to uncontrollable spread and is likely to extend its effects beyond the immediate location of incidence:**
 - (d) The potential adverse effects are irreversible:**
 - (e) The risk is not known or understood by the general public and there is little experience or understanding of possible measures for managing the potential adverse effects.**

Hazardous Substances and New Organisms (Methodology) Order 1998.

The way in which these factors will influence the Authority's position on risk will become clear over time through precedents established by the Authority's decisions. However, some initial guidance is provided by the following statements.

- The Authority will be more cautious and risk averse according to the extent to which the risk characteristics set out above exist:
- Conversely the Authority will be less risk averse and less cautious where the opposite characteristics apply for example, where exposure is voluntary, the risk is temporary, the adverse effects are reversible and so on.

The Authority will also be more cautious and risk averse with respect to some specific types of risk, which include but are not limited to:

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

The approach to risk embodied in decision-making precedents will be described within a framework which will enable the implications of the precedents to be analysed and used to promote consistency in future decisions. Information from sources other than precedents for example, research and investigations, may also be placed within the framework, if the Authority so chooses.

8.3.3 THE BOUNDARIES BETWEEN RISK ZONES

The boundary between unacceptable risks and risks which may or may not be tolerable is informed in the first instance by Schedule Two of the Act, in respect of new organisms, and by other relevant legislation such as the Ozone Layer Protection Act. These provide an indication of the organisms/substances which have risks associated with them that have been deemed by Parliament to be unacceptable, irrespective of the benefits that might be associated with particular uses/applications.

Similarly, definition of the boundary between negligible risks and risks which may or may not be tolerable will be informed in the first instance by the threshold regulations prepared pursuant to section 74 of the Act.

This specification of the boundary lines will be strengthened over time through consideration of the body of decisions made by the Authority. These decisions will take account of other relevant information including precedents set under other jurisdictions.

As certain precedents prove to be robust (i.e. justified against the information base built up) and consistently applicable to the decision-making of the Authority, they will be recommended as providing guidance to applicants.

The boundary lines will differ with different types of risk; for example between the risks posed by new organisms as opposed to hazardous substances.

8.3.4 ATTITUDE TO RISK

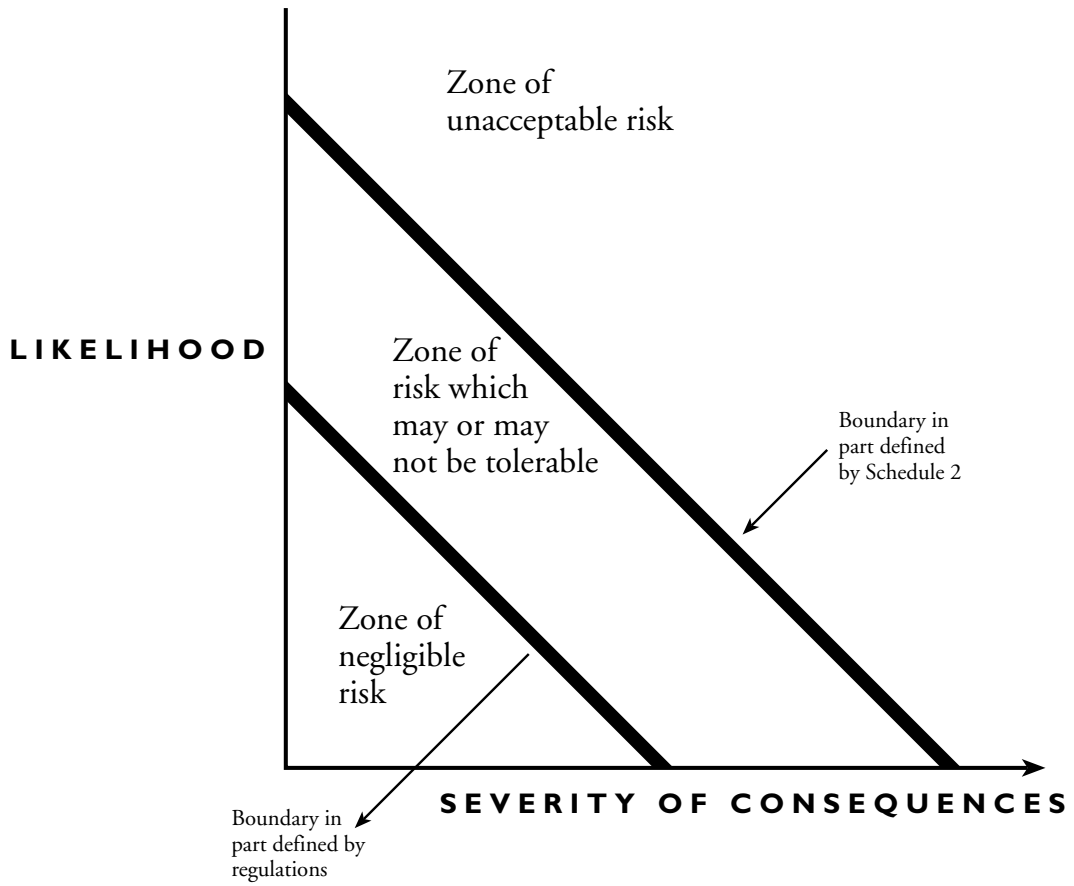
The Authority's attitude to risk will lie on a continuum within the range of risk averse to risk neutral, depending on the attributes of the application under consideration.

8.3.5 DEGREE OF CAUTION

The Act deals with taking account of the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects. However, the issue of "how cautious" is left open. In this respect the extent of caution exercised will be a function of the considerations identified in section 8.3.2 above, but there will be a presumption in favour of caution.

While the precautionary approach is applied specifically to scientific and technical uncertainty in the Act, the Authority will apply the same approach to other sources of uncertainty.

FIGURE 1: CATEGORISATION OF RISK



8.4 IDENTIFYING AND ASSESSING RISKS, COSTS AND BENEFITS

Particular substances or new organisms will create hazards which reflect the inherent characteristics of those substances/organisms. A standardised format will be applied to the risks, costs and benefits identified and assessed in every application.

8.4.1 IDENTIFYING RISKS, COSTS AND BENEFITS

Every application will be required to provide assessments which enable the Authority to carry out the requirements of the Methodology Order.

These requirements are as follows:

- 9. When evaluating the information provided by an applicant (including prescribed information and any additional information) so as to achieve the purpose of the Act, the Authority must -**
 - (a) Recognise risks, costs, benefits, and other impacts associated with the substance or organism in an application which relate to the safeguarding of the life-supporting capacity of air, water, soil, and ecosystems, and provide for this principle; and**
 - (b) Recognise and provide for the principle of maintenance and enhancement of the capacity of people and communities to provide for -**
 - (i) Their own economic, social, and cultural wellbeing; and**
 - (ii) The reasonably foreseeable needs of future generations; and**
 - (c) Take into account risks, costs, benefits, and other impacts associated with the substance or organism in an application which relate to -**
 - (i) The sustainability of all native and valued introduced flora and fauna; and**
 - (ii) The intrinsic value of ecosystems; and**
 - (iii) Public health; and**
 - (iv) The relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga; and**
 - (v) The economic and related benefits to be derived from the use of a particular hazardous substance or new organism; and**
 - (vi) New Zealand's international obligations.**

- 10. Where an application relates to a new organism, the Authority must also evaluate the information provided on the risks, costs, benefits, and any other impacts which relate to -**
- (a) The significant displacement of any native species within its natural habitat:**
 - (b) The significant deterioration of natural habitats:**
 - (c) The significant adverse effects on human health and safety:**
 - (d) Significant adverse effects on New Zealand's inherent genetic diversity:**
 - (e) The ability of the organism to establish an undesirable self-sustaining population anywhere in New Zealand:**
 - (f) The ease with which the organism could be eradicated if it established an undesirable self-sustaining population:**
 - (g) The ability to cause disease, be parasitic, or become a vector for human, animal or plant disease.**

Hazardous Substances and New Organisms (Methodology) Order 1998.

Applicants may also present information relating to the risks, costs and benefits of not introducing the new organism.

- 11. Where an application relates to a hazardous substance, the Authority must also evaluate information which 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:**
- (a) Explosiveness:**
 - (b) Flammability:**
 - (c) Capacity to oxidise:**
 - (d) Corrosiveness:**
 - (e) Toxicity (including chronic toxicity):**
 - (f) Eco-toxicity with or without bio-accumulation:**
 - (g) Any 1 or more of the above properties generated when the substance comes into contact with air or water.**

Hazardous Substances and New Organisms (Methodology) Order 1998.

Applicants may also present information relating to the risks and costs of not introducing the hazardous substance.

8.4.2 ASSESSING RISKS, COSTS AND BENEFITS

Further to the guiding principles, risk assessments provided to the Authority should enable the Authority to carry out the evaluations required by the Methodology Order. These evaluation requirements are as follows:

- 12. When evaluating assessment of risks associated with the substance or organism in an application, the Authority must take into account -**
 - (a) The nature of the adverse effects; and**
 - (b) The probability of occurrence and the magnitude of each adverse effect; and**
 - (c) The risk assessed as a combination of the magnitude of the adverse effect and the probability of its occurrence; and**
 - (d) The options and proposals for managing the risks identified; and**
 - (e) The uncertainty bounds on the information contained in the assessment expressed quantitatively where possible, but otherwise through narrative statements.**
- 13. When evaluating the assessments of costs and benefits associated with the substance or organism in an application, the Authority must take into account -**
 - (a) The costs and benefits associated with the application and whether the costs and benefits are monetary or non-monetary; and**
 - (b) The magnitude or expected value of the costs and benefits and the uncertainty bounds on the expected value; and**
 - (c) The distributional effects of the costs and benefits over time, space, and groups in the community.**
- 14. The costs and benefits are those that relate to New Zealand and that would arise as a consequence of approving the application.**

Hazardous Substances and New Organisms (Methodology) Order 1998.

In addition to the above, relevant costs and benefits may also include those which would not occur if the application is declined, ie, “opportunity cost” to New Zealand. Distributional effects, for example, over space, time and groups in the community, should also apply to risks as well as costs and benefits.

8.4.3 PLACING RISKS IN CATEGORIES

The assessments provided by applicants should enable risks to be categorised as follows:

1. Risks which are negligible taking account of the scope for management of risk (negligible risks).
2. Risks which may or may not be tolerable taking account of the scope for management of risk and the existence of associated benefits.
3. Risks which are unable to be categorised because of lack of information (undefined risks).

Risk identification and assessment should include consideration of synergistic or compounding effects, for example, whether two risks of equal severity in isolation might be more or less than twice as severe in combination.

8.4.4 ASSESSING SPECIFIC RISKS

The Authority will, over time, issue protocols which provide guidance on how the Authority will expect specific risks to be assessed. These protocols may refer, as appropriate, to Codes of Practice and Standards.

8.5 OVERALL EVALUATION: AGGREGATING AND COMPARING RISKS, COSTS AND BENEFITS

34. **When evaluating the combined impact of risks, costs, and benefits the Authority must as far as possible, -**
- (a) Combine groups of risks, costs, and benefits using common units of measurement, including, where applicable, monetary valuations; and**
 - (b) Use other techniques where common units are not possible, including, the identification of dominant risks (being risks that may have a deciding influence) and the ranking of risks in order of significance.**

Hazardous Substances and New Organisms (Methodology) Order 1998.

Combining the impact of risks does not imply 'additivity'.

The aggregate impact or balance of risks and costs against benefits will then be evaluated using techniques considered to be appropriate by the Authority and incorporating the Authority's approach to risk (Section 8.3). Inevitably this will involve the exercise of a degree of judgement. In considering the aggregate impact, the Authority will take account of distributional effects, in space and time and between groups in the community.

8.6 CONTROLS FOR HAZARDOUS SUBSTANCES

The Act provides for regulations to be made to classify hazardous substances and prescribe controls for each classification. When the Authority approves the importation or manufacture of a hazardous substance under section 29 of the Act, the Authority is required to give the substance one or more classifications. Prescribed controls then attach to the substance in accordance with the classification(s).

In accordance with Section 77 (3), (4) and (5) of the Act and under certain circumstances the Authority may substitute, add or subtract controls. The approach used by the Authority will aim to achieve the most cost-effective management of risks for the applicant and for the community. In most cases this will mean achieving satisfactory levels of risk management over the life cycle of the substance, at the lowest possible cost. Thus;

35. **When exercising the discretion under section 77 of the Act for the management of hazardous substances, the Authority must -**
- (a) Consider the costs and benefits of making the controls more or less stringent (including the likely effectiveness of the implementation of possible controls); and**
 - (b) Invite the applicant to comment on the cost-effective application of controls to achieve a specified level of risk management.**

Hazardous Substances and New Organisms (Methodology) Order 1998.

The Authority will also consider the likely effectiveness of possible controls and the ability for implementation to be monitored.

9. PRESENTING DECISIONS

36. (1) **The Authority must publicly notify its decision.**
- (2) **When giving its decision to the applicant and those persons who have made submissions, the Authority must -**
- (a) **State whether the application is approved, with or without controls, or declined; and**
 - (b) **State the criteria in the Act and in this methodology relied on by the Authority in reaching its decision; and**
 - (c) **Where the application relates to a hazardous substance and is approved, state the classification of the substance and -**
 - (i) **Whether the controls specified in the regulations for that classification have been attached to the substance; or**
 - (ii) **Whether those controls have been varied by the Authority and attached to the substance; and**
 - (d) **Where the application is approved and relates to a new organism or hazardous substance in containment, state the controls attached to that approval in accordance with the Third Schedule to the Act; and**
 - (e) **State the reasons for the Authority's decision.**

Hazardous Substances and New Organisms (Methodology) Order 1998.

It is expected that some applications will be declined because of uncertainty in the information considered by the Authority. In such cases, the decision will also identify the nature and extent of the uncertainty and its impact on the decision by the Authority.

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NGĀ KAIWHAKATŪPATO WHAKARARU TĀIAO
ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TĀIAO

ERMA New Zealand, Wellington, May 1998

ISNO 0-478-21504-5

ER-ME-01-2 8/98