

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY



NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

**Background Document -  
Consideration of  
Ethical Issues  
in HSNO Act processes**

**April 2005**



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## Introduction

This document contains the background material to the document ‘Consideration of Ethical Issues in HSNO Act processes – a discussion paper’. The first Section contains further information about the Ethics Advisory Panel, including details about its membership and terms of reference. Section 2 provides information about approaches to consideration of ethical matters adopted in different jurisdictions including international and national jurisdictions. Section 3 describes in more detail one of these frameworks developed by UNESCO and outlines how the Environment Risk Management Authority (ERMA New Zealand) has used this approach in developing its own framework. Section 4 provides more information about environment ethics. Section 4 provides information about the operation of ERMA New Zealand.

The purpose of the Hazardous Substances and New Organisms (HSNO) Act is to protect people and the environment from the harmful effects of hazardous substances and new organisms including genetically modified organisms. ERMA New Zealand’s formal role in doing this is by making decisions on applications to introduce new organisms or hazardous substances to New Zealand under the Hazardous Substances and New Organisms (HSNO) Act.

The information needed to make wise decisions under the HSNO Act goes beyond what might be considered ‘technical’ or ‘scientific’. It is also important to understand the ethical issues and implications of applications: essentially, the values and beliefs that people hold about the consequences of decisions about new organisms and hazardous substances, the factors that should be taken into account, and the way that decisions are made.

ERMA New Zealand has undertaken a considerable amount of thinking about ethical issues. Ethical principles are already reflected, for example, in ERMA New Zealand’s guidance material relating to public participation or consultation processes, and identifying the distribution of adverse and beneficial effects of applications made under the HSNO Act. Ngā Kaihautū Tikanga Taiao (Ngā Kaihautū), the Authority’s advisory committee on Māori issues, has helped develop thinking on principles relating to Māori interests and values. Ngā Kaihautū has recently developed a Protocol “*Incorporating Māori Perspectives in Part V Decision Making*” to assist decision makers by describing how the Authority will take account of Māori issues and Treaty considerations. These include ethical considerations alongside other dimensions. Thus ethical matters are currently included in consideration of applications, but in a rather *ad hoc* way.

ERMA New Zealand is committed to continual improvement of the way it implements its responsibilities under the HSNO Act and has recognised that more could be done to provide all those involved in HSNO processes with a clearer and more explicit framework for identifying and recognising ethical considerations. In April 2004, the Authority set up a three-person Ethics Advisory Panel. The Panel has made a major input to the development of the discussion paper this document is the background material for, which sets out the Authority’s proposals for a framework for considering ethical issues in HSNO Act processes.

The Authority believes that the framework will help to improve current approaches to considering applications by guiding the judgements to be made. This approach imposes discipline on all aspects of the HSNO application process, and makes the

consideration of ethical issues more transparent and more consistent. This will allow the Authority to demonstrate to applicants, submitters and the public how ethical considerations are taken into account.

# Section 1: The Ethics Advisory Panel to ERMA New Zealand

## The Ethics Advisory Panel and its role

In September 2003, the Authority agreed to establish an Ethics Advisory Panel to provide expert advice and assistance on ethical matters relating to hazardous substances and new organisms. This decision reflected a view that a more explicit and visible approach in this area would be desirable.

The Panel will provide advice to the Authority and the Agency in three general areas.

1. The Panel will provide advice in scoping the HSNO legislation and ethical ‘landscape’, and assisting in developing a more explicit framework for considering ethical and cultural aspects of HSNO applications.
2. The Panel may also be asked to provide advice on the handling of ethical aspects of particular applications, and
3. The Panel will at times be asked to consider generic ethical issues and provide *ad hoc* advice on the nature and handling of generic ethical issues arising under HSNO decision making.

The Authority appointed three members to the Panel in April 2004: Denise Church (Chair), a former Secretary for the Environment and consultant, Professor Don Evans, Director of the Bioethics Centre, Dunedin School of Medicine, University of Otago, and Professor Sylvia Rumball, Assistant to the Vice-Chancellor (Ethics and Equity), Massey University. The Panel operates under an agreed Terms of Reference with the Authority. These outline the roles and responsibilities and operational aspects of the Panel, and emphasise that the Panel’s role is an advisory rather than decision-making role.

The Panel started its work in May 2004; it is supported by Agency staff from the Strategy and Analysis Group. The focus of the Panel’s work has been to understand how ethical considerations are currently dealt with in HSNO processes, to explore how other decision-making regimes, both in New Zealand and elsewhere, deal with ethical issues, and to develop ideas on a more explicit framework for HSNO processes. The Panel led the development of the discussion paper.

## **Ethics Advisory Panel Members**

### **Denise Church (Convenor) QSO**

Denise Church has been a member and Convenor of the Ethics Advisory Panel since its establishment in April 2004. Denise has degrees in Zoology, Economics, Resource Management, and Urban and Regional Planning. She has worked in the field of environmental management since 1977, with experience in New Zealand, the USA, and the UK. From 1996 to 2001, Denise was Chief Executive at the Ministry for the Environment. She is now on the Boards of Landcare Research, the Wellington Zoo Trust, and WWF New Zealand and practises as a consultant in leadership development, and policy and strategic management.

### **Sylvia Rumball ONZM**

Sylvia Rumball has been a member of the Ethics Advisory Panel since its establishment in April 2004. She has an MSc (First Class Hons) from the University of Canterbury and a PhD in Chemistry from the University of Auckland. Sylvia has spent her academic career at Massey University, interspersed with periods overseas. At Massey University she conducted research into the structure and function of human milk proteins and taught chemistry for many years before becoming Dean of Science and now Assistant to the Vice-Chancellor (Ethics and Equity). Sylvia is involved with research ethics at the institutional, national and international level. She is Chair of the New Zealand National Ethics Committee on Assisted Human Reproduction, a member of the Health Research Council Ethics Committee and Chair of the Massey University Human Ethics Chairs Committee. Sylvia recently finished a six-year term as a member of the UNESCO International Bioethics Committee where she was a member of the Drafting Group that developed the recently adopted International Declaration on Genetic Data. She was also a member of the Working Party that drafted the Code of Professional Standards and Ethics for the Royal Society of New Zealand in 2002. Sylvia is also an auditor for the New Zealand Universities Academic Audit Unit.

### **Donald Evans**

Donald Evans has been a member of the Ethics Advisory Panel since its establishment in April 2004. He taught at the University of Wales for twenty nine years and was appointed Professor at the University of Otago in October 1997 where he is the Director of the Bioethics Centre. Donald developed the first European Masters degree programme in Medical Ethics, served as a member of the governing body of the Institute of Medical Ethics and has published numerous books and papers. Donald was elected a member of the Academy of Humanitarian Research, Moscow, in 1996, and has conducted research projects for the Ministry of Health and the UK Department of Health, and led two European Commission international research projects. Donald was a member of the Ministry of Research, Science and Technology's Independent Biotechnology Advisory Committee for three years. He has chaired and served on numerous ethics committees including those of the British Medical Association, the Royal College of Nursing, and the Association of Clinical Research Contractors. He is currently a member of the UNESCO International Ethics Committee, The Canadian Institutes of Health Research Stem Cell Oversight Committee, and the UNESCO Commission on Ethics.

## **Ethics Advisory Panel Terms of Reference**

### **Logistics**

- The Ethics Advisory Panel (EAP) will consist of a Chairperson plus other members, appointed by the Authority for set terms which will generally not exceed 3 years.
- Member fees will be set on a case by case basis, reflecting the circumstances of participants. Fees shall be proposed by the Chief Executive and approved by the Authority Chairperson.
- Executive support will be provided by the Group Manager, Strategy and Analysis.
- A budget for the activities of the EAP will be set each year by the Authority, and meetings and other activities will be scheduled and managed accordingly.
- As far as possible business will be conducted by methods which minimise operating costs i.e. email, fax, teleconference.

### **Development of a framework for dealing with HSNO applications raising ethical and cultural issues**

The EAP will provide advice and assistance to the Agency, and to the Authority if so requested, on the development of a more explicit framework for dealing with HSNO applications raising ethical and cultural issues. Assistance may comprise proposals developed by the EAP for Agency/Authority consideration, expert advice/peer review on proposals developed by the Agency and participation in workshops and seminars.

### **Consideration of generic ethical issues**

The EAP will, upon request from the Authority or the Chief Executive, provide *ad hoc* advice on the nature and handling of generic ethical issues arising under HSNO decision making. The advice will generally be provided in the form of a report.

### **Contribution to the consideration of specific Part V applications**

The EAP may be asked to provide advice on the handling of ethical aspects of particular Part V applications. Such advice may be either provided to the Chief Executive (by request) for inclusion in the staff evaluation; or provided to the decision-making body as an independent report (at the request of the decision maker, conveyed through the Chief Executive).

A terms of reference for the advice will be provided in each case, and will be agreed to by the EAP before work proceeds.

(NB this covers against the possibility of advice being requested which the EAP considers cannot be reasonably provided).

The EAP will make best endeavour to have a member of the Panel attend any public hearing, should the Authority so request. Where a Panel member is not available, the Panel will brief an Agency nominee to act as their representative.

## **Section 2: Approaches to ethics in environmental decision making in other jurisdictions**

The Panel reviewed a number of approaches to examining and considering ethical issues in decision making in a range of jurisdictions, and has prepared the following brief summaries. While a number of other organisations at international and national level are undertaking projects to help them to develop frameworks for the consideration of ethical issues in decision making, very few of them have as yet developed any models. Most of the material summarised relates to medical ethics or biotechnology. Much of the material on biotechnology relates to food matters.

### **International**

#### **United Nations - Universal Declaration of Human Rights**

On December 10, 1948 the General Assembly of the United Nations adopted the Universal Declaration of Human Rights.

The ethical principles espoused in the Declaration of Human Rights are:

- dignity
- equality
- freedom
- autonomy
- justice.

#### **United Nations Rio Declaration**

The United Nations Conference on Environment and Development in Rio de Janeiro in 1992 produced the Rio Declaration on environment and development. The Rio Declaration developed a set of 27 principles relating to the relationship of people and the environment, and the associated rights and responsibilities of States.

Some of the most relevant principles are

##### *Principle 1*

Human beings are at the centre of concerns for sustainable development. They are entitled to a healthy and productive life in harmony with nature.

##### *Principle 3*

The right to development must be fulfilled so as to equitably meet developmental and environmental needs of present and future generations.

##### *Principle 4*

In order to achieve sustainable development, environmental protection shall constitute an integral part of the development process and cannot be considered in isolation from it.

##### *Principle 10*

- stresses the importance of public participation in environmental decision making

##### *Principle 15*

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

### *Principle 22*

- reiterates the importance of supporting the identity of indigenous peoples.

Many of these principles have been incorporated in New Zealand legislation. The concept of sustainable development/management is a foundation of the Resource Management Act (1991) and the HSNO Act (1996). The HSNO Act also includes direct reference to adopting a precautionary approach.

## **United Nations Education, Scientific and Cultural Organisation (UNESCO)**

In 1997 (the year the UK rejoined) UNESCO adopted the 'Universal Declaration on the Human Genome and Human Rights'. This is a document of moral, but not legal, force. The International Bioethics Committee of UNESCO is charged with contributing to the dissemination of the principles set out in the declaration, and further examination of the issues raised therein and by the evolution of the relevant technologies.

The International Bioethics Committee has developed a working document on universal norms in bioethics (UNESCO, 2004). Since its release in draft form it has been developed further and it is proposed that it will be published as the UNESCO Universal Declaration on Bioethics and Human Rights. The scope of the declaration covers human beings and scientific and technological developments, and the first of its aims is to provide a universal framework of fundamental principles and procedures to guide States. The scope and aims of the draft declaration are described in Section 3.

Professor Don Evans is a current member of this committee. Professor Sylvia Rumball was previously a member<sup>1</sup>.

Genetic research, in particular the sequencing of the human genome, has opened the way for far-reaching medical research and biomedical applications. To address concerns that human genetic data will be used for purposes contrary to human rights and freedom, UNESCO developed an International Declaration on Human Genetic Data, which was adopted in late 2003 by the UNESCO General Conference.

## **Food and Agriculture Organization of the United Nations (FAO)**

The Food and Agriculture Organization of the United Nations (FAO) is undertaking an increasing number of activities related to ethics. *FAO Readings in Ethics* is a new series, which brings together the results of such activities, carried out as an integral part of the Organization's regular programme of work. To date there have been two volumes published:

- Ethical issues in Food and Agriculture
- Genetically modified organisms, consumers, food safety and the environment

The ethical principles outlined in these documents are derived from the Universal Declaration of Human Rights.

The first document describes a set of ethical values, the value of food, the value of enhanced well-being and the value of human health, the value of natural resources and the value of nature as the basis for a discussion on establishing a more equitable and ethical system for food and agricultural production.

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<sup>1</sup> New Zealand does not have a place on this committee as of right. Members of this committee are appointed as individuals but nominated by a country.

The second document concentrates on the right to adequate food, the right to informed choice and the right to democratic participation, and examines the relationship between genetically modified organisms (GMOs), the food supply chain, human health and the environment in this context.

### **Council of Europe - <http://www.coe.fr/index.asp>**

The Council of Europe, a body set up in 1949 and now composed of 41 Member States, considers ethical issues in the field of biomedicine through a Steering Committee on Bioethics (CDBI). The Convention on Human Rights and Biomedicine, which was opened for signature in 1997, contains overarching principles in the field of genetics dealing with unjustified discrimination, predictive genetic testing and interventions on the human genome. Work to develop a Protocol on Human Genetics, which will extend and amplify the Convention principles in the field of genetics, began 18 months ago. It is probable that the Protocol will consider issues arising in the health field and in non-health fields such as employment, insurance and other settings.

In May 1999, the Council of Europe held a conference on the ethical implications of biotechnology. One aim of that conference was to identify what actions it may be appropriate for the Council of Europe to take in this field. No decisions have yet been made concerning follow up to that conference.

### **Organisation for Economic Co-operation and Development (OECD) - [www.oecd.org](http://www.oecd.org)**

OECD's work in the field of ethics is limited, but its consideration of technical issues such as genetic testing and xenotransplantation may raise ethical issues, which may need to be addressed. In February 2000, OECD hosted a workshop on genetic testing sponsored by the UK and Austria. OECD includes representation from Europe, North America and Australasia.

### **European Commission (EC)**

The European Commission has no direct competence in biomedical ethics. The EC has an independent advisory group, the European Group on Ethics in Science and New Technologies, which produces opinions on general principles on issues in these fields.

### **World Health Organisation (WHO)**

Although the World Health Assembly adopted a resolution condemning human reproductive cloning, up until now WHO has had a very limited role in the field of biomedical ethics. In July 1999 WHO appointed a senior staff ethicist. Consideration is being given to the future role WHO should play in this field, but no firm conclusions are yet known.

## National<sup>2</sup>

### UK (Nuffield Council)

In 1999 the Nuffield Council published a report on the ethical and social issues relating to genetically modified crops. The working party concluded that there are three main types of principle that are relevant to the evaluation of policies or practices: general welfare (citizen's interests), the maintenance of people's rights (autonomy), and justice (including equity). Two other significant issues are addressed, the boundary between natural and unnatural, and taboos and moral conservation. The report describes and discusses the elements of decision-making processes relating to genetically modified crops and how these ethical principles relate to this.

### Canada

The Canadian Biotechnology Advisory Committee (CBAC) is a body of external experts established in September 1999 by the Government of Canada. CBAC reports to the Biotechnology Ministerial Coordinating Committee (BMCC), which is comprised of the Federal Ministers of Industry, Agriculture and Agri-food, Health, Environment, Fisheries and Oceans, Natural Resources and International Trade.

CBAC provides comprehensive advice to the federal government on current policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. It is also tasked with providing Canadians with easy-to-understand information on biotechnology issues, and providing opportunities for Canadians to voice their views on the matters on which CBAC is offering advice to the Government.

CBAC is conducting a special study to facilitate the integration of the social and ethical dimensions of biotechnology into public policy decision making and administration. It plans to strike a project steering committee to undertake public consultations and examine the following research questions.

- How can we identify the values that Canadians wish to see reflected in public policy on biotechnology?
- What procedures and/or structures need to be established to implement these values?
- How can the effectiveness of these procedures and/or structures be monitored and assessed?

### Australia

The Australian Gene Technology Ethics Committee (GTEC) has recently circulated a discussion paper which specifies a set of values and principles for dealings primarily with GMOs. The stated purpose is to provide a national reference for ethical consideration relevant to all dealings with GMOs.

The values are: knowledge, trust, human life (intrinsic value), environment (intrinsic value), freedom of choice, reason, integrity, equity, courage and wisdom.

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<sup>2</sup> This selection is representative only.

From these a set of Principles of Ethical Conduct have been derived. These principles take the form of a series of statements that relate in the first instance to sustainable development.

The first four principles repeat Rio Declaration principles 1-4, which can be summarised as

- human dignity,
- sovereignty,
- respect for future generations, and
- need for recognition of balance between development and environmental protection.

The remaining principles are based on respect for people, respect for all living beings, beneficence, double effect, and equity.

### **Switzerland and the Netherlands**

<http://www.ex.ac.uk/egenis/research/publications/IntegrityDignity.pdf>

In 1992 the Swiss parliament approved an amendment to the Federal Constitution of Switzerland entitled *Gene Technology in the Non-Human Field*. This contains the following text:

1. Persons and their environment shall be protected against abuse of gene technology.
2. The Confederation shall legislate on the use of the reproductive and genetic material of animals, plants, and other organisms. In doing so, it shall take into account the dignity of creation and the security of man, animal and environment, and shall protect the genetic multiplicity of animal and vegetal species.

There is, however, a difference between the German, English and Italian translations (above) and the French version which refers to respect for the *integrity* of living organisms. There has been some argument about whether ‘dignity’ and ‘integrity’ are the same.

A later section of this document describes ways in which an animal’s dignity may be violated by:

- inflicting unjustified suffering, pain, and harm on them, and also to frighten them without justification
- changing their appearance
- humiliating them, and finally,
- unduly instrumentalising them.

In 1992, the same year as the Swiss approved the amendment to the Constitution the Dutch passed a new law, the Animal Health and Welfare Act which states that making transgenic animals is forbidden, *unless* it can be shown ‘that there is no unacceptable violation of animal well-being and animal integrity connected with it’. A Committee on Animal Biotechnology was established and determined that the following actions would result in violation of an animal’s integrity -

- changing the genome
- changing appearance

- changing species specific behaviour
- impairing the ability to live autonomously.

## **New Zealand**

### **Independent Biotechnology Advisory Council (IBAC)**

The Independent Biotechnology Advisory Council (IBAC) was established in 1999 to meet the need for advice and informed public debate about biotechnology. It was disestablished in August 2002 immediately prior to the establishment of the Bioethics Council.

IBAC's role was to 'help New Zealand explore and consider issues arising from advances in biotechnology', to 'stimulate dialogue and enhance public understanding about biotechnology' and to provide independent advice to Government.

In its three years of existence IBAC published several booklets and reports on various aspects of biotechnology. Public comment received raised ethical issues relating to safety, equity, privacy and discrimination (with respect to new medical technologies) and liberty (biotechnologies). There was also a call for IBAC to develop a framework of agreed ethical principles to help in the understanding of biotechnology issues and to aid decision making.

### **Royal Commission**

The Royal Commission on Genetic Engineering presented its report in mid 2001. The report recognised a set of seven core values.

- The uniqueness of Aotearoa/New Zealand
- The uniqueness of our cultural heritage (the Treaty of Waitangi)
- Sustainability (kaitiakitanga)
- Being part of a global family
- The well-being of all (recognising that economic and social goals are symbiotic)
- Freedom of choice (for all)
- Participation (effective systems of consultation and shared decision making).

The recommendations of the Commission were based on these values. One of the key recommendations was for the establishment of a separate specialist body (Toi te Taiao: the Bioethics Council) to allow for proper debate of these values in the context of regulatory decision making.

### **Bioethics Council (Toi te Taiao)**

Following the report of the Royal Commission Toi te Taiao: the New Zealand Bioethics Council was established as a Ministerial Advisory Committee operating under its own Terms of Reference. The Council, which reports to the Government through the Minister for the Environment, has three functions.

1. To enhance New Zealand's understanding of the cultural, ethical and spiritual aspects of biotechnology
2. Ensure that the use of biotechnology has regard for New Zealand's values

3. The Council provides unbinding advice to the Government about New Zealanders' ethical, cultural and spiritual views in relation to biotechnology. The Council is an advisory body with no statutory powers.

The Council has recently completed a project looking at the 'issues arising from the transfer of and use of human genes in other organisms'. This project largely confirmed a number of the recommendations from the Royal Commission and made a number of its own recommendations which are of a general and reporting nature, rather than contributing to the development of an ethical framework.

### **Biotechnology strategy**

In 2003, the Ministry of Research, Science and Technology (MoRST) published the New Zealand Biotechnology Strategy, outlining which outlines the Government's vision and direction for the development of biotechnology in New Zealand.

The guiding principles for this policy are:

- Benefit for New Zealand – Focus on outcomes from biotechnology that benefit the wealth, health and environment of New Zealanders.
- Sustainable development – Meet present needs without compromising future generations, through integrating economic growth, social equity and environmental and cultural well-being.
- Responsibility and ethics – Responsible, ethical use and uptake of biotechnology, in a way that safeguards the well-being of both people and the environment, by effective identification and management of risks and uncertainty.
- Innovation – Foster and encourage innovative biotechnology developments.
- Partnership and participation – Work in partnership with the sector and involve citizens in public policy and ethical issues, through open information and participation processes that acknowledge diverse community interests.
- Treaty of Waitangi – Work in partnership with appropriate Māori authorities to empower Māori in development decisions that affect them and enable Māori to participate so as benefit their economic, social and cultural wellbeing.
- Biosecurity and biological diversity – Maintain biosecurity and protect biological diversity, particularly that of New Zealand's unique flora and fauna.

The strategy has a strong focus on ethical considerations and will be reinforced through the Biotechnology Task Force, which will be convened on a regular basis through MoRST.

## **Section 3: UNESCO Declaration on Universal Norms on Bioethics (Third Outline)<sup>3</sup>**

### **Scope and Aims**

#### **Article 1 - Scope**

The principles set out in this Declaration:

- (i) apply to human beings, while recognizing that human beings have responsibilities and duties towards other forms of life in the biosphere, and
- (ii) apply to issues raised by scientific and technological developments and their applications, as well as their availability and access.

#### **Article 2 - Aims**

The aims of this Declaration are:

- to provide a universal framework of fundamental principles and basic procedures designed to guide States in the formulation of their legislation and their policies in the field of bioethics, and to form the basis for guidelines in bioethical matters for the institutions, groups and individuals concerned;
- to ensure the respect for human dignity and the protection of human rights and fundamental freedoms in [the sphere of] bioethical decision making, in accordance with human rights law;
- to promote respect for biodiversity;
- to recognize the great benefit derived from scientific and technological developments, whilst ensuring that such development occurs within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms, and to prevent practices contrary to human dignity;
- to foster dialogue between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual and professional groups concerned, policy makers and society as a whole;
- to promote the sharing and the greatest possible flow of knowledge concerning scientific and technological developments as well as the sharing of benefits, in particular with developing countries;
- to safeguard the interests of present and future generations.

### **Use of the UNESCO working document on universal norms in bioethics relating to people**

In developing the proposed ethical framework, ERMA New Zealand has reviewed a number of existing ethical frameworks, and ethical principles (described briefly in Section 2). Many of these overlap, with some specific differences that may relate to

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<sup>3</sup> Since the development of this section of the discussion paper the form and structure of the UNESCO Declaration has changed. This version is described here as the concepts and structure aided the Panel to develop the framework described in this discussion paper. The final form of this draft declaration is entitled *Universal Declaration of Bioethics and Human Rights*.

their area of application, and no one framework is necessarily better than another in all circumstances.

However, the UNESCO working document on universal norms in bioethics relating to people (UNESCO, 2004)<sup>4</sup> was found to be particularly relevant. ERMA New Zealand drew heavily on version 3 of the UNESCO working document in developing the principles described in Section 2.2.

The scope of the declaration covers human beings and scientific and technological developments, and the first of its aims is to provide a universal framework of fundamental principles and procedures to guide States.

The declaration does not address environmental ethics in a specific way, and support for these matters is provided primarily through the precepts of the Rio Declaration.

Some of the principles on which the UNESCO document was based included:

- human beings are an integral part of the biosphere and have responsibilities and duties towards other forms of life,
- while scientific and technological developments have been of great benefit to humankind, these developments should always promote the welfare of individuals and society and recognise inherent dignity, human rights and fundamental freedoms, and
- ethical reflection is an integral part of scientific and technological development.

The UNESCO draft document describes three levels of principles:

1. general or fundamental principles,
2. derived principles, and
3. procedural principles.

The fundamental principles are based on concepts of respect and responsibility. They set the scene for the derived principles which elaborate more specifically on particular aspects of respect and responsibility. The procedural principles discuss what organisations might do when making decisions to acknowledge the different moral and ethical positions that individuals and communities might hold.

None of the material presented in the UNESCO principles is significantly different from other sets of ethical principles that have been developed in other jurisdictions. It is essential for all such frameworks that the principles are relevant to the application, consistent in their scope, and meet the purposes to which they are being applied.

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<sup>4</sup> This document is to be considered as ‘work in progress’ the version that is discussed here is described as ‘Third Outline of a Text’ and is not considered to be complete. It is dated 27 August 2004. The final form of this draft declaration is entitled ‘Universal Declaration of Bioethics and Human Rights’.

## Section 4: Environmental Ethics

### Environmental decision making

Recent New Zealand environmental legislation has adopted a very holistic approach to its interpretation of environment. For example, the purpose of the Resource Management Act (1991) is to –

*‘promote the sustainable management of natural and physical resources’*

and the purpose of the HSNO Act (1996) is to

*‘protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms’.*

The definition of ‘environment’ in both of these Acts includes: ecosystems and their constituent parts, including people and communities; all natural and physical resources; amenity values; and the social, economic, aesthetic and cultural conditions affecting or affected by these.

Although ERMA New Zealand’s use of the term ‘environment’ includes people and their social context, in this section the discussion about environmental decision making primarily relates to the natural environment, but is not inconsistent with the broader interpretation of environment. In the development of the framework as referred to in later sections, a distinction has been made between ‘the environment’ as being all inclusive and ‘the natural environment’ referring to flora, fauna and ecosystems.

Over the last thirty years there has been major development in the practice of environmental decision making in a legislative context. Many countries have legislation that sets out, in various ways, to protect the environment, promote sustainable development or support the sustainable use of resources. Looking at the general features of environmental decision making can give us some useful insights into how best to handle ethical considerations.

Even though environmental issues and environmental legislation differ from country to country, the practice of environmental decision making shares some common features. For a start, making decisions about proposals that might affect the environment requires taking account of a complex array of theoretical and practical factors.

These include:

- sparse or poor quality data
- uncertainty or lack of understanding of cause-effect relationships
- long lead times between cause of effect and realisation of harm or benefit
- the need for complex interactions between social, cultural, ecological, economic and technical aspects to be considered
- the perspectives and needs of multiple decision makers and stakeholders, and
- complications arising from multiple objectives.

Environmental decisions are seldom made in isolation from consideration of benefits, and environmental decision making often involves the balancing of relatively predictable short-term gain against relatively unpredictable long-term loss.

Common considerations or criteria used in environmental decision making are:

- efficiency – in terms of either economic efficiency (is this the best use of resources?), or procedural efficiency (has the process been transparent, consistent and inclusive of all interests?)
- effectiveness – (is the result likely to be one that achieves an outcome that all or most parties can accept, and are the goals for the process achieved?) and
- equity – (are the positive and negative aspects resulting likely to be equally distributed between all parties?).

A further criterion particularly relevant to environmental decision making is flexibility (the ability to learn from the past and hence to be willing to act differently in the future).

As noted above, there is often a long lead time before the outcomes of environmental decisions can be evaluated. This means that good environmental decision making often depends more on procedural efficiency than on effectiveness. Clearly, however, a good and informed process should lead to a good outcome.

Many decision processes rely not only on a weighing up of adverse and beneficial effects, but include an assessment of whether both individual risks and cumulative risks are acceptable. The notion of ‘acceptability’, which is common to many risk-based decision processes, requires consideration of values and hence ethical considerations. Most environmental decision making is complicated by uncertainty, since neither the adverse nor the beneficial effects are certain.

Decisions are rarely made solely on technical grounds. Many decisions (not only on environmental matters) have both technical and ethical dimensions. Some examples follow of decisions that require the weighing up of an action which is technically feasible in terms of its ethical consequences. They lead us beyond asking ‘can this be done?’ to ‘should this be done?’.

Consider the following examples of ethical dilemmas.

*There are effective interrogation methods using torture, but are they ethically justified?*

*Intensive ‘battery’ systems may produce the cheapest eggs, but is it ethical to subject hens to such conditions?*

*The use of nuclear weapons in 1945 undoubtedly hastened the Japanese surrender and saved perhaps a million military casualties, but were the civilian casualties an acceptable price for world society to pay?*

*The US moon landings project was stunningly successful, but was it worth spending billions of dollars to get a handful of men to land on the moon, when that funding could have supported health, education, or other important investments?*

Environmental decisions are often characterised by tension between competing views on what should be done. Tensions may be separated into two groups: interest tensions and value tensions. Interest tensions can sometimes be resolved by gaining more information or by some means of ‘transfer payment’ from one group to another. Where there is a clear tension between values (underlying beliefs about what is right) any decision will impact adversely on one group, and it is not easy to reach a consensus or ‘win-win’ solution. Nor can people be compensated for what they see as disrespect for their values.

There are ways that tension can be reduced. When exploring options and higher level issues, it is sometimes helpful to avoid focusing initially too closely on specific examples. It may be more helpful to begin with the bigger picture in social and environmental decision making, and to look for common ground. Once this has been achieved the points of difference can be analysed more closely.

Decision procedures should aim to achieve consensus at least on matters of general principle and technical questions, and preferably on their application. Where stakeholder groups do not get the result they want, they should at least be satisfied that their interests were taken into account.

Environmental decision making invariably requires choices between several options. Sometimes, it may appear that:

- there are only two possibilities
- it is impossible to decide between them, and
- neither of them is acceptable.

In fact

- there are almost always more than two alternatives
- further investigation will show that one is preferable to the alternatives, and
- one of them is usually acceptable – though not necessarily to all people.

In other words, avoiding ‘closing down’ on options too early is one of the ways that better solutions, that do more to recognise conflicting perspectives, can be found.

Environmental decision making is not value free. A recent United States National Research Council report noted that:

*‘Ethical considerations are generally normative<sup>5</sup> and cannot be resolved scientifically. Yet to ignore ethical concerns is to assume that science can and should be value-free. Moreover values can influence both the design of scientific inquiry and the interpretation of data and certainly motivate much of the pressure brought to bear on regulatory agencies and other government bodies to address impacts of biotechnology beyond those directly affecting health and the environment.’*

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<sup>5</sup> ‘Normative’ refers to conforming to standards. One way of viewing this is to say that the term normative relates to what ‘ought’ to be done as opposed to ‘positive’ which relates to what ‘is’ done.

Environmental decision making typically involves consideration of a range of technical matters and almost inevitably there are also ethical issues. There is often debate about what 'weight' should be given to scientific considerations- particularly where the science is well established and widely if not universally supported. Sometimes there is no single 'right' answer to technical problems. For example, an engineer designing a bridge may produce several designs each of which fits the structural criteria. But even where there is agreement on the technically right way to construct it, additional criteria, involving social, cultural, aesthetic and ethical considerations may need to be included to help make the decision.

Another example might be making a choice between different ways of producing electricity. Is it best to develop a new hydro electricity plant (with impacts on river flows, farming, fish, birdlife and recreation), a wind farm (with visual and noise impacts) or a coal fired plant (with carbon dioxide emissions)? While there will be technical information that can inform this choice, technical information alone will not be enough to underpin the complex choices needed.

Combining the two aspects of technical and ethical considerations, current practice in environmental decision making suggests that rational people of goodwill will be able to come up with a good decision.

## Section 5: ERMA

### HSNO applications and ERMA New Zealand decision making: current practice

#### ERMA New Zealand decision processes

HSNO decision processes rely on weighing up of adverse effects and beneficial effects, and include determination of whether both individual risks (adverse effects) and cumulative risks are acceptable or unacceptable. The notion of ‘acceptability’, which is common to many risk-based decision processes, requires consideration of values and hence ethical considerations. In approving a new organism or hazardous substance the Authority is deciding (on behalf of society) firstly, that the adverse effects of the organism or substance are ‘not unacceptable’ and secondly, that the beneficial effects are greater than the adverse effects. As for most environmental decision making this decision is complicated by uncertainty, since neither the adverse nor the beneficial effects are certain.

The Authority’s approach to making decisions on applications for new organisms and hazardous substances is defined by the HSNO Act and the Methodology<sup>6</sup>. Further guidance on the process applied and the methods and approaches that the Authority applies to decision making is provided in the Technical Guide *Decision Making: A Technical Guide to Identifying, Assessing and Evaluating Risks, Costs and Benefits* (ERMA New Zealand, 2004).

The HSNO Act specifically requires that decision makers must take account of:

- the life-supporting capacity of air, water, soil, and ecosystems
- the ability to provide for economic, social, and cultural well-being, 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<sup>7</sup>
- public health
- Māori culture and traditions and relationship to 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, and
- New Zealand’s international obligations.

The purpose of the HSNO Act (Section 4) and the matters that need to be taken into account in decision making (Sections 5 and 6) provide basic criteria for making decisions about whether to approve or decline hazardous substances and new

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<sup>6</sup> The ERMA Methodology is established as an Order-in-Council as required under Section 9 of the HSNO Act. It describes the formal decision-making process that ERMA New Zealand follows in making decisions on applications for new organisms and hazardous substances.

<sup>7</sup> Intrinsic values are defined in the HSNO Act as ‘in relation to ecosystems, means those aspects of ecosystems and their constituent parts which have value in their own right, including:

- (a) Their biological and genetic diversity; and
- (b) The essential characteristics that determine an ecosystem’s integrity, form, functioning, and resilience’.

organisms. Sections 7 and 8 also include decision-making criteria. Specifically, the Authority must ‘take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects’ (Section 7) and ‘take into account the principles of the Treaty of Waitangi (Te Tiriti o Waitangi)’ (Section 8). Other criteria are included in Section 26 which sets ‘minimum standards’ or bottom lines for some particular types of new organism applications.

The early steps of the process are all concerned with gathering, collating and analysing information. Where required by the Act a public notification process is followed, submissions are received, and a hearing is held. Following this the Authority undertakes a consideration<sup>8</sup>, where all the information is brought together for the purpose of making a decision.

The requirements for the consideration are specified in the Methodology. There are two basic steps: assessment and evaluation, defined as follows.

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

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

Evaluation can be described as weighing-up adverse and beneficial effects as is required in Sections 29, 38, 38C, 45 and 50 of the HSNO Act. Other decision-making sections of the HSNO Act, such as the ‘rapid assessment’ provisions, require consideration of adverse effects only.

The definition of ‘effect’ in the HSNO Act is broad, and includes certain and uncertain effects, as well as cumulative impacts. For the purposes of decision making all effects are assumed to have a magnitude of effect and a probability or likelihood of occurrence.

## **Taking account of ethical issues in HSNO processes**

### **ERMA New Zealand’s current approach**

Through existing practices, the Agency and the Authority address a range of ethical considerations both implicitly and explicitly.

ERMA New Zealand decisions are based on a weighing up of adverse and beneficial effects. Adverse and beneficial effects are identified and assessed in five main categories: ecological effects, effects on human health and safety, effects on Māori cultural and spiritual values, social and community effects, and effects on the market economy. Ethical considerations are inherent in all of these aspects, either implicitly or explicitly.

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<sup>8</sup> ‘consideration’ refers to the decision process that the Authority undertakes.

In addition the weighing up process is a mechanism for determining an acceptable level of risk – an ethical concept in itself. All Authority decisions therefore have a strong ethical component.

The Methodology outlines the way that the Authority makes decisions about new organisms and hazardous substances. It takes the requirements of the HSNO Act and turns them into a practical framework for decision making. The Methodology is useful to applicants and submitters because it discusses matters such as information requirements, how the Authority will address uncertainty, and the Authority's approach to risk.

The factors that the Authority takes into account in determining its approach to risk<sup>9</sup> are described in Clause 33.

They are the extent to which:

- (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, and/or*
- (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.*

As a further example of the way in which ERMA New Zealand already address ethical considerations, the HSNO Act and the Methodology require the Authority to take into account the capacity of people and communities to provide for the reasonably foreseeable needs of future generations, and impacts relating to the intrinsic value of ecosystems.

Other Authority policy documents, including Protocols and Policies, contain specific information about how the Authority interprets parts of the HSNO Act including definitions, decision paths, information requirements and some particular aspects such as requirements for consultation with Māori. These documents are intended to guide the Authority, but are useful for anyone interested in ERMA New Zealand processes.

The Authority publishes a number of documents specifically to help applicants and submitters to prepare applications and make submissions. These include the following:

- **Information Sheets** – general information about the HSNO Act and the Authority for anyone who has an interest in new organisms or hazardous substances.
- **User Guides** – information for applicants to help them fill in the application forms. While the User Guides are intended for applicants, submitters may also find them useful.

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<sup>9</sup> For further information see the Authority's document *Approach to Risk*

- **Technical Guides** – more detailed information about the types of analysis that an applicant might need to use, and an indication of how the Agency and the Authority will review and analyse information. These guides are for applicants, submitters, the Agency and the Authority.

From time to time the Authority publishes reports that have a research component about particular issues that are generic to types of application or parts of ERMA New Zealand's work. Examples include reports on Horizontal Gene Transfer (HGT), and the Authority's approach to risk. These documents are intended to provide information to the public and promote public debate on significant issues.

### **Ethical issues and 'call-in' provisions**

Part II of the HSNO Act establishes the context for making decisions under the Act. The principles relevant to the purpose of the HSNO Act require decision makers to recognise and provide for *'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'*, providing a clear statement of the need to address ethical considerations.

In addition, Section 68 of the Act discusses the circumstances in which the Minister for the Environment will 'call-in' an application. Section 68(1) states that:

*'the Minister may direct that he or she will decide an application under this Act if the Minister considers that the decision on the application will have – (a) significant cultural, economic, environmental, ethical, health, international, or spiritual effects; or (b) significant effects in areas in which the Authority lacks sufficient knowledge or expertise.'*

The underlined words referring to cultural, ethical and spiritual effects were added in a recent amendment to the Act. While this change, included in the New Organisms and Other Matters Act (2003) was noted as being part of the Government's response to the Report of the Royal Commission on Genetic Modification<sup>10</sup>, it applies to all applications to the Authority.

Profound value tensions associated with ethical considerations of particular new and controversial HSNO applications may raise major questions of public policy and public interest. These applications may be dealt with through the call-in process. When an application is called in, the Minister may appoint additional persons to sit with the Authority through its consideration process. The normal application process is followed, but instead of making a decision, the Authority presents a report and recommendations to the Minister. The call-in process has not yet been activated.

While there is a differentiation between the existence of significant cultural, ethical and spiritual matters that might trigger Ministerial call-in, and the consideration of such matters in normal day-to-day decision making, the effect of Ministerial call-in is such that the Authority and Agency undertake the normal process and recommend to the Minister. Therefore, the differentiation should be seen as a gradation rather than two discrete activities.

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<sup>10</sup> *Hansard 6 May 2003: New Organisms and Other Matters Bill First Reading.*

## Information

The information on which decisions are based comes from a variety of sources. The primary source of information is that provided by the applicant, which is then evaluated by the Agency staff. In some cases the Agency staff will also obtain information either directly or indirectly through engaging experts. Information required is specified in the application form and includes information about all the predicted effects of the organisms or substances including environmental (ecological and ecosystem) effects, human health effects, effects on Māori cultural and spiritual values, social and community effects, and effects on the market economy.

Applicants are encouraged to discuss their applications with Agency staff prior to submitting a formal application. This allows Agency staff to advise the applicant on areas of their application that may require more information or further elaboration. Some applicants, as a part of their pre-application processes, undertake discussions with interested stakeholders and actively seek ways to understand possible effects and to mitigate these in their proposals.

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

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

In the first instance this information is provided by the applicant; however, the Agency may source further information either through experts or directly. In addition, certain types of applications require public notification and a submissions process, and information is obtained through this process as well.

With respect to each of these types of information, the Authority examines the appropriateness, content and quality of the information (in line with the requirements of Clauses 8, 10 and 11 of the Methodology). The criterion for judging quality is directly linked to the source of the information. Scientific information is judged acceptable if it derives from a recognised national or international agency. It should be noted, however, that while the quality of such information may be considered acceptable the content might not necessarily be acceptable since it may have been developed for a different purpose.

Non-technical information may be either quantitative or non-quantitative. The main difference between technical and non-technical information is that in many cases the basis for non-technical information may be more difficult to verify. For example, technical information may be verified through references, expert knowledge and consultation with outside experts. Community interests may be reported either in the form of survey results (quantitative or qualitative) or as narrative of meetings (non-quantitative).

Ideally, all information would be equally reliable and thus be given the same weight. However, in practice there will always be differences in the quality of information depending on factors such as its source. While there will always be an element of judgement in evaluating this, there are some rules for determining the acceptability of scientific information. This also applies to non-technical information.

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

At times different stakeholders have different views on issues. These views commonly derive from different value foundations, rather than from differences about facts, and may not be able to be reconciled. In such situations, the Authority takes into account the views presented, the foundation for these views and the strength of conviction when making a decision.

### *Confidential Information*

The HSNO Act allows for certain types of information to be kept confidential. Most commonly, confidential information is information that is considered to be commercially sensitive. However, there may also be information that is confidential to iwi or hapū, or other groups. The Authority has the statutory discretion not to release confidential information to the public, but it relies on the applicant to identify it as confidential, and to justify this position. Where the Authority does not agree with the applicant, it will advise the applicant who then has the options of continuing on a non-confidential basis or withdrawing the application. In general the Authority requires 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 give reasons for its decisions. A key ethical consideration is that where an application has confidential information associated, some groups will have more access than others.

In conclusion, there are ethical considerations in the way that information is developed and reviewed. There may be ethical considerations around the way applicants derive, select and present information. There may also be ethical considerations relating to the way in which Agency staff analyse the information and present it to the Authority.

### **Assessment of community values**

Sections 5(b) and 6(e) of the HSNO Act provide for the assessment of general community value. Section 5 (b) requires decision makers to recognise and provide for –

*‘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’*

while Section 6(e) specifies that decision makers must take into account –

*‘The economic and related benefits and costs to be derived from the use of a particular hazardous substance or new organism’.*

To some extent these matters can be described in scientific terms. For example, surveys can tell us that a certain percentage of the population is in favour of, or opposed to an activity. However, in most cases this type of information is too generalised to be of any great use for specific applications and may not contain information about particular groups or communities of interest or the specific linkages between different groups. More qualitative or contextual information is needed to

support the scientific information. Nonetheless, the Agency recognises the value of survey results as information and when presenting this information to the Authority, endeavours to provide background context to help the Authority judge its significance.

Social assessment is a useful tool for determining the effect of specific activities on sectors of the community in defined locations. However, ERMA New Zealand applications are for the most part New Zealand wide applications, which make the use of social impact assessment more difficult and expensive. To date, no social assessment information has been provided by applicants.

So far, the discussion has focused on ethical positions that are based only on assessments of consequences (what might happen). However, there are also positions that are based on other considerations, for example, a fundamental sense of what is right or appropriate, or a position or set of values that emerges out of a cultural view about what is the right way to conceptualise or frame an issue, or to deal with a set of individual or collective responsibilities. The main characteristic of a tension that arises when different groups approach an issue using different sets of values is that it is seldom possible to reach any form of compromise. Where this has occurred in the past, for example early decisions allowing the insertion of human genes in sheep and cattle, the Authority has explained the different views, explained the nature of the tension and any common ground that exists, and has presented its decision acknowledging that there are areas of tension that cannot be resolved.

### **Assessing Māori cultural and spiritual values**

Māori interests in HSNO are much more than a subset of ethical considerations, as these interests may be wide ranging and derive from many different perspectives. Nevertheless, values and beliefs about the environment are often a significant element of information brought into HSNO processes.

The assessment of Māori cultural and spiritual values is provided for in Section 6(d) and Section 8 of the HSNO Act and is being specifically addressed in the development of user guides and other specific documentation. As noted earlier, Section 8 specifically provides that HSNO decision making processes *take into account the principles of the Treaty of Waitangi (Te Tiriti o Waitangi)*.

The Authority has developed a Protocol on incorporating Māori perspectives into ERMA decision making. This Protocol recognises that Māori have a relationship that is inextricably intertwined with the environment, spanning centuries of observation and experience from which a unique body of knowledge and cultural practice has developed. This experience is valuable, alongside that of Western scientific knowledge and experience, to the development of tools and processes for ensuring that the mauri (life force) of the environment is maintained and improved.

The Protocol notes that Māori have consistently indicated the following reasons for seeking recognition of cultural values and practices in relation to the management of the environment:

- the conviction that their cultural practices have a very strong environmental basis and could enhance the management process,

- an obligation, as kaitiaki, to protect the natural world<sup>11</sup>,
- the belief that spirituality is integral to the connection between Māori culture and tradition with the environment, and
- the Principles of the Treaty of Waitangi.

To the extent practicable and in accordance with Sections 6(d) and 8 of the HSNO Act 1996, the Authority seeks to establish relationships of mutual respect and co-operation at a hapū and iwi level consistent with partnership.

While this does not mean that Māori are always comfortable with all of the Authority's decisions, it does allow Māori to have their voice and views clearly heard and acknowledged in decisions.

## Ngā Kaihautū Tikanga Taiao

Ngā Kaihautū Tikanga Taiao (NKTT) is an advisory committee appointed by the Authority under clause 42 of the first schedule to the HSNO Act. The chair of NKTT participates in the Authority's governance meetings.

Ngā Kaihautū Tikanga Taiao advises the Authority on:

- taking account of the principles of the Treaty of Waitangi;
- how Māori approach risk and risk aversion;
- specific risks of concern to Māori;
- appropriate consultation with Māori where risks are identified;
- the extent to which applications satisfactorily address Māori perspectives;
- other advice on tikanga Māori as required.

Ngā Kaihautū Tikanga Taiao:

- has a direct relationship with the Authority rather than applicants;
- does not represent specific iwi or hapu;
- may have up to eight members;
- can co-opt more people with specific expertise if needed for particular issues;
- is provided with executive support by ERMA New Zealand.

Ngā Kaihautū Tikanga Taiao will act at all times to protect and uphold, the integrity of tikanga and mātauranga Māori and to ensure it is appropriately applied to HSNO issues.

In achieving this goal, Ngā Kaihautū will:

- provide advice on the development of policy and procedures that is consistent, where appropriate, with tikanga Māori and the principles of the Treaty of Waitangi;
- enhance the knowledge and understanding about HSNO issues and processes amongst Māori communities;
- develop Māori capability both internally and externally to ensure the effective participation of Māori, as Treaty partners to the crown, in HSNO requirements;

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<sup>11</sup> Ministry for the Environment (2003) *A Cultural Health Index for Streams and Waterways*. Ministry for the Environment, Wellington.

- ensure Part V decision making processes incorporate, enhance and protect tikanga Māori;
- assist in the identification and undertaking of research priorities identified by Māori relating to HSNO issues.

This will include:

- identification of educational needs and priorities of hāpu/iwi/Māori;
- development of educational resources and tools for hāpu/iwi;
- support for research to guide decision-making and provide information for iwi;
- auditing and monitoring HSNO processes; and
- continuing to advocate and participate in ensuring effective Māori participation.

Ngā Kaihautū Tikanga Taiao is the Māori advisory group to the Authority of ERMA New Zealand

## Decision making

ERMA New Zealand is very aware of its responsibility to ensure that ethical considerations are identified and acknowledged in decision processes. One way of eliciting information about ethical considerations of concern is through the public notification process. However, there are a number of applications that are not notified where ethical considerations may still be relevant. In these circumstances the Agency staff must be vigilant to identify these considerations and where necessary to bring them to the attention of the Authority. The proposed framework is seen as a support mechanism that the Agency staff can use to assist them to identify these circumstances.

Ethical issues have been actively considered in a number of recent decisions. Examples of applications where ethical matters have been considered include applications to:

- develop a breeding flock of transgenic ewes as a means of producing human alpha-1-antitrypsin, as treatment for Cystic Fibrosis and Atopic Dermatitis. The donor nucleic acid originated from an ovine gene isolated from sheep material and a human gene isolated from a Caucasian cell-line,
- insert synthetically coded genes from other species into potatoes,
- develop genetically modified cattle able to express a range of functional therapeutic foreign proteins in their milk,
- develop molecular genetic markers to assist in the conservation and management of Kaki (Black Stilt) by inserting DNA fragments from Kaki into approved vectors, and
- develop a non-living bait-delivered vaccine for the fertility control of possums.

Transparency of decision making is an important ethical consideration. All ERMA New Zealand decisions are publicly available through the website and *The Bulletin*. In addition, ERMA New Zealand undertakes a comprehensive public awareness programme, and there are recent examples of publications and seminars that are directly relevant to ethical considerations. Examples of events include the following:

- the Precaution in Environmental Risk Management: a review of recent policy and practice seminar (November 2001), and
- National Roadshow - *Managing Genetic Modification in New Zealand; understanding the issues; making it work* undertaken as part of the consultation

process for implementation of the New Organisms and Other Matters Act (November 2003).

In addition, over the past year several internal seminars and workshops on ethical matters and social assessment processes have helped to provide Agency staff and Authority members with up to date information about current thinking in these areas.

## **Steps of the ERMA New Zealand decision-making process**

The steps of the ERMA New Zealand decision making process are:

- (a) application received
- (b) further information is obtained from the Agency staff, submitters, experts and other agencies
- (c) the decision maker (the Authority) considers all the information in the context of the HSNO Act and the Methodology and makes a decision
- (d) the decision is published.

Applications are submitted to the Agency on application forms that are available electronically on the Internet, and applicants are encouraged to consult agency staff before submitting their application. The application forms have annotations to help applicants, and there is a user guide for each form that provides extra assistance.

Once the application has been received, the Agency staff begins to prepare an Evaluation and Review (E&R) Report.

The HSNO Act requires for particular types of applications to be notified, and in some cases the Authority has the ability to notify applications if it believes they would have significant public interest. Where an application is notified, an advertisement is placed in a specified set of newspapers, it is published on the website, and special notice is sent to stakeholders registered or known to have an interest in that particular type of application. Once submissions have been received, the Agency staff include this information in the E&R report.

The Agency will often also send the application to one or more experts in particular areas where the Agency decides that it needs some help. Any information received from experts is also added to the E&R report.

The format of the E&R report follows the requirements of the HSNO Act and the Methodology for the particular application type. While the format is not fixed (in the same way as the application forms), there are particular aspects that need to be addressed each time. The E&R report identifies, assesses and evaluates the potential adverse and beneficial effects of the substance or organism. The details of how this is to be done are in the Technical Guides.

If any person requests it then the Authority will hold a public hearing. The Corporate Manual specifies the process to be followed at a hearing. The applicant presents his or her case, the Agency staff present the E&R report and submitters present their case. The members of the Authority or committee of the Authority hearing the application may ask questions of any of the presenters, but there is no cross-examination.

Once the hearing has been completed the Authority begins the consideration process where they weigh up any adverse and beneficial effects of the substance or organism and decide whether to approve or decline it.

The following figure summarises the process, the participants and the support material available to each step.

	<b>Participants</b>	<b>Support Material</b>
Pre application	Applicants Agency staff	Application forms User guides Technical Guides
Application formally	Applicants Agency staff	Application forms User guides Technical Guides
Notification (where relevant)	Agency staff Submitters	Protocols Technical Guides
Submissions received (where relevant)	Agency staff Submitters	
Ministerial Call-In		
E&R report	Agency staff Experts	Protocols Technical Guides E&R templates
Hearing (where required)	Authority Agency staff Applicant Submitters	
Consideration	Authority	Methodology Worksheets Protocols Technical Guides
Notification of decision	Agency staff	