PUBLIC DISCUSSION PAPER

IMPROVING THE OPERATION OF THE HSNO ACT FOR NEW ORGANISMS

INCLUDING PROPOSALS IN RESPONSE TO RECOMMENDATIONS OF THE ROYAL COMMISSION ON GENETIC MODIFICATION

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Foreword

Genetic modification is a subject of great importance for New Zealand. Its applications are as diverse as medicine and food production, and its implications are far-reaching. Because of this the Government set up the Royal Commission on Genetic Modification, to look into and report on the issues surrounding genetic modification in New Zealand. The Royal Commission reported in July 2001.

The Royal Commission was satisfied that the basic regulatory framework for genetic modification in New Zealand is appropriate and that the key institutions carry out their functions conscientiously and soundly. However, suggestions were made to enhance the regulation of genetic modification.

We agree with the Royal Commission's view that New Zealand should preserve its opportunities with both GM and non-GM products and innovations, and proceed with caution.

Our detailed response to the Royal Commission outlined a package of changes that we intend to implement over the next two years. These changes include the establishment of a Bioethics Council, the formation of a comprehensive Biotechnology Strategy, and some immediate changes to the rules governing field tests of genetically modified organisms. We are also funding research to help us investigate the wider implications of this new technology, both on the environment and on society in general.

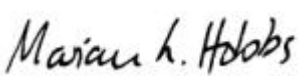
In Part A of this public discussion document, we seek your views on changes that might be made to the main piece of legislation controlling genetic modification – the Hazardous Substances and New Organisms (HSNO) Act 1996. The proposals range from seeking to make the Act more efficient, thus reducing compliance costs (for example, by delegating the approval for importation of low-risk genetically modified organisms to Institutional Biological Safety Committees); through to changes to the grounds for the Minister for the Environment to call-in an application for a HSNO approval. In some cases we have identified what we think is the best way forward on an issue. In other cases we have not yet decided on exactly how we want to proceed.

Part A also sets out the issues around liability for possible adverse effects from genetically modified organisms (GMOs). At this stage, we have not formed a view about liability issues and are not proposing any changes in relation to liability in respect of GMOs. Rather we have set out the issues and options to be considered and seek your comments on these.

Part B of this document discusses other changes to improve the operation of the HSNO Act. These changes do not relate to the recommendations of the Royal Commission, but it is opportune to raise them at this time. Genetically modified organisms are only one type of new organism under the HSNO Act. In the Act, 'new organisms' also includes exotic species kept in zoos or used for biological control. Many of the suggested changes would affect how such organisms are controlled. Finally, we seek your comment on several proposals that arise out of operational experience of the Act since it commenced in July 1998. Some of these proposals affect the hazardous substances part of the Act.

In addition to the options and proposals to change the HSNO Act described in this document, we will also be reviewing certain aspects of the Environmental Risk Management Authority's operations. This review will assess whether the Authority has the capacity to meet the demands placed on it by the HSNO Act. Some of the discussion in Part B of this document will be informative for this review.

The issues discussed in this document are of the utmost importance. I encourage you to tell us what you think of the ideas described and to suggest any alternative approaches you believe are better. I look forward to receiving your views.



Hon Marian Hobbs
MINISTER FOR THE ENVIRONMENT

Some Important Information

Meetings

Much of the information in this document is technical and complex due to the scientific nature of many of the areas addressed and the associated legal technicalities. The Ministry for the Environment will assist people/organisations interested in making written submissions. In order to do this, the Ministry will provide speakers to groups wishing to meet and discuss the issues. Please contact the Ministry to arrange speakers as soon as possible as our ability to do this is limited. Should the need arise, the Ministry will organise meetings for groups to assist in preparing written submissions. Please contact us if you wish to participate in such a meeting. Attendance at meetings will depend on the response, adequate notice and any scheduling constraints.

Ministry contacts

To contact the Ministry for the Environment staff working on the HSNO amendments, please:

E-mail: HSNOamend@mfe.govt.nz

or write to: HSNO Amendment
Ministry for the Environment
PO Box 10-362
Wellington

or phone: (04) 917 7400.

This document will be posted on the Ministry's website: www.mfe.govt.nz.

Submissions

Closing date

Written submissions on this discussion paper are requested by **Friday 15 November 2002**. Submissions should be sent to the address above. E-mail submissions are also welcome and should be addressed to HSNOamend@mfe.govt.nz. For E-mail submissions it is preferable that the submission be either text in an E-mail message or as a Microsoft Word document sent as an attachment to the E-mail. Submissions will be acknowledged either by E-mail or letter as soon as possible after we receive them.

Format

To help you to make your submission we have included questions throughout the document. If you are responding to a question, please refer to the question number. If you wish to comment on other issues, please refer to the relevant paragraph or section of the document.

Additional information requested

Please include an address, telephone number and email contact address in case we need to get in touch with you to clarify any matter in your submission.

In the introduction to your submission we would also like you to tell us a little about yourself. For instance, if you are making the submission as an individual:

- Where do you live?
- What is your interest in the proposed amendments?
- Do you have any relevant knowledge, experience or qualifications to mention?

If you are making a submission on behalf of an organisation, please tell us:

- How many people do you represent?
- What process has your organisation gone through in order to arrive at the views in the submission?

The Ministry's policy on disclosure of submissions is to treat any written material given to us as being in the public domain and available to any other person, on request, for the cost of photocopying. If you would like your submission to be kept confidential, please say so.

Next steps

The Ministry for the Environment will publish an analysis of submissions on this document as soon as possible after the closing date. Policy options will then be developed for the Government's consideration during early 2003.

Contents

Executive Summary

This document describes the key elements of the options and proposals for a variety of amendments to the Hazardous Substances and New Organisms (HSNO) Act 1996. The majority of the options and proposals are in response to the recommendations of the Royal Commission on Genetic Modification. Others address issues arising from experience with the operation of the HSNO Act and a transitional matter for zoo and circus animals.

The options and proposals are being presented here for discussion. We would like your input on options and proposals in regard to:

- Approval processes for laboratory research – to simplify the approval processes for both the development of low-risk genetically modified organisms (GMOs) in the laboratory in New Zealand and their importation from overseas laboratories, thereby reducing unnecessary compliance costs without changing the scope of what is considered low-risk
- Human cell lines and tissue regeneration – to address gaps in HSNO Act coverage options are proposed for ensuring appropriate regulatory oversight for research involving genetic modification of human cell lines, and for amending the HSNO Act to cover the regeneration from tissues, using cloning and related techniques, of organisms that are not currently in New Zealand. The proposed amendments would not extend to human cloning as the term organism in the HSNO Act specifically excludes human beings
- Conditional release of GMOs – to introduce another category of approval that would enable ERMA to approve organisms for release with certain controls attached to them
- Assessment of GMO medicines – to reduce duplication and streamline the assessment and approval of medicines that are or contain GMOs, four general options are presented for changes to the agencies responsible for the approval of GMO medicines and how the health and environmental risk assessments might be incorporated
- Confidential information – to revise the protection given to confidential information provided with applications for approvals: comment is sought on what level of protection is appropriate
- Ministerial call-in – to revise the grounds for ministerial call-in: the Minister is able to 'call-in' and decide on applications where she considers there may be significant effects; it is proposed that the grounds be extended to include 'significant cultural effects'
- Zoo and circus animals – to complete the transition to the HSNO regime for animals in existing registered zoos and circuses that are new organisms
- Enforcement agency for new organisms – to specify an enforcement agency for new organisms: it is proposed that the Ministry for Agriculture and Forestry's enforcement role for new organisms in containment be formalised
- Miscellaneous operational issues – to address a variety of issues arising from experience in the operation of the HSNO Act for new organisms, including:
  - a longer time for the Environmental Risk Management Authority (ERMA) to make and release its decision on applications
  - how to deal with the establishment of new organisms in New Zealand that arrive through natural means or as accidental 'hitchhikers'
  - problems with the classification of new organisms at the species level
  - shortening the time within which a compliance order must be complied with

- allowing a greater time to mount a prosecution
- review of the list of prohibited new organisms
- what constitutes a large-scale fermentation
- clarification of the decision making criteria for new organisms in containment.

In addition, the issues around liability for the possible impacts of GMOs are discussed. Submissions are sought on whether there are liability issues which are unique to GMOs, the adequacy of existing liability rules, and, if they are not adequate, the range of options for reform. This section does not presuppose legislative change in this area.

To help you make your submission we have included questions for discussion (in shaded boxes) throughout the document. If you are responding to a question, please refer to the question number. If you wish to comment on other issues, please refer to the relevant paragraph or section of the document.

PART A

Legislative and Policy Proposals in Response to the Royal Commission on Genetic Modification

1 Introduction

This document outlines options and proposals for amendments to the Hazardous Substances and New Organisms (HSNO) Act 1996. The majority of the options and proposals described are in response to the recommendations of the Royal Commission on Genetic Modification. Others address issues arising from experience in the operation of the Act and the need to replace the controls for existing zoos and circuses covered by the Zoological Gardens Regulations.

This section provides a brief outline of the HSNO Act, the Royal Commission on Genetic Modification and the Government's response to the Royal Commission, the areas covered, and how this discussion paper relates to the eventual amendment of the HSNO Act through the HSNO (New Organisms) Amendment Bill.

1.1 Hazardous Substances and New Organisms (HSNO) Act

The HSNO Act is a recent environmental and health and safety law, with two main parts. The part covering new organisms came into force on 29 July 1998 and that for hazardous substances on 2 July 2001.

The term 'new organism' refers to any organism not legally present in New Zealand before 29 July 1998. New organisms can include any new species of any animal, plant, fungus, bacterium or virus. The term also includes genetically modified organisms (GMOs). Broadly speaking, 'hazardous substance' includes any substance that can damage the environment or adversely affect human health and safety (other than substances that are solely radioactive, ozone-depleting or infectious).

Anyone wanting to introduce (import, develop, field test or release) a new organism or a hazardous substance must apply to the Environmental Risk Management Authority (ERMA) to do so. The Act establishes a consistent process for assessing the risks posed by hazardous substances and new organisms, and for setting national controls to manage their environmental effects and risks.

All users of new organisms and hazardous substances must comply with the controls imposed by ERMA on approvals for new organisms and hazardous substances.

The primary focus of the amendments discussed in this paper is on GMOs. However, in many instances the proposed amendments will also relate to new organisms in general, and in some cases to hazardous substances.

To find out more about the HSNO Act, please refer to *Your Guide to the Hazardous Substances and New Organisms Act* June 2001, available from the Ministry for the Environment at www.mfe.govt.nz, or visit the Ministry for the Environment's HSNO website at www.hsno.govt.nz. To find out more about ERMA and how it handles applications to introduce new organisms or hazardous substances, please visit the ERMA New Zealand website at www.ermanz.govt.nz.

1.2 Royal Commission on Genetic Modification

The Royal Commission on Genetic Modification was an independent body established by the Government in May 2000 to look into and report on the issues surrounding genetic modification in New Zealand. The Royal Commission reported to the Governor-General on 27 July 2001. More information on the Royal Commission is given in Appendix 1 and also at www.gmcommission.govt.nz.

A primary objective of the Royal Commission was to identify any changes considered desirable to the current legislative, regulatory, policy or institutional arrangements for addressing, in New Zealand, genetic modification, GMOs and their products. While satisfied that the basic regulatory framework for controlling genetic modification in New Zealand is appropriate and that the key institutions carry out their functions conscientiously and soundly, the Royal Commission recommended a number of improvements.

1.3 The Government's response to the Royal Commission

The Government released its initial response to the Royal Commission's report on 30 October 2001. The Government supports the overall strategy of preserving opportunities suggested by the Royal Commission. However, it has come to some different conclusions about how the overall strategy of preserving opportunities should best be implemented. The differences are in two main areas:

- the extent to which commercial release should be possible in the immediate future
- the conditions under which research should be able to proceed.

The Government decided that there is a need to restrict the release of GMOs (with limited exceptions) for a period while work, analysis and research identified as necessary by the Royal Commission is carried out. It has therefore passed the HSNO (Genetically Modified Organisms) Amendment Act 2002. This Act puts in place a legislated two-year restricted period during which time no applications can be lodged with ERMA for release of GMOs except those that provide direct benefits to human or animal health, or are in accordance with the existing emergency provisions of the HSNO Act.

The restricted period is to allow time to:

- put in place amendments to the HSNO Act, many of which are outlined in this document
- establish a Bioethics Council
- complete generic work on the economic impacts of any GM crop release on the strategy of 'preserving opportunities'
- establish or continue research programmes addressing areas of socioeconomic, ethical, environmental and agricultural research which were identified by the Royal Commission as needing additional work
- undertake appropriate work on other issues identified by the Commission.

To find out more about the overall response of the Government, please visit www.mfe.govt.nz/new/inquiry_into_geneticmod.htm. The information on this website includes the Cabinet papers advising on the Royal Commission on Genetic Modification, and a summary of the decisions the Government made on the individual recommendations presented in the report of the Royal Commission.

1.4 The aim of this discussion paper

This discussion paper examines proposals and options for amendments to the HSNO Act. Consequential or related amendments to other acts such as the Agricultural Chemicals and Veterinary Medicines (ACVM) Act 1997 and Medicines Act 1981 may also be required in specific cases.

The paper also discusses issues around liability for the possible adverse effects from GMOs. Several options, including the status quo, are identified. This section does not presuppose legislative change in this area.

The paper describes the intended approach to amend the HSNO Act and provides a basis for developing an amendment Bill. It is not a set of draft amendments, or a complete description of all amendments that may be proposed under this Bill. Rather, it represents work in progress and as such is more comprehensive in some sections than others. In some cases several options for amendment are merely outlined; in others more detailed proposals are discussed. The idea is to provide a basis for all those interested to comment on the proposals.

The next step in this process will be to analyse submissions, provide a summary to submitters and draw on these to develop final proposals for Government consideration. Once the Government has decided on the policy for amendments, the HSNO (New Organisms) Amendment Bill to enact the amendments will be drafted by parliamentary counsel. The Bill will then go to select committee, and interested parties will have an additional opportunity to comment on the proposals at that stage.

1.5 The main areas covered

1.5.1 Recommendations of the Royal Commission

The proposals for amendment in this paper address those recommendations of the Royal Commission relating to:

- simplifying approval processes for laboratory-based research that involves genetic modification
- gaps in HSNO Act coverage
- a new category of approval called 'conditional release'
- streamlining the approval process for medicines that are or contain GMOs
- confidential information supplied with applications for approval
- grounds for ministerial call-in of applications.

Further details of the relevant Royal Commission's recommendations and the Government's decisions on the recommendations are given in Appendix 2.

The Royal Commission also recommended that section 8 of the HSNO Act be amended to provide that effect be given to the principles of the Treaty of Waitangi (Recommendation 11.1). The Government has agreed that the HSNO Act should be amended so that it more appropriately reflects the Treaty of Waitangi relationship. It invited a group of Ministers comprising the Minister for the Environment, the Minister of Maori Affairs and the Associate Minister of Maori Affairs, the Minister of Research, Science and Technology and the Minister in charge of Treaty of Waitangi Negotiations to appoint a Maori Reference Group to assist in addressing this issue.

The Government is appointing a Maori Reference Group to provide input on how the HSNO Act could more appropriately reflect the Treaty of Waitangi relationship. These amendments are not discussed in this paper.

1.5.2 Zoo and circus animals

Under the current transitional arrangements in the HSNO Act, animals in existing registered zoos and circuses are deemed to be new organisms and the registrations are deemed to be approvals under the HSNO Act to import those organisms into containment. However, a number of issues have been identified as necessary to complete the transition of these animals to the HSNO regime. This paper also seeks comment on the amendments to the Act that are required.

1.5.3 Other issues

The HSNO Act is a major piece of legislation. A number of issues have arisen in light of experience with the operation of the Act, some of which have general application to all new organisms and hazardous substances. These issues are also discussed, and options and proposals for amendments are given.

2 Simplifying Approval Processes for Laboratory Research

2.1 Summary

This section addresses two proposals recommended by the Royal Commission on Genetic Modification aimed at simplifying the approval processes for low-risk genetic modification that occurs in contained laboratories:

- group (project-based) approvals for the development of low-risk GMOs
- delegation of approval of importation of low-risk GMOs to Institutional Biological Safety Committees (IBSCs).

These proposals also aim to better align the procedures with the way scientific research actually takes place. Overall they would reduce unnecessary compliance costs without changing the scope of what would be permitted as low-risk work, or altering the level of permissible risk.

Some related work suggested by the Royal Commission is already under way or has been completed (for example, new organism application forms and the standard covering safety practices in laboratories). Also, the HSNO (Low-Risk Genetic Modification) Regulations are being amended.

While the changes to the regulations go some way towards streamlining the approval process, the system may be further improved by changes to the HSNO Act itself. The following two sections address:

- how group approvals could be provided for instead of the current case-by-case approval of individual organisms
- how flexibility to use a range of low-risk procedures under one approval could be provided
- how the identification requirements for low-risk GMOs produced during the project could be simplified
- how approval of the importation of low-risk GMOs might be delegated to IBSCs.

It is proposed that, instead of focusing on the particular organisms being genetically modified, the HSNO approval process for low-risk experiments should focus on the broader circumstances or low-risk nature of the genetic modifications proposed in a research project. It is also proposed that a means be provided to vary the approval, where those circumstances change during the course of the research. The requirement to identify the organism resulting from the approved low-risk experiments would be removed or simplified.

The HSNO Act does not distinguish between low- and higher-risk genetically modified *organisms* (GMOs) in the same way it does for processes used in low- and higher-risk genetic *modifications*. In order to enable the delegation to IBSCs of approvals for the importation of low-risk GMOs, it is proposed that criteria be developed for defining a low-risk GMO in a manner similar to that for a low-risk genetic modification, and then allow both low-risk developments and low-risk GMO importations to be rapidly assessed by IBSCs.

2.2 Group approvals for the development of low-risk GMOs

The circumstances in which the genetic modification of an organism is considered a low-risk genetic modification are specified in the HSNO (Low-Risk Genetic Modification) Regulations 1998. Such genetic modification developments pose low-risk to public health and the environment, and include most of the routine laboratory genetic research and teaching work carried out by universities and research institutes. The Royal Commission recommended that applications to develop low-risk GMOs in containment be assessed by IBSCs[1] on a project rather than an organism basis. The Government accepted the *intent* of the recommendation, which was to simplify the assessment of low-risk laboratory (i.e. fully-contained) research involving genetic modification either by using defined criteria to assess organisms, or by providing for the approval of groups of organisms of similar types and risks, rather than requiring separate approvals for each organism.

2.2.1 How could group approvals be allowed for?

A research project is generally considered in terms of its overall purpose and output, although it is recognised that appropriate ethical (including animal welfare) and other approvals may be required for the different procedures that may be used. It is proposed that HSNO approvals focus on the broader circumstances or low-risk nature of the intended genetic modification. The HSNO (Low-Risk Genetic Modification) Regulations already allow for a focus on the circumstances of the development (genetic modification) rather than the resulting GMO. While the proposed amendments to these regulations provide a means for defining the low-risk work that may be allowed in a particular project they do not specifically address the 'project basis' issue.

It is therefore proposed that the HSNO group approval cover all the low-risk genetic modifications identified as being necessary to achieve the outcome of the particular research project.

2a What other ways are there to group (and handle/process) approvals for low-risk work?

Please explain your answer by setting out possible illustrative examples, and by relating your suggestions to the HSNO Act's present requirements.

[1] IBSCs are established by individual institutions to assess applications for low-risk genetic modifications (i.e. those developments that pose low-risk to public health and the environment). Approval to assess such applications is delegated to IBSCs by ERMA.

2.2.2 What happens if the research changes its course?

Often, all the likely low-risk genetic modifications are foreseen at the planning and approval stage of a project. Sometimes, however, the researcher may wish to perform different genetic modifications to meet the objective of the project. This may occur as the experimental procedures are tested and refined as the project progresses. Currently a new approval may be required.

To remove the need for a separate approval in this situation, the following process is proposed.

- The researcher either:
  - (where the changed circumstances clearly fit the criteria for a low-risk genetic modification) formally notifies the IBSC (or ERMA) of those changes and is then able to continue with the research after a certain period of time or
  - seeks a formal determination as to whether the circumstances fit the criteria for low-risk genetic modification (this option may occur in all cases, or only where there is uncertainty as to whether the changed circumstances fit the criteria for a low-risk genetic modification).
- The IBSC or ERMA would then either:
  - vary the approval as necessary or
  - advise that the alternative procedure does not fit the low-risk criteria, in which case a separate approval from ERMA would be necessary.

2b Is this approach workable?

Please consider in your comments both the extent to which the approach might streamline research procedures and the extent to which it might increase risks. If you consider there are problems with this proposal, please suggest alternatives and explain these as clearly as possible, referring, where necessary, to the relevant parts of the HSNO Act.

2.2.3 How could the requirements for identifying organisms be simplified?

For all GMO development applications, the HSNO Act requires that the organism being developed is identified at the time of the application, along with a description of the project and the experimental procedures to be used. Experience suggests that the identification requirement is overly complex for low-risk laboratory-based research that meets the criteria for low-risk genetic modification. GMOs created during a development may include, for example, 'libraries' of large numbers of related GMOs, which are created as intermediate stages in the process of identifying, isolating and copying particular genes. The Act also does not recognise that, in experimental situations, the exact identification and characterisation of the final resulting GMO typically cannot be made in advance.

Two possible options for amendment have been identified.

- ***Option 1:*** Remove completely the prior identification requirements in the HSNO Act for low-risk developments, while retaining the requirement to describe the project and the experimental procedures that will be used. This would ensure that the criteria for low-risk genetic modification and the level of risk could be ascertained.
- ***Option 2:*** As for Option 1, but instead require notification to the IBSC (or ERMA) within a specified time of the identity of the GMOs resulting from the approved low-risk experiments.

2c Which option is more appropriate?

2d What level of identification is required for intermediate and for resulting organisms?

2e When should the identification of the resulting organism occur?

Please consider in your comments both the extent to which simplifying the identification requirements might streamline research procedures and the extent to which it might increase risks. If you consider there are problems with these options, please suggest alternatives and explain these as clearly as possible, referring, where necessary, to the relevant parts of the HSNO Act.

2.3 Delegating approval of importation of low-risk GMOs to IBSCs

The Royal Commission on Genetic Modification recommended that the HSNO Act be amended to allow for the efficient importation of low-risk GMOs through delegation of the approval process to IBSCs. The Government has accepted this recommendation.

Currently, approval of the low-risk development of GMOs in containment in New Zealand may be delegated to an IBSC, whereas the importation of (potentially the same) low-risk GMOs into New Zealand requires approval from ERMA.

The HSNO Act distinguishes between low- and higher-risk developments through the HSNO (Low-Risk Genetic Modification) Regulations. These regulations specify the criteria for a low-risk genetic *modification*. The Act does not distinguish between low-risk and higher-risk genetically modified *organisms* for the purpose of importation.

2.3.1 Proposed amendments

It is proposed that criteria be developed for defining a low-risk GMO as well as a low-risk genetic modification, and that both low-risk developments and low-risk GMO importations be allowed to be rapidly assessed under section 42. Again two main options have been identified.

- ***Option 1:*** Define a low-risk GMO as an organism developed according to the criteria specified in the low-risk genetic modification regulations.
- ***Option 2:*** Develop a separate verifiable definition or criteria for a low-risk GMO.

2.3.2 Discussion of options

Option 1 raises a potential compliance issue of ensuring that the organism being imported is in fact the organism identified, and that it has been developed in the overseas laboratory in the circumstances specified as low-risk. Not all components of the low-risk modification procedure used can be determined from the organism itself (that is, the organism being imported). While the host and nucleic acid material inserted may be verified, if necessary, in many cases the use of a particular low-risk vector cannot be verified. While the vast majority of compliance under the HSNO Act is, of course, voluntary (as is the case for any statute), enforcement agencies must also be able to verify the status of an organism should verification be necessary.

This option may also not allow the importation of GMOs that are in themselves low-risk but that may have been developed using a procedure in which one or more elements is not specified in the low-risk genetic modification regulations.

With *Option 2*, for consistency it would be desirable to base the criteria for a low-risk GMO on those for a low-risk genetic modification; for example, those elements that can be independently verified (the host organism, the nucleic material being inserted, and the vector, where present).

Creation of separate criteria will require either amendment of the low-risk genetic modification regulations or promulgation of new regulations specifying the criteria for a low-risk GMO (and, in the latter case, creation of the power to make those regulations).

2f **Is it sufficient to base the criteria for a low-risk organism on the host organism, the nucleic material being inserted, and the vector, where present?**

2g **Will these criteria limit the importation of organisms that are demonstrably low-risk but have been developed according to other possibly higher-risk procedures?**

2h **What other criteria might be appropriate (e.g. the phenotype of the organism)?**

2i **Are there other general approaches to characterising low-risk organisms that may be better? If so, what are they?**

Please explain your answers by setting out possible illustrative examples and by relating your suggestions to the HSNO Act's present requirements.

3 Gaps in HSNO Act Coverage

3.1 Summary

This section addresses two gaps in coverage of the HSNO Act highlighted by the Royal Commission.

Genetic modification of human cell lines

A cell line is an established population of cells derived from tissues that will grow and divide indefinitely in the laboratory given the appropriate growth medium and space. Although the genetic modification of animal cell lines currently requires approval under the HSNO Act, the same modification of human cell lines does not. This is because humans, their tissues and their cells are specifically exempt from coverage under the HSNO Act through being excluded from the definition of an organism. Similarly, the Medicines Act covers clinical trials of new medicines involving human participants, but does not currently include laboratory research using human cell lines.

Two options have been identified to ensure that genetic modification of human cell lines for research purposes is subject to appropriate regulation. The first option would involve amending the HSNO Act to include applications for the development (genetic modification) of a human cell line or the importation of genetically modified cell lines. The other option is to address this matter in the Ministry of Health's current review of human cell and tissue research, possibly with guidelines to cover the genetic modification of human cell lines in the interim.

New organisms regenerated from tissues

Neither the importation of tissue samples nor any development activity (other than genetic modification) requires a HSNO approval. Improvements in cloning and related technologies since the commencement of the HSNO Act mean that it is now possible to produce an animal not currently in New Zealand (a new organism) from imported tissue using a surrogate mother, without a HSNO approval, thereby bypassing the usual requirements to fully evaluate the effects of introducing that new species of organism into New Zealand.

In addressing this gap it is proposed that the focus of the HSNO oversight remain the same; that is, on the nature of the new animals produced and their potential effects on the environment, not on the technologies themselves nor on any other direct use of the tissues.

Two options have been identified for amending the HSNO Act to include new animals produced using cloning and related techniques: either amend the definition of 'develop' to cover the regeneration of new organisms, or broaden the definition of 'new organism' or 'organism' and include a power to make regulations to provide that things are not 'organisms' or 'new organisms' for the purposes of the Act. It is proposed that the amendments extend to the artificial regeneration of organisms from all tissues, including plant and fungal tissues that are not capable of replicating themselves.

The proposed amendments would **not** extend to human cloning as the term organism in the HSNO Act specifically excludes human beings.

3.2 Genetic modification of human cell lines

The Royal Commission on Genetic Modification recommended that the HSNO Act be amended to clarify that research involving genetic modification of human cell lines or tissue cultures is covered by the Act. The Government agreed to accept the *intent* of the recommendation, which is to ensure that the genetic modification of human cell lines and tissue cultures is subject to appropriate regulation.

3.2.1 Nature of the issue

A cell line is an established population of cells, derived from human, animal or plant tissues, that will grow and divide indefinitely given the appropriate growth medium and space. The culturing of such cells *in vitro* (in a test-tube or other laboratory environment) is therefore often referred to as 'tissue culture'. Cell lines allow in-depth research into the properties of such cells, as well as research into numerous human and animal diseases and their treatment. They may also be used in the production *in vitro* of certain biological products.

The genetic modification of animal cell lines, including the insertion of human DNA into an animal cell, currently requires approval under the HSNO Act. The same modification of human cell lines does not require comparable approval. This is because humans, their tissues and their cells are specifically exempt from coverage under the HSNO Act through being excluded from the definition of an organism. The Medicines Act covers clinical trials of new medicines involving human participants, but does not currently include laboratory research using human cell lines.

The objective is therefore to provide appropriate regulatory oversight for research involving genetic modification of human cell lines. There are two main options.

- ***Option 1:*** Amend the HSNO Act to cover the genetic modification of human cell lines.
- ***Option 2:*** Address this matter in the Ministry of Health review.

3.2.2 Discussion of the options

Under *Option 1* the HSNO approvals that might be obtained would be for developing a GMO in containment or importing a GMO into containment. The approvals would be limited to the cellular level; that is, to the development (genetic modification) of a human cell line or the importation of a genetically modified cell line.

It is expected that appropriate experiments would be approved as low-risk genetic modifications by IBSCs. However, the types of genetic modification procedures that are categorised as low risk may also have to be considered and the regulations modified.

It is proposed that the scope of the amendments would cover:

- genetic modification of cell lines *in vitro* in containment in the laboratory (as well as importation of genetically modified human cell lines)
- genetic modification only and *not* activities such as nuclear transfer and cloning, stem-cell research, gene therapy, assisted reproductive technologies, and xenotransplantation (other than those parts of such activities that involve genetic modification)
- cell lines derived from somatic cells and possibly germ cells; but *not* gametes (sperm or ova), embryos or any subsequent reproductive stage capable of leading to a human individual.

At present ethical approval is not required for research involving human cell lines in containment. Ethical approval would, however, be required prior to collecting the initial human tissue sample from which the cell line is derived. This consent would specify the research for which the donor is prepared to have their tissue sample used. Any research not covered by the initial consent of the donor would need to be approved by an ethics committee.

Under Option 1 it is proposed that the HSNO Act be amended to cover the genetic modification of human cell lines, and that the HSNO (Low-Risk Genetic Modification) Regulations be amended to include human cell lines as host organism for low-risk genetic modification.

Option 2 arises as a possibility because the Ministry of Health has begun a review of all aspects of human cell and tissue research, including the collection, storage, use and disposal of bodies, organs, tissues and tissue samples, with a view to updating relevant legislation. Rather than address the genetic modification of human cell lines by way of an amendment to the HSNO Act, this matter could be addressed in the Ministry of Health review.

The advantage of this option is that the decision on exactly what is covered by the HSNO Act could be decided as part of a comprehensive review, thus ensuring that there are no future gaps or unnecessary overlaps in regulatory oversight. However, it would mean that the genetic modification of human cell lines remained unregulated until the Ministry of Health review.

3a Is it necessary to include genetic modification of human cell lines in the HSNO Act at this stage? If so, what do you think would be the best way of doing this? Please fully explain your comments and illustrate them with examples, where necessary.

3b Should consideration of the control of genetic modification of human cell lines be done as part of the Ministry of Health's wider consideration of all aspects of human cell and tissue research? Would guidelines be sufficient in the interim?

3c What is the likely impact to existing practice of the changes outlined in the options given above?

3.3 New organisms regenerated from tissues

The Royal Commission recommended that the HSNO Act be amended to cover procedures used in mammalian cloning, such as nuclear transfer or cell fusion. The Government agreed to accept the intent of the recommendation, to the extent that it ensures that new species of mammals (or other animals) cannot be imported as tissues and subsequently regenerated by cloning and released without an appropriate HSNO Act approval.

This section discusses options for amending the HSNO Act to cover the regeneration of animals that are not currently in New Zealand from tissues using cloning and related techniques. The purpose of the proposed changes is to ensure that new technology cannot be used to bypass the usual requirements to fully evaluate the effects of introducing a new species of animal into New Zealand. The cloning of animals that are already in New Zealand – such as cows and sheep – is not affected.

3.3.1 How did this issue arise?

This issue arose because neither the importation of tissue samples nor any development activity (other than genetic modification) requires a HSNO approval.

The importation into containment of tissues is regulated by the Biosecurity Act.[2] However, while a HSNO approval is required to import a new organism, the definition in the Act of an 'organism' does not include biological material such as tissue, which is itself incapable of unassisted self-replication, but which originates from a new organism. Therefore, because a tissue is not an organism, no HSNO approval is required.

Similarly, while a HSNO approval is required to develop a new organism, the Act restricts the meaning of 'develop' to the genetic modification of an organism. The current definition therefore excludes development in the sense of regenerating or creating an organism where no genetic modification is involved.

Cloning and related technologies have progressed significantly since the HSNO Act and associated regulations came into force. The advances in these technologies mean that it is now possible to produce an animal not currently in New Zealand (a new organism) from imported tissue using a surrogate mother, without a HSNO approval.

Although this regulatory gap has not caused problems so far, the use of cloning and other technologies is likely to increase in the future. In order to ensure unapproved new organisms are not developed and/or released in New Zealand there needs to be regulatory oversight in this area.

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[2] Animal tissues are classed as risk goods and their importation is controlled by permit. Animal tissues are directed to a laboratory approved as a transitional facility for biological products operating under the standard for biological products (MAF Reg Std:154.02.17).

It is proposed that the focus of the HSNO Act remains the same: to look at the nature of the new animal produced rather than the technology that was used to produce it. This would focus HSNO oversight on those animals that were new organisms and their potential effects on the environment.

Possible approaches for amendment

Two options identified for amending the HSNO Act to include non-GM animals produced using cloning techniques are as follows.

- ***Option 1:*** Amend the definition of 'develop' to cover regeneration of new organisms. (This would, however, require a new framework for dealing with the development of new [non-GMO] organisms.)
- ***Option 2:*** Broaden the definition of 'new organism' or 'organism' and include a power to make regulations to provide that things are not 'organisms' or 'new organisms' for the purposes of the Act.

3d How should the HSNO Act be changed to best cover new organisms produced using cloning technologies?

3e What other ways might there be to regulate these organisms?

Please fully explain your answers by setting out possible illustrative examples and by relating your suggestions to the HSNO Act's present requirements.

3.3.2 At what stage in the process should the HSNO assessment be carried out?

When a tissue from an organism not present in New Zealand is imported, there may be no intention to regenerate an organism from that tissue. Regulation at this stage is imposed by the Ministry of Agriculture and Forestry (MAF) under the Biosecurity Act.

Any tissue sample is subject to the requirements of an import health standard issued under the Biosecurity Act. The importer is required to obtain an import permit before importing the tissue. Tissue for *in vitro* use is directed to a transitional facility and held there. Permission must be obtained from the Director of Animal Biosecurity if the researcher wishes to do any *in vivo* work. Regeneration techniques are included, which means that the Director of Animal Biosecurity would be aware of any regeneration work, even if it was not stated as a purpose in the original application.

If a new category of approval was introduced for developing non-genetically modified new organisms in containment, and an approval was required before the regeneration work started, this would be a good stage to carry out an assessment under the HSNO Act, since for regeneration techniques this would be the stage at which a new whole organism is developed. If the new organism was later released from containment, it would undergo an assessment in the same way as any other new organism under the HSNO Act. Obviously if the tissue was imported expressly for the purposes of regeneration, an approval would be required before importation was permitted.

An alternative would be simply to assess the organism at the point of release from containment. However, this could mean that the level of containment may not be correct for the organism once regenerated, and that a new organism would be present in a containment facility without a HSNO approval and any HSNO controls prior to release.

3f At what stage do you think a regenerated new organism should be assessed under the HSNO Act?

Please explain your answer by setting out possible illustrative examples and by relating your suggestions to the HSNO Act's present requirements.

3.3.3 Regeneration of other new organisms

The Royal Commission recommendation refers to procedures used in 'mammalian cloning'. In its initial response the Government agreed that regulatory oversight should be provided for all animals that are new organisms, rather than just mammals. However, the same issues apply to all organisms, including plants and fungi.

Plants and fungi are commonly regenerated from tissues. In many cases this can happen naturally, in which case the tissue would fall under the definition of 'organism' ("a genetic structure capable of replicating itself") and would already require a HSNO approval. In other cases, special laboratory techniques would be required to produce the organism (for example, tissue culture). The possible approaches for amendment to the HSNO Act would similarly apply to all potential new organisms, and would therefore clarify regulatory coverage of all new organisms regenerated from imported tissue.

4 Conditional Release

4.1 Summary

Once released to the environment, new organisms (including both GMOs and imported species) are no longer considered 'new'. Currently, they are not subject to the HSNO Act and can be used freely by anyone, anywhere in the country. There is no intermediate stage between release and field-test, where new organisms must be held in containment. Some problems have been raised with this approach, such as the inability to carry out research on the environmental effects of a new organism in less contained conditions, or to monitor the impacts of organisms after they are released, or to limit their location (for example, to facilitate the co-existence of GM and conventional or organic agriculture).

The Royal Commission recommended that the HSNO Act be amended to provide for an additional category of approval, called 'conditional release' (Recommendation 6.8). This would allow ERMA to attach *controls* to approvals to release new organisms. The Royal Commission suggested that conditional release be used "as a further assurance of safety to enhance the management of risk".

Work on conditional release is at a relatively early stage, and this section seeks your response to the options and proposals discussed below. However, if the category is introduced, certain things are clear:

- ERMA would not be able to release any organism that breached the minimum environmental standards
- ERMA would still have to carry out a full risk assessment of the organism, including consideration of the ability of the organism to establish an undesirable self-sustaining population (and the ease of eradication if it did so), and
- conditional release would not replace full release, and the ability for ERMA to approve organisms without controls would remain.

Various uses have been suggested for conditional release, including enabling certain research outside strict containment, monitoring for impacts of released organisms, limiting the dissemination of the organism or its ability to persist, and controlling where and how organisms are used. Examples of possible controls include granting approval for extended field trials to a single user and stipulating how and where the research can be carried out; requiring monitoring of the effects of the organism on non-target organisms; requiring buffer zones, post-harvest segregation and identification of GM crops; and limiting the use of certain organisms to trained individuals only.

Compliance with and enforcement of controls on release would be an important issue, and possible measures to maximise and check compliance are discussed. The section also covers how the legislation could guide ERMA in setting controls. Guiding principles could stipulate, for example, that controls should be cost-effective and practicable, relevant to the organism, and enforceable. Finally the financial implications of introducing a new category of release are discussed.

In presenting options, the section includes the range of possible uses for a conditional release category. Feedback is sought on which if any of these possible uses should be allowed and whether there are other situations where conditional release should be used.

4.2 Why would we introduce conditional release?

4.2.1 How does the HSNO Act control new organisms at the moment?

The current regime for new organisms consists of the following approval categories:[3]

- development in containment/importation into containment – only for organisms held in laboratories, or other secure locations that are specially designed to prevent escape
- field-testing in containment – research outside the laboratory, strictly controlled so that the organism, and any heritable material, can be recovered after the trial (limited in time and location)
- importation for release or release from containment – no controls allowed, no time limit, no subsequent approvals required. Once approved for release, organisms can be used anywhere and by anyone. Persons releasing an approved organism within five years of its approval must notify ERMA.

Therefore, under the HSNO Act there are currently two possibilities: either the organism is a new organism and so fully contained in one of the above ways, or a decision has been made to release the organism, so it is no longer new, and it is not subject to any controls under the HSNO Act.

4.2.2 The ERMA decision-making process for releases

ERMA is required to assess release applications in accordance with the purpose of the HSNO Act[4] and the risk assessment and management processes set out in the Act. Applications are considered on a case-by-case basis after an assessment of risks and benefits, and after considering any public submissions. ERMA is required to take a precautionary approach when considering the scientific evidence relating to the application.

Because of the minimum standards in section 36, ERMA must decline a release application if the organism is likely to:

a) Cause any significant displacement of any native species within its natural habitat; or

b) Cause any significant deterioration of natural habitats; or

c) Cause any significant adverse effects on human health or safety; or

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[3] As of 20 March 2002 ERMA had approved five new organisms (all non-GM) for release, 128 new organisms for import or development in containment, and 13 GMOs for field-testing. No applications for a GMO release have been received (www.ermanz.govt.nz/applications/tableApps.htm).

[4] 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.

d) Cause any significant adverse effect to New Zealand's inherent genetic diversity; or

e) Cause disease, be parasitic, or become a vector for human, animal, or plant disease [unless that is the purpose of the application].

Section 38 of the Act states that ERMA can approve an application to import or release a new organism:

- if there is sufficient information available to assess the adverse effects
- if the organism meets the minimum standards, and
- if after considering the ability of the organism to establish an undesirable self-sustaining population (and the ease of eradication if it did so), the *positive effects of the organism outweigh the adverse effects*.

This introduces the concept of risk–benefit analysis: ERMA weighs up the benefits of the new organism against the risks. Because ERMA cannot put any controls on releases, when weighing up the risks and benefits they must assume that a new organism will spread to all parts of New Zealand.

4.2.3 Why controls were not included in the HSNO legislation

The policy work for new organisms regulation under the HSNO Act started during the 1980s. The legislation governing imports of new species at the time was much less restrictive than the HSNO Act and controls could only be placed on new organisms for the purpose of disease control. Controls used under the previous regime had been found to be either difficult to enforce or outside the power of the legislation, and several potential pest species were introduced to New Zealand; for example, the chinchilla, originally introduced for a fur industry, and freshwater marron crayfish, imported for a fish-farming venture. Both had the potential to breed, spread and cause environmental damage, could not be effectively contained, and were difficult to locate and control. The one breeding population of marron was eventually destroyed. Chinchilla farms proved to be uneconomic and the animals began to be sold as pets throughout New Zealand. There is still a risk they may form a wild population and breed.

Because of this, discussion about controls largely focused on the difficulty of *containing* animals in the farming environment. The inability to effectively confine such potential pest species led to the view that any new organism introduced to New Zealand (other than in strict containment) would eventually find its way to other parts of New Zealand, and that controls would not be able to prevent this. This was the basis for the HSNO Act having no provision to place controls on the release of new organisms.

However, little consideration was given to controls for species that did not have the potential to become pests and for which absolute containment was not essential. Similarly, little consideration was given at the time of the initial policy work to the possibility of using controls to manage GMOs. The commercialisation of GM crops did not begin until the 1990s, and the potential range of uses of GM technology had not been contemplated. GMOs present their own specific issues. For example, cows used as bioreactors for therapeutic proteins would not become pests, but would need to be carefully controlled to prevent them escaping and cross-breeding with non-GM cattle and entering the food supply.

4.2.4 Potential shortcomings with the current regime

Once a new organism has been approved for release, the HSNO Act allows the organism to be used at any time, by anyone and in any way. Because of this, ERMA has to assess the positive and adverse effects in all environments and in all parts of the country. This approach ensures that all known potential adverse effects are taken into account. However, it does not reflect the fact that the adverse effects of a new organism may depend on how and where it is used.

Since the Act came into force, thinking has changed on some aspects of how releases of new organisms should be handled. The following points have been made.

- The assumption that all new organisms will inevitably spread and establish may not be appropriate for *some* species that are easier to control in the environment than pest species. Even if escape is assumed, some species will be retrievable because they cannot persist without intervention (for example, highly domesticated crops) or are easily identified and retrieved (such as large mammals).
- Because GM field tests must be fully contained, it can be difficult to obtain all the necessary information about likely environmental impacts. Controlled research out of full containment (for example, to study the environmental effects of pollen from a GM plant) is not possible under the current legislation.
- There is no provision for monitoring organisms after release, which means that any unforeseen effects may not be detected unless they become a problem.
- (For GMOs specifically) Coexistence of GM and non-GM agriculture was not considered at the time of the policy development. A strategy of preserving opportunities may benefit from an intermediate stage before full release, and several Royal Commission recommendations may not be able to be implemented without the ability to set controls on GMO releases.

4.2.5 How would conditional release address these problems?

The conditional release category would enable ERMA to approve certain new organisms for release with controls attached to the approval. ERMA would still have to be satisfied that the positive effects of the organism outweighed the adverse effects, and would have to decline an application that failed to meet the minimum standards (see above).

Controls on release would change the assumption that all released organisms inevitably breed and spread throughout New Zealand. Controls would enable some effects of new organisms to be prevented or managed. ERMA would use controls to reduce potential adverse effects, and would take account of controls in their decision-making process. This would solve some of the difficulties with the current system. It could also lead to some new organisms being permitted for conditional release that would not be suitable for full release. Conditional release would not replace full release – ERMA could still approve organisms for release without controls.

Controls could be used to:

- limit the spread of genetic material from field research that is not fully contained, thus enabling research on environmental impacts that otherwise could not take place (see the potato example below)
- monitor for unforeseen impacts of new organisms (for example, on non-target insects or surrounding vegetation)
- limit the dissemination or persistence of the organism or its genetic material in the environment once it is out of containment (including managing the co-existence of GM and non-GM agriculture)
- control how a new organism is used (for example, to reduce the risk of insects developing resistance to incorporated pesticides such as Bt).

Not all of these suggested purposes would be appropriate for all organisms because different organisms will have different characteristics that determine their potential effects on the environment. Conditional release could potentially cover a large range of situations, from what are essentially larger and less stringently controlled field tests, to releases with very few controls. It would be possible to specify that some purposes would not be allowed for certain types of organisms, or that conditional release should not be used at all for some of these purposes.

For example, using conditional release to limit the spread of new organisms would rely on the controls being fully effective. If controls were breached, and if the organisms had the ability to establish, potential damage could result. ERMA would have to consider this possibility as well as the effectiveness of any proposed controls, the ability to identify a breach, the potential consequences of an escape, and the suitability of contingency plans when considering whether to approve the conditional release of an organism. An alternative would be to specify that conditions should only be used to limit the spread of organisms that do not pose additional risks to the environment (e.g. bioreactor cows).

Another approach might be to apply specific criteria to conditional release decision-making, such as requiring ERMA to assess organisms without taking controls into account, i.e. as if they were being fully released. Controls would thus be used only as an additional assurance of safety. Criteria could also ensure that less stringently controlled research was only undertaken if it could not be carried out in containment, and that any risks of irreversible impacts were negligible or able to be managed. Options for defining purposes, organisms, and controls for conditional release are discussed in section 4.3.2.

The range of purposes are discussed in more detail in the next section, together with some examples to highlight how they might work. This document seeks feedback on the overall objectives of the category, rather than the detailed mechanisms of how particular controls may be placed on organisms. It is also important to remember that some of the objectives of conditional release may more usefully be achieved using other pieces of existing legislation, for example those regulating food safety. In some cases organisms will automatically be subject to controls under these other laws.

4.3 How would the category work in practice?

Many aspects need to be considered when looking at how conditional release might work in practice. This subsection covers the controls that might be used, how the category may change the application process, how compliance with controls could be checked and enforced, and what the financial implications might be. A diagram representing some of the options is presented in Annex 1 at the end of this section. Examples of controls are summarised in Annex 2.

4.3.1 What could conditional release be used for, and how would it be used?

Research

Research on new organisms currently takes place in laboratories or glasshouses and in small-scale, tightly contained field tests. However, some research cannot be done under these conditions. Because the organism and any heritable material arising from it must be able to be removed and destroyed after the end of the field test, plants such as GM crops are not usually allowed to produce pollen or seeds. This makes it difficult to evaluate the performance and environmental effects of the crop – information which is important for ERMA in deciding whether the organism is suitable for release into the wider environment. Similarly, a clinical trial of a GM medicine may not be possible under the current regime. It would be difficult to get a release approval for such an organism, given that there would be uncertainty about its effects.

The controls that could be applied to conditional releases for research include:

- limits on the number of released organisms
- limits on where the organism can be released
- restrictions on how the organism is grown, raised or used (for example, using buffer zones)
- granting approval to a single user
- prohibiting commercial transactions involving the organism
- ensuring suitable disposal of a new organism at the end of the research.

Example – disease resistant potatoes

New Zealand researchers have developed a GM potato that is resistant to a certain virus. Field tests have shown that the modification works in a small plot in one location. However, before the positive and adverse effects of full release can be considered, performance must be tested in different soils and climates, and the environmental effects fully investigated. This is not possible in strictly contained field tests, where reproductive material must be removed from the plants. Although ERMA can use information from overseas to help in its assessments, such information may not always be available, and may not help to assess the effects on the New Zealand environment.

Release with controls might allow a single research institution to carry out trials in several different locations to compare the performance against conventional potatoes. Researchers could be required to monitor insect and neighbouring plant populations for any unintended effects, and ensure that all potatoes are destroyed at the end of the study. This use of conditional release would be close to the 'field test' end of the range of potential uses.

Monitoring for the impacts of new organisms

Monitoring the spread of the new organism and its effects on the surrounding environment would increase the chance of detecting any adverse effects – foreseen or unforeseen – before they became a significant problem. Users would be required to supply regular data to the relevant agency and notify it if adverse effects were seen. Adverse effects could lead to remedial action or the removal of the organism, if this was possible (eradication of pest species, for example, has proven a difficult and expensive task). Monitoring results would feed back into the risk assessment framework. If monitoring was the only control attached to an organism, this use would be very close to the 'full release' end of the spectrum of uses of conditional release.

Various factors could be monitored, including:

- spread from the point of release
- effects on non-target organisms (for example, insects, soil biota, surrounding vegetation)
- the level of out-crossing (breeding with related species).

Example – insect predator introduced for biological control

Biological control is the use of one organism to suppress another, and is commonly used to control populations of insect and plant pests. The five new organisms approved for release since 1998 have all been biological control agents imported for the control of a specific pest. Although laboratory experiments can test many features of such an organism, conditional release could specify that populations of non-target organisms and vegetation in the area surrounding release be monitored at regular intervals for adverse effects.

As with other controls, the user would be responsible for ensuring that monitoring was carried out and data supplied. However, the user may not be the most suitable person to carry out the work, and may need to contract out the work; for example, to a Crown Research Institute.

Monitoring could be time-consuming, technical and costly, depending on the amount and frequency of information required. Analysis and review of this information would impose administrative costs on the agency responsible, so the value and costs of any monitoring would need to be carefully assessed before these requirements were imposed.

Limiting dissemination or persistence (including enabling and managing co-existence of GM and non-GM agriculture)

As noted above, the assumption that an organism will inevitably spread and establish in New Zealand is not true in all cases. Many organisms do not have the characteristics required to persist in the New Zealand environment, such as highly domesticated crops, or species that only survive in a hot climate. For others, their spread by human or natural means and persistence in the environment could be prevented through controls such as limiting their ability to reproduce, or strictly limiting where they can be used.

Controls to limit dissemination could be used to enable and manage the co-existence of GM and non-GM agriculture in New Zealand. Co-existence was a major theme of the Royal Commission's report, and the Government has agreed to investigate it further, including the ability to place controls on releases of GMOs.

Controls may include:

- limits on where the organism can be released
- using buffer zones or other physical barriers to gene flow
- using sterility technology or other biological barriers to gene flow
- post-harvest segregation and identification
- labelling of seeds and nursery stock
- double fencing, electronic tagging and clear identification of animals
- strict controls on disposal of carcasses
- strict controls on disposal of GM medicines
- exclusion from the food chain, unless assessed by the Australia New Zealand Food Authority (ANZFA) and approved by the Australia New Zealand Food Standards Council (ANZFSC) (specifically for GM animals).

Example – camels for tourism

Camels are not present in the wild in New Zealand, and could damage the environment if released without controls. Conditional release might allow a single tourism operator to import a certain number of camels, with a requirement that they were all either of one sex or sterilised and therefore unable to reproduce, along with controls to ensure that any adverse effects of the animals were managed.

Example – 'bioreactor cattle'

Cows have been genetically modified to produce pharmaceutical proteins in their milk. These are highly valuable animals and their owners have strong commercial incentives to keep them secure. A conditional release might allow a small number of herds of these animals to be commercially farmed, but with strict requirements for security, labelling, and tracking to prevent them escaping and breeding with non-GM stock.

Controlling the way organisms are used

Sometimes the way an organism is used, rather than the organism itself, can lead to risks to the environment. Controls on use may be able to manage these potential risks.

Controlling the way an organism is used could, for example, help delay pest resistance developing to either pest-protected GM crops or biological control agents. Pests commonly develop resistance against control agents: this is a well-documented phenomenon and happens with both chemical and biological control agents, in insect and mammalian pests. Controls could also be used to restrict the use of biological control agents, maximise effectiveness, and hence manage risk (see below).

Controls could include:

- limits on when a new organism can be released
- limits on the numbers of new organisms released
- limits on the conditions under which a release can be made
- use only by trained individuals.

Example – Bt crops

GM crops have been developed to be resistant to insect pests through the expression of the toxin produced by the bacterium *Bacillus thuringiensis* (Bt). Bt has been used as an insecticide in New Zealand for many years, and is one of the few pesticides available for insect control on organic crops. It is clearly in New Zealand's interests to maintain the effectiveness of Bt as an insecticide and to delay the development of resistance. In areas overseas where Bt crops are being grown, resistance management is acknowledged as a priority for ensuring the long-term efficacy of Bt as a pesticide. Controls used include limits on the extent of use of the crop, refuges (areas of non-GM plants) within the crop, and requirements to monitor the crop for resistant pests and to notify authorities in case of suspected resistance development. Bt crops can also only be used by individuals who are trained in resistance management techniques. The Royal Commission recommended that a strategy for preserving the effectiveness of Bt be developed before Bt-crops are released in New Zealand.

Example – rabbit haemorrhagic disease (RHD)

One suggestion for using conditional release came out of the 1997 report by officials investigating the potential of using rabbit haemorrhagic disease (RHD) as a biological control agent for rabbits. The effectiveness of this virus was compromised by the way in which it was disseminated when farmers released it illegally in late 1997. Although conditional release could no longer be used for this particular agent, it shows how a strategy for use of biological control agents (for example, only under optimal conditions) could increase the chance of effectiveness in controlling environmentally damaging pests.

Location and land management controls

The Royal Commission recommended that ERMA have the ability to protect non-GM industries that could be vulnerable to contamination by GM crops. They considered the possibility of using the land management controls of the Resource Management Act 1991 to declare GM-free areas, but decided that the implementation of this approach would raise considerable practical difficulties, due to the potential for dividing communities and the potential for impinging on the rights of certain individuals. They also stated that blanket bans of GMOs in regions may be unnecessary since certain GM and non-GM crops, for example crops that cannot cross with one another, may be able to coexist.

Conditional release may provide another mechanism for location controls, but on a case-by-case basis rather than by declaring GM-free areas. ERMA could, for example, decide that a particular GM crop could only be used in a certain region of New Zealand. Alternatively, it could require the use of buffer zones to prevent contamination of nearby crops. The advantage here would be that the control could be applied wherever the crop was used, and would therefore not require a restriction on where the crop could be grown. Alternatively, ERMA could be required to recognise decisions to be GM-free on the basis of locality or industry that have been made by some other body; for example, the relevant industry association (based on the views of its members) or the local council. If this was the case, ERMA would not be able to set controls that were inconsistent with or overrode such decisions.

There are disadvantages to this approach in that other bodies do not necessarily have the expertise to assess the effects of new organisms. Parliament has established both special-purpose legislation (the HSNO Act) and a national, technical and non-political body (ERMA) to carry out these assessments. The HSNO process already involves a process for public input, and this mechanism provides an opportunity for citizens to have their say. It would not be desirable to duplicate processes or change the basis for decision-making.

4a In what situations should controls be used to manage organisms after release?

4b Are there any purposes outlined in the preceding section for which conditional release should not be used?

4c Are there any additional purposes that conditional release could be used for?

4d Should agencies other than ERMA be able to decide where GMOs are permitted? If so, on what basis?

4e Are there other ways in which location controls could be managed in practice?

Please explain your views and, if possible, illustrate them with examples.

4.3.2 Defining purposes, controls and organisms for conditional release

Conditional release spans a large range of possible situations, from specific and highly controlled research projects to commercial releases with few controls. Biotechnology is also rapidly changing, so that the future range and uses of new organisms is very difficult to predict. For both these reasons, ERMA will need some discretion about how and when to apply controls on releases. An important question is: How much discretion should ERMA have?

Overly prescriptive legislation or regulations are likely to require frequent amendments, which create extra costs without improving the management of new organisms. For example, it would not be feasible to try to prescribe lists of organisms that would or would not be suitable for conditional release. However, there are certain changes that could be made to the HSNO Act in order to give some structure and guidance to the control-setting process.

Firstly the Act could specify the purposes that conditional release could be used for, for instance:

- research
- monitoring for impacts of new organisms
- limiting dissemination or persistence (including enabling and managing the coexistence of GM and non-GM agriculture)
- restricting the way the organism is used.

There could also be the provision for ERMA to extend purposes to cope with unexpected circumstances.

Secondly, it may be appropriate to set some guiding principles for setting controls, such as:

- controls must be:
  - cost-effective and practicable (achieve the purpose at the least cost)
  - specific and relevant to the organism and its characteristics
  - enforceable and should not duplicate those applied via other pieces of legislation
- for research, whereby:
  - research should only be undertaken outside of strict containment if it is impossible for the same research to be carried out in containment, and if any risk of irreversible impacts is negligible or able to be managed
- for monitoring, whereby the:
  - purpose of the monitoring must be clearly defined
  - requirements must be cost-effective
  - benefits of monitoring must outweigh the costs
  - requirements should be reviewed, and monitoring could be scaled down or stopped, depending on the results of data analysis
- reassessment, whereby:
  - organisms released with controls should be reassessed after x years – this would require amendments to sections 62–63; controls should be reassessed if information arises to suggest a superior alternative approach.

There may also be certain standard controls applied to all conditional release approvals; for example, informing ERMA if the applicant, user or approval-holder becomes aware of additional information such as risks to health or the environment.

Finally the Act could provide a set of mechanisms that ERMA could use for increasing compliance with controls (see subsection 4.4.1).

4f How could purposes for the conditional release category be defined?

4g How tightly should ERMA's setting of controls be defined in the HSNO Act?

Please explain your reasons fully.

4.3.3 The application process

Currently, applicants who wish to release a new organism apply to ERMA for a release approval. There are two possible approaches for introducing another release category:

- ***Option 1:*** The applicant applies to release a new organism (a single release category) and ERMA decides whether the release should be made with or without controls.
- ***Option 2:*** The applicant applies specifically for either unconditional or conditional release (two release categories). For applications for conditional release, ERMA would make a decision on suitable controls.

Option 1 would leave the decision over whether or not controls should be applied, and which controls were suitable, to ERMA. ERMA would be guided in this decision-making by new criteria added to the HSNO Act.

Option 2 would give the applicant the choice of which type of release to apply for. The question then is: What would happen if a full release application was unsuccessful and ERMA considered the organism suitable for conditional release instead? If ERMA automatically approved the organism for the category they considered suitable, this would effectively be the same as Option 1. If correspondence between ERMA and the applicant and the submission of a new application form was required, this would increase compliance costs and may lead to a delay in a decision being made. The impact on costs of the two-category option would therefore depend on the ease of transition between one type of application and the other.

4h What would be the advantages and disadvantages of a separate approval process for conditional release?

4i How would you see the application process working?

Please fully explain your views and provide examples, if possible.

Reassessment and the interface with full release

Controls imposed on an organism may need to be changed over time. This means there should be a mechanism to review each approval and its controls. There are two options:

- ***Option 1:*** The applicant applies to ERMA to have the approval reviewed.
- ***Option 2:*** Put time limits on controls so that ERMA would be required to review them regularly.

It is possible that for some organisms all controls would eventually be removed (the organism would be approved for full release). Reassessment is already provided for in the HSNO Act (sections 62 and 63), covering both new organisms in containment and hazardous substances.

Reassessment can occur if new information becomes available about the effects or use of an organism or substance, and an application for reassessment is made. It is not an automatic event; which is to say, it does not happen after a specific time period.

4j How should the controls on conditional release approvals be reviewed?

4k Are the existing reassessment provisions in the HSNO Act sufficient for this purpose. If so why?

4l What alternatives would you propose and why?

4.4 Compliance and enforcement

Compliance means that users abide by the controls attached to the approval. Enforcement is the process of taking action against or prosecuting people who breach those controls.

Compliance and enforcement are major issues for conditional release. Because of the difficulties of recognising and detecting certain new organisms (especially GMOs), and the fact that organisms – unlike hazardous substances – can reproduce and spread, checking that controls are being complied with may be difficult. As with any law there is a chance of non-compliance. This will be affected by factors such as the cost of compliance, the potential penalties involved and the commercial incentives to comply.

ERMA would need to take these factors, and the feasibility and cost of checking compliance, into account when deciding on appropriate controls. It would need to be satisfied that the controls would manage adverse effects, that an acceptable level of compliance could be achieved, and that the enforcement agency has the capacity and ability to carry out its functions.

There is further discussion of liability issues relating to possible adverse effects from GMOs in chapter 8, which may be relevant to compliance and enforcement issues.

4.4.1 How could compliance be ensured and checked?

An important question for all legislation is how far authorities should go in checking compliance and prosecuting those breaking the law. For conditional release, controls may differ both in their importance in risk management and in their ease of checking.

The HSNO Act and the regulations for management of hazardous substances already contain mechanisms for different levels of compliance checking. The majority of controls on hazardous substances rely on levels of compliance checking being set by the relevant enforcement agency in conjunction with ERMA. However, in certain situations additional mechanisms are used for compliance checking. These include the requirement:

- for a test certificate for anyone permitted to handle the substance
- to notify an enforcement agency before certain activities are undertaken
- that substances are only permitted at certain locations meeting certain pre-conditions.

Similar machinery could be used to assure high levels of compliance with the controls on releases of new organisms. An analogue for test certificates, for example, might only allow certain qualified people to use the organism, or require that the systems used for managing the organism (such as an electronic tagging system) are subject to a certificate.

Requirements that help ensure controls are complied with would be set by ERMA at the same time as the controls themselves. For example, ERMA may approve a Bt-crop for conditional release, and attach controls not only governing how the crop should be used, but also stipulating that anyone using the crop must notify the enforcement agency of the location, time of planting and other matters concerning the crop, so that it would be able to check that the controls were being complied with.

This system of allowing ERMA to use special mechanisms to maximise compliance with controls gives a high degree of flexibility, and would allow the compliance mechanism to be tailored to the nature of the organism and the level of assurance required. This in turn may depend on various factors (for example, the consequences of non-compliance, or community concerns).

Knowing where an organism is being used is important for checking compliance with certain controls. This knowledge could be obtained either by requiring notification, as described for the Bt-crop example above, or by limiting the use of the organism to certain people.

Using different approval types

Different approval types could be used to enable limits to be placed on use of the organism. This would therefore act as an alternative mechanism for assuring compliance with certain controls. There are three options for approval:

- ***Option 1:*** single-user approval – a separate application is required from each person and in each location.
- ***Option 2:*** multi-user approval with permit – approval is given to an applicant who is then able to supply the organism to others; controls would state that any other users require a 'permit' from ERMA before they obtain the organism.

- ***Option 3:*** multi-user approval with supplier notification – approval is given to an applicant who is then able to supply the organism to others; controls would state that the supplier must provide ERMA or the enforcement agency with a list of users.

Option 1 would give the highest level of control, both in terms of the ability to check compliance and also for limiting the location of use of the organism. However, this system would be time-consuming if many different parties wanted to use the organism, or if the organism was being commercialised. Compliance costs would be high. It would be most useful for organisms used in research projects, or for cases where it was important to limit the location of the organism. The first application to release the organism would require a full assessment of all potential positive and adverse effects of the organism, including the cost–benefit analysis. Subsequent applications would only require an analysis of location-specific impacts. Compliance costs for the first application would therefore be higher than for subsequent applications, although the first applicant would be likely to gain from being first in the market.

Multi-user approvals would be less time-consuming and would impose lower compliance costs, but the enforcement agency would still have information on all users. The requirement for a permit from ERMA (Option 2) may give greater assurance of this, as a permit would be needed before the user was supplied with the organism. Option 3 (supplier notification) would rely on the supplier providing information to ERMA or the enforcement agency. The two multi-user options would carry similar costs, but they may be borne by different parties.

In fact using different approval types would have much the same effect as requiring notification as a condition of approval, but through a different mechanism. In all cases the aim is the same – to find out where the organism is being used so that compliance with controls can be checked. Using different approval types would not be essential for compliance checking, but does provide an alternative mechanism for obtaining knowledge about the location of organisms.

4m To what lengths should authorities go to check compliance with controls on release of new organisms?

4n What other mechanisms could be used to achieve a high level of compliance with controls placed on organisms under conditional release?

Please illustrate with examples, where possible.

4.4.2 Who would be responsible for compliance and enforcement?

The HSNO Act lists a number of agencies as being responsible for enforcing provisions of the Act that fall into areas covered by them for other reasons. For example, the chief executive of the Department of State, currently responsible for the Gas Act 1992, must ensure that the HSNO Act is enforced in, on, at or around any gas distribution system, installation or appliance. In addition, ERMA can appoint enforcement officers or authorise the chief executives of other agencies or local authorities to appoint officers and/or enforce the provisions of the HSNO Act as it sees fit. The Act also envisages and encourages the making of other arrangements for effective coverage.

This implies that each agency listed in section 97 has responsibility for hazardous substances and new organisms within its areas of coverage. No agency is separately listed in the HSNO Act as an enforcement agency for new organisms.

The provisions covering new organisms in containment are currently enforced by MAF under the Biosecurity Act. The Biosecurity Act requires new organisms to be held in containment facilities approved under that Act unless ERMA has given approval for release. MAF-appointed inspectors check containment facilities and their operators and ensure that HSNO controls are being met. A memorandum of understanding has been established between MAF and ERMA to outline the responsibility of each agency under their respective Acts. In section 10 we discuss formalising MAF's role as an enforcement agency for new organisms in containment.

However, controls on release would be out of containment and could not be enforced under the Biosecurity Act. Consideration therefore needs to be given to which agency or agencies might be responsible for enforcing these controls. The following table shows the types of task that enforcement officers would need to carry out, and the skills and knowledge they would require.

Tasks that would need carrying out	Knowledge required by enforcement officers
• Inspect organisms • Identify the organism (including its genetic modification if a GMO) • Inspect premises and places • Check documentation • Audit systems • Take action – in some cases immediately • Investigate alleged breaches • Obtain evidence and prepare cases for prosecution • Report to ERMA	• The biology or ecology of the organism • The environment in which the organism is located • The locality • Quality systems • Production systems or the industry • Elements of physical or behavioural containment • Nature of the genetic modification (if a GMO) • The law

Based on these requirements, there are three main options:

- ***Option 1:*** List an enforcement agency or agencies in the HSNO Act.
- ***Option 2:*** List an enforcement agency or agencies in the HSNO Act and enable other central or local government agencies to enforce specified controls.
- ***Option 3:*** Status quo.

Under Option 1, one or more agencies could be listed in the HSNO Act as being responsible for ensuring compliance with conditional release controls. The areas for which each agency is responsible would need to be defined clearly, and enforcement agencies would need to be able to either employ or contract suitable staff. Potential agencies include:

- Ministry of Agriculture and Forestry
- Department of Conservation
- regional councils
- city/district councils.

Under Option 2, as well as the agency or agencies listed for enforcement in defined areas of responsibility, ERMA would also have the ability to name another agency on a case-by-case basis as being responsible for ensuring that specific controls are complied with. The alternative agencies would be selected from a list of central and local government agencies. This option would provide greater flexibility, and a mechanism for controls to be enforced by the most appropriate agency. A process of consulting and gaining agreement with those agencies would be needed.

As an example, ERMA might give an approval for an organism to be held in certain regions only. Regional councils might be the most appropriate agencies to enforce such controls, although they would need to ensure that appropriately skilled personnel were employed to carry out such activities. ERMA could then specify those agencies as the enforcement agencies rather than rely on the ones listed as enforcement agencies for the majority of new organism controls.

Option 3 is the status quo. If no agency was listed as responsible for the enforcement of provisions of the Act relating to new organisms out of containment, the obligation would fall to the agencies listed in section 97. However:

- ERMA could continue to appoint enforcement officers or authorise the chief executives of other agencies or local authorities to appoint officers and/or enforce the provisions of the HSNO Act as it sees fit
- agencies could continue to make arrangements among themselves to ensure coverage (as they do at present for hazardous substances).

Whoever appointed officers would need to ensure they were suitably qualified.

Checking compliance with all these three options would rely on using the powers available under the HSNO Act. The HSNO Act contains powers to (among other things) enter premises, inspect organisms and undertake certain enforcement functions. Enforcement officers can require people to do certain activities within a specified period, or prevent people from doing certain things. If action was needed quickly, then the emergency provisions of the HSNO Act would need to be invoked.

4o What would be the most appropriate way to assign responsibility for ensuring compliance with and enforcement of conditional release controls?

4p Are there other models that could be effective?

Please explain your views with reference to specific circumstances or examples.

4.4.3 What would compliance and enforcement of controls on release cost?

Costs would depend greatly on which controls are attached to organisms, and (to a certain extent) which agency or agencies are chosen. If an agency does not already have a compliance-checking capacity there will be significant set-up costs. If local government were responsible, funding would be a particular issue. The work could be funded by the local body itself, central government or cost-recovered. Each of these funding options has different implications for who finally bears the cost – ratepayers, taxpayers or users.

Option 2 above, which gives ERMA most flexibility in setting enforcement agencies, could lead to a number of different agencies establishing and maintaining this capability, leading to increased costs. However, these costs could also be managed by several agencies utilising the same pool of expertise and reporting systems.

Compliance checking costs could be cost-recovered – this already happens under legislation such as the Biosecurity Act and the Resource Management Act 1991. Cost-recovery issues are dealt with in section 4.6.

4.5 What are the financial implications?

Specific financial implications have been discussed in other subsections. This subsection outlines the more general issues.

The financial costs arising from the creation of a conditional release category would consist of one-off set-up costs to central government, compliance costs to applicants and users of the category, and administration costs to the government agencies responsible for making the system work. The actual size of the costs would depend on the final policy chosen from among the options discussed above.

4.5.1 Cost recovery and the balance between compliance and administration costs

The need to assess costs against benefits is an overriding concern in the choice of policy instruments. Imposing controls is likely to generate compliance and administrative costs, and may have knock-on effects such as the loss of innovation opportunities or artificial impacts on investment decisions. These costs must be balanced against the benefits that will be derived from imposing controls. ERMA will need to assess these costs against the benefits – including risk reduction – given the circumstances of the individual application.

Whether the financial burden falls predominantly on government or applicants will depend on the options chosen. For example, if much of the cost of processing applications and subsequent enforcement is cost-recovered, then compliance costs are likely to be larger than administration costs. Conversely, if government funding is chosen in place of cost recovery, then administration costs are likely to be larger than compliance costs and the burden will probably fall on government rather than applicants.

There is a well-established precedent of cost recovery for applications in the areas of hazardous substances, new organisms and biosecurity. Applicants under the HSNO Act currently pay approximately 54 percent of the cost of processing their applications. The Government has signalled its intention to move towards full cost recovery for HSNO applications, although no date has been set for achieving this. A review of HSNO cost-recovery policy is scheduled for 2003, so any decision to deviate from current cost-recovery policy for the category of conditional release would seem premature. It is therefore likely that applications would be cost-recovered in the same way as applications under the HSNO Act.

The issue of cost recovery for compliance checking and enforcement is less clear. As outlined in subsection 4.4.2, under the Biosecurity Act the costs of compliance checking are cost-recovered from those with containment approvals. However, no enforcement agencies listed in section 97 of the HSNO Act cost-recover, except for territorial authorities under the Local Government Act. Cost recovery for checking compliance with conditional release controls would be possible, either by a levy, or individual cost recovery, or both. However, issues of precedent, practicality, equity, consistency and the economic impact of further cost recovery would need to be carefully considered before any decision could be made.

4q Is full/partial cost recovery appropriate for conditional release applications?

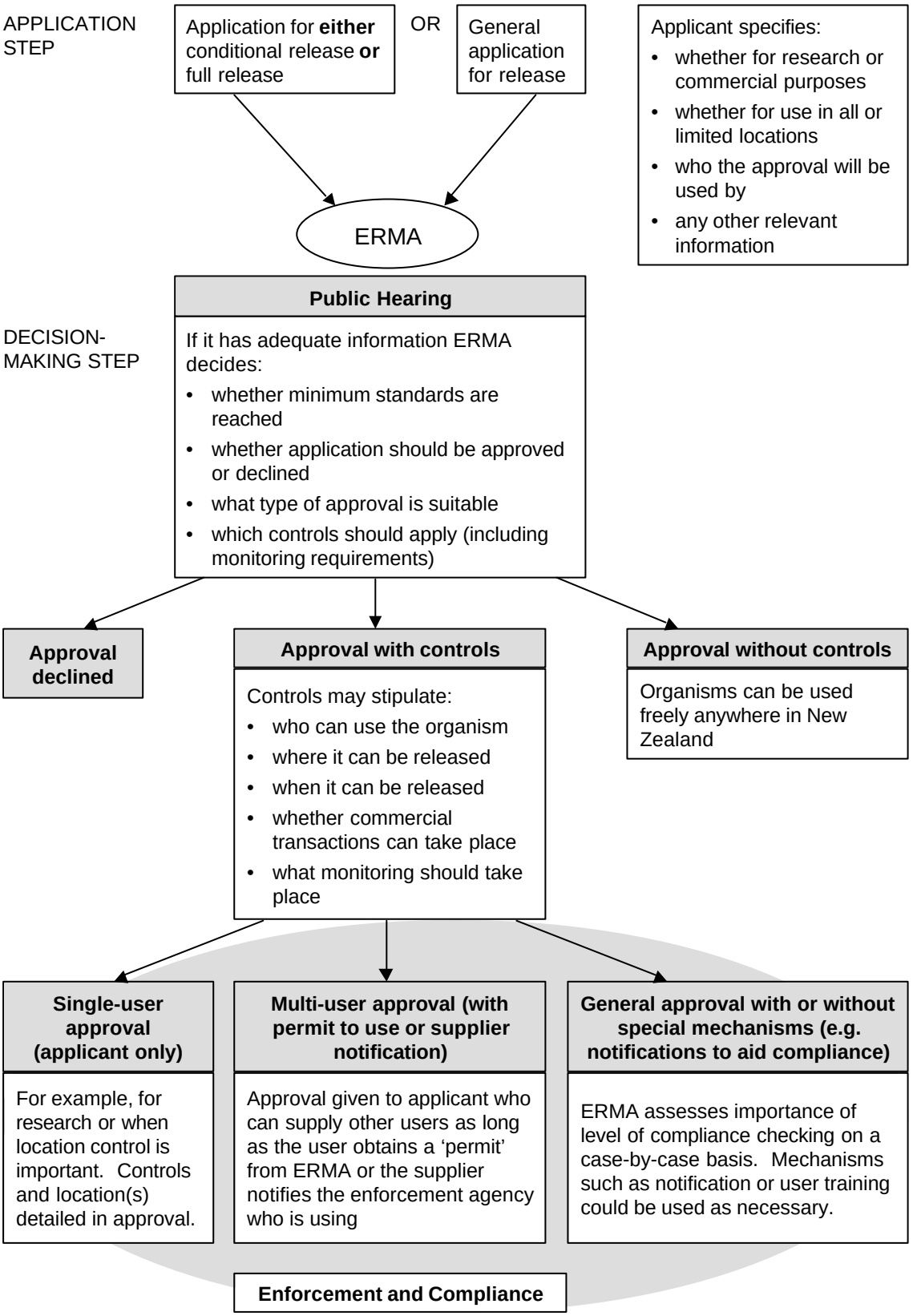
4r Who should bear the costs of compliance checking and enforcement of controls under conditional release?

4s After reading section 4, what do you believe the potential advantages and disadvantages of conditional release to be?

4t Should all releases continue to be made without controls (should the status quo remain)?

Please provide an explanation and/or examples to illustrate your views.

Annex 1: Decision-making steps for conditional release



Annex 2: Examples of the use of the conditional release category

Type of use	Research	Monitoring for impacts	Limiting the dissemination or persistence of the organism in the environment	Controlling how a new organism is used
Problem	Inability to carry out certain types of research without a full release approval, particularly research involved with studying environmental impacts	No provision for monitoring – unforeseen effects may not be detected until they become a problem	Assumption that organisms cannot be controlled in the environment is not true in all cases. Controls can limit the location of organisms and their ability to reproduce	Sometimes the way the organism is used, rather than the organism itself, has an effect that needs to be managed. Controls may be able to manage these effects
Example	Field trial of a GM potato to study the environmental effects of pollen release	Exotic insect used for biological control	A pharmaceutical company would like to raise GM cattle for the production of human proteins in their milk	Inappropriate use of Bt-crops can lead to resistance development in the pest population
Solution, including types of control	Research permitted with the following controls: • approval only granted to one applicant • temporal and locational restrictions • buffer zones around plot • limited number of GMOs used • no commercial transactions involving GMO	Approval given with the following controls: • area around release site to be checked for the organism used, adverse effects to surrounding vegetation, and impacts on native insect populations • monitoring results to be sent to ERMA • further use or spread of organism to be stopped if any adverse effects identified	Raising cattle permitted with the following controls: • GM cattle to be kept in a specific location • cattle to be double fenced, electronically tagged and identified as GM • animals to be disposed of in a suitable way, so that carcasses cannot enter the food chain	Use of Bt-crop permitted with the following controls: • limits on the total acreage of the crop • use limited to those individuals who have an approval and have been trained to use it • refuges planted within the crop to prevent the development of resistance • requirement to monitor crop for resistant insect pests, and to notify authorities in case of resistance development

5 Assessment of GMO Medicines

5.1 Summary

At present, medicines that are or contain a GMO require assessment and approval under both the Medicines and HSNO Acts. The Royal Commission on Genetic Modification recommended that imported medicines and pharmaco foods (see below) that include live GMOs be approved for use by Medsafe[5] without additional approval from ERMA.

In response, the Government directed officials to report on options to reduce duplication and streamline the approval processes under the Medicines Act and the HSNO Act for medicines. It noted that the recommendation was consistent with the precedent set for finished-dose forms of medicines, which are exempt from the hazardous substances part of the HSNO Act. The Government's response also included consideration of GMO medicines *developed* in New Zealand as well as those *imported* into New Zealand.

Four options have been identified for reducing duplication and streamlining approval processes for all medicines that are or contain new organisms (including GMOs). The options are:

- ***Option 1:*** retain approval under both the Medicines and HSNO Acts, but clarify the respective roles of Medsafe and ERMA;
- ***Option 2:*** approval under the Medicines Act only;
- ***Option 3:*** approval under the Medicines Act, with a environmental risk assessment of the medicine provided by ERMA; or
- ***Option 4:*** approval under the HSNO Act, with safety, quality and efficacy assessment of the medicine provided by Medsafe.

A similar situation arises with veterinary medicines that are assessed under the ACVM Act and the HSNO Act. Whether or not similar options should be considered in that situation is also discussed.

5.2 Medicines that are or contain GMOs

Currently medicines that are or contain GMOs and are administered to humans by conventional mechanisms – such as pills, capsules and injections for a therapeutic purpose – are considered to be medicines and require assessment by Medsafe and approval by the Minister of Health under the Medicines Act before they can be legally distributed in New Zealand. There are currently no GMO medicines available in New Zealand. GMO medicines are available overseas, including the cholera vaccine Orachol Berna.

[5] The New Zealand Medicines and Medical Devices Safety Authority. Medsafe is a business unit of the Ministry of Health and is responsible for the regulation of therapeutic products in New Zealand.

Medsafe uses international standards of safety, quality and efficacy to assess whether the risk–benefit profile of a medicine supports its use in humans. Medsafe's assessment is conducted from the perspective of individual human health benefit and risk. Other than for products such as vaccines, public health risk or benefit is not routinely built into Medsafe's evaluation.

In addition to Medsafe's assessment, live GMOs in medicines must also be assessed and approved by ERMA for risks to people, communities and the environment as required by the HSNO Act.

Medsafe assesses applications after obtaining input from an expert group. No public participation is required. In contrast, ERMA has a mandatory obligation to call for public submissions on applications for release and, if requested, to conduct a public hearing.

It should also be noted that new medicines containing GMOs are likely to consist of vaccines and medicines for the treatment of severe medical conditions that have limited alternative treatment options. The compliance costs of a full environmental assessment may result in these products not being available in New Zealand. Similarly, neither the HSNO Act nor the Medicines Act can provide complete control over the release of medications containing GMOs into the New Zealand environment. Travellers, for example, may enter the country freely after exposure to these medicines when overseas.

5.2.1 Medicines containing organisms other than GMOs

This section gives consideration to exempting from the HSNO Act medicines that are or contain *any* live new organism, not just GMOs, because this wider category of medicines gives rise to the same issues as GMO medicines. However, the only new medicines likely to be affected in the immediate future are GMO medicines. This is because the non-GMO organism in a medicine probably will also not be a new organism, and so would not require a HSNO approval.

5.2.2 Finished-dose form medicines

Medsafe generally assesses a medicine when it is ready for clinical trial on humans or commercialisation (when it is ready for release). The issue of duplication therefore only arises with *finished-dose form medicines* that are or contain new organisms and that are ready for clinical trial or commercialisation. These are medicines approved under sections 20, 23 and 30 of the Medicines Act.

The development and testing in containment of medicines that are or contain new organisms should remain within the ambit of the HSNO Act. Accordingly, if medicines that are or contain new organisms were to be exempt from the HSNO Act or subject to a streamlined approval process, the only applications that would be relevant would be ones to *release* such medicines. This would include both applications to 'import for release' and to 'release from containment'.

The Medicines Act provides for exemptions from Medsafe evaluation for medicines that are administered to a particular patient. These exemptions are not covered by this discussion because such medicines should remain within both the HSNO and Medicines Acts.

5.2.3 Development of a single trans-Tasman therapeutic agency

Options to reduce duplication and streamline approval processes for medicines that are or contain new organisms need to be co-ordinated with the policy work to develop a single trans-Tasman therapeutics agency. The Ministry of Health is leading this work for New Zealand.

5.2.4 Pharmaco foods

Pharmaco foods are excluded from this discussion. 'Pharmaco food' is a new term not in common currency. Without a clear and agreed definition it is not possible to include these products in any regulatory change. This does not mean that pharmaco foods would be unregulated if they become available. Live pharmaco foods involved in the treatment or prevention of disease would be considered a new organism and would be covered by the HSNO Act. Those considered a food would also be regulated by the Australia New Zealand Food Authority and the Australia New Zealand Food Standards Council, and those considered a medicine would be covered under the Medicines Act.

5.3 The options

Four options have been identified to reduce duplication and streamline approval processes under the Medicines Act and HSNO Act.

- ***Option 1:*** Retain approval under both the Medicines and HSNO Acts, but clarify the respective roles of Medsafe and ERMA.
- ***Option 2:*** Approval under the Medicines Act only – amend the HSNO Act to stipulate that new organism medicines that are the subject of an application for release into the environment are not included in the Act (an environmental risk assessment could be done by Medsafe as part of a Medicines Act approval).
- ***Option 3:*** Approval under the Medicines Act, with environmental risk assessment by ERMA – amend the HSNO Act as above so that new organism medicines are assessed and approved under the Medicines Act, but the assessment would include an environmental risk assessment provided by ERMA. ERMA could apply the same risk assessment to new organism medicines as it would to all new organisms, or it could apply a streamlined assessment that, for example, excluded public participation or allowed for submissions but no public hearing.
- ***Option 4:*** Approval under the HSNO Act, with safety, quality and efficacy assessment by Medsafe – amend the Medicines Act to exempt new organism medicines so that new organism medicines are assessed and approved under the HSNO Act, but the assessment would include a safety, quality and efficacy assessment of the medicine provided by Medsafe. Medsafe could apply the same safety, quality and efficacy assessment to new organism medicines as it does to all medicines.

All of the options would require amendments to both the Medicines Act and the HSNO Act.

5.3.1 Discussion of the options

The options outlined above aim to reduce duplication and streamline approval processes while ensuring that an appropriate environmental risk assessment framework is applied. They are assessed against the following questions:

- Does the option reduce duplication?
- Does the option streamline processes?
- Does the option ensure an appropriate environmental risk assessment is done?
- Does the option provide for appropriate public participation?

We note that there is a tension between the first two bullet points (which are aimed at reducing compliance costs) and the second two bullet points (which focus on robust risk assessment processes).

Option 1: Retain approval under both the HSNO and Medicines Acts but clarify the roles of ERMA and Medsafe

Option 1 requires clarifying the roles of Medsafe and ERMA. It could be made clear that Medsafe assesses the medicine for safety, quality and efficacy to the individual, while ERMA assesses the environmental effects. Clarification would also be required regarding public health assessments, as Medsafe's public health assessment is limited to the perspective of the individual with the disease and their immediate contacts, whereas the assessment conducted by ERMA is broader.

To further reduce duplication, amendments could be made to the HSNO Act and Medicines Act to establish a process whereby approval from Medsafe is required before an application is considered by ERMA. ERMA could then use Medsafe's assessment of safety, quality and efficacy to assess benefits to human health in its risk assessment.

Option 1 would reduce duplication and ensure that an appropriate environmental risk assessment was undertaken, including provision for public participation. However, two approvals would still be required. It is likely that compliance costs would be reduced only marginally, if at all.

Option 2: Approval under the Medicines Act only

Option 2 would require amending the HSNO Act so that ERMA does not assess and approve applications to release new organism medicines. The assessment and approval process would remain solely within the Medicines Act. This option would reduce duplication and streamline the application process. Unless stipulated, there would be no public comment on applications sent to Medsafe for assessment and approval by the Minister of Health. There would need to be assurances that an environmental risk assessment would be undertaken that is appropriate for New Zealand and consistent with international best practice and obligations. This option may also require amendment to the Medicines Act.

A recommendation to require all medicines containing a new organism to be assessed only by Medsafe means that these products may be subject to a limited environmental risk assessment. There are no internationally agreed guidelines for assessing the adverse ecological effects of a live organism medicine, so these would need to be developed nationally. It would be necessary to conduct further public consultation to determine whether the dataset developed for assessing the adverse ecological effects of live organism medicines is sufficient to satisfy the expectations of New Zealand consumers with respect to managing the general release of new organisms (particularly GMOs) contained in medicines.

In the absence of any international guidelines, a dataset could be developed based on the HSNO Act. Depending on the extent to which this dataset mirrored the HSNO Act, it may result in medicines that are or contain new organisms undergoing a similarly rigorous risk assessment as currently provided for in the HSNO Act (with or without public participation provisions). This could have implications for compliance costs. It would also require that Medsafe staff be suitably qualified, which could raise administrative inefficiencies; that is, two bodies (ERMA and Medsafe) would need to have environmental expertise.

Option 3: Approval under the Medicines Act, with environmental risk assessment by ERMA

Under Option 3 the environmental risk assessment would be provided to Medsafe by ERMA. Attention would need to be given to:

- the breadth of the environmental risk assessment conducted by ERMA (for example, focusing on natural resource or ecological impacts only, or including public health aspects)
- the extent to which the public participation process laid down in the HSNO Act is followed (for example, ranging from full submissions and hearings on the environmental risk assessment to consultation with key stakeholders)
- how much weight should be given to ERMA's assessment (for example, whether or not ERMA might have the ability to decline approval based on the environmental risk assessment).

Option 3 would reduce duplication and, depending on the approach, ensure that a comprehensive or streamlined environmental risk assessment was undertaken, including a broad public health assessment. Although only one formal application would be lodged under the Medicines Act, depending on the extent of the HSNO assessment required, it may not meaningfully streamline the application process. An advantage of Option 3 (and Option 4) is that there would be consistency between the environmental risk assessments for approvals for the development, field testing and release of the new organism medicine.

Option 4: Approval under the HSNO Act; with safety, quality and efficacy assessment by Medsafe

Option 4 is the reverse of Option 3, in that new organism medicine applications would be lodged with and approved by ERMA and not Medsafe. Medsafe would provide ERMA with an assessment of the medicine's safety, quality and efficacy. All non-new organism medicines would continue to be assessed by Medsafe and approved by the Minister of Health.

As with Option 3, Option 4 could be implemented in more than one way. For example, Medsafe could have the right to veto applications based on its assessment of safety, quality and efficacy of the medicine.

Option 4 would reduce duplication and ensure that a robust environmental risk assessment was undertaken, including a broad public health assessment. Although only one formal application would be lodged under the HSNO Act, depending on the extent of the HSNO assessment conducted, it may not meaningfully streamline the application process nor reduce compliance costs.

5a **Do you think medicines that are or contain new organisms (including GMOs) should be subject to a streamlined approval process for release? Why?**

5b **If yes, which of the options described above do you prefer? Are there any alternatives that you can think of that reduce compliance costs but also adequately consider environmental issues and public consultation?**

5c **Do you think that conducting an environmental risk assessment that does not include some of the areas currently covered in the HSNO Act (e.g. economic or cultural considerations) would be an appropriate way of streamlining the approval process for these medicines? Why?**

5d **Options 3 and 4 above propose to streamline the process by requiring only one formal application to the lead agency. Do you have a preference for which agency should lead the approval process: Medsafe or ERMA? Why?**

5e **What level of public participation and consultation should there be in the approval process for new organism medicines?**

5.4 What about veterinary medicines?

The Royal Commission did not make any recommendation about animal remedies that are or contain new organisms. However, under current legislation such animal remedies are also subject to a dual assessment and approval process. The ACVM Group of MAF Food is provided with regulatory powers under the Agricultural Compounds and Veterinary Medicines (ACVM) Act and performs the same regulatory function for animal remedies as Medsafe does for human medicines, including their assessment for safety, quality and efficacy.

Therefore, the four options described above for human medicines that are or contain new organisms are also relevant to animal remedies that are or contain new organisms.

Veterinarians can and do use human medicines to treat animals. However, in practice the use of human medicines for that purpose is small, and given that most medicines that are or contain new organisms will be designed to target only human illnesses and conditions, it is likely that these future medications will have limited utility in animals. That said, consideration would have to be given to the relevance of human remedies used for the treatment of animals, particularly if those animals entered the human food chain.

5f **Do you think veterinary medicines that are or contain new organisms (including GMOs) should also be subject to a streamlined approval process for release? Why? If not, why not?**

5g **If yes, which of the options described above do you prefer? Are there any alternatives that you can think of that reduce compliance costs but also adequately consider environmental issues and public consultation?**

5h **Do you think that conducting an environmental risk assessment that omits some of the areas currently covered in the HSNO Act (e.g. economic or cultural considerations) would be an appropriate way of streamlining the approval process for these veterinary medicines? Why?**

5i **Options 3 and 4 above propose streamlining the process by requiring only one formal application to the lead agency. Do you have a preference for which agency should lead the approval process: ACVM Group or ERMA? Why?**

5j **What level of public participation and consultation should there be in the approval process for such veterinary medicines?**

5k **Do you believe that human new organism medicines that have veterinary applications should be restricted to use in humans only?**

6 Confidential Information

6.1 Summary

The Royal Commission on Genetic Modification recommended that the HSNO Act and the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 be amended to give appropriate protection to all commercially sensitive or confidential supporting information provided with applications for approval.

As a result, the Government has directed officials to undertake consultation with key stakeholders to determine the level of protection that is appropriate for commercially sensitive or confidential supporting information provided with applications for approval, with a view to amending the HSNO and ACVM Acts.

Two main areas are addressed: the notification requirements in the HSNO and ACVM Acts relating to requests to release confidential information under the Official Information Act 1981 (OIA), and the special protection against release provided in accordance with the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

The HSNO and ACVM Acts require that suppliers of confidential information be notified when a request is received for that information under the OIA. If no response is received from that person, the Act allows for the information to be released without further reference to that person. Four options are presented for amending the notification provisions.

It is proposed that the special protection afforded in accordance with the TRIPs agreement be extended to confidential information supplied with all hazardous substances and new organisms that are the subject of innovative agricultural compound or medicine applications. We are seeking comment on the further extension of such protection to other innovative hazardous substance and new organism applications, and what the criteria for those applications might be. Additional comment is sought on related matters such as the cross-referencing of data and the length of the period of protection.

6.2 Confidential information: the issues

The concern is with the confidentiality of information (including confidential supporting information) provided to ERMA and the ACVM Group[6] with applications under the HSNO and ACVM Acts, respectively.

In general, such information is subject to both the New Zealand Bill of Rights Act 1990 and the OIA. Rights under the Bill of Rights Act include the right to seek, receive and impart information of any kind and in any form. The OIA presumes that information will be disclosed unless there are grounds for withholding the information. There are also other considerations favouring disclosure. For example, the HSNO Act (but not the ACVM Act nor the Medicines Act) has a strong emphasis on public participation. Sufficient information therefore has to be provided with applications for a submitter to adequately understand and comment on the effects of the organism.

Further, the general philosophy of the HSNO Act is that an approval relates to the substance or organism – not the applicant. This contrasts with the approach under the ACVM Act, where trade named products are registered to applicants. Under the HSNO Act anyone can do what the substance or organism has been approved for, provided they comply with the controls and conditions of the approval (published in the public register of applications). Section 29A of the HSNO Act (approval for innovative agricultural compounds and medicines) is an exception to that philosophy.

Release of confidential information may occur as part of agencies' general dealing with information submitted with applications or through a request under the OIA. The concern is that information might be accidentally divulged or made available through an OIA request to a third person, including an applicant's competitors, because of miscommunication or delays in an applicant responding under the current notification procedures specified in the HSNO and ACVM Acts.

6.2.1 Patents Act

One of the requirements of the granting of a patent is that the invention be novel. If information about an invention is released before a patent application is filed, then this may prejudice the grant of the patent, both in New Zealand and overseas, as the invention would no longer be considered novel.

Under section 60(1) of the Patents Act 1953, the novelty of an invention would not be destroyed if the invention is disclosed to a government department or to a person authorised by a government department to investigate the invention. If confidential information about an invention was inadvertently made public by a government department (or anyone else), then this would destroy the novelty of the invention.

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[6] The ACVM Group is responsible for the regulatory control of agricultural compounds (veterinary medicines/plant compounds), and their importation, manufacture, sale and use on behalf of the Director-General, Ministry of Agriculture and Forestry, under the ACVM Act 1997.

An amendment to the Patents Act proposed as part of the current review[7] of that Act would provide that disclosure of an invention by way of a breach of confidence would *not* destroy the novelty of an invention. This provision would, however, only apply in relation to the grant of a patent in New Zealand. The accidental release of confidential information could still prevent the grant of a patent in other countries that do not have similar provisions in their patents legislation.

6.2.2 Special protection

New Zealand has certain obligations in relation to protection of confidential supporting information through the fact that it is party to the WTO TRIPs agreement.

Article 39.3 of the TRIPs agreement provides:

> *Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.*

The rationale behind this provision is that protecting confidential data supports the aim of fostering innovation. To obtain regulatory approval, people are required to disclose to government authorities commercially valuable information that would otherwise remain secret. To encourage full and frank disclosure of such information as is necessary for regulatory approval to be given, people need to be certain that the information they provide is properly protected. It is also in the public health interest for there to be regulatory control of dealings with products that could harm public health.

Section 55 of the HSNO Act and Part 6 of the ACVM Act include the provision of protection to confidential supporting information in recognition of these objectives. Under the HSNO Act such protection is provided for hazardous substances that are also the subject of innovative agricultural compound or innovative medicine applications under the ACVM and Medicines Acts. In submissions to the Royal Commission there were, however, concerns as to whether the extent of that protection is more limited than under the previous regulatory regime.

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[7] For further information on the Patents Act review, visit www.med.govt.nz/buslt/int_prop/ patentsreview/index.html.

6.3 What is confidential information?

Neither 'commercially sensitive' nor 'confidential supporting information' are defined directly in the HSNO Act. However, the relevant provisions of the ACVM Act and the Medicines Act apply in some circumstances. Those Acts have the following definitions:

> *Confidential supporting information means confidential information given –*
>
> *(a) In, or in relation to, an innovative [agricultural compound/medicine] application; and*
>
> *(b) About the [agricultural compound/medicine] that is or was, as the case may be, the subject of that application:*
>
> *[Confidential information includes –*
>
> *(a) Trade secrets; and*
>
> *(b) Information that has commercial value that would be, or would be likely to be, diminished by disclosure:]*

The question then arises: Is this definition of confidential information too broad? The OIA refers to situations whereby the disclosure "would be *likely unreasonably* to prejudice the commercial position of the person". Similarly, the Australian Gene Technology Act,[8] for example, refers to:

> *(a) a trade secret; or*
>
> *(b) any other information that has a commercial value or other value that would be, or **could reasonably be expected to be**, destroyed or diminished if the information were disclosed; or*
>
> *(c) other information that:*
>
> *(i) concerns the lawful commercial or financial affairs of a person, organisation or undertaking; and*
>
> *(ii) if it were disclosed, **could unreasonably affect** the person, organisation or undertaking; …*[emphasis added]

6a Should the definition of confidential information also include the element of reasonableness?

[8] For further information on this Act and the Office of the Gene Technology Regulator, see www.ogtr.au/publications/legislation.htm and www.ogtr.gov.au/, respectively.

A related question is: Who decides what is confidential information? Under the HSNO and ACVM Acts, applicants are able to identify or classify information they consider to be confidential or commercially sensitive. However, where a request is received under the OIA, generally the regulator may make its own decision as to what information may be withheld under the OIA if it is satisfied that "the withholding of that information is not outweighed by other considerations which render it desirable, in the public interest, to make that information available". In contrast, the Australian Gene Technology Act requires that a formal application be made to the Gene Technology Regulator for a declaration that the information supplied is confidential commercial information for the purposes of the Gene Technology Act. Similar to the OIA, the Gene Technology Act must be satisfied that the public interest in disclosure does not outweigh the prejudice that the disclosure would cause to any person.

6b Should there be a formal process in the HSNO and ACVM Acts for identifying what is confidential or commercially sensitive information?

6.4 OIA requests for information

In the case of an OIA request for official information, the standard OIA grounds for withholding information apply. However, when an OIA request is made, the HSNO (section 57) and ACVM (section 12) Acts require that the person who classified the information as commercially sensitive be notified of the request. If that person does not respond within 10 days, ERMA or the Director-General of MAF may release the information. There is no express obligation under the OIA to notify the person who supplied the information; although in practice natural justice and general principles of administrative law would require an agency to contact that person.

These provisions give an opportunity for the original classifier to put forward reasons why the information should not be released. However, some industry sectors have expressed concern that a lack of response (for whatever reason) may be interpreted by ERMA or the ACVM Group (in exercising their power to withhold or release the information) as indicating that the information is no longer confidential or commercially sensitive. Conversely, these sections are seen by some as increasing the emphasis on freedom of information by increasing the likelihood of release of information that might otherwise have been withheld.

The options here are to:

- ***Option 1:*** Retain the status quo.
- ***Option 2:*** Amend the HSNO and ACVM Acts:
  - (i) by deleting the notification requirement completely (therefore relying solely on the OIA); or
  - (ii) to clarify what is required by 'notification'; for example, to ensure that direct contact is made with either the person who supplied the information (or their organisation), or at least a reasonable attempt is made; or
  - (iii) so that the reference is to the action that may be taken under the OIA (to decide whether or not non-disclosure is outweighed by the public interest in release) rather than to the action of release.

6c Which option do you prefer, and why?

6d Have you been notified of an OIA request for information you have supplied? If so, please let us know how you found the above process.

6.5 What are appropriate levels of protection?

6.5.1 Pharmaceutical or agricultural chemical products

The special protection afforded under s55 of the HSNO Act to confidential supporting information in accordance with the TRIPs agreement is only available where it relates to applications for *hazardous substances* that are *also* the subject of innovative agricultural compound or medicine applications under the ACVM and Medicines Acts, respectively.

The Royal Commission was concerned that when the HSNO Act came fully into force for hazardous substances[9] (and, with the ACVM Act, replaced the Pesticides Act 1981 and the Animal Remedies Act 1967), confidential supporting information submitted to ERMA with GMO applications would not have the protection it has under the ACVM and Medicines Acts and had under the Pesticides and Animal Remedies Acts.

This concern arises because the definition of hazardous substance in the HSNO Act does not include certain organisms (including GMOs) that come within the definition of a medicine or an agricultural compound under the Medicines Act and the ACVM Act, respectively. Therefore, the scope of the protection available for confidential supporting information, now that the HSNO Act is fully in force, may be more limited than previously.

This means that information provided in relation to applications for marketing approval for agricultural or pharmaceutical products, *other than* 'hazardous substances' that use new chemical entities, are not granted any special protection from disclosure and instead are subject to the ordinary application of the OIA.

It is therefore proposed that the special protection provided to confidential supporting information by the HSNO Act be extended to all hazardous substances or new organisms that are the subject of an innovative agricultural compound or medicine application. This would ensure the same level and breadth of protection for confidential supporting information as existed prior to the HSNO Act coming fully into force.

6e Do you have any comments on this proposal?

[9] The ACVM Act and the remaining provisions of the HSNO Act for hazardous substances came into force on 2 July 2001.

6.5.2 Other new organisms or new hazardous substances

The Royal Commission correctly identified that there is no protection for confidential supporting information provided to ERMA with applications for any new organisms (whether genetically modified or not). Such protection is not required under the TRIPs agreement unless the organism can be considered part of a pharmaceutical or agricultural chemical product that utilises new chemical entities.

A relevant point here is that the HSNO Act is unusual internationally in requiring formal regulatory approval for GMOs. Where no formal regulatory approval is required, the situation does not arise as no application and therefore no confidential supporting information is required.

The Australian Gene Technology Act is another example where regulatory approval is required. As noted above, a person making an application to the Gene Technology Regulator may seek a declaration that certain information is confidential commercial information. However, there is otherwise no special protection from disclosure and instead the information is subject to the ordinary application of the Australian Freedom of Information Act 1982 – the equivalent of the OIA. In refusing to declare that the information is confidential commercial information, the Regulator must be satisfied that the public interest in disclosure outweighs the prejudice the disclosure would cause to any person.

A similar situation to that for new organisms may arise with new hazardous substances that are not the subject of innovative agricultural compound or medicine applications, but that may be considered 'innovative' hazardous substances.

6f Should the TRIPs-based protection provided to confidential supporting information by the HSNO Act be extended to those applications for new organisms or new hazardous substances that are not the subject of an innovative agricultural compound or medicine application (i.e. that do not also require parallel approval under the ACVM or Medicines Act) or is the protection under the OIA sufficient?

If it is considered that the protection should be extended, then the question arises as to what new organism or new hazardous substance applications should be covered; or, alternatively, what is an 'innovative' organism or hazardous substance application? In effect, this raises the question of whether all special protection should be made specific to the HSNO Act and not dependent on provisions in the ACVM or Medicines Acts.

In the cases of hazardous substances or new organisms that are the subject of an innovative agricultural compound or medicine application, the requirement is driven by the requirement for approval (and their status) under the ACVM and Medicines Acts. Innovative agricultural compound and medicine applications under those Acts refer to the active ingredient of the trade-named agricultural compound or of the medicine, for which no prior application has been made (other than for provisional consent). Article 39.3 of the TRIPs agreement refers to a "new chemical entity". On that basis, a pragmatic approach may be to consider a chemical or biological (new organism) entity as new when it has not been previously submitted for regulatory approval in New Zealand.

6g Do you agree that the special protection be specific to the HSNO Act?

6h For what applications should such protection be available?

Please illustrate your comments with examples and refer to the relevant provisions of the HSNO Act where necessary.

6.5.3 Cross-referencing data

Consideration needs to be given to the situation where confidential supporting information provided as part of one application is used in the assessment of another application (for example, one made by a competitor).

For hazardous substances that are the subject of innovative agricultural compound or medicine applications, the HSNO Act refers to the ACVM Act and Medicines Act:

> *If [the] information [held by ERMA] ... in respect of [those] substances includes trade secrets or information that has commercial value that would be, or would be likely to be, diminished by disclosure,–*
>
> *the provisions of ... with the necessary modifications, apply to that information as if the information were confidential supporting information as defined in ... that Act.*

These provisions require, during the protected period, that reasonable steps be taken to ensure that the confidential supporting information is kept confidential and that the information must not be used for the purposes of determining whether to grant any other application. There are exceptions for disclosure: on the consent of the applicant, or (on condition that reasonable steps are taken to ensure that the information is kept confidential) where necessary to protect the health and safety of members of the public, and for the purposes of a government department or statutory body or international regulatory agency.

As noted above, the Act provides an exception to the general philosophy of the HSNO Act – where an approval relates to the substance or organism, not the applicant – for hazardous substances that are the subject of an innovative agricultural compound or medicine application. These provisions support that exemption.

6i If the special protection is extended to other applications, as above, should the prohibition on cross-referencing data be extended also?

Please give your reasons.

6.5.4 Length of protected period

The HSNO Act refers to both the ACVM Act and the Medicines Act. These Acts provide a five-year protection period while the agricultural compound or medicine is being developed; for example, while under a provisional registration or consent. If a decision to register occurs within that five-year period, a second five-year period is provided.

6j Do you agree or disagree that this period be changed?

Please give your reasons.

7 Grounds for Ministerial Call-in

7.1 Summary

The Minister for the Environment is able to 'call-in' and decide on applications on the grounds that she considers they will have significant effects. The Royal Commission recommended that the HSNO Act be extended to include significant cultural, ethical and spiritual issues as grounds for the Minister's call-in powers. The Government agreed to include significant cultural, ethical and spiritual effects as grounds for call-in of an application.

It is proposed that the call-in grounds be amended to include significant cultural effects and that 'cultural' be defined in the Act to include 'ethical or spiritual'. This would allow the Minister to make a decision on an application that she considers to have significant cultural, ethical and spiritual effects after considering advice from ERMA.

7.2 Call-in powers

The call-in provisions in the HSNO Act are based on the Resource Management Act 1991 and have the same purpose: to enable the Minister for the Environment to decide on an application that may have significant national implications. However, unlike the call-in provision in the Resource Management Act, which allows the Minister to call-in a proposal that she considers has 'national significance', the equivalent provision in the HSNO Act sets out an exclusive list of the matters that can be called in. Currently the Minister for the Environment may call-in and decide an application if she considers it will have:

- significant economic effects or
- significant environmental effects or
- significant international effects or
- significant health effects or
- significant effects in an area in which ERMA lacks sufficient knowledge or experience.

If the Minister decides to call-in an application, she could appoint any person or any body with relevant knowledge to sit with ERMA and consider the application. ERMA would then report (including recommendations and reasons) on the application to the Minister having regard to all relevant matters under the HSNO Act and the Minister's reasons for calling in the application. It is important to note that even though the Minister makes the decision on a called-in application, it is not a political decision but one that must be made according to the provisions set out in the HSNO Act.

Call-in powers are rarely used. There has been one application called in under the Resource Management Act since its enactment in 1991, and none have been called in under the HSNO Act. Extending the grounds for call-in as recommended by the Royal Commission may result in requests to call-in an application on cultural, ethical or spiritual grounds. This does not necessarily increase the likelihood that applications would be called in. However, it would allow the Minister to make a decision on an application that she considers to have significant cultural, ethical and spiritual effects after considering advice from ERMA.

7.3 Proposed amendment

7.3.1 Is the proposed amendment necessary?

The Royal Commission commented in its report that in ERMA's determination of applications on a case-by-case basis the ethical, cultural and spiritual dimensions of genetic modification were almost impossible to deal with, and that a broader, contextual approach was required.

Section 68 sets out a specific list of 'effects' that justify an application being called in. The section is consistent with the HSNO Act's purpose and the matters relevant to the purpose (sections 5 and 6). However, while economic, international and health matters are referred to in section 68 as well as in the purpose sections, section 68 does not mention 'cultural' matters (although this term is mentioned in sections 5 and 6). An argument that 'culture' is included in 'environmental effects' in section 68(1)(b) (given the definition of 'environment' in section 2) is not particularly strong as the section 2 definition also refers to 'economic', which is specifically referred to in section 68. Further, although the Minister in exercising her call-in power would be required to take into account the principles of the Treaty of Waitangi (section 8), because there is no specific reference to the Treaty in the list of call-in matters section 8 would not provide a basis by itself for a call-in. That said, 'cultural' interests are broader than section 8 considerations.

Accordingly, section 68, as it is presently enacted, does not permit the Minister to call-in an application on the grounds of 'cultural' effects. Some amendment is therefore necessary.

7.3.2 Implications of including 'cultural, ethical and spiritual effects' in section 68

Difficulties may arise if section 68 is amended to include significant cultural, ethical and spiritual effects. There may be some interpretation difficulties given that the word 'cultural' is used in the purpose provisions of the Act, but 'spiritual' and 'ethical' are not used elsewhere. If all three words were used in section 68, an issue that would arise would be whether all three matters would have to be satisfied before the Minister could call-in an application, or whether it would be possible for an application to be called in if just one of the three matters was satisfied. This issue could be resolved by referring to 'significant cultural, or ethical, or spiritual effects'.

However, the term 'cultural' can be defined broadly so as to make it clear that it covers 'ethical' and 'spiritual'. Accordingly, the Royal Commission's recommendation could be given effect to if section 68 was amended to refer to 'significant cultural effects'. Such an amendment would be consistent with the purpose provisions in the Act. To avoid any ambiguity or doubt, section 2 would be amended to include a definition of 'cultural' that includes (but is not limited to) 'spiritual' and 'ethical'.

7.3.3 'Effects' or 'issues'

As noted earlier, the Royal Commission recommended that "cultural, ethical and spiritual *issues*" be included as grounds for call-in, while the Government's direction referred to "cultural, ethical and spiritual *effects*" (emphasis added).

The use of 'effects' is consistent with the scheme of the legislation (for instance, sections 2, 4 and 68 refer to effects), whereas 'issues' is a more nebulous term and would be likely to create confusion, as it is not used elsewhere in the Act. Accordingly, 'effects' could be used in section 68 (consistent with the other grounds for call-in listed in the section).

7.3.4 Proposed amendment

It is therefore proposed that section 68 be amended to include 'significant cultural effects', and that 'cultural' be defined in section 2 to include 'ethical and/or spiritual'.

7a Do you agree or disagree with this proposal?

Please give your reasons.

8 Liability Issues

8.1 Summary

This section addresses the issue of liability for harm that might be caused by GMOs. It asks whether the existing liability regime is sufficient to deal with harm that might be caused by GMOs, and goes on to identify options that may be considered if it is determined that the current regime is not adequate.

It must be clearly emphasised that, unlike other sections of this document, the Government is not at this point proposing any changes in relation to liability in respect of GMOs. This section simply sets out the issues and options to be considered and invites comments on these.

Liability issues were considered by the Royal Commission, which took the view that the current liability regime is adequate and recommended that, for the time being, there was no need to change existing liability rules. It was not persuaded that from a legal liability perspective there is anything so radically different in GM as to require new or special remedies. The Commission recognised, however, that liability issues raise difficult questions and suggested that the Government might wish to refer them to the Law Commission for more intensive study. The Law Commission's examination of liability issues was set out in its study paper, *Liability for Loss Resulting from the Development, Supply or Use of Genetically Modified Organisms*.

The Law Commission identified a number of reasons why existing liability rules may not always operate effectively in the context of harm that might be caused by GMOs. It also noted that existing liability rules will not ensure that all harm that could potentially be caused by GMOs will be compensated, and that it is unlikely that any liability regime could guarantee this. Some commentators have suggested that difficulties in applying existing liability rules should be addressed by introducing new liability rules. Others consider that the issues identified by the Law Commission will arise in relation to any liability regime, and that there is little or no benefit in adopting new liability rules. It has also been suggested that regulatory responses – such as providing for conditional releases, where ERMA specifies the precautions that must be taken, and monitors compliance (as discussed in section 4 above) – may be more effective in encouraging users of GMOs to take appropriate precautions to prevent harm.

As recognised by the Law Commission, a preliminary and fundamental question is whether the issues and risks associated with GMOs are so different from those associated with other activities or technologies that GMOs should be treated differently for liability purposes.

This section briefly discusses:

- whether there are liability issues unique to GMOs
- the functions of civil liability rules
- the existing liability rules that might apply where harm is caused by GMOs
- the difficulties that have been identified in applying these rules
- the broad range of options for responding to the liability issues raised by GMOs spanning no change to the status quo, modifications to the existing liability regime and a generic liability regime.

Submissions are sought on whether there are liability issues that are unique to GMOs, the adequacy of existing liability rules, and, if they are not adequate, the range of options for reform.

8.2 Why are liability rules relevant?

Most of the work outlined in this discussion paper is about whether the regulatory system in New Zealand is strong enough to support the government's basic policy direction of proceeding with caution while preserving opportunities in this area. The primary focus is the HSNO Act, which regulates dangerous substances and new organisms to ensure that only things that are judged safe are authorised to enter New Zealand. The current work to review that regime is designed to ensure that it is robust enough for GMOs.

There is another body of law, which sits behind any regulatory regime, that is relevant to these goals. Tort law sets out rules on when someone is liable to another for harm that they have caused. Tort law has traditionally had two main purposes: encouraging safe behaviour, and compensating for loss. It works to encourage safe behaviour because it creates liability for the consequences of harm that can be foreseen. A reasonable person can therefore be expected to work to minimise their potential liability by taking steps to prevent foreseeable harm. The law does not usually require you to compensate a person, through tort, for harm that could not have been foreseen.

The liability rules in tort are therefore relevant to the current policy exercise, because they are another tool in the legal framework for promoting safe behaviour. They already support that goal through the ordinary rules of negligence, nuisance and so forth. But it is worth considering whether there is merit in adapting them in some way to further buttress the regulatory regime.

It is also important to understand the relationship with the ordinary tort rules from the point of view of compensation. Internationally, there has been considerable thought given in recent years to the development of general regimes for environmental damage, and GM issues are a part of that larger picture. If New Zealand were to start to tackle those questions, the work would need to be aligned with the overall direction of the regulatory regimes such as HSNO, to ensure that the effect of any liability rules did not cut across the basic goals of the overall regime. In particular, it would clearly be counter-productive to design liability rules that provided full compensation in all eventualities, if the practical consequence was that the costs and risks of engaging in the activity were prohibitive. Liability rules must fit with the basic goal of preserving opportunities.

8.3 Are there liability issues unique to GMOs?

It is a fundamental premise of our legal system that like should be treated with like. In its study paper, the Law Commission identified special features of GMOs that may pose difficulties for a liability regime, but noted that these features may not be unique to GMOs. It is therefore important to determine whether GMOs are uniquely different from other organisms, and whether the potential environmental or other harmful effects of GMOs are different from those of other organisms or activities. For example, are there relevant differences between the risks and potential harm associated with GMOs compared with other new organisms introduced to New Zealand? Or between potential harm caused by GMOs and products created by other breeding techniques, such as mutagenesis?

There are three main kinds of damage that might be caused by a GMO: personal injury, property and environmental damage, and financial or economic loss. Examples could include a potential allergic reaction, invasiveness in the environment, or loss of organic certification by contamination by GM crops, respectively. In each case parallels exist for other products or activities. For example, unknown peanut traces cause allergic reactions in some people, shipments of conventional crops can be infested with weeds, and organic certification could be at risk from pesticide spray drift from a neighbouring farm.

Unlike many other products or human activities, before a GMO can be imported, developed or released in New Zealand it must first undergo a safety assessment by the Environmental Risk Management Authority (ERMA). A GMO that is a food will also require a safety assessment by Food Standards Australia New Zealand (FSANZ), and will need to be approved by the Australia and New Zealand Food Regulation Ministerial Council. Products produced by other breeding techniques (e.g. selective breeding, cell fusions or mutagenesis) are not subject to such an assessment process. The fact that GMOs will be rigorously assessed before being approved for use is an important consideration when looking at liability issues, given that other products do not undergo such an assessment.

GMOs are defined in the HSNO Act as organisms that have had their genes or other genetic material modified by *in vitro* techniques. There are specific exclusions from this broad definition for organisms created by certain techniques. This approach is consistent with that taken in other jurisdictions.

There is a spectrum of techniques available to manipulate the genetic material of plants, animals and micro-organisms. The point on the spectrum at which an organism is, or is not, a GMO is not always clear. It is sometimes possible to create identical organisms using different techniques, with one falling within the definition of a GMO and the other outside the definition. It is also appropriate to compare the potential harmful effects of GMOs with those of other organisms that arrive here from other places, some of which may become established and have harmful effects.

It may create anomalies to draw a distinction between these types of organisms and GMOs if the nature of the potential harm caused is similar. For example, herbicide-resistant canola can be made by genetic modification techniques and also by natural genetic selection processes. Thus, one herbicide-resistant canola would be regulated as a GMO, and the other, with exactly the same traits, would not.

Once the issue of whether and, if so, to what extent GMOs may be different from other activities or technologies for liability purposes is decided, consideration needs to be given to whether the existing liability regime is adequate, and if not, what changes are needed to this regime.

8a For the purposes of considering liability issues, are GMOs and their effects significantly different from other activities or technologies?

8b Where a GMO has been approved for release and the conditions for release have been complied with, how much weight do you think should be placed on this in considering whether the existing liability rules are adequate?

Please explain your views.

8.4 The functions of liability rules

Liability rules perform two principal functions. They can:

- encourage firms and individuals to take appropriate precaution to prevent or reduce harm
- provide compensation to persons who suffer harm.

As mentioned in section 1.3, the Government agrees that New Zealand should take a precautionary approach on how to proceed with GM, and in that context supports the Royal Commission's overall strategy of preserving opportunities. The Government also agrees that New Zealand should proceed carefully and implement GM selectively and cautiously, minimising and managing risks. The liability rules that apply to GMOs should be consistent with these objectives.

It is important to consider the effectiveness of liability rules in relation to GMOs in the context of other aspects of the regulatory regime that applies to GMOs, as these can also encourage precaution or provide for compensation. These include the approval process for a trial or experiment, and criminal sanctions for breaches of statutory rules. The regulatory regime that applies to GMOs is discussed in previous sections of this paper. It includes the HSNO Act, the Resource Management Act 1991 and the Biosecurity Act 1993. If provisions of the HSNO Act (including those proposed elsewhere in this discussion paper) or other statutes are likely to ensure that users of GMOs take appropriate precaution, for example, the importance of liability rules for achieving this goal is reduced.

8.5 Existing liability rules

If a person were to suffer harm caused by a GMO, they may be able to bring a tort claim to recover the loss they have suffered. Claims could potentially be brought in reliance on the following common law torts.

- *Negligence* – where a defendant owes a duty of care to the person harmed, and fails to take reasonable care, they are liable for the resulting harm. A duty of care will normally arise where harm to the claimant was foreseeable if the defendant acted negligently. A regulatory body such as ERMA may be liable if approval for a trial or experiment is given negligently and the trial or experiment subsequently causes harm to a third party.
- *Nuisance* – where a defendant uses his or her land to carry out an activity that causes something harmful or offensive to affect the land of a neighbour, the defendant is liable for the harmful effects on the neighbour's land (and on the neighbour's use of that land). The activity may cause actual damage to the neighbouring land or it may interfere with the enjoyment of the land without physically damaging it. The interference must be unreasonable, but proof of negligence is not required.
- *The rule in Rylands v Fletcher* – where a person brings on his or her land and collects and keeps there anything likely to do harm if it escapes, and that amounts to a 'non-natural' use of the land, that person is liable for all harm caused if that thing escapes from his or her land.
- *Breach of statutory duty* – where a statute imposes an obligation on a person, and that person fails to comply with the obligation, that person will, in certain circumstances, be liable to others who suffer harm as a result of their breach.

If the harm suffered is personal injury, rather than harm to property or to economic interests, the ACC regime will apply in certain circumstances specified in the Injury Prevention, Rehabilitation and Compensation Act 2001. In particular, the ACC regime is likely to apply if personal injury is caused by ingestion on a specific occasion of a genetically modified organism or product (other than a virus, bacterium, protozoan or fungus), or by a medical mishap or medical error arising out of use of GMOs or GM products, or by a work-related disease arising out of exposure to GM activities. Compensation could be sought from ACC, and no tort claim could be brought to recover compensation in respect of that harm.

The existing liability rules and the ACC regime are explained in more detail in Chapter 12 of the Royal Commission report, and in a paper prepared for the Commission by Professor Stephen Todd. For a copy of this paper, please visit:
www.gmcommission.govt.nz/inquiry/responses/Professor Stephen Todd.pdf.

There are a number of reasons why existing liability rules may not be effective in encouraging precaution or providing compensation in relation to harm that may be caused by GMOs, including:

- the potential for harm to a large number of people, or to the environment generally, rather than to a limited number of identifiable plaintiffs
- difficulties in identifying the person responsible for the harm
- difficulties in showing that harm to the plaintiff was reasonably foreseeable
- difficulties in showing that the plaintiff's loss was caused by the relevant GMO

- difficulties in quantifying losses
- the potential for significant time lags between release of a GMO, and harm caused by it
- the likely cost and complexity of litigating GMO liability issues.

8c Do you consider that existing liability rules will be effective in encouraging precaution in relation to harm that might be caused by GMOs?

8d Do you consider that existing liability rules will be effective in providing compensation in relation to harm that might be caused by GMOs?

Please explain your views.

8.6 Mechanisms for encouraging precaution

The HSNO Act already provides a range of regulatory mechanisms which are intended to ensure that appropriate precaution is taken in relation to GMOs, in particular by requiring consents at various stages, and imposing criminal penalties if those requirements are breached. Previous sections in this discussion paper identify additional mechanisms that could be introduced, such as conditional releases where ERMA would identify the precautions that should be taken in connection with the release of a GMO, and would impose relevant conditions on any release.

However, if existing liability rules coupled with the broader regulatory regime are not considered adequate to encourage appropriate precaution in relation to GMOs, some further options for encouraging precaution include:

- extended liability rules, and/or
- additional regulatory mechanisms (e.g. further approval requirements, or licensing and inspection regimes with criminal sanctions for breach, and statutory powers to require compliance).

Liability rules could be extended in the following ways.

- The negligence regime could be altered to provide for various presumptions. For example, legislation could provide for a presumption of liability where, if crop contamination occurs and the plaintiff establishes that one of several defendants must be responsible for contamination, the burden of proof shifts to each of the defendants to show that they are not responsible.
- Statutory civil liability could be imposed by the HSNO Act for harm caused by non-compliance with specified requirements in that Act (e.g. breaching conditions relating to containment of GMOs or their conditional release).
- Strict liability (i.e. civil liability regardless of fault) could be imposed in relation to harm that might be caused by GMOs, unless the defendant can establish specified defences. Possible defences might include that the cause of the harm was outside their control, that all reasonable steps had been taken to avoid the harm, or that the harm was caused by a deliberate act of a third party.
- Absolute liability (i.e. civil liability regardless of fault could be imposed in relation to harm that might be caused by GMOs, with no defences available to the defendant.

- Bonds could be required from persons supplying or using GMOs. This might involve depositing a sum of money, which would be forfeited if there was a breach of any conditions relating to the use of GMOs, or to cover the cost of any harm caused by the use of GMOs.
- Compulsory liability insurance could be required for persons supplying or using GMOs, or ERMA could have a discretion to require insurance as a condition of granting a particular application for release of a GMO.

Liability could be imposed on the person seeking consent for release of a GMO, on any person using GMOs, and/or on the directors and responsible executives of companies releasing or using GMOs.

In some contexts liability rules are effective to encourage an appropriate degree of precaution. In other contexts, regulatory mechanisms are more effective. In particular, regulatory mechanisms can have advantages over liability rules in encouraging an appropriate degree of precaution where:

- regulators have better information than potential injurers and victims (or their insurers) about risks and appropriate precaution
- regulators are better placed than insurers to monitor relevant forms of precaution
- probabilities of harm are very small
- the amount of loss that may be caused is large relative to injurers' wealth
- insurance is not readily available
- the activity generates a public benefit, so that imposing the full cost of the resultant harm on the person carrying out the activity may be inconsistent with the broader public interest in having the activity continue
- the activity may cause diffuse harm to large numbers of victims
- the difficulties and cost associated with claims mean that liability rules will not be effective in imposing the full costs on the injurer (e.g. because of problems with identifying victims, identifying injurers, causation, quantifying loss, time lags between action and harm, and between harm and payment of compensation, cost of bringing claims relative to the value of claims, harm to non-economic interests)
- liability rules will be expensive to implement, compared with the likely value of claims
- the standard of care that will be set by a court (if a fault-based rule is adopted) is uncertain, and difficult to predict in advance.

Any move to a more onerous liability regime may have negative impacts. Depending on the strength and design of the regime, it may create a disincentive for investment in GM and GM-based innovation. This disincentive may be particularly acute for those technologies at the 'cutting-edge' end of the spectrum, as there is less information on risks and ways to manage these risks. The economic costs are also increased where there is less certainty in a liability regime, or where the appropriate standard of care is unclear or likely to change over time (e.g. where liability is applied irrespective of whether decisions were made on the best scientific knowledge available at the time). A more onerous liability regime may also disadvantage investors in GM technology compared to those investing in equally risky non-GM technology, leading to inefficient investment decisions.

There can also be negative impacts from adopting a tighter regulatory regime, either in place of, or as a substitute for, more onerous liability rules. Regulation can distort investment decisions by artificially increasing the costs of some technologies and not others. The extent of these costs depends on the design and scope of the regime, particularly whether regulations are outcome based or prescriptive. Complying with regulations can also impose significant costs on businesses, which, at the margin, may have an effect on investment decisions.

8e Are the factors that limit the effectiveness of liability regimes significant in relation to GMOs?

8f In the context of GMOs, is an appropriate level of precaution most likely to be achieved through:

- **the current mix of regulation under HSNO and existing liability rules?**
- **extended liability rules?**
- **new regulatory mechanisms?**
- **some combination of these approaches?**

8g What are the costs and benefits of any extension of the liability rules or regulatory regime to achieve the appropriate level of precaution?

8h If you consider that extended liability rules are desirable, what liability rules should apply and who should be liable?

8i If you consider that further regulatory mechanisms are desirable, what should they include and how would they be enforced?

8j Should any extended liability rules or regulatory mechanisms only apply in certain situations, such as:

- **where a GMO has not been approved for release?**
- **where it has been approved for release but the conditions have not been complied with?**
- **where the operator has been negligent?**

8k Should those extended liability rules or regulatory mechanisms apply where the harm is caused by the actions of a third party?

8l In relation to questions 8j and 8k, what would be the risks, costs and benefits of these approaches?

Please explain your answers.

8.7 Mechanisms for providing compensation

Liability rules are most effective in providing compensation to victims where:

- there is an easily identifiable injurer
- the amount of the loss that may be caused is likely to be within the means of most injurers to pay, or most injurers insure their full liability
- insurance is readily available
- the activity is only likely to cause harm to a limited number of identifiable individuals
- it is relatively easy to demonstrate causation and to quantify loss
- claims can be resolved and compensation obtained with relative ease, speed and modest cost.

However, in some contexts liability rules only provide compensation to a small subset of persons who suffer harm, and involve considerable cost and delay. The poor performance of liability rules in providing compensation to personal injury victims was one of the reasons for introducing the ACC system in New Zealand.

The Law Commission's inquiry suggested that the existing liability rules will not ensure that all harm that could potentially be caused by GMOs will be compensated. However, it considered it unlikely that any liability regime could guarantee this.

This outcome is not unique to GMOs. New Zealand law does not seek to ensure that all harms will be compensated. These uncompensated losses are borne by the persons who suffer them – or by their insurers if the victims have insurance. The losses are 'socialised' – that is, borne by the members of society on whom they happen to fall.

Thus the question is not simply whether some GMO-related harms will not be compensated, but rather whether *appropriate* compensation is available in respect of GMO-related harms under the existing law – and if not, how this should be remedied.

If existing liability rules would not achieve an *appropriate* level of compensation for harm caused by GMOs, alternative mechanisms for providing compensation to persons harmed by GMOs might include:

- extended liability rules along the lines described in section 8.6 above
- compulsory insurance for those who may suffer harm (e.g. earthquake insurance provided by EQC)
- a statutory compensation fund, funded out of general taxation (such as the non-earners' ACC account)
- extended ACC coverage for personal injury caused by GMOs that does not fall within the current ACC scheme.

The alternative compensation mechanisms identified above would be likely to ensure that, if there were victims of GMO-related harm, more would receive compensation. However the funding of that compensation, and the costs associated with providing it, vary significantly between the different options.

Compulsory insurance for those who suffer harm does not seem likely to be a useful or practicable approach in relation to harm that might be caused by GMOs. The very few situations where compulsory insurance is required by law for those who may suffer harm tend to involve an identifiable class of potential victims (e.g. homeowners in relation to earthquake insurance), whereas harm that might be caused by GMOs could affect any person. It would be impractical to require all New Zealanders to insure against GMO-related harm.

The options of compulsory insurance or a statutory compensation scheme also highlight the question of whether GMO-related harm is sufficiently different from other kinds of harm to justify using these mechanisms (see section 8.3 above).

An issue that is closely related to compensation for harm that might be caused by GMOs is remediation, or the putting right of that harm. One argument sometimes advanced in favour of liability rules is that they will enable victims to meet the costs of remedying harm that might be caused by GMOs, or prevent or contain the spread of such harm. On the other hand, it has been pointed out that remedial action must usually be taken promptly to be effective, while claims for compensation can often take many months or even years to resolve. Where the harm is suffered by a large number of victims, or affects the environment rather than identifiable individuals, a claim for compensation to fund remedial action may be impossible or impracticable.

Where remedial action is required urgently, to prevent harm to the environment or to large numbers of individuals, it is most likely to be taken by a government agency. The costs of this action will be borne by taxpayers, unless the law specifically provides for those costs to be recovered from a person who caused the harm, or from a specified class of persons such as all users of GMOs.

Any decision to impose more onerous liability rules or regulations may have negative economic consequences. These are more fully explained in section 8.6.

8m Are existing liability rules likely to result in an appropriate level of compensation for harm that might be caused by GMOs?

If not:

8n What is an appropriate level of compensation in this context?

8o Are extended liability rules likely to be an effective mechanism for achieving an appropriate level of compensation?

8p Are other compensation mechanisms likely to be more effective in achieving an appropriate level of compensation?

8q How effective will liability rules or other compensation mechanisms be in ensuring funding for action to remedy or contain GMO-related harm?

8r Where action is taken by a government agency to remedy or contain GMO-related harm, should the costs of that action be recoverable by the government from persons who caused the harm, and/or from a levy on a specified class of persons such as users of GMOs?

8s What do you see as the costs and benefits of any extension of the liability regime to achieve the appropriate level of compensation?

Please explain your answers.

8.8 Insurance of GMO liability

The availability of insurance, and the terms on which it is available, will have an important influence on the effectiveness of any liability regime. For example:

- if insurance is not readily available, liability rules will be less effective in providing compensation to victims
- it would be inconsistent with the basic policy decision to proceed with caution to introduce mandatory requirements to obtain insurance of a kind that could not be obtained in practice.

Requiring liability insurance for those supplying or using GMOs is one of the options mentioned in section 8.6.

8t To what extent is insurance for GMO-related liabilities currently available in New Zealand or overseas? On what terms?

8u How is the market for such insurance likely to evolve over the next five to 10 years?

8.9 Overview – the options

In summary, there are four basic options for addressing the liability issues raised by GMOs (and possibly a wider range of activities).

- ***Option 1:*** Rely on the status quo; that is, the existing liability rules and existing regulatory regime (modified as proposed in the other sections of this paper).
- ***Option 2:*** Extend the existing liability rules.
- ***Option 3:*** Introduce new regulatory mechanisms to encourage precaution and/or provide compensation.
- ***Option 4:*** Introduce a mix of new liability rules and new regulatory mechanisms.

Another option, but longer term, might be to consider liability issues in the context of a wider regime for environmental harm covering a broader range of technologies and activities, including GMOs.

8v Which, if any, of these options do you think should be adopted?

8w Should any of these options *not* be adopted?

8x Are there any other options you think should be considered?

Please explain your answers.

PART B

Improving the Operation of the HSNO Act for New Organisms

9 Zoo and Circus Animals

9.1 Summary

Under the transitional arrangements in the HSNO Act animals at existing registered zoos and circuses are deemed to be new organisms under the Act and the registrations are deemed to be approvals to import into containment. The approvals are then subject to the condition that the animals remain at the place of registration, and to the relevant controls in the Zoological Gardens Regulations 1977 carried forward as part of the transitional provisions.

A number of issues have been identified as necessary to complete the transition to the HSNO regime for animals in zoos and circuses that are new organisms.

It is proposed that the HSNO Act be amended to achieve this. These proposed amendments include giving ERMA the discretion to apply, on a case-by-case basis, containment controls and any other controls necessary to give effect to the purpose of the Act to animals that are new organisms in existing registered zoos and circuses.

In other respects, these animals will be treated as any other new organism in containment. This means that the Animal Welfare Act 1999 will deal with animal welfare matters. The relevant containment standard will apply and registration and other matters relevant to the containment facility and its operation would be dealt with by MAF under the Biosecurity Act. However, current MAF registrations as zoos and circuses will need to be replaced with MAF approvals as containment facilities.

9.2 Controls on animals in existing zoos and circuses

9.2.1 Current transitional arrangements

Under the transitional arrangements in the HSNO Act animals at existing registered zoos and circuses are deemed to be new organisms under the Act and the registrations are deemed to be approvals to import into containment. The approvals are then subject to the condition that the animals remain at the place of registration, and to the relevant controls in the Zoological Gardens Regulations 1977 carried forward as part of the transitional provisions. The Zoological Gardens Regulations were originally made under the Animals Act and outline the registration and other requirements for both zoos and circuses.

9.2.2 What can be achieved under the HSNO Act?

The controls that may be imposed under the HSNO Act are limited by the purpose of the Act (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). In addition, the HSNO Act focuses on approval of *new organisms*, and not of *facilities* such as zoos and circuses, and does not specifically address matters such as animal health and welfare. Approval of facilities and animal health matters are dealt with under the Biosecurity Act, while animal welfare matters are addressed under the Animal Welfare Act 1999.

From the HSNO perspective, the aim is complete the transition to the HSNO regime for existing zoo and circus animals, including replacement of the provisions in the Zoological Gardens Regulations that apply to the keeping of zoo and circus animals under the deemed approvals in a manner consistent with the requirements for new organisms generally, such that the adverse effects on the environment and human health are addressed.

9.2.3 Proposed amendment

It is proposed that existing zoo and circus animals that are new organisms should in principle be treated in the same way as other new organisms approved under the HSNO Act. It is proposed that the Act be amended to give ERMA the discretion to apply, on a case-by-case basis, containment controls and any other controls necessary to give effect to the purpose of the Act, to the approvals for these animals.

9a Do you agree or disagree with this proposal?

9b What alternative approaches might there be to replace the Zoological Gardens Regulations?

Please explain your answer by setting out possible illustrative examples and by relating your suggestions to the HSNO Act's present requirements.

9.2.4 HSNO controls

The matters that are to be addressed by containment controls under the HSNO Act are provided in the Third Schedule to that Act. In addition, the Act provides that an approval may include additional controls that provide for any other matters in order to give effect to the purpose of the Act.

9c Are there any additional controls specific to zoo and circus animals that you think should be:

(a) considered by ERMA for existing zoo and circus animals or

(b) expressly listed in the Third Schedule and that might be applied to future approvals for new zoo and circus animals?

Please explain your answer by setting out possible illustrative examples and by relating your suggestions to the HSNO Act's present requirements.

9.3 What does this proposal mean for existing zoos and circuses?

9.3.1 Registration

Under this proposal, registration and other matters relevant to the facility and its operation would be dealt with by MAF under the Biosecurity Act. However, current MAF registrations of zoos and circuses as such will expire when the Zoological Gardens Regulations expire, and those zoos and circuses will need to be approved as containment facilities. The HSNO Act will not distinguish between zoos and circuses and any other places of public display (such as butterfly houses) or from containment facilities in general, except through the requirements of the relevant containment standards. MAF will still maintain a register of all approved containment facilities.

9.3.2 Containment standards

The proposal would mean that containment requirements for all zoo and circus animals will be set out in containment standards. A draft standard for zoo animals is being prepared by ERMA and MAF, and a circus animal standard will follow. Both will be circulated for public comment.

However, no provision currently exists in the HSNO Act to approve containment standards, although this function is conferred on ERMA by the Biosecurity Act. An amendment to the HSNO Act is therefore also needed to enable containment standards to be approved under the HSNO Act.

9.3.3 Enforcement

The inspection and enforcement of zoo and circus containment controls would continue to be undertaken under the Biosecurity Act. MAF-appointed inspectors would ensure compliance with the controls applied to the HSNO approvals. Any organism that escaped from a containment facility would also be managed under the Biosecurity Act.

In section 10 of this discussion paper it is proposed that MAF's enforcement role for new organisms in containment under the HSNO Act should be formalised. This decision will not change the way the new organism provisions are currently enforced and so should not create any exceptional enforcement issues for zoo and circus animals.

9.3.4 Animal welfare

With the proposed change in regulation of zoos and circuses, there will be a division between matters of control and containment and those of animal welfare. This division will be the same as that which currently applies for all new organisms. The HSNO Act, together with the Biosecurity Act for the containment facilities, will cover how animals should be contained, their health, and how any adverse effects on the environment and human health should be managed. The Animal Welfare Act 1999 will deal with matters to do with animal welfare.

Codes of welfare for zoo and circus animals are in place under the Animal Welfare Act. These codes are being reviewed, and the revised codes are expected to be in place by the end of 2002.

9.3.5 Transfer

Zoo and circus animals are sometimes transferred both internationally and within New Zealand (for example, for the continuation of captive breeding programmes), including temporary absence from the containment facility (such as a visit to the vet). Existing zoos and circuses are subject to a condition that the animals remain at the place of registration. It is expected that this kind of transfer would be provided for through the containment controls and the relevant containment standards being developed. The HSNO Act may therefore need to be amended to remove that condition.

9.3.6 Purpose of containment

The HSNO Act lists purposes for which ERMA may approve the importation of new organisms into containment. These include 'public display', which lists zoos and circuses as examples. Other possible purposes are the conservation of genetic material and research. The Act may also need to be amended to allow for additional purposes for the approval of existing zoo and circus animals.

9.3.7 Transitional arrangements

Existing zoos and circuses will need to meet the requirements of both the HSNO controls that are applied to the approvals and the relevant containment standard. A transitional period would need to be provided for in the legislation to enable any zoos and circuses that have not yet met the requirements of a standard or the HSNO controls to meet these requirements.

9d **Do you agree that a transition period should apply to existing zoos and circuses that do not meet either the requirements of a containment standard or HSNO controls? If so, what factors would impact on the ability to meet those requirements?**

10 Enforcement Agency for New Organisms

10.1 Summary

The HSNO Act lists persons and agencies responsible for enforcement of the Act in certain situations. These provisions do not differentiate between enforcement for hazardous substances and enforcement for new organisms and no agency is listed as having responsibility for enforcement of new organism provisions in containment, although in practice MAF has been undertaking this role.

This section discusses options for clarifying the agency responsible for new organism enforcement in containment. The preferred option is that MAF be formally identified as the primary agency responsible for that situation.

10.2 Current system for enforcing HSNO provisions for new organisms

10.2.1 Who is currently responsible?

Section 97 of the HSNO Act lists persons responsible for enforcement of HSNO provisions in certain situations for which they are already responsible in some way; for example, for gas installations, on motor vehicles, or for the protection of public health. ERMA can also appoint enforcement officers, or authorise the chief executives of other agencies to appoint officers and/or enforce the provisions of the HSNO Act as it sees fit. The Act also allows for making other arrangements to ensure effective coverage.

As it stands, however, the Act does not provide explicitly for any agency to have responsibility for new organisms enforcement. One interpretation of the Act is that the Occupational Safety and Health Division of the Department of Labour (OSH) has responsibility, as the chief executive of that department must ensure that the provisions of the Act are enforced in any place of work.

However, the containment of new organisms (at the importation, development and field-testing stages) is currently enforced by MAF, and OSH has queried its responsibility with respect to new organisms enforcement in light of the traditional role MAF has played in this area. The current understanding is that while OSH is technically responsible, it can be satisfied that MAF undertakes enforcement of the containment of new organisms. OSH is considered to be responsible for ensuring that new organism controls are enforced in any work place where no other agency has that responsibility.

10.2.2 What problems exist with the current system?

MAF currently undertakes enforcement activities for new organisms under the provisions of the Biosecurity Act rather than under the HSNO Act. While this arrangement works well for imported new organisms and those held in containment facilities, there are gaps where some new organisms are not covered by Biosecurity Act provisions.

An example would be where GMOs are found in New Zealand without an ERMA approval. The Biosecurity Act may not apply because the GMOs may not fall within the definition of 'risk goods' or 'unwanted organisms' considered a risk under that Act. Even though it is an offence under the HSNO Act if an approval from ERMA has not been obtained to develop, import or release those organisms, no agency currently ensures that those approvals are obtained.

If it is accepted that OSH is responsible under the HSNO Act for ensuring the enforcement of new organisms in places of work, this raises issues of:

- OSH's expertise to deal with these situations, given that specialist knowledge might be needed
- the possibility of a duplication in enforcement effort if the provisions of the Biosecurity Act are triggered
- whether there are any non-workplaces where a GMO might be found, thereby leaving an enforcement gap.

10.3 What changes are proposed?

It is proposed that MAF's enforcement role for new organisms in containment under HSNO should be formalised. MAF has the expertise in the field for undertaking enforcement of new organisms in containment, and should be given the flexibility to use HSNO provisions in circumstances that do not warrant a Biosecurity Act intervention. Identifying MAF as the primary agency responsible for new organisms enforcement for containment and existing HSNO provisions would remove the uncertainty in this aspect of enforcement and cover the current enforcement gaps. However, this may require an extension of MAF's functions beyond the scope of the Biosecurity Act.

An alternative could be to define OSH's role for areas not covered by MAF. However, this would require careful consideration of how the two agencies could work together to ensure that there were no gaps. It would also require extensive training of OSH personnel to ensure an appropriate level of skill and knowledge. Duties could be contracted out, but some level of expertise would still be required to manage such contractors.

10a Do you agree with the proposal to formalise MAF as an enforcement agency for new organisms in containment?

10b If not, what alternatives do you suggest?

Please illustrate your comments with examples and refer to the provisions of the HSNO Act where necessary.

11 Issues Arising from Operation of the HSNO Act

11.1 Summary

The HSNO Act commenced for new organisms on 29 July 1998 and for hazardous substances on 2 July 2001. The following issues have arisen in light of experience under the Act, and are considered in this section:

- The time to release a decision – it is proposed that this be extended from 15 to 30 days in order to allow ERMA sufficient time to adequately consider, decide and publicly notify its decisions on significant applications.
- The definition of 'new organism' – there are issues with the identification of organisms at a species level. Possible amendments could be to improve the ability to use the risk species provision of the Act to distinguish between subspecies, varieties, strains and cultivars presenting different risks and/or changes to the definition.
- The definition of 'organism' – this could be amended to include prions.
- Compliance orders – (a) the current minimum four-day period, from the time the notice is served for compliance to occur, could be changed to a reasonable period in the circumstances; (b) the requirement that the notice state the last day on which a notice of appeal can be lodged could be deleted (thereby relying on the requirements of the District Court Rules).
- The time to lay information for a prosecution – there are issues of consistency with the Biosecurity Act on the one hand and the Resource Management Act and Health and Safety in Employment Act on the other. Changes could be made to both the time period (from 120 working days to two years) and to when the time period commences (from time of knowledge of the offence to time the offence occurred).
- A review of the Second Schedule (prohibited new organisms).
- Large-scale fermentation – criteria could be developed for what can be considered large scale that better reflect the risk, rather than relying on a figure of 10 litres.
- Clarification of the decision-making criteria for new organisms in containment – to address questions as to the operation of section 45.

11.2 The time to release a decision

The Act requires ERMA to publicly notify its decision on an application not later than 15 working days after the conclusion of the hearing, or, where there is no hearing, after the consideration of an application for a HSNO approval.

In practice ERMA has found that it is often impossible to consider, decide and publicly notify a decision within 15 days of the conclusion of a hearing. The High Court in the Bleakley decision on the GM cattle application by AgResearch also noted that in a case of that significance the time limit was impracticable. However, the Court also noted that the timelines in the Act are directory only, and therefore the breach of the time limit did not invalidate the decision.

Proposed amendment

It is proposed that the time period be extended to not later than 30 working days after the conclusion of the hearing.

This extension would provide more time for ERMA to undertake consideration of significant applications, but would retain some security of timeline for applicants. The other time periods (for public notification, submissions, etc) would remain the same. The maximum time for ERMA to process a publicly notified application with hearing would therefore be increased from up to 85 days to up to 100 working days. However, ERMA is not obliged to take the full period available to release its decision. In using 'not later than' 30 working days, decisions on other applications may be released earlier.

11a Do you agree that the time to release a decision be extended to 30 days?

If not, please suggest alternative ways to enable ERMA to have adequate time to consider, decide and publicly notify its decisions on significant applications, and explain these as clearly as possible, referring, where necessary, to the relevant parts of the HSNO Act.

11.3 Definition of 'new organism'

The HSNO Act defines a 'new organism' as follows:

(1) A new organism is –

(a) An organism belonging to a species that was not present in New Zealand immediately before 29 July 1998:

(b) An organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation:

(c) An organism for which a containment approval has been given under this Act:

(d) A genetically modified organism:

(e) An organism that belongs to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand.

(2) An organism ceases to be a new organism when an approval has been given in accordance with this Act for the importation for release or release from containment of an organism of the same kind as the organism.

(3) Despite the provisions of this section, an organism present in New Zealand before 29 July 1998 in contravention of the Animals Act 1967 or the Plants Act 1970 is a new organism.

(4) Subsection (3) does not apply to the organism known as rabbit haemorrhagic disease virus, or rabbit calicivirus.

11.3.1 Non-deliberate introduction of new organisms

New organisms may arrive in New Zealand through natural means or as accidental 'hitchhikers'. While these new arrivals may become established in the New Zealand environment, they still remain new organisms under the HSNO Act and any deliberate importation of such species requires a HSNO approval.

Possible amendment

A possible amendment is to provide a power to declare that an organism is established in New Zealand and is no longer 'new', despite the fact that it meets the strict definition of new organism (in the sense that it was not present in New Zealand immediately before 29 July 1998).

This declaration could be done by Order in Council, or by ERMA after consultation with the appropriate agencies (for example, the Department of Conservation and MAF). There may also need to be an amendment to the definition of 'new organism' to exclude from the definition any organisms that have been declared to be 'not a new organism'.

There may also need to be a set of criteria by which to decide that an organism should be declared 'no longer new'. This could include being satisfied that the organism has formed a self-sustaining population and that the population is not undesirable. Similarly, the Act states minimum standards for the approval of new organisms applications. Some or all of these minimum standards could be adapted as criteria.

A further criterion might be that the organism was not deliberately imported or released in contravention of any Act. However, consideration would need to be given to achieving the correct balance between making the criteria too strict (therefore making it difficult to prove that an organism has not been brought here illegally) or too loose (then possibly providing an incentive to smuggle new organisms into New Zealand in order to subsequently claim they had become established).

11b Do you agree that there is a need to provide for organisms that arrive by natural means or as accidental hitchhikers? Can you provide examples of where a HSNO approval has been considered necessary for such organisms?

11c What mechanism would you favour: by an Order-in-Council or by ERMA after consultation with other agencies? What alternative mechanism do you suggest?

11d What criteria do you consider appropriate for deciding that such an organism is no longer 'new'?

Please explain your comments as clearly as possible, including examples and referring, where necessary, to the relevant parts of the HSNO Act.

11.3.2 Use of the term 'species'

Experience has shown that while the identification of organisms at the species level is appropriate in most cases, especially for organisms in the animal kingdom, the term is less appropriate from a risk assessment perspective for plants and micro-organisms.

In the case of plants, the nature of plant breeding means that it is often difficult to accurately identify some plants at the species level; for example, some hybrids can be more usefully identified (from a risk assessment perspective) at a higher level, such as by genus. Orchids are a good example. Because of the nature of orchid breeding and nomenclature, it is virtually impossible for applicants to identify the full range of species that orchids are bred from. As a result, ERMA has not received one application that raises the risk of new orchids being actively imported without approval. It would be useful for ERMA to have the flexibility to consider and approve plant organisms at a higher taxonomic classification than species and then use the risk species provision in the Act to manage sub-groups that may pose unacceptable risks.

The case of micro-organisms such as bacteria is the reverse, in that there are crucial differences within species: some strains of some species are pathogenic to humans and animals, while other strains are not (for example, *E. coli* strain K12 is not but *E. coli* strain 0157 is). In such cases it is inappropriate to approve micro-organisms at the species level. It is preferable to be able to expressly identify the strain of micro-organism for which approval has been given, thereby requiring a separate application and exclusion of those strains posing an unacceptable level of risk.

The risk species provision in the Act is intended to enable differentiation between subspecies, infraspecies, varieties, strains or cultivars. The provision allows regulations to be made by Order in Council for the purpose of prescribing:

(i) Any species as a risk species where any subspecies, infraspecies, variety, strain or cultivar of that species may have adverse effects on the health and safety of people or the environment; or

(ii) Any subspecies, infraspecies, variety, strain or cultivar as a risk species, where that subspecies, infraspecies, variety, strain or cultivar may have adverse effects on the health and safety of people or the environment.

This provision allows ERMA to distinguish between organisms at any level below the species level. However, the current mechanism of promulgating regulations is time consuming because of the statutory processes required, and is therefore clumsy to put in place in response to a risk species event. It also requires ERMA to be proactive, to have knowledge of the range of risks for a range of organisms, and to have risk species regulations in place before any importation occurs. No such regulations have been promulgated.

Possible amendments

(i) Approving at a level below the species level

The use of 'risk species' could be re-examined, for example, by allowing the declaration of a species or subspecies as a risk species by Gazette notice rather than by regulation. A declaration could then be made at any time. Such an amendment would also need to specify criteria against which ERMA would make the declaration, and require prior consultation with appropriate agencies (for example, Department of Conservation and MAF).

An alternative option is to include the phrase 'any subspecies, infraspecies, variety, strain or cultivar' in the definition of 'new organism'. Any unapproved subspecies infraspecies, variety, strain or cultivar would remain a new organism.

11e Is the risk species process adequate to deal with organisms at a level below the species level? How could it be improved?

11f Do you see any problems with the inclusion of the phrase 'any subspecies, infraspecies, variety, strain or cultivar' in the definition of new organism?

11g What other mechanisms might be used to address the above issues?

Please explain your comments as clearly as possible, including examples and referring, where necessary, to the relevant parts of the HSNO Act.

(ii) Assessment at the genus level

One option is to allow ERMA the flexibility to consider plant organisms at a higher taxonomic classification than species, and then use the risk species provision (as above) to manage sub-groups that may pose unacceptable risks.

11h What other examples are there in addition to orchids where it might be appropriate to have approvals at a level above the species level?

11i What other mechanisms might be used to address this issue?

Please explain your comments as clearly as possible, including examples and referring, where necessary, to the relevant parts of the HSNO Act.

11.4 Including prions in the definition of 'organism'

A related issue is whether or not prions should be included in the definition of 'organism'.

Prions are small, infectious protein particles that cause fatal neurodegenerative diseases in animals (for example, scrapie, mad-cow disease) and humans (kuru, Creutzfeldt-Jakob disease). These prion proteins do not contain genetic material such as DNA and are not self-replicating, but instead induce changes in a specific host organism protein, resulting in disease.

Until 1997 the Biosecurity Act and the HSNO Act used the same definition of 'organism'. However, in 1997 the Biosecurity Act definition was amended as follows: "(f) includes any particle that is a prion". The same amendment was not made to the HSNO Act definition. As a result the HSNO Act does not currently cover prions.

Given the infectious nature of prions, consideration should be given to amending the HSNO Act to mirror the definition of an organism in the Biosecurity Act. Such an amendment would cover prions derived from both humans and animals. This is because prions do not contain genetic structures, and under subparagraph (a) of the definition only a "human being or a genetic structure derived from a human being" is excluded.

Possible amendment

Amend the HSNO Act in line with the Biosecurity Act to include prions in the definition of 'organism'.

11j Should the HSNO Act definition of 'organism' include prions?

11k Do you see any negative implications for such an amendment? What are they?

11.5 Compliance orders

11.5.1 Time to comply with an order

The HSNO Act requires that a compliance order state a time period for compliance, which cannot be less than four days from the time the notice is served. ERMA has indicated that a minimum four-day period makes it difficult to deal promptly with non-compliance or incidents that do not qualify as an emergency requiring immediate action.

The issue was raised before the select committee considering the original HSNO Bill. The Bill had a minimum seven-day period. At that time it was considered that any matter deemed to require more immediate attention should be attended to by an officer exercising their emergency response powers. An emergency may be declared for two consecutive 48 hours periods, and the time was reduced from seven to four days. However, it is doubtful in some cases whether the circumstances would actually meet the criteria for declaring an emergency (actual or imminent danger to human health or safety; or a danger to the environment or chattels so significant that immediate action is required to remove the danger). OSH and some territorial authorities also report that they have resorted to non-HSNO powers to deal with HSNO matters because the compliance order procedure (and the four-day rule) is impractical.

An 'infringer' may appeal a compliance order. However, filing a notice of appeal does not act as an automatic stay of the order, and the person must apply to the district court for a stay at the time the appeal is lodged. Observance of the principles of natural justice would require that the person be given a realistic time within which to respond before they are considered to be in non-compliance.

Proposed amendment

The equivalent provisions in the Resource Management Act for abatement notices were originally subject to similar requirements (a minimum seven-day period), and were also found to be impractical. The Resource Management Act was amended in 1997 so that the abatement notice came into effect at a period stated on the notice, and so that that period must be a reasonable period to take the action required or to cease the action in the circumstances. It is proposed that the HSNO Act should be similarly amended.

11l Do you agree or disagree with this proposal?

Please give your reasons, including examples and referring, where necessary, to the relevant parts of the HSNO Act.

11.5.2 Last day for notice of appeal

The 1997 amendment to the Resource Management Act also removed the requirement that an abatement notice state the last day on which a notice of appeal can be lodged, whereas the HSNO Act (still) has that requirement for compliance orders.

Possible amendment

An option is to delete the requirement that the compliance order state the last day on which an appeal can be lodged. The time period would remain that stated in the District Court Rules.

11m Do you agree or disagree with this option?

Please give your reasons.

11.6 The time to lay information for prosecutions

The HSNO Act enables any information relevant to offences to be laid within 120 working days of the time the offence "first became known, or should have become known".

This time period has apparently prevented some offences for new organisms being pursued under the HSNO Act, since specialist legal advice or specialist evidence relating to the identification of the new organism or of its genetic modification may take more than 120 days to gather. It has been proposed that the Act be amended to lengthen the 120-day period.

The current period is in line with the equivalent provision in the Health and Safety in Employment Amendment Bill and the Resource Management Act (six months, which approximates 120 working days), but not with the Biosecurity Act 1993 nor with the ACVM Act. In section 10 of this discussion paper it is proposed that MAF be formalised as an enforcement agency for new organisms. The main other Act and agency for enforcement for new organisms are the Biosecurity Act and MAF, whereas for hazardous substances they are the Health and Safety in Employment Act and OSH. Consideration may therefore also need to be given to differentiating between offences involving hazardous substances and those involving new organisms.

The Biosecurity Act and ACVM provisions are "at any time within two years of/after the time when the matter of the information arose", which means they differ both in the starting and ending times. The rationale of 'time of knowledge' versus 'time of offence' relates to views on how soon the offence is likely to be discovered. If there is likely to be a delay in discovering the offence, as with chemical hazards, then 'time of knowledge' would be the better option.

Possible amendments

Possible amendments are to lengthen the 120-day period currently in the HSNO Act and alter the starting time from 'time of knowledge' to 'time of offence'.

11n Do you consider that there should be a change in the:

- **(a) starting time – from 'time of knowledge' to 'time of offence'?**
- **(b) period of 120 working days in which to lay information?**

11o Should these times be aligned with those in the Health and Safety in Employment Act or the Biosecurity Act?

11p Do you consider it necessary to differentiate between offences for hazardous substances and for new organisms?

Please explain your comments as clearly as possible, referring, where necessary, to the relevant parts of the HSNO Act.

11.7 Second schedule (prohibited new organisms)

The Second Schedule to the HSNO Act lists new organisms, the importation or release or development of which is prohibited under the Act. However, a number of the organisms listed in the Second Schedule are already present in New Zealand in an uncontained environment; some have been explicitly approved by MAF under previous legislation before the HSNO Act commenced.

Note that the context of the Second Schedule is that of a 'new' organism. Native species or species already present in New Zealand before 29 July 1998 are not affected by the prohibition.

Proposed amendments

It is proposed that the Second Schedule be revised as follows.

(a) Organisms to be removed:

- *Asclepias tuberosa* (pleurisy root)
- *Castanospermum australe* (Moreton Bay chestnut; black bean)
- *Echinceae angustifolia*
- *Eleocharis dulcis* (Chinese water nut)
- *Monarda punctata* (horsemint)
- *Rhamnus purshiana* (cascara sagrada).

(b) Correction of errors in scientific names. Replace:

- *Bufomarinus* with *Bufo marinus*
- *Rhammus pur**sch**iana* with *Rhammus pur**sh**iana*
- *Tourre**t**ia volubilis* with *Tourre**tt**ia volubilis.*

There is also inconsistency in the way the list is presented. Animal organisms are listed by common name then scientific name, whereas plant organisms are listed by scientific name then common name. This could be amended to be more consistent.

11q Do you agree or disagree with the proposed changes?

Please give your reasons.

11r Are there other changes you consider should be made?

11.8 Large-scale fermentation

Large-scale fermentation of micro-organisms is included in the definition of 'field test', but 'large scale' is not defined in the Act. ERMA, in its *Interpretation and Explanation of Key Concepts* document has interpreted 'large-scale fermentation' as involving volumes greater than 10 litres. All such applications require public notification and full assessment and consideration by ERMA.

Possible amendment

Criteria and containment requirements could be developed for large-scale fermentation of micro-organisms that better reflect the risks, rather than relying on the 10-litre figure. This would enable, for instance, applications for the fermentation of micro-organisms that meet the criteria for low-risk GMOs (see section 2.3 of this document) and that have additional controls to address the use of larger volumes, to be rapidly assessed.

11s Do you agree or disagree with this proposal?

Please give your reasons.

11t What other mechanism(s) might be used to address this issue?

11.9 Clarification of the decision-making criteria for new organisms in containment

The HSNO Act sets out the criteria to be used in making different types of decision. For applications involving new organisms (including GMOs) in containment, the relevant part of the Act is section 45. There are two main criteria in section 45 – first that the beneficial effects (benefits) associated with the application must outweigh the adverse effects (risks and costs) should the organisms escape, after taking account of a range of matters. These matters include the ability of the organism to escape and to establish an undesirable self-sustaining population. Secondly, ERMA must be satisfied that the organism can be adequately contained.

Questions have arisen as to the operation of section 45 – in particular the relationship between the (innate) ability of the organism to escape and the adequacy of containment in the requirement to weigh up the adverse effects against the beneficial effects. This issue was raised in the High Court in late 2001 in an appeal on the decision made by ERMA to approve the field testing of GM cattle by AgResearch. The Court did not make a formal determination on the operation of section 45 but did express its views.

In these views the Court expressed its satisfaction that: "This approach *[taken by the ERMA]* to the section avoids the potential absurdity of balancing benefits of field testing in containment against adverse consequences in event of escape with no regard at all to likelihood in fact of escape". It upheld the approach that had been adopted by the ERMA in regard to the decision on the field testing of cattle.

ERMA's approach was to merge consideration of both the ability of the organism to escape from containment and the adequacy of containment as one. ERMA's view is that the impact of containment controls on mitigating risks (including the risk of escape and any resulting consequences of that escape) should be considered as a part of the process of weighing benefits against risks and costs. However, the consequences of potential escape should also be considered. If these consequences are sufficiently severe that should be able to influence the weighing up process directly.

Given that section 45 is a key decision making provision and remains open to varying interpretations, it is highly desirable that this section is clarified so that an unambiguous decision-making path is specified.

Proposed amendment

It is proposed to amend section 45 of the HSNO Act so that it is clear that in weighing up of beneficial effects against adverse effects (benefits against risks and costs) an integrated view is to be taken of all of the relevant matters. These matters include (among the other matters referred to in the Act) the risks that would arise should the organism escape from containment or the controls otherwise fail, but also the impact of containment and other controls in mitigating risks.

11u Do you agree or disagree with this proposal?

Please give your reasons, including examples and referring, where necessary, to the relevant parts of the HSNO Act.

Glossary

ACVM Act	Agricultural Compounds and Veterinary Medicines Act 1997.
ANZFA	Australia New Zealand Food Authority.
Biotechnology	Any technological application that uses biological systems, living organisms or derivatives thereof (whether genetically modified or not) to make or modify products or processes for general use.
Bt	*Bacillus thuringiensis*.
Chromosome	Components in a cell that contain genetic information. Each chromosome contains numerous genes.
Clone	• (of DNA): an identical copy. The term may be applied to a fragment of DNA, a plasmid that contains a single fragment of DNA, or a bacterium that contains such a plasmid • (of animal or plant): an identical offspring, artificially created by transferring an identical nucleus into a recipient egg or by taking a cutting from a plant. Cloning need not be artificial – identical twins are natural clones of a single egg.
Containment	Restricting an organism or substance to a secure location or facility to prevent escape. This includes, in respect of genetically modified organisms, field-testing and large-scale fermentation.
DNA	Deoxyribonucleic acid, the molecule present in the cells of living things, which controls the structure, function and behaviour of each cell. It carries genetic information during reproduction.
ERMA	Environmental Risk Management Authority (also known as 'the Authority'), an independent authority set up under the HSNO Act.
ERMA New Zealand	The organisation that supports the activities of the Environmental Risk Management Authority (ERMA).
Field test	The carrying out of trials on the effects of the organism, under conditions similar to those of the environment into which the organism is likely to be released. The organism, or any heritable material from it, must be retrieved or destroyed at the end of the trials. 'Field test' includes large-scale fermentation of micro-organisms.
Gene	A sequence of DNA on a chromosome that contains an instruction for inherited characteristics.
Genetic engineering (GE)	Another term for genetic modification.
Genetic modification (GM)	Using modern biotechnology to alter the genetic material of cells or organisms in order to make them capable of making new substances or performing new functions. Also referred to as *genetic engineering*.

Germ cells	The reproductive cells in multicellular organisms.
GM	Genetically modified or genetic modification.
GMO	Genetically modified organism. A plant, animal or micro-organism whose genes have been altered using genetic modification by the inclusion of foreign genetic material or by the alteration of some DNA. The foreign material may come from other individuals of the same or a different species, or it may be synthetic.
Heritable material	Viable biological material, including gametes and spores, arising from an organism that can, without human intervention, regenerate the organism or reproduce a new generation of the same species of the organism.
HSNO Act	Hazardous Substances and New Organisms Act 1996.
IBSC	Institutional Biological Safety Committee.
In vitro	In a test-tube or other laboratory environment.
In vivo	In the living body.
MAF	Ministry of Agriculture and Forestry (formerly Ministry of Agriculture and Fisheries).
Medsafe	New Zealand Medicines and Medical Devices Safety Authority.
OIA	Official Information Act 1982.
OSH	Occupational Safety and Health Service, Department of Labour.
Plasmid	A small, circular piece of DNA found outside the chromosome in bacteria. Plasmids are the principal tools used for inserting new genetic information into micro-organisms or plants.
Release	Under New Zealand law, 'releasing' a genetically modified organism means it can be used without any environmental controls on it, and the necessary permission has been obtained. Overseas, 'release' is taken to mean a commercial application for a genetically modified organism or release onto the market, and it may have voluntary or mandatory controls on it.
Somatic cell	Any cell of a multicellular organism that will not contribute to the production of gamates; i.e. most cells of which an organism is made, other than germ cells.
WTO TRIPs Agreement	World Trade Organisation agreement on Trade-Related Aspects of Intellectual Property Rights.

Appendix 1: Royal Commission on Genetic Modification

The Royal Commission on Genetic Modification was an independent body established by the Government in May 2000 to look into and report on the issues surrounding genetic modification in New Zealand.

The Royal Commission had two objectives:

- to identify the strategic options available to enable New Zealand to address, now and in the future, genetic modification, GMOs and products arising from them
- to identify any changes considered desirable to the current legislative, regulatory, policy, or institutional arrangements for addressing, in New Zealand, genetic modification, GMOs and products.

The Royal Commission undertook a comprehensive public consultation process over the inquiry period. It held a planning hui, public scoping meetings, hearings for interested person status, 15 public meetings, formal hearings, 28 Maori consultation workshops, 10 regional hui, one three-day national hui and a youth forum; and it conducted a public opinion telephone survey of 1153 individuals. It received more than 10,000 public submissions. 107 groups or individuals were granted interested person status – which recognised that they had an interest in the inquiry greater than the public, such as an ethical, religious, Maori, business, research or health interest – and they were heard, along with local and international witnesses, by the Commission during its 12 weeks of formal hearings.

The Royal Commission reported to the Government on 27 July 2001. Its findings and 49 recommendations were published in a 464-page report and three volumes of appendices. Copies of the report are available from Bennetts or other bookshops selling government publications. The report is also available on CD Rom or from the Royal Commission's website at www.gmcommission.govt.nz. Submissions and other documents relating to the work of the Royal Commission are also available on the website.

The major theme of the Royal Commission's report was that of 'preserving opportunities'. The Commission thought it unwise for New Zealand to turn its back on the potential advantages on offer from genetic modification, but recommended that New Zealand should proceed carefully and implement genetic modification cautiously, minimising and managing risks. In drawing this conclusion it explicitly rejected the idea of a New Zealand free of all genetically modified material at one extreme and the option of unrestricted use of genetic modification at the other.

Voluntary moratorium

At the time the Royal Commission was established a voluntary moratorium was agreed between the Government and the main scientific and commercial organisations involved in GM work. This meant that until the Royal Commission reported there would be no applications for approvals for release of GMOs. The moratorium also applied to field testing, with some limited exemptions. The moratorium was extended until 31 October 2001 to enable the government to consider the Royal Commission's report without any applications to field test or release GMOs being lodged. The Government's response to the report of the Royal Commission is outlined in section 1.3 of this document.

Appendix 2: Relevant Recommendations of the Royal Commission

This appendix lists the recommendations of the Royal Commission addressed in this discussion paper, along with the Government's decisions on the recommendations.

Rec	Summary of the content of the recommendation	Government's decision
Simplifying approval processes for laboratory GM research		
6.1	Assessment of low-risk applications for research on a project basis	Agreed to accept the intent of Recommendation 6.1, which is to simplify the assessment of low-risk laboratory GM research either by using defined criteria to assess organisms, or by providing for the approval of groups of organisms of similar types and risks, rather than requiring separate approvals for each organism.
6.4	Amend the HSNO Act to allow IBSCs to approve imports of low-risk GMOs	Agreed to accept Recommendation 6.4.
Gaps in HSNO Act coverage		
6.6	Amend the HSNO Act to cover genetic modification of human cell lines or tissue culture	Agreed to accept the intent of Recommendation 6.6, which is to ensure that the GM of human cell lines and tissue cultures is subject to appropriate regulation.
6.9	Amend the HSNO Act to cover procedures used in mammalian cloning	Agreed to accept the intent of Recommendation 6.9, to the extent that it ensures that new species of mammals (or other animals) cannot be imported as tissues and subsequently regenerated by cloning and released without an appropriate HSNO Act approval.
Constraints on release		
6.8	HSNO be amended to provide for a new approval category called 'conditional release'	Directed officials, led by the Ministry for the Environment (MfE), to report to POL and Cabinet by 30 April 2002 with advice on implementation of a new category of release, including the purpose and scope of the new category, the criteria for conditions and any compliance and enforcement issues. Directed officials to explore the work involved in developing co-existence frameworks as far as is practicable in the absence of releases, and use that to complement the development of conditional release policy. Directed officials to investigate the options for imposing location controls as part of considering the Commission's recommendation 6.8 on the establishment of a conditional release category.
Medicines approvals		
9.4	Imported medicines and pharmaco foods that include live GMOs be approved for use only by Medsafe (and not by ERMA also)	Directed officials (Ministry for the Environment lead) to report on options to reduce duplication and to streamline the approval processes under the Medicines Act and the HSNO Act for medicines by April 2002 as part of the report to POL on a HSNO amendment bill.

Rec	Summary of the content of the recommendation	Government's decision
Confidential supporting information		
10.7	HSNO and ACVM be amended to give appropriate protection to all commercially sensitive or confidential supporting information provided with applications for approval	Directed officials from the Ministry of Agriculture and Forestry and Ministry for the Environment to undertake consultation with key stakeholders to determine what level of protection is appropriate for commercially sensitive or confidential supporting information provided with applications for approval, with a view to amending the Hazardous Substances and New Organisms Act 1996 and the Agricultural Compounds and Veterinary Medicines Act 1997.
Liability		
12.2	For the time being there be no change in the liability system (but that the matter could be referred to Law Commission for further analysis)	Agreed that further work should be undertaken on the liability system during the constraint period. Agreed that, for the time being, there be no change in the liability system for GM. Invited the Minister Responsible for the Law Commission to report to POL and Cabinet by 30 November 2001 on whether this work should be included in the Law Commission's work programme.
Ministerial call-in		
14.1	Extend call-in powers under section 68 of HSNO to include cultural, ethical and spiritual issues as grounds for Ministerial call-in	Agreed to amend section 68 of the HSNO Act 1996 to include significant cultural, ethical and spiritual effects as grounds for Ministerial call-in of an application.

About the Ministry for the Environment

The Ministry for the Environment works with others to identify New Zealand's environmental problems and get action on solutions. Our focus is on the effects people's everyday activities have on the environment, so our work programmes cover both the natural world and the places where people live and work.

We advise the Government on New Zealand's environmental laws, policies, standards and guidelines, monitor how they are working in practice, and take any action needed to improve them. Through reporting on the state of our environment, we help raise community awareness and provide the information needed by decision makers. We also play our part in international action on global environmental issues.

On behalf of the Minister for the Environment, who has duties under various laws, we report on local government performance on environmental matters and on the work of the Environmental Risk Management Authority and the Energy Efficiency and Conservation Authority.

Besides the Environment Act 1986 under which it was set up, the Ministry is responsible for administering the Soil Conservation and Rivers Control Act 1941, the Resource Management Act 1991, the Ozone Layer Protection Act 1996, and the Hazardous Substances and New Organisms Act 1996.

Head Office
Grand Annexe Building
84 Boulcott Street
PO Box 10-362
Wellington
Phone (04) 917 7400, fax (04) 917 7523
Internet www.mfe.govt.nz

Northern Regions Office
8–10 Whitaker Place
PO Box 8270
Auckland
Phone (09) 913 1640, fax (09) 913 1649

South Island Office
Level 4
Price Waterhouse Centre
119 Armagh Street
PO Box 1345
Christchurch
Phone (03) 963 0940, fax (03) 963 2050