



**Consideration of
Ethical Issues
in HSNO Act processes**

A discussion paper

May 2005

Foreword

The main purpose of the Environment Risk Management Authority (ERMA New Zealand) is to protect people and the environment from 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 choices 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 proposals: 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.

The Authority 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.

The Authority 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. The Authority is committed to continuing improvement of the way it implements its responsibilities. In April 2004, the Authority set up a three-person Ethics Advisory Panel. The Panel has made a major input to the development of this discussion paper, 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 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 principles are taken into account.

The Authority welcomes all views and comments about the proposed framework.



Neil Walter

Please contribute your views

We welcome your views and comments on the proposals set out in this paper.

Your comments can be sent to ERMA New Zealand by **25 July 2005** in writing or by email, to the following address

*ERMA New Zealand
Attention: Ethics Advisory Panel
P.O. Box 131
Wellington*

Email: info@ermanz.govt.nz

You can also check the ERMA website (www.ermanz.govt.nz) for information.

During the development of the proposed ethical framework considerable work was done to survey relevant international approaches on ethics in environmental decision making. This information is summarised in a Background Paper available on the ERMA website at www.ermanz.govt.nz. The Background Paper also contains information about ERMA New Zealand, and on current approaches to dealing with ethical considerations in HSNO processes. Printed copies of the Background Paper are also available on request from ERMA (ERMA New Zealand, P.O. Box 131, Wellington).

Questions for discussion

You may find it helpful to construct your response around these questions but you are also welcome to comment on any aspects of the proposed ethical framework in any format you wish.

1. Would development of an ethical framework along the lines suggested in this discussion paper enhance current HSNO processes?
2. Does the scope of ethical issues outlined in the discussion paper adequately incorporate the issues that are important to New Zealand communities, and users of HSNO processes? If there are gaps, what are these?
3. The discussion paper suggests one approach to categorising ethical issues: are there alternative frameworks that could be more effective?
4. Are the practical steps suggested for HSNO process and ERMA New Zealand practice sufficient? What alternatives or modifications could be useful?
5. Are there risks, including regulatory burden, posed by the development of an ethical framework? If so, what are these, and how could they be mitigated?
6. In general, what other approaches would lead to a widely shared view that HSNO processes comprehensively and effectively identify and deal with ethical considerations?

Summary

Consideration of Ethical Issues in HSNO Act Processes

Introduction

- This discussion paper sets out a proposed framework for the consideration of ethical issues in HSNO processes, and requests comment on the proposals. The paper introduces concepts of thinking about ethics and outlines the responsibility that HSNO and ERMA New Zealand have to consider ethical issues, and describes the challenges of ethics and environmental decision making. ERMA New Zealand's approach to developing an ethical framework is explored.
- The paper acknowledges that it is common for there to be tension between different ethical values and principles. In these circumstances a choice may need to be made between two 'goods' or 'rights', posing an ethical dilemma. While an ethical framework will be helpful in identifying and resolving some ethical dilemmas, decision makers will still need to apply judgement when choices must be made.

The Proposed Framework

- The purpose of applying an ethical framework is to ensure that ethical matters are given due consideration in ERMA New Zealand decision making. Thus the framework outlined in this discussion paper is, in effect, a set of reference points to be applied to the many different dimensions of ERMA New Zealand processes.
- The proposed framework has three components: ethical principles, procedural standards and operational processes.
- The proposed fundamental or general ethical principles are "respect for persons" (past, present and future generations) and "respect for the natural environment". Each of these fundamental principles is embodied in the terms of reference of ERMA New Zealand. It is important to point out that they are interrelated and that the framework is not intended to encourage their employment in isolation from each other in the evaluation of applications. Underneath the two fundamental principles is a set of derived principles: autonomy, co-operation, cultural identity, human rights and dignity, justice and equality, well-being, animal welfare, and sustainability. These derived principles are described in the context of the fundamental principles.
- The procedural standards relate to the derived principles. They require all persons working under the framework to: act with honesty and integrity, ensure transparency and openness, adopt scientific and rational methods, take account of community and expert consultation, and to adopt a fair decision-making process.
- The third element of the framework describes the way in which these principles and standards are included in ERMA New Zealand processes and procedures, and how they are relevant to different participants in the process.
- This discussion paper also describes how the adoption and implementation of the framework will enhance current practices under the HSNO Act, including the Ministerial call-in powers.

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1 Introduction

1.1 Purpose of this paper

This discussion paper outlines a proposed framework for consideration of ethical issues in Hazardous Substances and New Organisms (HSNO) applications and decision making. It is envisaged that the framework will help applicants, the Environmental Risk Management Authority (ERMA) New Zealand, and the wider community.

1.2 Thinking about ethics

In day to day life, we all make choices that have ethical dimensions.

Should we spend an extra hour working and fulfil what we see as our responsibilities to customers or colleagues, or should we leave early to watch a school sports game and meet family responsibilities?

Should we, as we sell our used car, tell the purchasers about an upcoming repair need?

Most of us could state quite clearly, from our perspective, what we regard as ethical behaviour, although we might not all agree on the specifics.

As a society, we use legislation to define what are, and are not, acceptable activities. The making of legislation or regulation carries with it ethical consequences. Debates on legislation, particularly on sensitive issues such as abortion or capital punishment, have a strong ethical component.

Many professional groups, including doctors, lawyers and engineers, have clearly expressed ethical guidelines, such as codes of ethics, to guide the behaviour of members. These guidelines provide indications of what is, and is not, likely to be considered as acceptable behaviour.

Even though we are used to dealing with ethical issues in everyday life it is not always easy for people to understand the wider field of ethical considerations in decision making. Words are not always used consistently. This paper makes the assumption that the words “morals” and “ethics” broadly reflect the same concept.

Ethical issues are fundamentally about our individual, group or societal answers to the questions ‘what do we value as good’ and ‘what is the right thing to do’¹. These are questions that we necessarily encounter in making decisions about environmental issues, including the management of new organisms and hazardous substances.

This discussion paper is about how one specific area of environmental decision making – the HSNO Act processes administered by ERMA New Zealand – might be enhanced through implementation of a formalised framework for considering ethical issues.

¹ The language of morality includes nouns such as ‘rights’, ‘responsibilities’ and ‘virtues’ and adjectives such as ‘good’ and ‘bad’ (or ‘evil’), ‘right’ and ‘wrong’, ‘just’ and ‘unjust’.

1.3 HSNO and ERMA New Zealand's responsibility to consider ethical issues

The purpose of the HSNO Act is 'to protect the environment and the health and safety of people by preventing or managing the adverse effects of hazardous substances and new organisms'. Social values, and an acceptance or assumption of ethical or value judgements, are embedded in the language of the HSNO Act; expressions such as 'intrinsic value', 'relationships of Māori to their culture and traditions', 'economic and related benefits', the 'maintenance and enhancement of the capacity for people and communities to provide for their own economic, social and cultural well-being', and the definition of 'environment' itself. These expressions are referenced in the purpose and principles of the HSNO Act, and their importance was strengthened in the recent amendment to Section 68(a) adding 'cultural, ethical and spiritual' to the list of significant effects allowing for Ministerial call-in of applications.

A specific example of an application to ERMA New Zealand that involved consideration of a range of ethical issues was an application to insert human genes into cattle. The ethical issues included: distributive justice, where the beneficial effects were expected to accrue to one group and the adverse effects to fall on another, animal welfare considerations, and cultural and spiritual concerns. Another recent application was for approval for an aquatic herbicide. This substance has significantly improved ability to kill water weed in lakes and streams, but its use has the potential to cause adverse effects on downstream farmers and communities ranging from inconvenience (not being able to use water during a withholding period) to adverse effects on people's health.

What people believe to be 'good' and 'right' shapes our views about proposals for hazardous substances and new organisms. Concepts of what is good and right also shape views on how decision-making processes should work.

HSNO processes already reflect ethical considerations in a number of ways including public participation processes and the factors that the Authority considers in determining how risk averse it will be in particular decisions. In addition, Part 4A of the HSNO Act establishes a committee to be called Ngā Kaihautū Tikanga Taiao (Ngā Kaihautū) to provide the Authority with 'advice and assistance' from a Māori perspective on 'matters relating to policy, process, and applications'. Ngā Kaihautū's terms of reference focus on specific effects of concern to Māori, how Māori approach risk and risk aversion, and appropriate consultation with Māori where risks are identified. Ethical considerations are significant in these areas, though Ngā Kaihautū's interests extend beyond ethical matters.

Consideration of Māori issues and concerns, both in terms of Māori cultural and spiritual values and matters relating to the Treaty of Waitangi, is an integral part of ERMA New Zealand processes and decision making. 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. While the proposed ethical framework includes consideration of issues relevant to Māori and does not intend to imply a separation of Māori and non-Māori ethical consideration, it is complementary to processes being developed by Ngā Kaihautū.

Although these foundations of ethical consideration in ERMA New Zealand processes exist, the Authority has not previously carried out a detailed review of how and where ethical considerations are reflected in HSNO processes. Nor does ERMA New Zealand currently

have an explicit framework for the identification and recognition of ethical issues and implications.

1.4 Ethics and environmental decision making

The practice of environmental decision making has a number of features that raise ethical considerations including:

- 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 the 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 decision making often involves the balancing of relatively predictable short-term gain against relatively unpredictable long-term loss.

Many environmental decisions have both technical and ethical dimensions. Some decisions require the weighing up of a technically feasible action in terms of its ethical consequences. This leads us beyond asking ‘can this be done?’ to ‘should this be done?’

People have widely differing views on the best way to manage hazardous substances and new organisms. These views are often influenced by an individual’s cultural or spiritual background, their understanding of the technologies involved, their views about the rights and welfare of animals and ecosystems, and their personal or family needs.

A significant issue in environmental management involves people’s beliefs about the relationship between humans and nature. There are many different world views. Some people believe that species and ecosystems have an integrity that should not be compromised. Feeling part of an overall system of being, life or nature is an important part of the ethical and spiritual beliefs of many people which often carries with it perceived responsibilities of stewardship. On the other hand, meeting people’s needs, especially to maintain life or address health issues, is considered by some to be a basic imperative for humanity.

There are other related issues that pose challenges. For example, ecosystems change and evolve over time. As we think about managing the effects of hazardous substances and new organisms on the environment, and the integrity of ecosystems, should our reference points be today’s highly modified ecosystems, or should the aim be to restore ecosystems to some earlier, unmodified state?

These features of environmental decision making need to be taken into account in designing and applying an ethical framework for HSNO processes.

1.5 ERMA New Zealand's approach to developing an ethical framework

During the development of the proposed ethical framework considerable work was done to survey relevant international approaches on ethics in environmental decision making. This information is summarised in a Background Paper available on the ERMA website at www.ermanz.govt.nz. The Background Paper also contains information about ERMA New Zealand, and on current approaches to dealing with ethical considerations in HSNO processes. Printed copies of the Background Paper are also available on request from ERMA (ERMA New Zealand, P.O. Box 131, Wellington).

While ethical problems do not necessarily have a single 'right' answer, where ethical insights and reasoning are included in the decision-making process it is more likely that better informed and more acceptable decisions will result.

An ethical framework is in practice the gathering together of a range of relevant ethical concepts into a 'tool' either as an aid to decision making or as a foundation for making structured comments on issues where ethical matters are of concern. A framework may include guidance as to how the concepts might be used to assist in decision making. An ethical framework constructed in this way provides the context for a consistent approach to consideration of a wide range of issues.

Ethical thinking in the areas of religion, medicine and animal research is relatively well developed. For example, codes of medical ethics² contain statements of broadly agreed and consistent ethical principles. There are no equivalent international statements in relation to agreed environmental ethical principles, though particular disciplines, such as engineering and mining, may have ethical statements or codes that relate to their interaction with the environment.

A number of environmental regulatory bodies are now seeking a more explicit and well-understood approach for dealing with ethical considerations in decision making. Useful work on ethical issues is being done in New Zealand by organisations such as the Bioethics Council, in relation to biotechnology.

The Agency's review of existing approaches to ethical issues showed that there are a number of jurisdictions where ethical concepts have been brought together in the form of 'declarations' or 'statements' or groups of principles (see Appendix 2 in the background document). The International Declaration of Human Rights, the Rio Declaration and the proposed UNESCO Universal Declaration on Bioethics and Human Rights are examples of high level international approaches. At national and regional levels, codes of practice and codes of ethics have been developed for treatment of and research on both people and animals. At a national level, some statements of ethics do include examples (NZ Nurses Organisation Code of Ethics) and practice notes on particular topics (New Zealand Planning Institute Code of Ethics, <http://www.nzplanning.co.nz/ethics.html>).

² Medical ethics focuses primarily on issues arising out of the practice of medicine. It is closely related to bioethics (biomedical ethics) which is concerned with the moral issues raised by developments in the biological sciences more generally.

There are, however, no readily available models of relevant ethical frameworks on which ERMA New Zealand can draw. In developing an ethical framework for HSNO decision making, ERMA New Zealand will be one of the first international bodies to take ethical considerations from concepts through to practice in environmental regulation.

At the same time, ERMA New Zealand's proposed framework is broadly consistent with emerging international thinking on ethics in environmental decision making. The examples mentioned above were developed in recognition of a need to develop international or widely agreed standards of acceptable behaviour that take into account fundamental values or concepts such as respect for persons, respect for the natural environment, equality, informed consent and sustainability. Most of the existing material relating to ethics and decision making concentrated on identifying the values and principles that (should) underpin the particular decision-making process. Thus the review identified the critical concepts that need to be considered in developing an ethical framework and the proposed framework has drawn on these.

In developing the framework, the Authority also considered how ethical issues are already dealt with in HSNO processes, and what kinds of ethical considerations have arisen in HSNO applications.

Each of the five categories of effect (environmental, human health, Māori culture, society and community and the market economy) that the Authority is required to consider in making decisions has ethical dimensions, so ethical considerations are already a fundamental part of the ERMA New Zealand decision process.

A related question was whether ethical issues are a distinct set of factors to be placed alongside physical, biological, cultural, community, and other considerations. International thinking and practice suggest instead that ethical considerations can be a dimension of all these other factors.

For example there are ethical considerations in:

- determining which of conflicting views on physical impacts or economic effects should have most credibility
- deciding how much weight to put on scientific uncertainty
- assessing whether specific community groups have had sufficient opportunity to present their views, and
- deciding how to handle information that is culturally sensitive or commercially confidential.

In other words, there is no tidy box labelled 'ethical considerations' that exists separately from the other complex considerations that need to feed into environmental decision making. The proposed framework suggests a clear approach that is fully integrated with other facets of HSNO processes.

In developing the framework the Authority considered the relative merits of two approaches that a framework could take:

- a list of tightly defined rules, and
- a set of high level principles.

The first approach raises issues of the potential for tension between rules, and inability to deal well with circumstances that were not considered when the framework was developed. The second approach of developing a set of high level principles requires considerable skill and expertise to apply and may be much less clear in terms of its practical effects than a set of rules. The proposed framework aims for consistency and clarity, without being unduly prescriptive.

It is also important to be realistic about what a framework can and cannot do. Having an ethical framework does not eliminate the need for careful consideration and judgement. A framework will not necessarily make complex decisions easier, but it should enable good decisions to be made with confidence, increase transparency and help justify decisions.

It is common for there to be tension between different ethical values and principles. In these circumstances a choice may need to be made between two 'goods' or 'rights'; posing an ethical dilemma. An ethical framework will be helpful in identifying and resolving some ethical dilemmas, but decision makers still need to apply judgement when choices must be made.

2 The Proposed Framework

2.1 The contents of the framework

The purpose of applying an ethical framework is to ensure that ethical matters are given due consideration in ERMA New Zealand decision making. Thus the framework outlined in this discussion paper is, in effect, a set of reference points to be applied to the many different dimensions of ERMA New Zealand's processes.

A framework is able to acknowledge that individuals and communities hold a range of ethical positions. It is not simply a recipe, a checklist or a set of decision criteria (though it may contain these elements). A framework is a structure that can help to increase confidence that ethical considerations will be identified and respected, and that all relevant information will be available and considered. It can be considered as a tool for assisting all participants in the ERMA New Zealand decision process to:

- ask the 'right' questions in order to identify areas where there are ethical matters to be considered, and
- use the answers to these questions to explore whether and how ethical considerations need to be addressed in decision making.

This framework has three elements:

- ethical principles,
- procedural standards, and
- operational processes.

The ethical principles proposed are the foundation of the proposed ethical framework. The procedural standards describe the ethical dimensions of the processes that are used to make decisions. The operational processes incorporate the principles and procedural standards into day-to-day operational processes to ensure that the stakeholders in the ERMA New Zealand decision process, including applicants, submitters, the Agency, the Authority and the general public ask the 'right questions' at each stage of the process.

Thus the responsibility for ensuring that the framework is embedded in the decision process becomes a joint responsibility of all parties. Appendix 2 shows the application of the framework and the interactions between the different parties to the process.

As noted earlier, development of the current framework does not imply that ethical considerations are absent from current HSNO processes. Many elements of the proposed framework are already implicit in these processes. For example, the HSNO Act requires persons exercising powers and functions to take into account the principles of the Treaty of Waitangi. Similarly the HSNO Act has specific requirements for decision makers to publicly notify particular activities and to take submissions into account. What the proposed framework seeks is to make consideration of ethical dimensions more explicit and visible.

2.2 Ethical principles

The proposed fundamental or general principles are:

- respect for persons (past, present and future generations), and
- respect for the natural environment.

The derived principles flow from these, and are outlined in Table 1. They are described in more detail in Appendix 1.

ERMA New Zealand believes that the fundamental and derived principles outlined provide a comprehensive and adequate set of reference points to meet the requirements of the HSNO legislation. These principles reflect current international thinking in terms of ethical principles and values, and are found (albeit at times expressed differently) in a wide range of different cultural contexts.

Table 1: Ethical principles

Fundamental principles	Derived principles	Sample expressions of derived principles
Respect for Persons	Autonomy Respect for persons requires acknowledgement of autonomy and the protection of those with diminished autonomy.	Respect for privacy, confidentiality, and informed consent.
	Co-operation (defined as including solidarity) Any decision or activity should respect the solidarity of humanity, ensure equity and encourage international co-operation.	All stakeholders have standing.
	Cultural identity/pluralism Decisions and activities should respect the world view of all cultures or communities.	Make an effort to ensure that minority groups participate fully.
	Human rights Decisions and activities should be made or carried out with full respect for the human rights and fundamental freedoms.	Protection of vulnerable groups e.g. children and the aged.
	Human dignity Decisions and activities should be made or carried out with full respect for the inherent dignity of the human person.	Sharing of benefits. Non discriminating/ stigmatising

	<p>Justice and Equality Decisions and activities should be made or carried out with full respect for the universal principle of justice.</p>	<p>decisions made or activities carried out.</p> <p>Ensure equitable decisions are made.</p>
	<p>Well-being/non-harm Persons should be treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being.</p>	
Respect for the natural environment	<p>Animal welfare Decisions should be made and activities should be carried out with respect for animals and with concern to minimise any suffering of animals.</p>	<p>The “3Rs” principle advocated by ANZCCART – replacement, reduction, refinement.</p>
	<p>Sustainability Decisions should be made and activities should take account of managing resources in the present taking into account the needs of future generations.</p>	<p>Precautionary approach should be taken.</p>
	<p>Well-being/non-harm In addition to the basic concepts of well-being and non-harm with respect to flora, fauna and ecosystems, decision making and activities may require active intervention to ensure maintenance and enhancement of biodiversity, and species integrity.</p>	<p>Precautionary approach adopted. Biodiversity strategy implemented. Intrinsic values of ecosystems and species taken into account.</p>

How the fundamental principles relate to each other

Each of the fundamental principles is embodied in the terms of reference of ERMA New Zealand. It is important to point out that they are interrelated and that the framework is not intended to encourage their employment in isolation from each other in the evaluation of applications.

The principles can overlap in two ways. Firstly, respect for the environment may be called for as a means of protecting the welfare of people – a consequentialist consideration. Sustainability is often seen as a derived principle in the sense that the welfare of future generations depends on our protection of the environment. It might be claimed that in such cases the first fundamental principle is predominant.

The second kind of overlap occurs when the environment is seen to have intrinsic rather than instrumental value. In such cases it calls for protection for its own sake. People's views will differ about the character of the environment. For example, some will see species boundaries as being sacrosanct. To interfere with these boundaries by means of genetic manipulation would be morally repugnant to such people. So the welfare of these people would be affected by such activities in that they would be morally offended by them. However, where the environmental is seen as having intrinsic value the second fundamental principle takes precedence.

2.3 Procedural Standards

The procedural standards, as the name suggests, relate to the ethical dimensions of the processes that are used to make decisions. Their application helps to provide mechanisms and criteria for ensuring that the fundamental and derived principles are upheld.

Procedural Standards
Honesty and Integrity
Transparency and Openness
Scientific and rational methods
Community and Expert Consultation
Fair Decision-Making Process

These standards are relevant to all participants, including applicants and submitters, and there is an expectation that all participants will adhere to them.

2.4 Operational Processes

The following sections describe the practical ways in which the principles appear in the HSNO application and decision making process. It describes how consideration of ethical issues in HSNO processes will actually occur.

Most of the practical opportunities to recognise the principles arise in the HSNO application process. As outlined above, the critical need in decision making is to ensure that the Authority has access to comprehensive information about the ethical dimensions of an application. For the Authority to have all the information in front of it therefore the right questions have to be asked of the applicants at the right times. In addition, achieving comprehensive coverage of ethical dimensions is likely to be enhanced if applicants and interested stakeholders have a good understanding of these issues from the outset.

The implementation of the ethical principles and procedural standards will be facilitated by the steps set out in the following table. For further details about the relationship between the principles and the process see Appendix 2.

Table 2: Key features of operational processes for ERMA New Zealand, applicants and submitters

Stage	Operational processes	
	ERMA New Zealand Agency or Authority	Other parties Applicant or submitter
Pre-application stage	<ul style="list-style-type: none"> Provision of guidance by Authority to applicants which includes clear and helpful reference points on potential ethical considerations, and how to identify these in relation to a specific proposal. When alerts about ethical considerations are raised at the pre-application stage the Agency staff may contact the Ethics Advisory Panel for an opinion as to whether or not further information is required³. Informal interaction with the applicant at this stage may resolve a number of issues, or serve to highlight that ethical considerations will be a factor in the decision and/or the presentation of material. 	Applicants <ul style="list-style-type: none"> Adhere to guidelines provided by ERMA New Zealand. Identify the ethical considerations relevant to the application. Initiate early discussions with stakeholders who may have significant ethical concerns or questions.
Application	<ul style="list-style-type: none"> Inclusion of appropriate questions in application form, see Appendix 2 for further detail. 	Applicants <ul style="list-style-type: none"> Ensure that applications contain an appropriate level of detail on ethical considerations, supported by well evidenced information on how ethical concerns have been anticipated and mitigated, as prompted by the questions in Appendix 2.
Submissions	<ul style="list-style-type: none"> Guidance to submitters includes clear and helpful reference points on how to identify and present ethical perspectives. 	Submitters <ul style="list-style-type: none"> Identify ethical issues in a constructive way, supported by clear information on the basis of these ethical issues, and any steps that might help to mitigate them.
Assessment	<ul style="list-style-type: none"> Agency staff are well versed in relevant ethical concepts and principles and use these 	Submitters and applicants <ul style="list-style-type: none"> Have confidence in the assessment process and

³ Since the Panel is a committee of the Authority, Agency contact with the Panel will be through the Authority.

	<p>appropriately in making judgements about the need for further information.</p> <ul style="list-style-type: none"> ▪ Ethical considerations are comprehensively recognised in the process of identifying and assessing risks, costs and benefits. ▪ Transparent and consistent approaches are applied in assessing and weighing up ethical considerations. ▪ Preparation of corporate manual items and technical guides for Agency staff. 	<p>participate constructively in interactions with Agency staff</p>
Evaluation and decision	<ul style="list-style-type: none"> ▪ The Authority is fully aware of the complete range of ethical considerations associated with an application. ▪ The Authority uses a transparent and consistent approach in weighing up all information including ethical considerations. 	
Communication of decision	<ul style="list-style-type: none"> ▪ Decisions are communicated in a way that makes clear how ethical considerations have been dealt with. References in decisions to ethical issues are framed in a way that builds stakeholder confidence that ethical considerations are given serious and appropriate recognition. 	<p>Applicants and submitters</p> <ul style="list-style-type: none"> ▪ Have a clear understanding of the basis on which decisions have been reached

2.5 Enhancement of current practice

2.5.1. Role of the Ethics Advisory Panel

The Ethics Advisory Panel may be asked to provide advice at the pre-application or application stage, and where the issues cannot be resolved satisfactorily, the Agency staff will document the interaction and include it in the Evaluation and Review Report, and the Decision document.

Where the Panel provides advice directly to the Authority at the consideration stage of the process, material relating to this exchange will be included in the Decision document.

When requested, the Panel may assist the Authority in addressing ethical issues.

2.5.2 Role of Ngā Kaihautū Tikanga Taiao

Ngā Kaihautū Tikanga Taiao (Ngā Kaihautū) is established by statute as the Māori advisory committee to the Authority (Sections 24A-24D of the HSNO Act). The committee provides advice on matters relating to policy, processes and applications received by ERMA New Zealand.

The purpose of Ngā Kaihautū is to uphold and protect the integrity of tikanga and matauranga Māori and to ensure it is appropriately applied to HSNO issues. The achievement of this role involves the provision of advice on ERMA New Zealand planning and policy development and ensuring that ERMA New Zealand takes account of Māori perspectives and provides for Māori participation. Other functions undertaken by Ngā Kaihautū consist of recommending and participating in strategies to enhance the knowledge, understanding and supporting participation of Māori in HSNO processes, monitoring decision making by ERMA New Zealand and IBSCs and providing independent reports on applications that involve significant issues for Māori. Ngā Kaihautū will work with the Ethics Advisory Panel as and when mutually determined, on a case-by-case basis.

2.5.3 Relationship of the framework to Ministerial call-in (MfE and the Minister)

The Minister for the Environment has the power to call in an application where the Minister considers that the application will have significant cultural, economic, environmental, ethical, health, international or spiritual effects, or if the decision on the application may have significant effects in an area where the Authority lacks sufficient knowledge or experience. The decision whether or not to call-in an application must be taken very shortly after the application has been received by the Agency.

While MfE will provide advice to the Minister as to whether to call-in an application it is likely that the Agency will be involved in providing information that will be used to make that determination.

The framework may be used to provide advice or alerts to the Agency at an early stage (pre-application). MfE may also choose to refer to the framework as a formal mechanism in developing its own advice on Ministerial call-in but this is outside the scope of ERMA New Zealand's direct responsibility.

When an application is called in, the Minister may appoint additional persons to sit with the Authority through its deliberation process. The normal application process is followed, but instead of making a decision, the Authority presents a report and recommendations to the Minister.

2.5.4 Other ways of recognising ethical issues in ERMA New Zealand's operations

The proposed ethical principles and procedural standards are relevant to all of ERMA New Zealand's activities, and should be reflected in the practices and culture of the organisation.

Ways of achieving this, in addition to developing specific guidance as described above, include the following:

- recognition of ethical issues in the ERMA New Zealand statement of intent,
- ensuring that ethical considerations are recognised in ERMA New Zealand’s core values,
- alerting new staff and new Authority and Ngā Kaihautū members to the ethical considerations inherent in ERMA New Zealand decision making through induction material (written and presented),
- reinforcing ethical practices in training processes, including study of the proposed ethical framework,
- ensuring that ethical considerations are included in all relevant sections of the Agency’s operating procedures, and
- adding ethical considerations to project planning templates to place ethical thinking in the forefront of the minds of the Agency staff.

The Authority and the Agency will need a mechanism for regular review of ethical practice and, where necessary, the development of new guidance or other methods for dealing with new issues.

2.6 Implementation costs

In developing these proposals, ERMA New Zealand is aware of the need to manage the burden of regulatory processes on applicants and others. The proposed ethical framework is not intended to cause a significant increase in the volume of information sought, or the complexity of application processes. Instead, it will aim to bring information on ethical considerations to the right stages of the application and decision-making process in an effective way.

The framework may in fact help to reduce the costs and time associated with applications that would otherwise encounter significant opposition founded on differences over ethical issues. For example, early signalling of the need to consider ethical dimensions in a comprehensive way should influence pre-application work by applicants. Early identification of ethical considerations may enable mitigating steps to be taken in planning for a proposal.

Appendix 1 - Ethical Principles

Sources for descriptions: United Kingdom Nuffield Council, UNESCO Declaration, National Health and Medical Research Council (NHMRC) (Australia), Canadian TriCouncil Policy Statement on Ethical Conduct for Research Involving Humans, United States of America National Institutes of Health: Belmont Report.

Fundamental Principles

Given the HSNO Act's all encompassing definition of 'environment', there could be a view that there should be only one Fundamental Principle, 'respect for the environment'. However, for pragmatic reasons it is more useful to separate that Principle into two; 'respect for persons' and 'respect for the natural environment'.

Respect for persons

Respect for persons incorporates a range of ethical convictions including that individuals should be treated as autonomous agents, individuals are members of groups, and those (individuals and groups) with diminished autonomy are entitled to protection.

All individual human beings are presumed to be free and responsible persons. The central concern is respect for the individual as well as individual decision making. These ideas are related to a range of ethical concerns, including recognition of, and respect for, the inherent value of persons, recognition of the value of self-determination to the well-being, happiness and moral development of individuals, and respect, within our liberal democracy, for individual freedom, including freedom of choice.

There is also a cultural aspect to respect for persons. Individuals are also members of groups of one sort or another and realise their values, in part, through their interactions with other members of those groups. Respect for persons, then, includes respect for the groups with which members identify.

Respect for persons must also include respect for those whose capacities for self-determination and the exercise of personal choice are compromised or absent.

Respect for the natural environment

Respect for the natural environment is often linked to sustainable development/management. Other significant aspects of respect for the natural environment include respect for species, and ecosystem integrity and biodiversity.

Activities should not be unnecessarily detrimental to the environment, any animal or plant populations, or any natural, historical or cultural site. Decisions and activities should have due regard for impact on all forms of life and their interconnection and the special responsibility of human beings for the protection of biodiversity and the biosphere within which human beings exist, as well as natural, historical or cultural sites.

The environment is a resource for humans (from food to aesthetic enjoyment), as well as other forms of life, and it is the right of humans, as well as a necessity, to use it. However, that use must be sustainable in that it protects, and maintains or enhances the resource.

Ecosystems may be viewed as a collection of interdependent components. Decisions need to consider the integrity of ecosystems, by taking account of the relationship between of the components of each other and to the whole. The form (type) and function (what it does) of the ecosystem under consideration must also be factored in. Over time ecosystems change and evolve both through internal interactions and in response to external stimuli. Consideration of the integrity of ecosystems therefore requires consideration of these dynamics.

The concept of ‘intrinsic value’, that is, the value ascribed to something over and above the benefit gained by putting it to some use. In this sense, the value is inherent. Intrinsic, or non-use, value has relevance both for ecosystems and ecosystem components, and is an essential component of respect for the natural environment. Many natural and historic places also have intrinsic value.

Respect for the well-being of the natural environment means that it must not be unnecessarily harmed and actions which improve it should be favoured. Sentient beings, by virtue of their capacity to suffer, demand additional consideration. Organisms, communities and ecosystems should be seen as valuable in themselves, in addition to whatever benefits (or harms) they may represent. It is also important to respect the adaptive qualities of natural organisms and consider limiting human intervention in some circumstances.

Derived Principles

Animal welfare

Research, testing and teaching organisations and their personnel are required by the New Zealand Animal Welfare Act 1999 to minimise any suffering of animals in their care and undergoing manipulations. Minimisation of suffering is inclusive of the notions of reducing the use of animals where possible, refining experiments to ensure least harm or damage, and replacing animal models by other models where possible.

A related issue is that of species integrity. The primary concern here is xenotransplantation, the use of living non-human animal cells tissues or organisms to treat humans⁴.

Autonomy

Respect for persons requires acknowledgement of autonomy and the protection of those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons’ considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person’s considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

Respect for autonomy is therefore incompatible with paternalism.

⁴ For further information refer to the Bioethics Council document (see Bibliography).
Consideration of Ethical Issues in HSNO Act Processes

Co-operation (defined as including solidarity)

Any decision or activity shall respect the solidarity of humanity, ensure equity and encourage international co-operation, and actively seek to avoid discrimination and stigmatisation of any individual or group.

Cultural identify /pluralism

Decisions and activities should respect the world view of all cultures or communities, including oral history and traditional knowledge concerning culturally significant objects and human material including bones⁵. Information about culturally sensitive objects may not be readily available, and it is the responsibility of applicants and promoters of activities to actively seek it out, and to consult with knowledgeable members of the appropriate communities before using the material in any way.

Human rights

Decisions and activities should be made or carried out with full respect for human rights and fundamental freedoms.

Human dignity

Decisions and activities should be made or carried out with full respect for the inherent dignity of the human person.

Justice and Equality

Decisions and activities should be made or carried out with full respect for the universal principle of justice.

For people, justice relates to the concepts of ‘fairness in distribution’ and ‘what is deserved.’ An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed without good reason. Another way of conceiving the principle of justice is that equals ought to be treated equally. This requires consideration of who is equal and who is unequal in relevant respects, and introduces a requirement to determine which considerations justify departure from equal distribution. Distinctions based on experience, age, deprivation, competence, merit and position may sometimes constitute criteria justifying differential treatment for certain purposes.

In terms of respect for the natural environment, judgements may need to be made as to whether one species is more valuable than another, or whether one ecosystem type should be given a higher weighting than another.

⁵ Canadian Museums Association Ethical Guidelines
Consideration of Ethical Issues in HSNO Act Processes

Sustainability

Sustainability is linked to the concept of managing resources in a way that takes account of the needs of future generations. At a practical level, indicators of sustainability may include biodiversity measures (such as loss of species) complemented by considerations related to the long term viability of ecosystems and their constituent parts.

Well-being/non-harm

Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. This concept covers acts of kindness or charity that go beyond strict obligation. Two complementary rules address this principle: (1) do not harm and (2) maximise possible benefits and minimise possible harms.

In the context of the natural environment, well-being/non-harm may go beyond the concept of absence of harm and require active intervention to ensure maintenance and enhancement of biodiversity, and species integrity. This principle also requires consideration of the intrinsic value of ecosystems.

Procedural Standards

The Procedural Standards have been adapted from the UNESCO Draft Declaration on Universal Norms, where they comprise Articles 14 through 18.

Honesty and Integrity

Any decision or practice within the scope of HSNO decision making will be:

- (i) be conducted with independence and intellectual honesty
- (ii) respect the need for integrity in scientific and other research
- (iii) avoid conflict of interest and duty or if this is not possible, manage it appropriately, and
- (iv) pay due regard to the need to share knowledge about such decisions and practices with the persons affected, the scientific community, relevant bodies and civil society.

Transparency and Openness

Any decision or practice within the scope of HSNO decision making will be:

- (i) be made transparently and openly
- (ii) be determined with particular regard to the circumstances known to the persons concerned
- (iii) be subject to respect for privacy and confidentiality
- (iv) be available for appropriate scrutiny by the persons concerned and by civil society, and
- (v) be susceptible to informed debate, including in the media.

Scientific and Rational Methods

Any decision or practice within the scope of HSNO decision making will:

- (i) be made on the best available scientific information
- (ii) pay due regard to any different information on the subject reasonably available to the decision-maker
- (iii) be considered rigorously and in a principled manner
- (iv) observe, when appropriate, proper procedures of risk assessment, and
- (v) be considered individually, allowing for the possibility of exceptions to general rules and practices.

Community and Expert Consultation

Any decision or practice within the scope of HSNO decision making will take into account the need to reconsider regularly the state of such knowledge and different opinions about it and the need to engage in a regular dialogue with:

- (i) persons affected by any such decision or practice
- (ii) members of relevant disciplines
- (iii) appropriate bodies, and
- (iv) civil society.

Fair Decision-Making Process

Any decision or practice within the scope of HSNO decision making will, where differences arise, be resolved following full and free discussion in which the complexity of human and ecological systems and inter-relationships between them is acknowledged, and in accordance with fair procedures⁶.

⁶ Within the scope of the legal requirements.

Appendix 2 - Application of Ethical Framework

This table demonstrates how ethical principles can be taken into account within ERMA New Zealand processes. It consists of a series of questions to be addressed by the different participants, throughout the application and decision process. There are two aspects to this: firstly, the framework of principles provides assurance that relevant issues have been addressed, and secondly, a set of indicators is used as triggers for Panel involvement in the process.

The fundamental principles, 'respect for persons' and 'respect for the natural environment' apply to all questions.

This framework is in a development stage and will be modified over time as experience is gained in its application.

There may be other ethical questions that need to be considered at a general level. One such question is 'Has secondary evidence been collected ethically?' An example of this might be the results from an experiment where information about pesticide effects was collected from deliberate exposure of human subjects who had been paid to take part in the experiment.

Other similar questions are –

Are all 'issues' subject to equal scrutiny? Does it appear that some issues have not received adequate attention?

Can the objective be achieved (is it reasonable/feasible)? Do the objectives and the proposed benefits appear unrealistic?

Is the objective worthwhile? Can the objective be achieved by other means?

Questions	Trigger for Panel ‘intervention’ (screening Qs)		Derived Principles (of direct relevance ⁷)	Procedural standards ⁵	Current/Practice Comment
Application form	Agency Evaluation	‘NO’ to Questions A, G, M, N or ‘YES’ to any other Questions will trigger further action			
1. Provide details of any consultation undertaken with parties affected by the proposed activity.	a. How effective has the consultation been? b. Was the consultation superficial or substantive? c. Is the information supplied comprehensive, truthful and available in a style which allows for understanding? d. Is the consultation comprehensive i.e. have all affected individuals /groups /communities had the opportunity to express their views? e. Have these views modified the proposed project?	<i>A. Have all materially affected people been consulted?</i> <i>B. Do submissions or responses indicate that they did not consider the consultation to be adequate?</i> <i>C. Does the Agency consider that there are affected groups that have not been heard and that they require a voice?</i> <i>D. Have submitters expressed concern about respect or dignity (people and the environment)</i>	Autonomy Co-operation Human rights Human dignity Justice and Equality	Community and Expert Consultation	<i>The notification requirements of the HSNO Act, and specific requirements for consultation with Māori (Protocols and User Guides) provide the basis for consultation.</i> <i>Agency staff comments on the adequacy of consultation with Māori.</i>

⁷ The listing of principles in this column is not intended to be all-inclusive. In some circumstances other derived or procedural standards will be relevant.

Questions	Trigger for Panel 'intervention' (screening Qs)		Derived Principles (of direct relevance ⁷)	Procedural standards ⁵	Current/Practice Comment
	f. Are there some individuals/ groups/ communities affected by this project who will be unable to express their views?				
2. Will information about the outcome of the project be shared with persons consulted?	g. Is there any ongoing relationship with concerned/affected parties?		Co-operation Human dignity Justice and Equality	Honesty and Integrity Transparency and Openness Community and Expert Consultation	
3. Where appropriate, is there evidence of approval by an animal ethics committee?		<i>E. Taking into account submissions, does the Agency consider that there are outstanding issues relating to animal welfare or ethical use of animals?</i>	Animal welfare Autonomy Well-being/non-harm	Transparency and Openness Community and Expert Consultation	
4. What future choices would be affected if the application is approved/declined?	h. Will the choices of individuals/groups/communities be restricted if this application is approved/declined?	<i>F. Are any changes irreversible?</i>	Autonomy Human rights Human dignity Justice and Equality	Transparency and Openness Scientific and Rational Methods Fair Decision-Making Process	<i>NOTE: If changes are irreversible then the Authority is required (by the Methodology) to be more risk averse. Therefore this question may not necessarily trigger Panel intervention.</i>
5. Have persons involved given voluntary informed consent?	i. Is the information available to those involved in the project sufficient and in an appropriate form to make informed choices?	<i>G. Where persons are involved in a research project, is there evidence of ethical approval?</i>	Autonomy Human rights Human dignity Justice and Equality Well-being/non-harm	Honesty and Integrity Transparency and Openness Community and Expert Consultation Fair Decision-Making Process	<i>While this may not appear to be applicable there may be circumstances where DNA is sourced from individuals, in which case it would be relevant.</i>
6. Does research affect	j. Have Māori rights		Autonomy	Honesty and Integrity	

Questions	Trigger for Panel 'intervention' (screening Qs)	Derived Principles (of direct relevance ⁷)	Procedural standards ⁵	Current/Practice Comment
Māori as Māori? If yes, how has this been addressed?	under the Treaty been provided /protected?		Co-operation Cultural identify /pluralism Human rights Human dignity Justice and Equality Well-being/non-harm	Transparency and Openness Community and Expert Consultation Fair Decision-Making Process
7. Does this research impact on cultural or spiritual beliefs of people?	<p>k. What assumptions does the proposal make about which values/beliefs should prevail?</p> <p>l. What do people believe about these issues (right/wrong)?</p> <p>m. Are the claims being made by the applicant substantiated by other evidence?</p> <p>n. Are the claims made by persons submitting substantiated by other evidence?</p> <p>o. Is the information provided by the applicant trustworthy/accurate?</p>	<p><i>H. Do submissions indicate that individual's and community's values are 'affronted'?</i></p> <p><i>I. Is there potential conflict of interest?</i></p>	Autonomy Co-operation Cultural identify /pluralism Human rights Human dignity Justice and Equality Well-being/non-harm	<i>No specific question required – one issue is whether benefits are overblown – see below</i>

Questions	Trigger for Panel 'intervention' (screening Qs)	Derived Principles (of direct relevance ⁷)	Procedural standards ⁵	Current/Practice Comment
	<p>p. Is the information supplied by persons submitting accurate?</p> <p>q. Has the applicant disclosed other interests which may suggest a potential conflict of interest?</p>			
8. What is the objective of the project	r. Has full disclosure been made?	<i>J. Is there concern that full disclosure may not have been made or that there may be undisclosed objectives?</i>	Justice and Equality	Honesty and Integrity Transparency and Openness Scientific and Rational Methods
	s. Are the objectives as stated or are there undisclosed objectives?			
9. Provide evidence of applicants' competency to undertake this work	t. Does the applicant have the background and skills to undertake this work?			Scientific and Rational Methods
10. Describe the risks and benefits of the proposed activity including the distribution of risks and benefits.	u. Are the proposed benefits actual or potential?	<i>K. Is there a clear inequity? i.e. the applicant gains the benefit and specific identifiable individuals or communities bear the cost?</i>	Autonomy Co-operation Justice and Equality Well-being/non-harm	<i>NOTE: These matters are all addressed in the E&R report. It is not clear that they would require Panel intervention</i>

Questions	Trigger for Panel 'intervention' (screening Qs)		Derived Principles (of direct relevance ⁷)	Procedural standards ⁵	Current/Practice Comment
	v. Are there other risks which the applicant has not identified?				
	w. Are the benefits and the burdens of the project fairly distributed?				
11. How will those risks be managed	x. Are these appropriate measures to reduce risk?			Scientific and Rational Methods Fair Decision-Making Process	
	y. Does the potential benefit of the project outweigh the potential harm?				<i>NOTE: This is the Authority's decision, not the Agency's. The Agency may make an implicit judgement.</i>
12. Who owns the intellectual property?		<i>L. Is there a clear inequity in terms of access to information?</i>	Animal welfare Autonomy Co-operation Cultural identify /pluralism Human rights Human dignity Justice and Equality Sustainability Well-being/non-harm	Honesty and Integrity Transparency and Openness	
13. How will IP benefits be distributed (justice issues, financial benefit; limits on publication)?	z. Who has access to what information?	<i>M. Has sufficient information been provided in the public arena for submitters to make informed submissions?</i>	Animal welfare Human rights Human dignity Justice and Equality Sustainability Well-being/non-harm	Honesty and Integrity Transparency and Openness	<i>This question relates to information, and may not be relevant since in most cases the applicant will own the IP.</i>

Questions	Trigger for Panel 'intervention' (screening Qs)		Derived Principles (of direct relevance ⁷)	Procedural standards ⁵	Current/Practice Comment
	aa. How equitable is access?				
14. Who owns the material used?	bb. What is the risk of bio-piracy (exploitation, theft)?	<i>N. If the applicant is not the owner has specific permission been given to use the material?</i>	Co-operation Human rights	Honesty and Integrity Transparency and Openness	

Glossary

Authority (the Environmental Risk Management Authority) – the body that makes the decisions regarding applications for the approval of hazardous substances and new organisms in New Zealand.

Agency – the staff of ERMA New Zealand.

Bioethics – the ethics of medical and biological research.

Environmental ethics – the ethics of the environment and its relationship to people.

ERMA New Zealand – both the Agency and the Authority of the Environmental Risk Management Authority.

Ethics – for our purposes, ‘ethics’ and ‘morality’ are synonymous; in other contexts, morality denotes moral philosophy.

HSNO – Hazardous Substances and New Organisms Act 1996 which established ERMA.

Intrinsic – the value of something in and of itself, independent of its usefulness to someone else.

Methodology – 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.

Ngā Kaihautū Tikanga Taiao – the Authority’s advisory committee on Māori issues.

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