SUMMARY OF SUBMISSIONS

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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Executive Summary

Introduction

This document summarises submissions received in response to the 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* published by the Ministry for the Environment in September 2002.

In the Discussion Paper, key elements of the options and proposals for a variety of amendments to the Hazardous Substances and New Organisms (HSNO) Act 1996 are described. The majority of these options and proposals were in response to the recommendations of the Royal Commission on Genetic Modification. Others addressed issues arising from experience with the operation of the HSNO Act and a transitional matter relating to zoo and circus animals.

Response

1011 submissions were received by the Ministry for the Environment. The majority of submissions were from private individuals and were one of three variations of form submission containing similar or identical text. Some of these appear to have been generated from paragraphs on one or more websites to which, in some cases, submitters added further specific comments. These submissions conveyed general views about genetic modification and associated risks as well as some points more relevant to chapter headings in the Discussion Paper. These submissions arrived by email, post and fax.

Nearly 100 submissions were received from organisations and groups. For the purposes of summarising submissions these organisations have been divided up into a number of key interest groups. These groups were environmental groups; the science/research community; the Māori community; religious/ethics groups; universities; the agribusiness/forestry sector; local authorities; organics producers; a medicines and veterinary medicines supplier; individual researchers; legal organisations; a risk manager and a health organisation.

Views received

The Discussion Paper was organised into an introduction and ten other chapters, each relating to a broad area of interest and contained specific questions for discussion. The discussion and proposals of the Discussion Paper covered:

- simplifying approval processes for laboratory research
- gaps in HSNO Act coverage
- the creation of a category of conditional release
- assessment of GMO medicines
- the identification and protection of confidential information
- expanding grounds for Ministerial Call-in to cover cultural, ethical and spiritual issues

- liability issues arising from the introduction and release of genetically-modified organisms
- the management of zoo and circus animals
- the formal confirmation of an agency to enforce compliance with legislation and processes regarding new organisms
- a range of issues arising from the operation of the HSNO Act.

All chapters of the Discussion Paper received some response. The majority of responses were on the issues of liability and conditional release and the least on issues relating to zoos and circus animals. The remaining chapters received a moderate response from a slightly smaller range of sectors.

In general, the views of science/research organisations, the agribusiness/forestry sector, individual researchers, and to some extent universities were in favour of changes that would reduce the time and costs involved in compliance.

Individuals, organics producers, local authorities, environmental groups, religious/ethics groups tended to be in favour of retaining the status quo or increasing the level of overall scrutiny of GMO developments and importation. These groups were generally against any form of GMO release for reasons of ensuring public safety and preventing environmental damage.

PART A:
Overview of the submissions summary

A1.0 Introduction

A1.1 Scope and purpose

This report summarises responses received in response to the Ministry for the Environment's call for submissions on the 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.*

The purpose of this summary of submissions is to provide a public record of submissions to submitters and other interested parties. It has been provided to all submitters who provided addresses in their submissions, and is publicly available on request from the Ministry and through the Ministry for the Environment website (www.mfe.govt.nz).

A1.2 Overview of document

Part A of this document provides an overview of the Discussion Paper, the associated consultation process and an overview of the response received by the Ministry for the Environment both in terms of a profile of submitters and an overview of key viewpoints expressed in submissions.

Part B presents a detailed summary of response to the questions raised in each chapter the Discussion Paper.

Part C summarises the comments received that were not directly related to particular topics covered in the Discussion Paper (e.g. views on genetic modification in general). It also summarises comments received about the consultation process and about the Discussion Paper.

The Appendices provide background information from the Discussion Paper, an overview of the methodology used to summarise submissions, and the names of individuals and organisations that made submissions (except those who stated they wished their details to remain confidential) as well as the text of the main varieties of form submissions.

A2.0 The Discussion Paper

A2.1 Context

The Ministry for the Environment's call for public submissions on proposed changes to the Hazardous Substances and New Organisms (HSNO) Act and related issues forms part of a whole-of-government response to the recommendations made by the Royal Commission on Genetic Modification. Other elements of the response to the Royal Commission's recommendations include:

- the recent formation of *Toi te Taiao:* the Bioethics Council
- evaluation of the possible economic effects of use of genetic modification in New Zealand production systems
- the setting up of research programmes to investigate the environmental effects of genetically-modified organisms (GMOs) as recommended by the Royal Commission
- the development of a biotechnology strategy to provide a coherent way forward for all aspects of biotechnology in New Zealand.

The Ministry for Agriculture and Forestry (MAF) were seeking views on coexistence at the same time as the Ministry for the Environment. MAF were seeking input on specific proposals relating to how the proposed conditional release of genetically-modified organisms may assist in achieving co-existence.

A2.2 Content

In the Discussion Paper, possible amendments to the HSNO Act were described and public input was requested on both the amendments and on the issues underlying those amendments. Appendix 1 contains the aims of the consultation process.

The proposed amendments described in the Discussion Paper address the recommendations of the Royal Commission related to:

- simplifying approval processes for laboratory research
- gaps in HSNO Act coverage
- conditional release
- streamlining approval for medicines which are or contain GMOs
- confidential information
- grounds for ministerial call-in of applications.

The Discussion Paper also addresses:

- liability issues arising from the introduction and release of GMOs
- amendments to the HSNO Act required to complete the transition of animals in zoos and circuses to the HSNO regime
- formalisation of an enforcement agency for new organisms
- issues arising from the operation of the current HSNO Act.

Not included in the Discussion Paper were considerations of how the HSNO Act could more appropriately reflect the Treaty of Waitangi relationship. The Minister for the Environment has, in consultation with other Ministers, appointed a Māori Reference Group to examine this issue as a separate but related exercise.

A2.3 Publication and call for submissions

The Discussion Paper was published in September 2002, and was available both electronically on the Ministry's website (www.mfe.govt.nz) and in hard copy. The paper was distributed by the Ministry for the Environment using a mail-out list compiled from:

- local government database: a list of people and organisations known by the Ministry to be interested in this subject
- information provided by other Government departments
- websites providing membership information
- the list of 'interested persons' from the Royal Commission.

In addition, individuals and organisations made approximately 100 requests for copies of the Discussion Paper.

A2.4 Meetings and liaison

The Ministry for the Environment recognised that much of the information in the Discussion Paper was technical and complex due to the scientific nature of the areas addressed and associated legal technicalities. The Ministry offered to assist people or organisations interested in making written submissions. This assistance involved providing speakers to forums organised and chaired by interested groups. Additional support was available, when requested, to ensure that these meetings could occur (for example, payment of fees for venue hire and publicity). At these meetings the Ministry provided an overview of the issues being addressed in the Discussion Paper and assisted in clarifying issues of interest to each group. Ministry staff encouraged groups and individuals to then make written submissions.

The Ministry for the Environment also contracted with a consulting company (Commonground Associates Limited) to contact and liaise with all groups known to have an interest in the areas covered in the Discussion Paper. This involved offering appropriate speakers, if required, and liaising with groups to ensure that the meetings, where Government speakers were brought in to assist the groups, would be run effectively.

A2.5 Consultation with Māori

The Ministry for the Environment organised seven hui in Auckland, Rotorua, Whangarei, Gisborne, Whanganui, Wellington, and Hamilton. These hui were attended by relatively small numbers of people. However many of these people were both knowledgeable about the subject of genetic modification and actively involved in areas of Māoridom likely to be affected by how genetic modification is regulated. The kaupapa of the hui was to outline the proposed changes, record directly the views provided and where possible encourage written submissions. Ministry for the Environment provided recorders at each hui to take detailed notes which have been

provided to all those attendees who left contact details with the recorders. These notes were also considered in the same way as written submissions in policy work with submissions. Several submissions were subsequently received from those who attended hui.

In addition to organising hui, letters were sent to approximately 85 Māori organisations listed on a Ministry database outlining the nature of the consultation, inviting people to obtain copies of the full discussion document, and foreshadowing the hui. Wherever possible, several individuals in each organisation were contacted.

Many at hui also expressed interest in the work of the Minister's Māori Reference Group and records of the hui and related information were provided to the Group. The Reference Group is expected to meet with key people identified at these hui as part of its work.

A3.0 Overview of response

A3.1 Number and nature of submissions

1011 submissions were received in response to the Discussion Paper. Submissions could generally be classified into two major groupings:

- **Proforma or brief** – these submissions were from private individuals, environmental groups and producers/retailers of organic products. These submissions were sent by fax, post and e-mail. The majority of submissions were from private individuals and were one of five types of form submission containing similar or identical text. Some of these appear to have been generated from paragraphs on one or more websites, where, in some cases, submitters added further specific comments or attached articles from publications or websites. These submissions conveyed general views about genetic modification and associated risks as well as some points more relevant to chapter headings in the Discussion Paper.

  Many submitters indicated on the submission that they wished to be notified of the outcome of the submission process as well as whether or not they wished their details to be kept confidential.

- **Detailed** – these submissions tended to be from organisations or from individuals with specific expertise or experience (e.g. laboratory-based scientists, legal, or risk-management experts). Some of these submissions responded to the questions included in the Discussion Paper directly. Others chose to use the headings within chapters to organise their material. It was obvious from reading these that some submissions had been circulated as they were referred to in other submissions or virtually identical wording was used.

A3.2 Source of submissions

As stated earlier, most of the submissions received were from private individuals and/or were a variation of one of the three main types of form submission. The remaining submissions were detailed submissions from organisations. The following table provides an indication of the numbers of submissions received from each organisational type.

Detailed submissions by organisational type	Number received
Agribusiness/forestry sector	16
Environmental groups	14
Science/research community	12
Māori organisations	8
Local authority	9
Religious/ethics groups	5
University	5
Legal organisations	4
Organics producers	3
Other organisations (e.g. unions, Zoo Association, other professional bodies, etc)	5

A3.3 Content of submissions

A3.3.1 Overview

Submitters were most interested in the conditional release and liability chapters of the Discussion Paper, indicated by the largest range and number of submitters. There was moderate interest in simplifying approval processes, gaps in HSNO coverage, medicines, confidential information, ministerial call-in, enforcement agencies and issues arising from the operation of the HSNO Act from a slightly smaller range of sectors. There was very little interest in transitional matters relating to zoos and circus animals. In addition, a number of submissions made general comments relating to their views on genetic modification or specific comments relating to the call for submissions process or the Discussion Paper.

A3.3.2 By chapter

Chapter 2 – Approval processes for laboratory research

Options and proposals were outlined for simplifying approval processes for both the development of low-risk 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.

Those in favour of retaining the status quo preferred:

- a continuation of the current case-by-case organism-based approvals process,
- identification of organisms as fully as possible at more stages of the research, and
- if delegation to Institutional Biological Safety Committees (IBSCs) did occur, were in favour of a high degree of public scrutiny.

Concern for public safety was a priority. Some expressed scepticism at the ability of the Environmental Risk Management Authority (ERMA) to categorise GMOs into high- and low-risk categories.

Those in favour of moving to a project-based approval process preferred:

- fewer requirements to identify low-risk organisms, and
- delegation to ISBCs to reduce the amount of time required on compliance.

They tended to be confident about the categorisation of low-risk GMOs particularly in the context of full containment. Many mentioned use of phenotype as the best way to assess and manage risk. Reducing the size of application forms, streamlining consultation with Māori, and use of log books to record details of organisms and their characteristics, which would be monitored by IBSCs, were all seen as favoured approaches.

Chapter 3 – Gaps in the HSNO Act

Options were 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 of organisms that are not currently in New Zealand. The proposed amendments did not extend to human cloning as the term 'organism' in the HSNO Act specifically excludes human beings.

Many submissions from individuals made general points against any form of human cloning and the need for separate legislation to cover this area because of the ethical and spiritual issues involved. Those submissions commenting on the options for regulatory oversight of work with human cell lines agreed that some form of oversight was needed but were divided in their views of the most appropriate approach.

There was general recognition that low-risk GMO work with human cell lines was of particular concern to some members of the community and that a greater focus on mechanisms for addressing ethical considerations was appropriate. The ability of ERMA and MAF to regulate in this area was questioned by some. There were differences between organisations on whether any work with human cell lines or using cloning and related techniques can be categorised as low-risk. Human pathogenicity was highlighted as a risk factor by one organisation. Renaming the HSNO Act to reflect these techniques was advocated by a few. Other submissions were concerned about the possible effects of cloning native species, effects on the stock of species and the high risks of deformities in cloned animals.

Chapter 4 – Conditional release

This chapter looked at the introduction of another category of approval that would enable ERMA to approve new organisms for release with certain controls attached to them.

The majority of individual submissions and some submissions from organisations were against any form of release and favoured all GMO research (if it had to be done at all) being undertaken in fully-contained conditions. Many cited overseas evidence that stated that control measures such as buffer zones do not work and did not trust the categorisation of some genetic modification work as low-risk. Of those submissions (principally from organisations) that did see that conditional release could play a role, there was general support for the purposes that were outlined in the discussion paper.

Chapter 5 – Assessment of GMO medicines

Options and proposals were outlined for reducing duplication and streamlining the assessment and approval of medicines that are or contain GMOs. Four general options were presented for changes to the agencies responsible for the approval of GMO medicines and how the health and environmental risk assessments might be incorporated.

Most organisations addressing the issue supported both human GMO medicines and veterinary GMO medicines being subjected to a streamlined assessment process, while all individuals addressing the issue did not. Most organisations addressing the issue suggested that some level of public participation in the approval process for human new organism medicines was appropriate when a significant environmental impact is expected from the introduction of the GMO medicine concerned. Opinions were divided about the role of public participation in assessing veterinary medicines. One individual considered there should be more routine public participation in approvals of human and veterinary medicines.

Most organisations addressing the issue stated that human new organism medicines with veterinary applications should not be restricted to use in humans only, while all individuals addressing the issue disagreed.

Chapter 6 – Confidential information

This chapter contained proposals and options for revising the protection given to confidential information provided with applications for approvals: comment was sought on what level of protection is appropriate.

Of those that responded to each question, most organisations did not think that the definition of confidential information should include the element of reasonableness. The one individual responding stated the same view.

Most organisations did not favour a formal process for identifying what is confidential or commercially-sensitive information. The one individual addressing the issue considered that there should be one. Most favoured amending the HSNO and Agricultural Compounds and Veterinary Medicines (ACVM) Acts to clarify what is required by notification.

Organisations addressing the issue were divided on the proposal to extend the special protection provided to confidential supporting information by the HSNO Act to include new organisms that are the subject of an innovative agricultural compound or medicine application. The one individual responding opposed the proposal.

Chapter 7 – Ministerial call-in

This included a proposal to extend the grounds for ministerial call-in to include ‘significant cultural effects’.

Most organisations addressing the issue supported the proposal to broaden Ministerial call-in powers to include ‘significant cultural effects’, and that ‘cultural’ be defined to include ‘ethical and/or spiritual’. Most individuals addressing the issue also supported the proposal.

Chapter 8 – Liability issues

Views were 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.

Most of the individual submissions and some from organisations had very strong views on liability issues. They considered GMOs to be unique because of unknown risks, the lack of effective control measures and the potentially irreversible effects on the environment, humans, animals and insects, the organics industry and on the food chain more generally. This meant they favoured the strongest liability regime possible, with GMO developers and users bearing the cost burden and the burden of proof in the case of an event.

Other organisations did not see GMOs as being significantly different and did not feel that changes to liability laws or the regulatory regime would contribute to encouraging precaution or the provision of appropriate compensation.

Chapter 9 – Zoo and circus animals

This included a proposal to complete the transition to the HSNO regime for animals in existing registered zoos and circuses. Zoo and circus animals are 'new organisms' under the HSNO Act.

Among the few submissions on this topic there was general agreement on completing the transition to the HSNO regime with additional consideration being given to particular containment and importation provisions. A few were concerned about the possibility of GMOs being developed and displayed in zoos.

Chapter 10 – Enforcement agency for new organisms

This proposed that the Ministry for Agriculture and Forestry's enforcement role for new organisms in containment be formalised.

Nearly all of the organisations addressing the issue supported the proposal to formalise MAF as an enforcement agency for new organisms in containment. All the individuals addressing the issue also supported the proposal.

Chapter 11 – Issues arising from the operation of the HSNO Act

Proposals were made to address a number of unrelated operational issues arising from experience in the operation of the HSNO Act for new organisms.

- **A longer time for ERMA to make and release its decision on applications:** Of the organisations that responded, most supported the proposal that the time for ERMA to release a decision should be extended to 30 days. One individual addressing the issue also supported the proposal.

- **How to deal with the establishment of new organisms in New Zealand that arrive through natural means or as accidental 'hitchhikers':** Most organisations addressing the issue agreed with the statement that there was a need to provide for organisms that arrive by natural means or as accidental 'hitchhikers'. No individuals addressed this issue.

- **Problems with the classification of new organisms at the species level:** Views were mixed among the submissions received on this issue. Some organisations supported inclusion of the phrase – *'any subspecies, infraspecies, variety, strain or cultivar'* as part of the definition of a risk species. Other issues raised in relation to this included:
  - difficulties in identifying which subspecies or infraspecies an organism belongs to when applying terminology; and
  - determining presence of some taxons in New Zealand.

  Some favoured use of phenotypic properties as an alternative.

- **Including prions in the definition of an organism:** About half of the organisations addressing the issue stated that prions should be included in the HSNO definition of an organism. The other half suggested inclusion in the definition of a hazardous substance. One individual addressed the issue and considered agreed with the proposal.

- **Shortening the time within which a compliance order must be complied with:** Most organisations addressing the issue agreed with the proposal to amend the HSNO Act so that compliance notices come into effect at a period stated on the notice and that the period on the notice must be a reasonable one in which to take the action required or to cease the action in the circumstances. One individual also agreed with the proposal.

  Most of the organisations addressing this issue agreed with the proposal to delete from the HSNO Act the requirement that the compliance order state the last day on which an appeal can be lodged. No individuals addressed this issue.

- **Allowing a greater time to mount a prosecution:** Most organisations addressing the issue indicated support for a change in the start time from 'time of knowledge' to 'time of offence'. One individual opposed this change. A change in the 120-day period in which information for a prosecution can be laid was supported by most. One individual also supported this change.

  Organisations were divided over whether times should be aligned with the Health and Safety in Employment Act or with the Biosecurity Act. No individuals addressed this issue.

  The majority of submitters considered it was not necessary to differentiate between offences for hazardous substances and offences for new organisms. This came from organisations. No individuals addressed this issue.

- **Review of the list of prohibited new organisms:** Of the few organisations that responded to this area, most agreed with the proposed changes. One individual researcher wanted the cane toad *Bufo marinus* to be removed from the schedule of prohibited new organisms. Another submission noted a spelling error in the proposed list of corrections.

- **What constitutes a large-scale fermentation:** Most organisations supported the proposal to develop criteria and containment requirements for large-scale fermentation. No individuals addressed this issue.

- **Clarification of the decision-making criteria for new organisms in containment:** Most organisations addressing the issue supported the proposal to amend the HSNO Act so it is clear that an integrated view is to be taken of all relevant matters in weighing up benefits against risks and costs. No individuals directly stated agreement or disagreement with the proposal.

General comments

In addition to answering submission questions, submitters commented on the Discussion Paper and the consultation process. Submissions from a small number of organisations and individuals expressed concern about the time available to complete and file submissions.

Submitters also made a range of comments about issues not directly addressed in the discussion document. These comments concerned:

- economic and environmental impacts
- impacts on food supply and health
- administrative, process and legislative issues
- perceived risks and benefits (including who takes risks and who benefits)
- the precautionary approach
- the future development of New Zealand
- political considerations.

PART B:
Details of Response by Chapter of the Discussion Paper

B1.0 Introduction

This section of the document provides a summary of the responses received by submitters to the questions outlined in Chapters 2 to 11 of the Discussion Paper. Also included are responses that contain material generally related to a chapter heading but that do not appear to address questions directly.

As stated earlier, the number of submitters commenting on each issue varied widely. This means that in some cases very few submitters responded to issues raised in a chapter, while in other cases all the 'form' submissions contained a statement about the issue. This is indicated in the text. Where it appears that submissions from particular sectors were responding in a characteristic way this is also noted.

B2.0 Simplifying approval processes for laboratory research

B2.1 Introduction

Chapter 2 of the Discussion Paper describes the Government's response to the Royal Commission's recommendations on laboratory research. These recommendations concern approval processes for low-risk genetic modification undertaken in contained laboratories and for the importation of low-risk GMOs. Public submissions were requested on simplifying the approval process for laboratory research.

The circumstances defining a low-risk genetic modification are set out in the HSNO (Low-Risk Genetic Modification) Regulations 1998. Most routine laboratory genetic research and the teaching work carried out by universities and research institutes falls into this category. In this case 'low-risk' relates to a low-risk to public health and to the environment.

At the moment, when each new low-risk GMO is developed it must be approved separately (on a case-by-case basis) either by the Environmental Risk Management Authority (ERMA) or by an Institutional Biological Safety Committee (IBSC). IBSCs are delegated this authority by ERMA by powers provided under the HSNO Act. Approval is based on an assessment of each separate organism. This does not create a problem where the entire range of likely low-risk genetic modifications are anticipated at the planning and approval stage of a project. However, in the course of testing and refining experimental procedures, a researcher might find they wish to perform additional low-risk genetic modifications in order to meet the objective of a project. If this is the case, a new approval would be required which may increase compliance costs (time to complete and application fee) as well as delays in research.

B2.1.1 Proposal 1: for 'project-based' approvals

The Royal Commission recommended that applications to develop low-risk GMOs in containment be approved by IBSCs on a project basis rather than on an organism basis. 'Project-based' refers to approval of a research programme involving a group of organisms rather than requiring a separate approval for each organism developed. The Government accepted that the intent of the Royal Commission's recommendation is to simplify the assessment of low-risk laboratory (i.e. fully-contained) research involving genetic modification by either of the following means:

- using defined criteria to assess organisms
- providing for the approval of groups of organisms of similar types and risks, rather than requiring separate approvals for each organism.

This proposed simplification of approval processes would help to align procedures with the way scientific research actually takes place and would reduce unnecessary compliance costs. This would be achieved without changing the definition of what low-risk work involves or the overall risk profile of the work being undertaken.

B2.1.2 Proposal 2: for delegation of approval of importation of low-risk GMOs to IBSCs

The second recommendation of the Royal Commission is to amend the HSNO Act to allow for the efficient importation of low-risk GMOs through delegation of the approval process to IBSCs. The Government accepted this recommendation. This would bring the approval process for **importation** of low-risk GMOs in line with that for the **development** of low-risk GMOs. The Act would also need to be amended to make a distinction between low-risk and higher-risk GMOs in the same way as it currently distinguishes between low-risk and higher-risk development. It is suggested that either the definition of a low-risk organism could be based on the criteria specified in the low-risk genetic modification regulations or that a separate verifiable definition or criteria be developed.

This chapter attracted response from some private individuals and some organisations from the science/research community, organics producers, the agribusiness/forestry sector, environmental groups, religious/ethics groups and the Māori community.

B2.2 General views on streamlining approval processes

A number of submissions from individual researchers, and science/research community and universities expressed frustration at current compliance requirements, both in terms of the length of the application and processing times. One institution said that their science group was currently working under 15 different applications and suggested that the process would be better understood and easier if all applications were incorporated into one document. A few researchers explained how completion of forms and delays in processing had compromised the direction of their research. A non-profit science/research organisation commented that current costs involved with compliance were unsustainable in the long-term and this is likely to prohibit the development of further independent research organisations. Some submissions did not address specific means of simplifying the approval process but expressed general support for simplifying and streamlining processes. These submissions came from the agribusiness/forestry sector, individual researchers, universities, and science/research organisations.

Others were not happy with the proposed changes. These submissions came from organics producers, private individuals, environmental groups, and from religious/ethics groups. Most of these submissions were concerned that decisions to classify organisms as low- or higher-risk were being made on the basis of insufficient information, as all effects of organisms are not yet known. They favoured continuing with a case-by-case organism-based approval process.

B2.3 Project-based approvals

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?

The Discussion Paper presented a proposal for a process to be followed if a research project changes course. This proposal aimed to eliminate the need for a separate approval in the situation where a researcher finds during the course of a project they wish to perform different genetic modifications to meet the objective of the project.

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 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.

B2.3.1 Views on project-based approvals

2b Is this approach workable?

A number of submissions directly addressed the question of project-based controls. Views are summarised in the following table. Submissions in favour of project-based approvals were from researchers in universities and science organisations and the agribusiness/forestry sector. Some environmental groups supported simplification as long as approvals only related to research in fully contained laboratories. Submissions against project-based approvals were from individuals, other environmental groups, religious/ethics groups and from the Māori community.

In favour of project-based approvals	Against project-based approvals
• Project-based approvals pose no risk to environment and would substantially save time (through researchers not having to complete repetitive application forms). • Approvals given should be broad and robust enough to allow one initial proposal to cover the life of the average research project (e.g. three years). • Duplication of effort by research organisations could be reduced by ERMA developing generic application forms and a list of appropriate controls available for low-risk genetic modification experiments. • Approvals could be granted for a particular procedure to be carried out involving a group of organisms (e.g. molluscs or invertebrates). • Agree in principle, with proviso that IBSCs have independent experts from another institution and any concerns are referred to ERMA, a national committee or similar for mediation. Research where organisms used are pathogenic to humans should have a requirement to monitor and report incidences to the MOH for purposes of prevention and control. • Support for low-risk laboratory research but not for research in the environment. • Project-based approvals will enable more meaningful and manageable consultation with Māori.	• Concerned about the overall definition/classification of 'low-risk' and the variation in organisms classified as low-risk. There must be ongoing monitoring to scrutinise for safety and ethical issues. • The risk is that the definition of the allowed organism could incrementally change in ways to create unforeseen risks. • Every application should be fully detailed as to inputs and expected outcomes and methods of preventing escape. • Project-based approvals would increase scope for errors of judgement and could be used as a means of getting around approval requirements. They may lead researchers to provide only minimal information. • The Bioethics Council should have a role in the ERMA/IBSC approval process. • Concerns about the health and safety of laboratories. • The Act needs to address the health and safety of the community at large as well as allowing experiments to forge ahead with the assurance of caution. • Acceleration and simplification of approval processes go against the tenets of the Ministry for the Environment. • Simplifying approval processes could be better achieved by improving form design.

B2.3.2 Other ways of streamlining/simplifying approval processes

A small number of submissions from the agribusiness/forestry sector favoured replacing low-risk assessment by IBSCs with an annual warrant or audited approval of containment facilities that have authorisation to conduct defined low-risk research.

A number of research institutions thought that further simplification could be achieved through ERMA developing some generic applications and appropriate controls available for low-risk genetic modification experiments. For example, it was suggested that a shorter one- to two-page application could replace the current 14-page document and outline the nature of the development (e.g. the host-vector systems to be employed) and the phenotype of the resulting organism. This would reduce duplication.

Others favoured a laboratory log book into which all features and processes used for organisms developed within a facility would be recorded (some saw the recording of intermediates as unnecessary). This book would be open to scrutiny by IBSCs or ERMA.

An alternative approval processes was presented by a few submissions from both science/ research and agribusiness/forestry sector organisations.

- All research organisations operating one or more MAF transitional and containment facilities and intending to create GMOs within it should be required to set up their own IBSC. The IBSCs would review all applications made by workers from their home institutions and could refer them to ERMA for advice or decisions in difficult cases. Applications to the IBSCs should outline the molecular biology processes to be used and cover broad classes of organisms (e.g. native or non-native vertebrates, invertebrates, non-pathogenic micro-organisms).
- Applicants would submit the generic application (as outlined above) to their IBSC for record-keeping. This would speed up the process and IBSCs could then focus on project applications not covered by the generic approvals. The IBSC should be the delegated authority to consider all work that is not an application for release. A register of organisms required for containment would provide a record of work that could then be audited. MAF/ERMA could audit both containment facilities and IBSC operations.
- MAF/ERMA would be responsible for the development national standards.

B2.4 Simplifying the identifying of organisms

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

B2.4.1 Options for amendment

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, 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?

The following table presents a summary of the views and suggestions received about the requirement to identify organisms prior to application. Environmental groups and organics producers were against any relaxation. Science/research and university submitters were generally in favour of removing the requirement for prior identification and agreed with the need to keep records.

Option 1 – Completely remove prior identification requirements	Option 2 – Requiring notification of identification to the IBSC (or ERMA)
• There is no need to completely identify an intermediate or resulting organism which is to continue in containment since the hazard has already been defined by the category of work and containment. • A number of submissions favoured removing all prior identification but continuing to require records of methodologies used and/or the identities of low-risk organisms currently held. IBSCs or ERMA could then audit these records. Alternatively there could be a requirement to notify the IBSC within specified time of the identity of resulting GMOs. • The IBSC is well qualified to approve low-risk organisms but the activities of the committee must be subject to regular audit. • Option 1 is more appropriate during the construction and manipulations of genes, for example of *E coli*. However if during the final stages an altered gene is to put back into the host then Option 2 requiring notification would come into play.	• Keep the identity requirement in applications as this is the only means for ERMA or the Bioethics Council to use in determining if an organism is low-risk. • The reporting should not be limited to identity but extend to other characteristics such as behaviour and environmental feedback loops. This should be based on a regular cycle and built into work programmes. Notification should occur within a specified period following the conclusion of the work while physical constructs such as organisms, data sets, experimental assemblages are still available. • Only support if novel organisms have risk characteristics that fall outside normal parameters for organisms from that species or genera. • Would require substantial paperwork and reporting requirement for no gain in safety of reduction in risks. • Opposing relaxation of requirement to identify organisms in relation to environmental release (it is the only means to allow ERMA and Bioethics Council to determine if development is low-risk).

B2.5 Identification requirements

B2.5.1 Level of identification for intermediate and resulting organisms

In general the university researchers, agribusiness/forestry sector and science/research community organisations that responded thought that the level of identification detail required should be consistent with the risks involved (i.e. less for low-risk and more for higher-risk GMOs). Religious/ethics groups and private individuals thought that full identification was always necessary.

- An agribusiness/forestry sector organisation favoured compulsory definitions and use of identifying genetic markers at the approval stage.
- An organics group thought that reporting should not being limited to identity but extend to other characteristics such as behaviour and environmental feedback loops.
- Several individuals thought that no risk approval should be given unless the genes being worked on or sought are clearly identified. They supported a clear and full description of the GMO before work began and at the intermediate stages including explanations and a rationale for any differences.
- Several submitters thought libraries of GMOs required special attention. Private individuals thought that libraries of unidentified GMOs could be treated under a carefully-considered and established category under the HSNO Act. Another individual favoured amending the regulations so approval for the construction of DNA libraries using a specified host and vectors could be granted once (this could be at the level of marine invertebrates or phylum, molluscs).
- An agribusiness/forestry sector organisation did not think that formal permanent records were necessary for low-risk GMOs that are completely disposed of soon after production.
- Another agribusiness/forestry sector organisation thought that there was no need to identify organisms fully during development but the focus should be on the risk criteria.
- A health organisation thought that all resulting organisms should be identified, as well as any intermediate organisms that are going to be used in other research.

B2.5.2 When should identification of the resulting organism occur?

As mentioned, some organisations and private individuals favoured an approach that ensures that the greatest level of detail of information is available at all stages of development and considered this was necessary for assessing which risk category an organism belonged to.

A range of opinions were held by those in the science/research community, agribusiness/ forestry sector organisations, universities and the health organisations about when identification of the resulting organism should occur. Responses given included:

- within a reasonable time of construction
- at the point when an altered gene is to be put back into the host form
- if not a pathogenic form of *E. coli* then on completion of the research
- identification of novel organisms and their risk characteristics should be undertaken by researchers and notified to IBSCs

- when it is be considered for release or where containment can no longer be assured (e.g. in field trials or for general release)
- when an application to develop is made
- not during development where the focus should be on risk.

B2.6 Criteria for 'low-risk' GMOs

The Discussion Paper outlines how 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.

B2.6.1 Proposals and questions

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 importation be allowed to be rapidly assessed under section 42 of the HSNO Act. Again two main options were identified.

- **Option 1:** Define a low-risk GMO as an organism developed according to the criteria specified in the low-risk genetic modification regulations. This involves a compliance issue of ensuring the organism imported is the organism identified and that it has been developed in the overseas laboratory in circumstances specified as low-risk. This presents problems because not all components of the process of developing the organism can be determined from the organism itself.
- **Option 2:** Develop a separate verifiable definition or criteria for a low-risk GMO (this would be based on elements that can be independently verified such as the host organism, the nucleic material being inserted and the vector, where present).

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?**

B2.6.2 Criteria for identifying low-risk GMOs

Views were sought on whether basing the criteria for assessing a low-risk organism on the host organism, the nucleic material being inserted and the vector when present would be sufficient.

Opinion was divided with most science/research organisations and an individual researcher agreeing that these criteria would be sufficient (but they did not provide detailed reasons). Others did not agree, including other individual researchers, religious/ethics groups, a health organisation and organics producer. A health organisation stated that human pathogenicity also needs to be considered.

An agribusiness/forestry sector organisation thought criteria for defining low-risk should avoid schedules of approved organisms, vectors, and techniques and instead focus on the properties of the new organisms.

B2.6.3 Limiting importations that have been developed according to higher-risk procedures

Very few submissions responded to the question of whether the specified criteria (host organism, nucleic material being inserted and any vector) would limit the importation of low-risk organisms that have been developed according to possibly higher-risk procedures.

Submissions from the agribusiness/forestry sector thought it would limit importation. One university thought that procedures used in development would not necessarily be reflected in hazards associated with the new GMO. The focus should be on the hazards in the host/source/ vector and the phenotype of the resulting organism. A science/research organisation agreed but also thought no information was needed about the vector if it was no longer present.

An individual and a religious/ethics group suggested it was necessary to establish that a non-low-risk procedure had not produced a non-low-risk organism. They suggested that the current criteria is flawed because it fails to account for unexpected effects and complex interactions.

B2.6.4 Alternative criteria to defining low-risk organisms

A small number of submissions from the science/research community, universities and a religious/ethics group strongly favoured use of phenotype. The health organisation was concerned that human pathogenicity be included. One science/research organisation suggested negative mutation techniques while another suggested the issue be workshopped.

B2.6.5 Other approaches to defining low-risk organisms

An agribusiness/forestry sector organisation favoured comprehensive identification, taxonomic name, strain and a complete identification of all components comprising integrated DNA sequences and precise identification of vector backbone.

An organics producer suggested a process that considers the totality of the organism(s), the experimental process, the containment and the provisions for 'fire fighting' (management of failures in the containment system).

A science/research organisation suggested that the current basis for determining low-risk is scientifically flawed because it is not based on the risk of individual organisms but on how they are produced. This organisation suggested that major change is needed so those organisms are characterised on actual risk. This would involve the inclusion of characteristics such as the ability of the host to be ecologically aggressive without human intervention; global knowledge and expertise with known gene constructs; involvement of novel or new proteins not found in the food chain; and the presence or absence of self-replicating virus constructs. This organisation also suggested that legislation, regulatory process and official interpretation often treats pollen like a pesticide and is not based on scientific knowledge of pollen biology and breeding systems.

Another science/research organisation focused on ability to survive in the environment for a significant period of time. They suggested that overproduction and additional genes contribute to increasing risk associated with field isolates because of their ability to survive in the environment from which they were isolated. They stated that it is impossible to assess all the genetic material at this point in time.

B2.7 Other issues

Other comments included the following.

- The categorisation into low- and high-risk is flawed because there is not yet enough knowledge or technical precision to make this distinction.
- Distinguishing between organisms that pose a risk because of their genetic make up and the risks involved in manipulating organisms in containment was favoured.
- There was some support for approvals being based on the containment facility rather than the organism at all.
- Streamlining of processes involved with fulfilling the requirement for Māori consultation was favoured as part of the approvals process. There were concerns about the amount of time taken, the cost, and the delays created by the required consultation process, sometimes for little response. This was seen to have particular impact on the undertaking of short-term projects.
- A return to the Advisory Committee on Novel Genetic Techniques (ACNGT) permit system was favoured because simpler and would be in line with international global practice (with the inclusion of consultation with Māori).
- It was suggested to amend the regulations be amended to provide for GMOs developed before the HSNO Act but which may be being propagated without being subject to the same containment requirements. The suggestion is that all GMOs may only be propagated in solid, liquid or aerosol culture in a MAF-registered facility and with the approval of the local IBSC.
- All GMOs produced must be in full and permanent containment and been produced ethically.
- Confusion is often caused by defining organisms in containment as low- or not low-risk. Properly defined and operated containment practice means that any GMOs held in a laboratory will pose minimal and acceptable environmental risk. The issue to be considered is hazard, particularly to the health of the experimental personnel and the risk of the organism escaping.

- The restriction of low-risk work to the laboratory is an arbitrary and inappropriate distinction. While giving the impression of increased control it adds nothing to safety while greatly increasing compliance costs. All work up to and including certain securely-controlled (physical and/or operational) field trials should be categorised as low-risk.

B3.0 Gaps in HSNO coverage

B3.1 Introduction

Chapter 3 outlines the proposals to address two gaps in coverage of the HSNO Act highlighted by the Royal Commission. The following two areas are not currently subject to regulation:

- the genetic modification of human cell lines
- new organisms regenerated from tissues.

B3.1.1 Genetic modification of human cell lines

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

Currently the genetic modification of animal cell lines, including the insertion of human DNA into an animal cell 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 by the HSNO Act as they are 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 to provide regulatory oversight for research involving genetic modification of human cell lines.

The Royal Commission recommended that the HSNO Act be amended to clarify that research involving genetic modification of human cell lines or tissue culture is covered by the Act. The Government agreed to this recommendation.

B3.1.2 New organisms regenerated from tissue

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 accepted 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 be subsequently regenerated by cloning and released without an appropriate HSNO Act approval.

The Discussion Paper described how this issue arose. Neither the importation of tissue samples nor any development activity (other than genetic modification) requires a HSNO approval. 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 no HSNO approval is required to import tissue.

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 order to ensure unapproved organisms are not developed and/or released in New Zealand there needs to be regulatory oversight in this area.

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.

B3.2 The genetic modification of human cell lines

In the Discussion Paper, two options were outlined:

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

Under Option 1 HSNO approvals would be obtained either for developing a GMO in containment or importing a GMO into containment. The approval would be limited to the cellular level: that is to the development (genetic modification) of a human cell line or 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 human 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)

- human 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.

Currently ethical approval is not required for research involving human cell lines in containment. However, this would 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.

Option 1 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.

The MOH 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 MOH review (Option 2).

The advantage of Option 2 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 MOH 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?

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?

Responses were received on the issue of regulating the genetic modification of human cell lines from environmental groups, Māori community, agribusiness/forestry sector, religious/ethics groups, the science/research community and universities.

B3.2.1 How should the genetic modification of human cell lines be addressed?

Reasons for inclusion in HSNO Act	Reasons for inclusion in (MOH) review
• It is illogical for human cell lines to be excluded from coverage in the HSNO Act. • To regulate separately will duplicate approval processes and would place an unnecessary burden on scientists to duplicate the approval process of an extremely low-risk and identical technology. • It is preferable that all research using GMOs is covered by the HSNO Act especially when using commercially bought human cell tissues. • Human cell lines should qualify as mammalian cell lines approved in Schedule 2 of low-risk organisms. They pose little or no risk, as they cannot support outside special sterile media and a controlled environment. • HSNO assessments and approvals should be required for development of human cell lines rather than for the resulting organism.	• The consideration of human cell lines is best dealt with as part of comprehensive review of all aspects of human and cell tissue research. • The MOH is best placed to deal with ethical issues associated with use of human tissues and cell lines that have the potential to provide medical treatments in the future. • Only those issues relating to cell lines directly obtained from patients need to be referred to the MOH review. All lines other than commercial lines should be subject to guidelines as agreed with researchers and with appropriate scrutiny. The risk to the environment and people associated with stem cell modifications is extremely low given the sensitive environmental conditions such cells require and their inability to survive outside a sterile environment. • It is better to work through the MOH review first before considering if changes need making to the HSNO Act. • Agree with inclusion with the MOH review and to the development of guidelines providing done in consultation with those research institutions and researchers who will be using them. This type of work will already be subject to Medical Ethics Committee consideration. • While they should be part of the MOH review the genetic modification of human cell lines should be subject to ERMA oversight and ultimate control.
Reasons against inclusion in HSNO Act	
• No category of low-risk genetic modification has been proposed for human cell lines. • Inclusion may prove a strong deterrent for innovation in university-based biomedical research. • Placing human cell lines under the HSNO Act places them under MAF who are not necessarily equipped to handle the ethical or medical aspects that are involve. • ERMA would need to employ additional health expertise in-house.	

B3.2.2 Impact on existing practices

The following points were made about the impact of changes on existing practices:

- Where risks posed by genetic modification of a human cell line are high in relation to the criteria specified by the HSNO Act then scrutiny by ERMA is appropriate. Otherwise this work should be managed in same way as all other approvals for genetic modification research.
- There is likely to be only a minimal effect on existing practices providing work is classified as low-risk and operation of ERMA is simplified. If this does not happen then the effect will be to slow down valuable medical research and the diversion of research funds into compliance costs.
- There may be problems in defining scientific research as distinct from medical treatments. The IBSCs may need to work through human ethics committees on ethical issues.

- Given cultural sensitivities it is appropriate that the amendment bring these experiments under statutory control. The most important impact will be the hindrance placed on the importation of genetically-modified human cell lines. This effect would be lessened if the amendment allows IBSCs to adjudicate on importation of GMOs into containment.
- If IBSCs are delegated low-risk work on human cell lines, they may need to work through human ethics committees on ethical issues.
- Hoping that amendment provides clear and precise regulation on the use of human genes because of the inherent risk of breaking the species barrier.
- Expect it to be a legal minefield with human error being another factor to consider in assessing risks of research.

B3.3 New organisms regenerated from tissues

To ensure that organisms created in this way from imported tissue using a surrogate mother are covered by the Act. This involves amending either the definition of 'develop' to cover the regeneration of new organisms, or broadening the definition of 'new organism' or 'organism'. In addition, including the power to make regulations to provide that things are not 'organisms' or 'new organisms' for the purpose of the Act.

The proposed amendments extend to the artificial regeneration of organisms from all tissues, including plant and fungal tissues that are not capable of replicating themselves, but do not extend to human cloning as the term organism in the HSNO Act specifically excludes human beings.

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?

B3.3.1 Amending the definition of 'develop' to cover regeneration of new organisms

Two submissions commented on the proposal to amend the definition of 'develop' to cover regeneration of new organisms. Both suggested that emphasis should be on the phenotype of the organism produced rather than on the process used to produce it.

B3.3.2 Changing the definition of 'new organism' and 'organism'

Several science/research organisations suggested the broadening the definition of organism within the HSNO Act to ensure cloning of tissue imported under a MAF permit for other purposes cannot occur. Suggested wording was *'the addition of an organism, whether genetically modified, or not that is not present in NZ that has been regenerated from somatic cell nucleic material to the definition of new organism'.*

One of these submissions did not believe it was necessary to change the definition of new organism as the current definition already covers the regeneration of a new organism by use of cloning technologies.

B3.3.3 Other ways to regulate the organism

Several submissions from the science/research organisations favoured changing the name of the HSNO Act to 'The Hazardous Substances, New Organisms and Gene Technology Management Act'. They suggested that this name change would simplify the handling of the issue of regeneration of a new organism from somatic tissues. It would allow a definition of genetic technology to be added and the regeneration of an organism that is not present in New Zealand to be included in this definition.

One submitter suggested that the issue is not the definition of 'development' but rather the definition of 'importation' of a new organism that requires attention. The definition of importation in the Biosecurity Act 1993 could be broadened to include importation through the regeneration of a new organism. The tissues should be treated as new organisms at the point a viable cell or group of cells is produced which could develop into a new organism.

B3.4 Stage for undertaking HSNO assessment

The Discussion Paper set out the issues relating to the timing of a HSNO assessment that would be required if a new category of approval was introduced for developing non-genetic modified new organisms in containment.

Currently, 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. MAF, under the Biosecurity Act, imposes regulation at this stage (including requirements that import health standards are met). An 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.

- **Option 1:** It was suggested that it would be good to carry out the assessment under the HSNO Act before regeneration work started. When using regeneration techniques, this is the stage at which a new whole organism is developed. If the new organism were 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.

- **Option 2:** The alternative would be to assess the organism at the point of release from containment. The disadvantage of this would be 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 HSNO approval or controls prior to release.

3f At what stage so 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.

A small number of submissions from science/research organisations, the agribusiness/forestry sector, university researchers and an individual commented on the alternatives for timing of the HSNO assessment.

An individual was in favour of approval being obtained at all stages. A researcher thought that an approval at introduction of the new organism was the appropriate time and that at importation would be too early and at release too late.

One science/research organisation advocated for an approval at the time of the original application or whenever intent to create a new organism was signalled. Another science/ research organisation, along with a number of agribusiness/forestry sector organisations, were in favour at the point a fertilised embryo is transferred from the laboratory into the surrogate mother.

Another science/research organisation suggested that regulations would need to be drawn up to cover the regeneration from somatic tissue of an organism not presently in New Zealand. While it is likely that ERMA would wish to adjudicate on proposals concerning animals, the applications for the regeneration of plants or fungi or other eukaryotic micro-organisms to be held in containment for experimental purposes should be delegated to IBSCs. Any proposal for release of such a regenerated organism from containment would of course be handled by ERMA under the normal requirements of the HSNO Act.

B3.5 Other issues

- There should be a total ban against any form of human cloning and inheritable genetic modification of human beings (designer humans).
- There should also be a ban on animal cloning, mentioning high levels of defects.
- There was a call for a separate Act to regulate risk management of human cell lines and other human material as well as an effective and accountable system to regulate other human genetic technologies such as stem cell research, pre-implantation genetic diagnosis and human somatic gene therapy.
- New legislation altogether is required, as the HSNO Act was never constructed to manage GMOs. Given the complexity and contention involved with GMOs the existing statute is inappropriate.

- The options identified were too restrictive for plants and could increase compliance costs. The amendment should not apply to plants or to fungi as regenerating plants from tissue culture is not genetic modification. The changes would mean that commercial tissue laboratories would require approval from ERMA.
- New Zealand could lose its basic stock of native species.
- There needs to be regulation on exporting for regeneration purposes (e.g. exporting kiwi tissue).
- Concern that while gaps in the HSNO Act may need addressing that the proposed changes may lead to vagueness and misinterpretation.

B4.0 Conditional release

B4.1 Introduction

Chapter 4 described the Government's response to the recommendation of the Royal Commission to amend the HSNO Act to provide for an additional category of release called 'conditional release'.

This provision would allow ERMA to give approval to release new organisms on condition that specified controls, limitations or restrictions are adhered to. In accordance with other requirements of the Act, ERMA would still need to be satisfied that the positive effects of the organism outweighed the adverse effects and to decline an application that failed to meet the minimum standards as set out in section 36 of the HSNO Act. This section requires ERMA to decline an application if a new organism is likely to cause significant displacement of native species within its natural habitat or the deterioration of any natural habitat or adverse effects on human health and safety or to New Zealand's inherent genetic diversity or disease, be parasitic or become a vector for human, animal, or plant disease (unless that is the purpose of the importation or release).

This amendment to provide for a conditional release category aims to address the current situation where there is no intermediate state between the category of release and the category of field-testing in containment. At the moment, once released into the environment an organism (genetically modified or imported) is no longer defined as 'new' and is therefore no longer subject to the HSNO Act. Release means it can then be used anywhere and by anyone.

Controls on release would change the assumption inherent in the HSNO Act that all released organisms inevitably breed and spread throughout New Zealand. They would enable some effects of new organisms to be prevented or managed. ERMA could use controls to reduce potential adverse effects and would take account of controls in the decision-making process. It may lead to some organisms being permitted for conditional release that would not be suitable for full release. Conditional release would not replace full release and ERMA could still approve organisms for release without controls.

The Discussion Paper provided the context of the development of the HSNO legislation and current regime and explains why there was no controlled release category in the original legislation. A key shortcoming of the current regime is that ERMA now must, in its assessment of applications for release, consider the positive and adverse effects in *all* environments and in *all* parts of the country. This does not reflect the reality that 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.

- It may not be appropriate to group all new organisms together and assume they will inevitably spread and establish. Species vary in their ease of control, ability to be identified and retrieved in the case of escape (e.g. large mammals) and to persist without intervention (highly-domestic crops cannot persist).
- Because field tests of GMOs must be fully contained, it can be difficult to obtain all the necessary information about likely environmental impacts. Controlled research out of full containment 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.
- Coexistence of genetically-modified and non-genetically modified agriculture was not considered at the time of policy development.

The Discussion Paper proposed that controls could be used for:

- research – to limit the spread of genetic material from field research that is not fully contained, thus enabling research that otherwise could not to take place
- monitoring – the unseen impacts of new organisms (e.g. on non-target insects or surrounding vegetation)
- limiting 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 genetically-modified and non-genetically modified agriculture)
- controlling use – how a new organism is used (e.g. reduce the risks of insects developing resistance to incorporated pesticides) or where it is used (location controls).

Submissions received on conditional release have been organised under the following broad headings.

- Why introduce conditional release?
- How would the category work in practice?
- How would compliance and enforcement be achieved?
- What would be the financial implications of introducing the category?

B4.2 Why introduce conditional release?

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 genetically modified organisms are permitted? If so, on what basis?**

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

General views on 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)?**

B4.2.1 Views on conditional release

Virtually all the proforma submissions from individuals contained a number of statements against any form of release, including conditional release. A lack of confidence in control measures (particularly buffer zones), irreversibility of effects on the environment and the current and likely future lack of an appropriate liability regime were the main reasons given. Many of the proforma submissions said New Zealand should learn from overseas experience where organic and conventional crops have not been protected by buffer zones. Their view was that the best way of managing the unknown risks was for approval to be given only to research undertaken in fully-contained laboratories.

Of the more detailed submissions that responded to this area, opinion was spread between those supporting a conditional release category and those against it. Those from the science/research community, universities, agribusiness/forestry organisations as well as individual researchers and some legal professionals tended to support the amendment. Those expressing reservations or opposition included local authorities, some Māori groups and a risk management professional. Some were concerned that while organisms are assessed as low-risk there are still too many unknown factors and others were not satisfied that control measures would work. Local authorities and some Māori organisations were concerned that conditional release would go against the wishes of some geographic areas to be 'GE-free'. An environment group provided a detailed critique of the control mechanisms listed in the Discussion Paper and the assumptions behind the approval category.

A science/research organisation had, in their submission to the Royal Commission, proposed a similar four-category scheme. Their category 'partially contained field test' was most similar to the conditional release approval category and also aimed to overcome the 'all or nothing' situation that exists at present.

A risk-management professional favoured retaining the category 'full release without controls' because it places the rigour back into the research. The addition of a conditional release category had no merit as a risk management tool.

B4.2.2 When would conditional release be appropriate?

The Discussion Paper suggested that release with controls might be appropriate for research and/or monitoring purposes; to limit the dissemination and persistence of an organism; or to control use of an organism (i.e. who handles or uses it and/or where it is used).

Some submissions from the agribusiness/forestry sector, universities and the science/research community echoed these as being appropriate reasons for release. This table summarises the range of views received on when controlled release would and would not be appropriate. These reasons have been grouped under broad headings – some may fit under several headings. Where a means of control was suggested this is also included.

Appropriate reasons for using conditional release
Research
• Extension of research into a more natural setting. For example to provide a less restrictive and more natural environment for husbandry of large animal low-risk GMOs (e.g. camels, bioreactor cattle).
• To conduct semi-contained field trials of crops where there is flower and seed production – to be controlled by the stipulation of disposal measures and restricting the raising and handling of GMOs to specified institutions, companies or individuals.
• To gain an understanding about an organism that would help assess the benefits of the new technology and/or those of existing practices or land use.
• To establish a level of tolerance in non-genetic modified seed.
• For all plant introductions.
• To test the effects of containment or sterility.
Monitoring
• Where ERMA requires the developer to undertake further research into the ecological impacts such as risks of adverse effects arising from cross-pollination of other plants, horizontal gene transfer and impacts on other species.
• To assess the impact of the environment on the organism as well as of the organism on the environment.
Limiting dissemination and persistence
• Where the applicant does not want full release and intends to clean up the site and where it can be assured that no uncontrolled release can occur.
• Establishing best practice for managing potentially commercial transgenic plants, for example for buffer zones and for herbicide and pesticide control.
Controlling use
• Managing the separation from other land users/ testing effectiveness of control measures/developing best practice guidelines.
• The permanent segregation of non-food GMO crops from non-GMO approved for food use crops in field and post-harvest setting – to be controlled by an appropriated post-harvest segregation regime.
• Where GMOs contain human genes (e.g. with genetically-modified sheep there are special requirements regarding the cultural and spiritual concerns of some sections of the community) – to be controlled through requirements for waste disposal and other issues similar to those for field release; to mitigate the impact of the new or novel species on existing species; to be controlled through conditions such as refugia.

Not appropriate reasons for using conditional release
• Where risks of pollen drift and or the protection of 'GE-free' areas preclude even a conditional release (for example, where it compromises organic status of bee-keepers' ability to produce non-genetically modified products). • Where the aims of an experiment can equally be achieved in a fully-contained laboratory, for example analysing chemical composition. Some included the assessment of health impacts such as toxicity, allergenicity, development of antibiotic resistance on humans and animals in this category. • Simply as a means of allaying concerns or to satisfy spiritual objections. • Where an organism is considered too high a risk (for example, pathogenic organisms). As stated above, many individuals think that there are no appropriate reasons because they lack of confidence in any control measures, believe there are too many as yet unknown risks and are concerned about lack of a suitable liability regime.

B4.2.3 Who should decide where GMOs are permitted

The Discussion Paper set out some alternatives for making decisions about where GMOs are permitted. It begins by outlining the Royal Commission's recommendation that ERMA has the ability to protect non-genetically-modified crops that could be vulnerable to contamination by genetically-modified crops. The Royal Commission had first considered the possibility of using the land management controls of the Resource Management Act 1991 to achieve this through declaring 'GE-free' areas, but decided that this option had the potential to divide communities and infringe on certain individual's rights. They also stated that blanket bans of GMOs in regions may be unnecessary since some genetically-modified and non-genetically-modified crops may be able to coexist because they cannot cross with each other.

First alternative – use of conditional release as a mechanism for controlling where genetically-modified crops may be grown. ERMA would make decisions about conditional release on a case-by-case basis rather than declaring GM-free areas. It could set controls such as limiting a particular genetically-modified crop to a certain area of New Zealand or requiring the use of buffer zones to protect contamination of nearby crops. The advantage of setting a control attached to a crop is that it is applied wherever the crop is grown and does not restrict where it is grown.

Second alternative – ERMA would be required to recognise the decisions made by other bodies to be GM-free on the basis of industry or locality (e.g. by relevant industry organisations or local authorities). This would mean that ERMA could not set controls that were inconsistent with or overrode such decisions. The disadvantages of identified with this approach are that other bodies do not necessarily have the expertise to assess the effects of new organisms. Parliament has established special purpose legislation (the HSNO Act) and a national, technical and non-political body (ERMA) to carry out the assessments. The HSNO process already involves a process for public input and the opportunity for citizens to have their say. It would not be desirable to duplicate processes or change the basis for decision-making.

Submissions from the science/research community, universities and the agribusiness/forestry sector tended to support ERMA as decision maker, whereas submissions received from the Māori community, local authorities and organics producers supported the second alternative. This would require ERMA to follow decisions made by local authorities or industry groups.

The following table summarises the reasons provided in submissions in support of each alternative.

ERMA – the sole agency	Local authority/industry role
• Any other arrangement would involve increased costs and the potential for inconsistency in decision-making. • Agree that release should be apolitical and based on sound risk management and scientific criteria and that ERMA has the expertise. However ERMA needs to proactively work with other agencies that have roles in managing coexistence, for example local councils. Consultation also helps to ensure the efficacy and cost-effectiveness of controls imposed. • ERMA is the only organisation with an adequate decision-making framework. Local government and industry do not have adequate processes. • As the application process is publicly notified, there is nothing to stop other agencies making a submission to ERMA concerning a release.	• Local authorities should be part of the decision-making process when transgenic field trials or GMOs could have adverse effects on other land uses (e.g. organic farming). • ERMA must recognise decisions by other organisations to be 'GE free' on basis of locality or industry. ERMA must not be able to set controls that override such decisions.

Some submissions provided additional comments on how location controls could be managed and work in practice.

- A number of agribusiness/forestry organisations advocated adoption of the process used by certified seed producers to maintain and meet crop purity and quality standards. This involves local consultation, quality assurance programmes and agreement.
- A couple of submissions commented that some controls (e.g. buffer zones) will require a high degree of co-operation between neighbouring farmers. Regulatory experience suggests that sometimes landowners are uncooperative and resistant. This means that a conditional release system will need to be sufficiently robust not to rely on landowner co-operation. One submission suggested that buffer zones should be located on the same property as the area containing the conditionally-released GMOs (unless an agreement between neighbours can be reached).
- Further work is required on the interface of the Resource Management Act and the HSNO Act over land use control and discharge issues.
- Some advocated 'GE-free' or GMO exclusion zones of sufficient size to be pursued where there is little or no likelihood of cross-contamination (e.g. the South Island).

B4.3 How would the category work in practice?

The Discussion Paper looked at three aspects of the practicalities of introducing a conditional release category. The first area is the degree to which the HSNO Act needs to tightly define purposes for which conditional release may be used as well as ERMA's setting of controls. The second area is the application process and consideration of whether an application is made solely for conditional release (i.e. a separate application) or whether one application could be made for all types of release leaving the decision to ERMA. The third area concerns developing a mechanism for reviewing the controls on organisms over time.

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?

The application process

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?

Reviewing, reassessment and the interface with full release

4j How should the controls on conditional release 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?

B4.3.1 Definitions

Purpose of conditional release

Submissions that addressed defining the purpose of conditional release were from the science/ research community, agribusiness/forestry sector, Māori organisations and a legal organisation. A few submissions simply agreed that defining purposes was appropriate. A legal organisation thought guiding principles were all that was necessary and an agribusiness/forestry firm thought that specifying criteria was not appropriate as it should be available to all. Most of the agribusiness/forestry sector organisations together with one from the science/research community made two points. First, that conditional release should be used where scientific evidence establishes that there could be a risk to the environment that needs to be assessed or mitigated against. Secondly, that the conditions are imposed until further research establishes that the risk is eliminated, acceptable or unacceptable.

Other views on purposes included:

- applicants being able to specify they wish conditional release
- the ability to provide for the coexistence of GM and non-GM agriculture – it is a trade-off between certainty and flexibility
- providing more information on characteristics (viability, environmental tolerance) or growth in different climes or habitats
- appropriateness of setting guiding principles within the Act – these should be developed in consultation with the Māori Reference Group.

Controls

Views on the need to define controls varied with submissions from the agribusiness/forestry and science/research communities and a legal organisation favouring a loose approach. A Māori group favoured the setting of guiding principles, which should be developed in consultation with the Māori Reference Group. A local authority favoured a tighter definition to avoid any possibility of contamination. The comments from the agribusiness/forestry sector, universities and the science/research community included the following.

- Risk factors of a new organism will have been identified through prior research in laboratories or in field trials. The nature of the organism and of its modification influences the scope for unanticipated risks. Judgements about risks need to be made during application on a case-by-case basis (while being conscious of precedent decisions).
- Conditions placed on release need to be cost effective and practical, specific and relevant to the organism and provide the greatest amount of new information to the developer.
- Conditions must be enforceable and not duplicate those applied through other legislation.
- Genetic modification is a changing technology and ERMA must maintain flexibility in decision-making.

A legal organisation advised against prescription on the grounds that it leads to frequent amendments and extra costs, which may not improve the management of new organisms.

Application process

The Discussion Paper suggested two options for making an application for conditional release.

- **Option 1:** The applicant applies to release a new organism (a single release category) and then ERMA makes the decision about whether the release should be made with or without controls.
- **Option 2:** The applicant specifies whether they are applying for conditional or unconditional release (two release categories). For applications for conditional release, ERMA would make a decision on suitable controls. This option gives the applicant the choice of which type of release to apply for. The Discussion Paper explored how this might work in practice. For example, an application might be made for unconditional release of an organism and be unsuccessful even though ERMA thought the organism was suitable for conditional release. To keep compliance costs down and prevent delays in decision-making there would need to be an easy transition between the two categories.

Most submissions from universities, the science/research community, and the agribusiness/ forestry sector favoured a combination approach where applicants make one application but specify on the form their preferred release category. A small number of submissions from a science/research organisation and a religious/ethics group believed all release should be conditional. A submission from an environment group thought that ERMA should make a judgement based on implications of full release and then impose conditions.

Some agribusiness/forestry sector organisations detailed a process that could be followed.

B4.3.3 Review and reassessment

The Discussion Paper suggested two possibilities for reviewing containment requirements.

- **Option 1:** involve an applicant applying to ERMA to have the approval reviewed.
- **Option 2:** involve putting time limits on controls so that ERMA would be required to review them regularly.

Views on controls were split between the two options. Whether or not time limits were favoured the key feature of most responses was the need for applicants to have the flexibility to approach ERMA for a review in the light of new information. Some did not favour the time limit approach because they believed it would involve an increase in costs to the applicant.

B4.3.4 Sufficiency of reassessment provisions

Few responded to the question about the sufficiency of reassessment provisions. A couple of submitters thought it was sufficient. Others thought amendments were necessary to cover the following:

- To allow an applicant the opportunity to have input into ERMA's decision about whether a reassessment needs to occur.
- To provide for a review of the conditions in which the organism was released in a way that is consistent with the RMA.
- The need for a parallel Māori group to work alongside and with the Minister and Ministry for the Environment.

B4.4 Compliance and enforcement

The Discussion Paper suggested compliance is ensuring that users abide by the controls attached to the approval and enforcement is the process of taking action against or prosecuting people who breach controls. Both are seen as problematic and major issues for conditional release because of the difficulties in recognising and detecting certain new organisms (especially GMOs) and because organisms can reproduce and spread. This means checking compliance with the controls set, as a condition of approval may be difficult. The chance of non-compliance is recognised and that this may be influenced by the costs of compliance, the potential penalties and commercial incentives to comply. These are all factors which it is recognised that ERMA must take into account – in other words, be satisfied that controls were going to 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. The experience that ERMA has had in checking compliance mechanisms for the management of hazardous substances has lead to the development of options for new organisms. Knowing where an organism is being used is important for checking compliance with certain controls. This knowledge could be required by requiring notification before certain activities are undertaken or by limiting use of the organism to certain people.

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.

Three options of approval type for limiting the use of organisms were outlined in the Discussion Paper. The aim of each approval type is the same – to find out where an organism is being used so that compliance controls can be checked.

- **Option 1:** Single-user approval – provides the greatest level of control. Involves a single user approval where a separate application is required from each person and in each location. It has the disadvantage of being potentially more time consuming and costly.

- **Option 2:** Multi-user approval with a 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. Both this and the third option would be less costly and time-consuming and would mean that the enforcement agency would still have information on all users.
- **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. This option would rely on the supplier providing this information to ERMA or the enforcement agency.

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?

Consideration needs to be given to which agency or agencies might be responsible for enforcing these controls. The Discussion Paper identified three main options.

- **Option 1:** List an enforcement agency or agencies in the HSNO Act. Here 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: MAF, the Department of Conservation, regional/city/district councils.
- **Option 2:** List an enforcement agency or agencies in the HSNO Act and enable other central or local government agencies to enforce specified controls. Under this option 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. A process of consulting and gaining agreement with those agencies would be needed.
- **Option 3:** 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 under 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?

B4.4.1 Approval types

Of those that specified a preference for approval types, most were split between Option 1 – single user approval and Option 2 – multi-user approval with permit. One legal organisation preferred Option 3 – multi-user approval with supplier notification – but did not provide reasons.

Reasons given for preferring the single user-approval were because risks are different for each combination of user, location and organism and that this level of control was the best means of achieving the goals of the HSNO Act.

One submission supported Option 2 provided that ERMA permit requirement is sufficient to deal with longer-term release of different GMOs in the same geographic locations. In the initial stages of release it will be critical for the authority to take a strong stance on monitoring compliance to allay public concerns.

Several submissions supported use of both Options 1 and 2 and envisaged that as more information was gathered a release might naturally move from one type of approval to another.

B4.4.2 Other mechanisms for achieving compliance

A university was in favour of an interim approval category. On gaining approval for conditional release an applicant would gain interim approval for a set period (maximum one year) during which compliance with controls and negative impacts would be stringently monitored. After a year with good compliance and minimal or acceptable environmental impact the applicant would receive full approval.

An agribusiness/forestry organisation advocated inclusion of audits and reporting as part of required controls.

Other submissions from the agribusiness/forestry sector were in favour of responsibility being weighted towards the approval holder who would have responsibilities to notify ERMA of entities contracted to distribute and or use the approved organism.

Several submissions commented on the need for a 'clear and transparent process' which might involve a MAF audit every six or 12 months.

A number of submissions favoured a sharing of duty between the authorities and approval holders. Monitoring should be the responsibility of the applicant or approval holder. If they did not have the necessary skills they should contract to a third party who did.

A religious/ethics group advocated full liability even for unforeseen damage as the key mechanism for achieving a high level of compliance.

B4.4.3 Enforcement agency

No agency is separately listed in the HSNO Act as an enforcement agency for new organisms. The Discussion Paper pointed out that only provisions covering new organisms in containment are currently enforced by MAF under the Biosecurity Act. Controls on release are out of containment and not enforced under the HSNO Act and therefore a consideration is needed on which agency or agencies might be responsible for enforcing these controls. The Discussion Paper set out the types of tasks that would need to be carried out, the knowledge required by enforcement officers and the potential agencies that could have an enforcement role.

B4.5 What are the financial implications?

The Discussion Paper outlined the financial costs arising from the creation of a conditional release category as consisting 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. It then discussed factors influencing the balance between administrative costs and compliance costs.

Decisions need to be made about cost recovery options for applications for conditional release for which there is a precedent in the areas of hazardous substances, new organisms and biosecurity. Less clear is the issue of cost recovery for compliance checking and enforcement.

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?**

Submissions from local authorities, the environment group, organic producers and religious/ ethics groups, and a risk manager were in favour of full-cost recovery.

Submissions from the agribusiness/forestry sector, science/research community and universities tended to favour an approach where the costs of assessment should lie 'where they fall' or to beneficiaries which includes a public interest component.

B4.6 Other issues

A number of general concerns about the relationship between conditional and full release were contained in some submissions. Those from the science/research community and universities and the agribusiness/forestry sector were concerned that conditional release not be a prerequisite for full release. Others believed that all releases should be conditional.

A Māori group emphasised the need to give recognition to section 8 of the HSNO Act which requires taking account of the principles of the Treaty of Waitangi. They also recommended an addition be made to the minimum standards set out in section 36 to include 36(f) *'Cause adverse cultural effects to the kaitiaki of the area in which the organism is to be released'*.

Some submissions made comments on their views of the zero tolerance policy for organic foods and the implications for controls. One legal organisation commented that the question of the adventitious content of seed which requires resolving and its impact on the economy. They suggest wording for an additional subsection for modification of section 41 of the HSNO Act to address this issue. They also suggested that conditional release for research and for production were clearly separated as they believed the approach, likely risk profile and subsequent steps differ markedly.

B5.0 Assessment of GMO medicines

B5.1 Introduction

The Royal Commission recommended that imported medicines and pharmaco foods which include live GMOs be approved for use by Medsafe without additional approval from ERMA. In response, the Government directed officials to report on options to reduce duplication and streamline the approval processes for medicines under the Medicines Act and the HSNO Act. The Government's response included consideration of GMO medicines developed in New Zealand as well as GMO medicines imported into New Zealand.

The Discussion Paper excluded examination of pharmaco foods. The current lack of a clear and agreed definition of these products means it is not possible to include these products in any regulatory change.

Questions in the Discussion Paper included:

- whether GMO medicines should be subject to a streamlined approval process
- which agency or agencies should be involved in the assessment of GMO medicines, and which should be the lead agency
- whether conducting a limited environmental assessment is appropriate in assessing GMO medicines
- what an appropriate level of participation is in the assessment of GMO medicines
- whether human GMO medicines which have veterinary applications should be restricted to human use only.

This chapter attracted responses from a small number of organisations and very few individuals. The organisations represented were chiefly from the science/research and agribusiness/forestry sectors, along with a smaller number of universities, environmental organisations, ethics/ religious groups, a medicines/veterinary medicines supplier, Māori, and local authorities.

B5.2 Assessment and approval of GMO medicines

The Discussion Paper outlined a number of issues related to the assessment and approval of medicines that are or contain GMOs. These were that:

- medicines require assessment by Medsafe (for human medicines) or the Agricultural Compounds and Veterinary Medicines (ACVM) Group (for veterinary medicines), and then approval by the Minister of Health under the Medicines Act or ACVM Act, before they can be legally distributed in New Zealand
- the HSNO Act requires that ERMA assess live GMOs in medicines for risks to people, communities and the environment, and approve the use of these GMOs in New Zealand. ERMA must call for public submissions, and conduct a public hearing if required
- 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 Discussion Paper proposed that human and veterinary medicines that are or contain GMOs should be subject to a streamlined approval process.

B5.2.1 Approval process for human medicines

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

Most submissions from organisations responding supported human GMO medicines being subjected to a streamlined assessment process. These submissions came from all the research organisations, agribusiness/forestry organisations and the single medicines/veterinary medicines supplier who responded. Submissions from these organisations noted confidence in the approach followed under the Medicines Act and/or in the testing of medicines prior to approval being sought for distribution as reasons for their support. A small number of submissions from universities and ethics/religious organisations opposed a streamlined approval process. All these submissions raised concerns about the risk of environmental or public health issues arising from inadequate assessment and most sought maintenance or strengthening of the role of ERMA in assessing GMO medicines.

All the individual submissions addressing this issue opposed a streamlined approval process on the grounds of public safety and/or a need for public input.

B5.2.2 Approval process for veterinary medicines

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?

Most submissions from organisations responding supported the proposal. These submissions came from science/research organisations, agribusiness/forestry organisations, some universities, and ethics/religious groups. These submissions noted a range of reasons, including costs and competitiveness and confidence in testing and assessment processes. All the submissions from organisations opposing a streamlined assessment process for veterinary medicine, noted public and environmental safety concerns. These submissions came from some agribusiness/forestry organisations and some universities, as well as environmental organisations and local authorities.

All submissions from individuals responding opposed the proposal for a streamlined approval process for veterinary medicines on the grounds of public safety and/or a need for public input.

B5.3 Which agency should undertake a streamlined approval process, and how?

Four options were identified for reducing duplication and streamlining approval of human medicines and four similar options for approval of veterinary medicines.

B5.3.1 Agencies approving human medicines

For human medicines, the four options outlined for consideration were:

- **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
- **Option 4:** approval under the HSNO Act, with safety, quality and efficacy assessment of the medicine provided by Medsafe.

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?

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?

Most submitters responding on this issue supported either retaining approval under both the HSNO and Medicines Acts (with roles clarified) or approval under the Medicines Act with environmental risk assessment by ERMA. Submissions from agribusiness/forestry organisations and local authorities were more likely to support retaining approval under both the HSNO and Medicines Acts while submissions from research organisations and universities were more likely to support approval under the Medicines Act with an environmental risk assessment by ERMA.

A small number of submissions from agribusiness/forestry organisations and universities supported approval under the Medicines Act only, while a very small number of submissions from local authorities and research organisations supported approval by ERMA with an environmental assessment under the Medicines Act.

Most submissions from organisations responding supported Medsafe being the lead agency for approval of human GMO medicines. These submissions came from all agribusiness/forestry organisations, universities and medicines/veterinary medicines suppliers responding, along with most research organisations. These submissions suggested that Medsafe had the necessary experience in considering the safety of medicines and/or that environmental assessment was a relatively minor role in approving medicines.

Most submissions from the very small number of individuals responding sought the option under which Medsafe and ERMA worked together to assess all the health and environmental risks of human GMO medicines, rather than having one lead agency. One individual submission suggested that ERMA in its present form should have no role in assessing medicines.

B5.3.2 Agencies approving veterinary medicines

For veterinary medicines, the four options outlined were:

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

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?

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?

Most submissions from organisations responding were divided between approval under the ACVM Act only and approval under the ACVM Act with environmental risk assessment by ERMA. Submissions from agribusiness/forestry organisations and medicines/veterinary medicines suppliers tended to support approval under the ACVM Act only, while submissions from universities and research organisations tended to support approval under the ACVM Act with an environmental risk assessment by ERMA.

Submissions from organisations supporting approval under the ACVM Act only suggested that the ACVM Group had more appropriate structures and experience for the task than ERMA. Submissions from organisations supporting approval under the ACVM Act with ERMA approval noted that most of these compounds would come under the HSNO definition of new organisms.

All submissions from organisations responding stated that the ACVM Group should be the lead agency in the approval of veterinary medicines.

Two submissions from individuals supported processes under which ERMA and the ACVM Group worked together, rather than there being a single lead agency.

B5.4 Is conducting a limited environmental assessment appropriate?

The Discussion Paper proposed conducting a risk assessment, which did not consider some of the areas covered by the HSNO Act, as one option to streamline the approvals of human and veterinary medicines.

B5.4.1 Assessment of human medicines

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?

Most submissions from organisations responding considered that an environmental risk assessment that did not include some areas covered in the HSNO Act would be an appropriate way of streamlining the approval process for these medicines. These submissions came from most agribusiness/forestry organisations, ethics/religious organisations and universities responding. Some submissions supporting this proposal stated that the degree of assessment should reflect potential risks and benefits, while others suggested that vaccines and medicines will not contain organisms capable of forming sustainable populations 'in the wild'.

The small numbers of submissions from organisations opposing the proposal were mostly from research organisations. Submissions from these organisations suggested that medical products are an issue of personal choice, so processes other than environmental assessment would be appropriate in approving medicines for use.

Both submissions from individuals responding opposed this proposal, seeking instead a widening of the environmental risk assessment to cover cultural and ethical considerations.

B5.4.2 Assessment of veterinary medicines

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?

Most submissions from organisations supported the proposal, including most universities and research organisations who responded. One submission from a research organisation considered that some factors considered by the HSNO Act are irrelevant to veterinary medicine and that environmental risks are in any case assessed with most applications to the ACVM Group. One submission from an environmental group opposed the proposal on the grounds that the HSNO risk assessment should be widened to cover animal welfare.

One submission from an individual suggested that cultural and economic factors should be considered as well as environmental factors.

B5.5 Appropriate level of public participation

The appropriate level of public participation and consultation in the process for approving human and veterinary medicines was also looked at.

B5.5.1 Participation in approvals of human medicines

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

Most of the submissions from organisations responding suggested that some level of public participation in the approval process for human new organism medicines was appropriate when a significant environmental impact is expected from the introduction of the GMO medicine concerned. Submissions supporting this view came from all of the agribusiness/forestry organisations and most of the research organisations responding.

Submissions from a small number of other organisations suggested that public participation should be invited more routinely than this. These submissions came from some research organisations and from all universities, environmental groups and religious/ethics groups. Submissions from some research and ethical groups suggested further education or a review after three years in the light of compliance costs and public engagement.

One submission from an individual also suggested that public participation in the approval of human GMO medicines should become more routine, and that more emphasis should be placed on informed consent to exposure to GMO medicines.

B5.5.2 Participation in approvals of veterinary medicines

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

A small number of submissions from organisations were divided between favouring more routine public involvement, favouring public involvement when there are likely to be significant environmental effects, and favouring reliance on a regulatory authority representing the public interest. Submissions favouring more routine public involvement came mostly from universities and ethics/religious groups, while those supporting involvement when significant environmental effects were likely mostly came from research organisations. A submission from a medicines industry practitioner favoured reliance on a regulatory authority. Submissions from some research and ethical organisations suggested further education or a review after three years in the light of compliance costs and public engagement.

One submission from an individual also suggested that public participation in the approval of veterinary GMO medicines should become more routine, and that more emphasis should be placed on informed consent to exposure to GMO medicines.

B5.6 Should human GMO medicines with veterinary applications be restricted to human use?

Veterinarians can and do use human medicines to treat animals. However, in practice the use of human medicines for that purpose is small. In addition, most medicines that are or contain new organisms will be designed to target only human illnesses and conditions, so 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.

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

Most submissions from organisations responding stated that human new organism medicines with veterinary applications should not be restricted to use in humans only. These submissions came from all research organisations, medicines/veterinary medicines suppliers, agribusiness/ forestry organisations and universities responding. However, most organisations giving this opinion noted a need for care in using human new organism medicines to treat animals. Issues raised included:

- the need for case-by-case decisions about using human new organism medicines in this way
- the need for further research about the use of human new organism medicines in animals
- the cultural or other issues which may arise in using human new organism medicines to treat animals.

The submission of one ethics/religious group opposed the use of human new organism medicines to treat animals. This submission noted a lack of understanding of the consequences of the movement of genetic material across species and concerns about development of resistance to medicines.

Both submissions from individuals responding stated opposition to the use of human new organism medicines in treating animals. This opposition was based on concerns about increasing the risk of human disease through animals via contact or the food chain, the current lack of knowledge about the consequences of moving genetic material across species, and the development of resistance to medicines.

B5.7 Other issues

Several other issues concerning GMO medicines and pharmaco foods were raised in submissions. These included:

- a suggestion that human and animal medicines should be subject to a single assessment process regardless of whether or not they were GMO medicines
- statements that ERMA did not have the confidence of submitters as an agency involved in assessing medicines
- concerns about interference with rongoa (plants traditionally used by Māori for medicine) and creation of GMOs from these plants without the consent of Māori
- concern that gene therapy is unsafe, unproven, misleading and will not address the cause of many illnesses suffered by Māori
- concern that oral medicine can mutate in the body then enter the environment
- concerns that assessment of medicines is not streamlined at the expense of safety
- the importance of assessing pharmaco foods as medicines rather than foods.

B6.0 Confidential information

B6.1 Introduction

The Royal Commission recommended that the HSNO Act and the ACVM Act be amended to give appropriate protection to all commercially sensitive or confidential supporting information provided with applications for approval. In response, the Government directed officials to undertake consultation with key stakeholders to determine the level of protection that is appropriate for commercially sensitive or supporting confidential information provided with applications for approval, with a view to amending the HSNO and AVCM Acts.

The Discussion Paper outlined a number of issues below which related to the process by which information is or is not released.

- The HSNO and AVCM Acts both require that suppliers of confidential information be notified when a request is received for that information under the Official Information (OI) Act. If no response is received from that person, the Act allows for the information to be released without further reference to that person.

- The OI Act presumes that information will be disclosed unless there are grounds for withholding the information.
- The Patents Act requires that inventions be novel for a patent to be granted. Release of information to a third party/competitor or inadvertent public release before a patent application is filed may prejudice the granting of patents.

There are a number of issues related to the identification and protection of confidential information including:

- the process for identifying information that should be treated as confidential
- current notification requirements, which must be met before the release of information, and proposed options to amend these
- whether special protection of confidential information under section 55 of the HSNO Act should be extended to include innovative medical or veterinary compounds that include new organisms
- the length of time for which information should be protected.

This chapter attracted responses from a moderate number of organisations and few individuals. The organisations represented were chiefly from the research and agribusiness/forestry sectors, with a smaller number of environmental groups, ethics/religious groups, Māori organisations and legal/risk management organisations.

B6.2 Identification of confidential information

The Discussion Paper sought views on the process for identifying which information should be treated as confidential. In particular, whether submitters thought:

- the definition of confidential information should include the element of reasonableness
- there should be a formal process in the HSNO and AVCM Acts for identifying what is confidential or commercially sensitive information.

B6.2.1 Inclusion of an element of reasonableness

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

Most of the submissions from organisations responding stated that the definition of confidential information should not include the element of reasonableness. These submissions came from most agribusiness/forestry organisations and most research organisations, as well as all legal/risk management organisations, all Māori organisations, all ethics/religious groups, and all environmental organisations responding. These submissions suggested that the inclusion of the element of reasonableness would not narrow the definition of confidential information in a meaningful way or would introduce subjectivity or uncertainty into decisions about what information was confidential.

Submissions supporting the proposal came from universities, a small number of agribusiness/ forestry organisations and a small number of legal/risk management organisations. Submissions from one of these organisations supporting the proposal considered it would assist open dialogue, while another supported the definition of confidential information included in the AVCM Act.

One submission from an individual stated that the definition of confidential information should not include the element of reasonableness on the grounds that 'reasonableness' has no role in creating greater secrecy about an enterprise that the submitter saw as 'fundamentally unreasonable'.

B6.2.2 Inclusion of a formal process to identify confidential information

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

Most of the submissions from organisations responding stated that there should not be a formal process for identifying what is confidential or commercially sensitive information. These submissions came from all research organisations and most of the agribusiness/forestry organisations responding, as well as most of the legal/risk management organisations responding. These submissions rejected the proposal on the grounds that additional procedures would add unnecessary bureaucracy and/or costs to a process that works adequately or would do so if the definition of confidential information were simplified.

Submissions from a small number of organisations supported a formal process for reasons of transparency and as allowing applicants a forum to specify confidential information. These submissions came from universities, legal/risk management organisations and ethics/religious organisations. One Māori organisation noted inadequate consideration of traditional use and knowledge in the identification and assessment of individual property.

One submission from an individual supported a formal process, on the grounds that it would assist in identifying genuinely confidential information and in making information available in confidence for independent assessment of proposals.

B6.3 Should the notification process be changed?

B6.3.1 Change to current notification requirements

Views were sought on current notification requirements under the HSNO and ACVM Acts, and on four proposed options for amending the notification provisions. These options were:

- **Option 1:** retain the status quo
- **Option 2:** amend the HSNO and AVCM Acts by deleting the notification requirements completely (therefore relying solely on the Official Information Act)
- **Option 3:** amend the HSNO and AVCM Acts to clarify what is required by notification (e.g. example to ensure that direct contact is made with either the person who supplied the information or their organisation, or at least that an attempt is made)

- **Option 4:** amend the HSNO and AVCM Acts so that the reference is to the action, which may be taken under the Official Information Act (to decide whether or not non-disclosure is outweighed by the public interest) rather than to the action of release.

6c Which option do you prefer, and why?

Most submissions favoured the third option (i.e. amend the HSNO and AVCM Acts to clarify what is required by notification). These submissions came from most research and agribusiness/forestry organisations, as well as all ethics/religious and legal/risk management organisations responding. Concern to ensure that the principles of natural justice are recognised in the notification process and that failure to respond is not taken for consent, were the most common reasons for supporting the third option.

A small number of the submissions favouring the third option also favoured the fourth option (amend the HSNO and AVCM Acts so that the reference is to the action which may be taken under the Official Information Act rather than to the action of release). These submissions came mainly from research and agribusiness/forestry organisations.

One environmental group supported maintenance of the status quo regarding notification processes, and one legal/risk management organisation considered that none of the options offered were desirable on the grounds that public interest was a nebulous and problematic concept.

One submission from an individual favoured options which prioritised public rights to information and promoted transparency in decision-making, without specifying which (if any) of the options given best met these criteria.

B6.3.2 Experiences with the notification process

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.

Two submissions from organisations described experiences of Official Information Act requests being received for information the organisation had supplied. One research organisation expressed concern that they were not formally notified when the request was made. This submission noted that location information released, without notification, was subsequently used in an attack by 'activists'.

An agribusiness/forestry organisation had opposed release of location information when notified, on the grounds that ERMA considered confidentiality of this information a means of protection against spread of genetic material by theft or sabotage. This submission noted that the location information concerned was subsequently released, and that there is an unresolved issue of liability for costs of any restoration following dispersal of genetic material once the location was made public.

B6.4 Should special protection be extended?

The Discussion Paper outlined issues surrounding the special protection against release provided in accordance with the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). In particular, TRIPs requires signatory governments to:

- protect against unfair commercial use undisclosed data which the signatory governments may require as part of approving the marketing of pharmaceutical or agricultural chemical products and which involves a considerable effort to compile
- protect such data against disclosure, except where:
  - disclosure is necessary to protect the public
  - steps are taken to ensure that the data are protected against unfair commercial use.

In recognition of these objectives, the HSNO Act offers protection for confidential supporting information provided with applications for hazardous substances, which are also the subject of innovative agricultural compound, or innovative medicine applications under the ACVM Act or the Medicines Act respectively. However, the Royal Commission heard concerns that the extent of that protection may be more limited than under the previous regulatory regime.

B6.4.1 Extension of special protection for specified applications

Comment was sought on a proposal to extend special protection to confidential information supplied with all applications concerning hazardous substances and new organisms that are the subject of innovative agricultural compound or medicine applications.

6e Do you have any comments on this proposal?

Submissions from organisations responding were divided on the proposal to extend the special protection provided to confidential supporting information by the HSNO Act. Submissions from research organisations, universities, and legal/risk management organisations tended to support the proposal, while submissions from agribusiness/forestry organisations, ethics/ religious groups and Māori organisations tended to oppose it.

Where a reason was given, submissions supporting the proposal did so on the grounds that:

- it was important to ensure consistency between the HSNO Act and other legislation such as the ACVM Act
- there was no risk to the public from the research concerned so information could be protected to maintain novelty for patents.

Submissions opposing the proposal did not offer reasons for this position. One ethics/religious group opposing the proposal suggested a reversal of the proposed amendment, aimed at ensuring that public rights to information under the Official Information Act had priority over protection of information under the HSNO Act.

One legal/risk management organisation suggested that it was unclear whether information protection related to the new chemical biological entity or the mixture of which it is a part (e.g. if an organism required approval as a new organism and as part of a hazardous substance).

One submission from an individual opposed the extension of special protection, suggesting that the HSNO Act provisions for special protection of information related to hazardous substances should not restrict public access to information.

B6.4.2 Extension of special protection to other applications

Additional comment was also sought on whether the protection offered by TRIPs should be extended to information related to applications for other hazardous substances or new organisms.

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?

Most submissions considered that the TRIPs-based protection in the HSNO Act should be specifically extended to new organisms and hazardous substances that are not the subject of an innovative agricultural compound or medicine application, rather than relying on Official Information Act protection. These submissions came overwhelmingly from agribusiness/ forestry organisations and research organisations, along with a smaller number of universities and legal/risk management organisations.

Submissions supporting the proposal pointed to the need to treat applications consistently regardless of the subject of the application or to the need for legislation to adapt to advances in technology.

One submission from an agribusiness/forestry organisation supported extension of this protection to hazardous substances that are not the subject of an innovative agricultural compound, without mentioning new organisms.

One environmental organisation noted that other international instruments in addition to TRIPs apply to New Zealand and have relevance to the issue of confidential information. Additional instruments noted were:

- the 'Biosecurity Convention' which specifies information which shall not be considered confidential – this information includes the name and address of the notifier, a general description of the organism/s concerned, a summarised risk assessment, which includes impacts on conservation, biodiversity and human health, and emergency response plans
- the 'Convention on Biological Diversity' which requires environmental impact assessment, allowing for public participation where appropriate.

B6.4.3 Extension of protection to other legislation

Extension of special protection raises the question of whether special protection should be made specific to the HSNO Act or made 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, while Article 39.3 of the TRIPs agreement refers to a 'new chemical entity'. 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? Please illustrate your comments with examples and refer to the relevant provisions of the HSNO Act where necessary.

Most submissions stated that the special protection should be specific to the HSNO Act. These submissions came from all research organisations, most agribusiness/forestry organisations, all universities and all legal/risk management organisations responding. Where reasons were given, submissions from these organisations sought this protection so that equal protection was given for all applications processed under the HSNO Act.

One agribusiness/forestry organisation disagreed with the proposal, stating that TRIPs-based protection must be extended across all three Acts (HSNO, Medicines and ACVM) where the nature of the information warrants it.

Submissions from two organisations suggested that other legislative modifications would be necessary before the extended special protection was provided in the HSNO Act. One submission from a university suggested that confidentiality should only apply to specific supporting information directly related to technical details. One submission from a legal/risk management organisation suggested that the working of the HSNO Act should be clarified to ensure that protection is provided for all confidential information whenever the application relates to a new chemical or biological compound.

B6.4.4 Range of applications for which special protection should be available

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.

Of the small number of submissions from organisations responding, most indicated that the protection should be available for any application that contains commercially sensitive or confidential information. These submissions comprised most agribusiness/forestry organisations and all research organisations responding.

The remainder of submissions from organisations responding specified applications for development in containment and/or applications for conditional release of new organisms as meriting such protection. These submissions came from universities, legal/risk management organisations and one agribusiness/forestry organisation.

B6.4.5 Extension of the prohibition on cross-referencing data

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.**

Of the very small number of submissions from organisations responding, most supported the extension of the prohibition on cross-referencing to other applications. These submissions came from research organisations, medicines industry practitioners and legal/risk management organisations. The submissions giving a reason for supporting this proposal stated that it was reasonable to exclude competitors from being able to cross-reference existing information when making their own applications.

One ethics/religious group and one individual each opposed extension of the prohibition on cross-referencing. In both cases, this opposition was on the grounds that free access to information and the ability to cross-reference is vital for proper medical and scientific oversight by regulators and by the community.

B6.5 Length of time information is protected for

The HSNO Act refers to both the ACVM and the Medicines Acts. 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?**

Submissions from organisations responding were evenly divided between those stating that the length of the period for which information is protected under the Medicines Act and ACVM Act (currently five years) should be changed, and those stating that it should not. Agribusiness/ forestry organisations and research organisations tended to consider that the time period should be changed, while ethics/religious organisations and legal/risk management organisations tended to think that it should not.

Organisations supporting the change suggested that an extension to the protection period was needed to reflect the protection offered internationally and/or the length of time required to realise an investment of a GMO development. One agribusiness/forestry organisation opposing the change considered that the current protection was sufficient, while a research organisation opposed any clause involving a period after which protection lapsed on the grounds that some trade secrets need to be kept in perpetuity.

Rather than responding directly with agreement or disagreement, some submissions made other comments on the proposal that the period of protection be changed. These submissions came from agribusiness/forestry organisations, legal/risk management organisations and a medicines/ veterinary medicines supplier. Among these submissions, some noted that there was currently no reason to change the period of protection or that consultation should be conducted to determine whether periods of protection are sufficient. Another noted that there was a higher risk of disclosure of confidential information in New Zealand than in other jurisdictions and suggested that amendments would need to provide for protection from cross-referencing and for protection for innovative use of existing products as well as for protection of information.

B6.5 Other issues

A range of other issues and suggestions related to the definition and management of confidential information were raised in submissions.

- Applications are normally made to ERMA at the pre-patent stage, when applications are the subject of ongoing research and of particular commercial interest to competitors. The level of protection offered to information included to support applications should consider this status of the organism/substance concerned.
- Information can be provided to the public without compromising full technical information about the nature of the application (e.g. members of the public wishing to make a submission on an application need summary information (e.g. scientific abstracts) rather than full technical information). Protocols for public access to confidential information could be developed.
- Two types of information appear to be at risk under current HSNO rules:
  - commercially sensitive information about research being conducted
  - information about staff and locations involved in approved development projects or trials.
- That the official information regime for local government needed to be considered, given the obligation of local government organisations to provide information about prior use of land.
- The importance of public access to information as a safeguard on the operation of legislation and as a necessary tool for scientists to work independently to contribute views which can help make decisions.
- The proposal to protect commercially sensitive or confidential information is open to abuse, makes proper review or assessment impossible, and relies on trust in ERMA which the submitter does not consider has been earned.
- That the public are unable to make full decisions with only part of the information.
- That the public right to information should come before private interests in managing and releasing confidential information.

The suggestions made were that:

- the Ministry for the Environment engage with the Office of the Ombudsman as part of the review of issues related to confidential information
- conditional release could be undertaken with limited public release of information and full release of information would be required before unconditional release of the product
- applicants should have the option to withdraw an application, cease all related activities and therefore withhold all information on the grounds that no application means no risk and therefore no justification for releasing information – this option should be available to organisations at any time as a means of vetoing the release of any information requested
- protection of information available under the ACVM Act achieves an appropriate balance between protection as an incentive for innovators and as a disincentive for competitors to enter the market
- applicants should be allowed to define which information is commercially sensitive and/or confidential.

B7.0 Grounds for Ministerial call-in

B7.1 Introduction

Chapter 7 covered a proposal to extend the powers of the Minster for the Environment to 'call in' and decide on applications on the grounds that she considers will have significant cultural, spiritual or ethical effects.

This chapter attracted responses from a moderate number of organisations and a small number of individuals. In addition, a large number of submissions from individuals included general comments about Ministerial 'call-in' and about the treatment of ethical, cultural and spiritual issues. These submissions were mainly standardised from submissions that did not specifically address support for the proposal outlined in the Discussion Paper. Organisations represented included research, agricultural/horticultural, Māori, legal, environmental and ethical/religious organisations.

B7.2 Support for extended Ministerial call-in powers

Under section 68 of the HSNO Act, the Minister for the Environment may call-in and decide on 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.

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.

Extending the grounds for call-in as recommended by the Royal Commission 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. However, the HSNO Act would require amendment to permit the Minister to call-in an application on additional grounds.

The Discussion Paper proposed an amendment to section 68 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.

Most of the submissions from organisations responding supported the proposal. These submissions came from research organisations, legal/risk management organisations, Māori organisations, local bodies and some of the agribusiness/forestry organisations. Reasons for supporting the proposal included a view that the term 'significant' sets a high threshold for the use of call-in powers and that consideration under the HSNO Act of cultural, ethical and spiritual issues is appropriate.

The support for the proposal stated in a number of submissions was conditional, however, with submissions emphasising the need to:

- retain and define the term 'significant' (Māori organisation, agribusiness/forestry organisation)
- ensure transparent decision-making (agribusiness/forestry organisation)
- consider Ministerial call-in as a backstop to ERMA's consideration of a full range of factors including cultural, ethical and spiritual matters (environmental organisation)
- involve the Bioethics Council and Māori Advisory Groups in decisions on applications (environmental organisation, local body)
- clarify the definition of cultural groups to relate to groups recognised in existing legislation (Māori organisation)
- consider all cultural systems, rather than only Māori (local body)
- manage the system carefully to avoid frivolous objections (legal/risk management organisation)
- avoid relying on the call-in process (agribusiness/forestry organisation, legal/risk management organisation).

The majority of submissions from individuals included a statement supporting the inclusion of 'cultural, ethical and spiritual issues' as a part of the criteria for assessing all applications and not just part of the Ministerial 'call-in' powers.

A small number of submissions from agribusiness/forestry organisations and universities opposed the proposal. Reasons for opposing the proposal were that:

- ethical, cultural and spiritual issues were poorly defined
- the term 'issues' has more scope than the term 'effects' to give effect to the recommendation of the Royal Commission
- the Māori Advisory Group and a biotechnology strategy advisory group have a clear role in the management of applications
- extending Ministerial call-in powers risked subjective, politicised and emotional decision-making
- there appeared to be no good reason for departing from dictionary definitions of cultural, ethical and spiritual
- spiritual considerations should not be grounds for Ministerial call-in, as they are neither rational or tangible in terms of cost-benefit assessment
- ethical issues could be dealt with by the Bioethics Council without requiring an extension of Ministerial call-in powers
- a judicial decision has been made that there is no right of appeal granted on the substance of a decision because the technical and specialist expertise to make decisions under the HSNO Act was beyond the scope of the traditional judiciary
- changing grounds for Ministerial call-in to include a vague or undefined category such as spiritual, cultural or ethical effects establishes the possibility for a *'carte blanche'* veto power on any specific application by the Minister, even when the application has received ERMA approval.

Rather than directly expressing agreement or disagreement with the proposal, submissions from a very small number of organisations commented on the proposal. Comments included that:

- economic activity and the construction of health as a social good are as much 'cultural' as ethical and spiritual issues
- different sets of expertise may be needed to assess cultural, spiritual and ethical dimensions of applications
- assigning ethical, spiritual and cultural issues a level of significance in a legal sense is difficult
- the Minister will need to consider that the application may have a particular effect, rather than that it will have the effect
- there should be more robust analysis of applications by ERMA in areas in which Ministerial call-in powers are established
- cultural, ethical and spiritual issues need to be considered as part of all applications, not just as part of Ministerial call-in powers
- Ministers should not need to be involved in a judicial or quasi-judicial function like call-in if ERMA has 'a balanced mix of expertise and knowledge of all matters likely to come before the Authority' (section 16 of the HSNO Act).

Rather than directly expressing agreement or disagreement with the proposal, submissions from a very small number of individuals commented on the proposal. Comments included that:

- the submitter supported Ministerial call-in powers to consider spiritual, cultural and ethical issues, rather than effects
- cultural, ethical and spiritual grounds should be considered separately as part of Ministerial call-in, rather than defining cultural grounds as including ethical and spiritual grounds.

B7.3 Other issues

A number of other issues listed below were raised in response to the discussion of Ministerial call-in powers.

- The importance of including cultural, ethical and spiritual issues as part of the normal criteria for considering all applications, not just for Ministerial call-in.
- The importance of the HSNO Act and the regulatory process dealing with ethical and cultural issues in a meaningful way. It was noted that this may involve a regulatory role for the Bioethics Council, including a power of veto.
- The need for the Bioethics Council to protect community values and to have real influence. Concern was expressed that the formation of the Council was too slow, that there should be public consultation on membership of the Council, and that field trials were already being approved without consultation with the Council.
- Ministerial call-in powers should be extended to 'cultural, ethical, social or spiritual implications' and 'significant effects in an area in which the Authority lacks sufficient knowledge or experience'. In addition, that these matters should be specifically included as issues to be considered in determining all applications.
- The Minister for Conservation should be included in consultation and decision-making as hazardous substances have downstream effects.
- Cultural and spiritual concerns tend to take a longer-term view than economic ones, and the long-term view is needed for GM applications where the impact is irreversible.
- The Bioethics Council should not be concerned with race or religion but should be concerned with preserving the environment.
- IBSCs should have a public representative due to the ethical issues they deal with.

B8.0 Liability issues

B8.1 Introduction

Chapter 8 on liability issues sought responses on whether the existing liability regime is robust enough to cover GMOs and their effects or whether there are liability issues that are unique to GMOs that require additional measures and if so, what those measures might be. Unlike other sections in the document, the Government is not proposing any changes in relation to liability of GMOs. This chapter simply set out the issues and options to be considered and invited comments on these. The challenge for the regulatory system for GMOs is that it needs to be strong enough to support the Government's basic policy direction of proceeding with caution while preserving opportunities in this area. In practical terms this means that a regulatory regime will be developed that encourages an appropriately cautious approach to genetic modification but will not be prohibitively costly and stop development.

The Royal Commission considered liability issues and took the view that the current liability regime is adequate and recommended to the Government that there was no need to change liability rules. However, they did suggest that the Government might like to refer the difficult questions that GMOs raise to the Law Commission for more intensive study. The Government followed up on this suggestion. The Law Commission produced a report in which they identified several reasons why existing liability rules may not operate effectively in the context of the harm that might be caused by GMOs. They noted that existing liability rules do not ensure that all of the harm that could potentially be caused by GMOs will be compensated. They said it was unlikely that any liability regime could guarantee this.

The Discussion Paper suggested consideration of the following points concerning liability issues.

- The relevance of tort law, which sets out rules about when someone is liable to another for harm they have caused. This body of law has two main purposes: to encourage safe behaviour which is encouraged through creating liability for the consequences of harm that can be foreseen; and in determining appropriate compensation. Tort law sits behind any regulatory regime.
- Any compensation-related liability rules and mechanisms should not increase costs and risks to prohibitive levels cutting across the basic goal of preserving opportunities.
- A fundamental premise of our legal system is that 'like' should be treated with 'like'.
- 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.
- A key question is 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.
- There are three main kinds of damage that might be caused by a GMO: personal injury; property and/or environmental damage; and financial or economic loss. The Discussion Paper illustrated how similar damage could be caused by non-GMO factors.

	Example One	Example Two	Example Three
Damage type	Personal injury	Property or environmental damage	Financial or economic loss
Harm caused by GMO	Potential allergic reaction	Invasiveness in the environment	Loss of organic certification by contamination by GM crops
Non-GMO equivalent	Unknown peanut traces	Shipments of conventional crops can be infested with weeds	Organic certification could be at risk from pesticide spray drift from a neighbouring farm

- GMOs already undergo safety assessments (ERMA and by other bodies as well if a food GMO is involved). Products produced by other breeding techniques (e.g. selective breeding, cell fusions or mutagenesis) are not subject to these safety assessments.

This chapter attracted a great deal of response from individuals, science/research community, universities, organics producers, environmental groups, agribusiness/ forestry sector, religious/ ethics groups, and Māori groups.

B8.2 Adequacy of existing liability regime

Are there liability issues unique to GMOs?

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?

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?

B8.2.1 Are there liability issues unique to GMOs and their effects?

Views were split on whether the effects of GMOs are significantly different from other organisms. Submissions from individuals, environmental groups, organics producers, Māori groups, and religious/ethics groups thought that GMOs and their effects were significantly different. Those from the agribusiness/forestry sector, the science/research community and universities and legal views did not consider there to be a difference.

GMOs are significantly different	GMOs are not significant different
• Traditional remedies (e.g. injunction and/or payment of money) will be inadequate protection against the potential harm that accompanies the introduction of GMOs. • GMOs introduce into the biosphere living transformative organisms. • New Zealand's principal agricultural market sees them as radically different. • Safety must include more than local impacts or physical health but also safety relating to effects over time, changes in scale, cultural and community values, mental health, tourism, export marketing and sustainable development. • Uncertainty due to imprecision in combining genes and unpredictability of how the introduced gene will react in the environment. • An area currently lacking in the current definition of liability is potential psychological distress or harm that could occur due to cultural or spiritual insensitivity especially with respect to Treaty of Waitangi obligations. • Irreversibility of contamination. • Zero tolerance in organic production standards means that organic farmers can potentially lose certified status. • Generic pollution is passed to new generations indefinitely unlike other chemical developments.	• Other technologies and industries present similar risks to genetic modification. Both trade and tourism have the potential to bring in know pests to New Zealand (e.g. painted apple moth, varroa bee mite). • Any liability regime should treat activities that pose a similar risk in a like manner – it would be inequitable and unjust to subject GMOs to a more stringent liability because the technology used to create the organism was different to conventional techniques and technology. • There could be an unfair bias for investment in a particular technology irrespective of the risk or safety of that technology and unfair prejudice against GM technology. • Have recently collaborated in a major review of ecological risk which illustrates that there is an increasing body of knowledge from industrial and developing countries that current GM crops can offer safe and effective technology.

B8.2.2 Weight to be given to compliance with release conditions when considering adequacy of existing legislation

Views were split down similar lines as above with scientists, research organisations, the agribusiness/forestry sector and legal bodies believing that significant weight should be given to compliance. The main reasons given were:

- that ERMA processes for risk assessment and establishing controls would mitigate risks substantially and reduce the likelihood of any harm
- existing regulatory compliance is much stronger that that for most other products and additional liability laws are unlikely to add to the precautionary measures that would be taken by applicants for product release
- one submission commented that the rigorous review of development and importation means that GMOs are likely to be safer than most other technologies or new organisms.

Those who thought little or no weight should be given to compliance included individuals, organics producers and environmental groups. Reasons for this view included:

- lack of public confidence that the conditions applied by ERMA are achievable given evidence that proposed controls have failed elsewhere
- delays and cost associated with current liability laws will be a significant impediment to those affected being able to obtain compensation, especially if they have been the victims of an event that has taken away their source of income

- compliance with ERMA controls should not be a defence unless ERMA is also held liable in cases of it being negligent
- controls are not an acknowledgement of safety, only a means to reduce risk of harm.

B8.2.3 Will current liability rules be effective in encouraging precaution?

Views were split three ways on the effectiveness of current liability rules in encouraging precaution in relation to the harm that might be caused by GMOs. The major split was between those who wanted changes to be made to the liability regime and those who felt it was adequate. A very small number of respondents from the science/research community maintained a third view, which was that liability rules do not have much effect on the encouragement of precautionary behaviour at all but rather act as a very strong disincentive for investment in New Zealand.

Those who viewed current liability rules as being effective included organisations from the science/ research community, universities, legal sector, and the agribusiness/forestry sector. Those that did not think current rules are effective included private individuals, environmental groups, local authorities, organics producers, religious/ethics groups and Māori. Comments made in relation to each of these viewpoints were as follows.

Current liability rules are effective in encouraging precaution
• GMOs are technically no different from any other new organism or potentially hazardous substance. They may be safer than others due to existing levels of regulation. • Adequate penalties already exist for negligence. • The existing system should prove adaptable to new situations, is broad in coverage, precautionary in outlook and capable of addressing the concerns of innocent parties. • While recognising that there are issues in terms of existing liability rules (including the potential to harm a large number of people, identifying the person causing the harm, quantification of losses, and complexity of litigation) common law principles have shown an ability to keep pace with technological advancement and to develop new remedies for novel situations. There is a constant weighing up of conflicting interest of public vs private good. For each case involving GMO there will therefore be differences. No single formula will provide a better substitute than the current mix. • The adequacy of current rules combines with the weight of maintaining scientific/professional credibility in addition to commercial consequences other than those associated with liability.
Current liability rules are not effective in encouraging precaution
• Under current law a defendant could claim that the harm caused was not foreseen. • Absolute liability for damage caused (regardless of steps taken) is the only way to encourage precaution. • New Zealand has a poor record of holding those responsible for the release of unwanted organisms to account. • As in other areas of environmental pollution the 'polluter pays' principle should apply.

B8.2.4 Will current liability rules be effective in providing compensation?

A similar spread of opinion by sector occurred in relation to views on the effectiveness of current legislation in regards to providing compensation in relation to the harm caused by GMOs.

Current liability laws will not be effective in providing compensation
• It is generally acknowledged that any compensation system will be unable to provide full compensation. • While existing rules may not be effective in providing compensation it is not unique to the GMO industry. Similar complications exist in relation to getting compensation for other industries (e.g. tobacco companies and toxic chemicals). Compensation will still be available in as effective a manner as for these industries. • There is also a need to consider the harm that might be caused to GMOs as well as by them. • Damage to the environment is recoverable under the Resource Management Act and orders to reimburse for actual and reasonable expense in avoiding remedying or mitigating adverse effects on the environment.
Current liability laws will be effective in providing compensation
• The HSNO Act places heavy reliance on controls and penalties for breaching controls. The problem with this approach is that the regulator must accurately foresee all the circumstances in which something could go wrong and be able to prescribe for these in advance. Financial fitness must be made a condition for securing ERMA consent for either experimentation or release of GMOs. • It is not reasonable that the public are left to pay for errors in commercial enterprise through negligence by ERMA or through ACC coverage. • The Law Commission identified two situations where injured parties would be left without a remedy and uncompensated loss would be suffered. These are: where there is catastrophic damage of a type or magnitude that the responsible party, its insurance company or even a compensation fund are unable to cover; and irreversible damage such as loss of biodiversity. For tort action there needs to be an identifiable defendant(s), quantifiable damage and a causal connection between the defendant and damage. Where damage is widespread and diffuse and the possible sources and contribution to damage uncertain, finding a remedy is no longer a matter for disputation between citizens. Some aspects of damage by genetic modification such as plants developing resistance to herbicides and damage to beneficial insects may raise this problem.

B8.3 Achieving an appropriate level of precaution

The HSNO Act already provides a range of regulatory mechanisms that 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. Some of the other proposed mechanisms may also help ensure precaution. For example, with conditional release 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.

The Discussion Paper presented some options for those who do not consider that existing liability rules together with the broader regulatory regime is adequate to encourage appropriate precaution in relation to GMOs. These options included extending liability rules or introducing additional regulatory mechanisms. It explained that in some contexts liability rules are effective to encourage an appropriate degree of precaution. In other contexts, regulatory mechanisms are more effective.

B8.3.1 Extending the liability rules

The negligence regime could be altered in the following ways.

- 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 for harm caused by non-compliance with specified requirements in the HSNO 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. Alternatively ERMA could have the 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.

B8.3.2 Additional regulatory mechanisms

The Discussion Paper provided examples of regulatory mechanisms including:

- further approval requirements
- licensing and inspection regimes with criminal sanctions for breach
- statutory powers to require compliance.

It then outlined situations where regulatory mechanisms have advantages over liability rules in encouraging an appropriate degree of precaution:

- 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.

Negative impacts from extending liability rules or regulatory mechanisms were also described and include:

- disincentives for investment in GM and GM-based innovation especially for technologies at the 'cutting-edge' end of the spectrum, as there is less information on risks and ways to manage these risks
- increased economic costs 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)
- disadvantaging investors in GM technology compared to those investing in equally risky non-GM technology, leading to inefficient 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?**

B8.3.3 Are the factors limiting the effectiveness of liability regimes significant in relation to GMOs?

As well as the overall split between those that thought that there are significant factors affecting the effectiveness of liability regimes, some submitters did not appear to have much confidence in liability regimes in general.

Some organisations from the agribusiness/forestry sector, environmental groups and local authorities that responded thought there were significant factors. Key themes from this group were:

- implementing liability rules will be expensive compared with the likely amount of claims
- regulators are better places to monitor relevant forms of precaution than insurers
- imposing full cost of any risk or harm on the person or activity would be inconsistent with the broader public interest in permitting the activity or investment
- while the factors are significant this highlights the importance of the regulatory framework to provide adequate precaution
- tort law will be insufficient to deliver recompense
- the HSNO Act currently makes no provision to ensure that an applicant is financially fit to a shoulder a damages claim should it be liable.

Those that thought that these factors were not significant included a legal organisation and the science/research community. These organisations tended to think that GMOs were not considered to be significantly different from other hazardous substances and organisms.

B8.3.4 Best means of achieving an appropriate level of precaution

Submissions from environmental groups, organics producers, Māori, and a religious/ethics group favoured extending the liability rules or a combination of extending liability rules and new regulatory mechanisms. Science/research community, university and agribusiness/forestry organisations supported the current mix of regulation under the HSNO regime and the existing liability rules.

B8.3.5 Costs and benefits of extending liability rules

Benefits of extending	Costs of extending
• 'Absolute' or 'full and unlimited' liability for damage caused (regardless of steps taken to avoid damage) is the only way to encourage precaution. • Under current law, defendant could claim that the harm caused was not 'foreseen'. • New Zealand has a poor record of holding those responsible for unwanted organisms to account for release of unwanted organisms. • There may be a distinction between liability relating to legitimate contained use of GMOs (where controls are reasonably achievable) and attempts to conditionally or fully release. • Support the Law Commission's finding that existing liability rules will not provide compensation for GMO contamination in all situations. Socialisation of compensation moves costs away from those that cause the liability and may be a disincentive for precaution.	• Liability rules will be expensive to implement compared with the likely amount to be claimed. • Regulators are better placed to monitor relevant forms of precaution than insurers. • Imposing full cost of any risk or harm on the person carrying out the GM activity would be inconsistent with the broader public interest in permitting the activity or investment. • Would act as a very strong disincentive for investment in New Zealand. • Existing system should prove adaptable to new situation, is broad in coverage, precautionary in approach and capable of addressing concerns of innocent third parties. • Would involve greater costs and time for researchers and applicants to the detriment of development and bias against GM technology. • Significant costs – delay, expense, initial uncertainty, inefficiency and inflexibility. • Any increases in costs through changes to the liability will only exclude small to medium enterprises from the process, force New Zealand research offshore and reduce potential benefits from the technology. • Extension of liability rules creates a blunt instrument discouraging innovation. A regulatory approach can be tailored to each case.

8.3.6 Extension, application and enforcement of extended liability rules and/or regulatory mechanisms

Some science/research community and agribusiness/forestry sectors were not in favour of any extension of liability rules. Reasons included that a strict liability regime would be inequitable where risks, if any, are unknown and would not encourage any extra precaution where risks cannot be foreseen. Risks would include reduced innovation, investment and benefit to society from the appropriate and responsible use of GM technology.

Submissions from nearly all private individuals, environmental groups, a religious/ethics group, local authorities, and Māori groups were in favour of strict or absolute liability and many were in favour of the burden of proof resting with the defendant. One local authority was in favour of compulsory insurance and bonds.

Among the submissions which addressed the concept of extended liability rules or regulatory mechanisms only applying in certain situations, most disagreed. Some of these did not believe in extending the liability rules or regulatory mechanisms at all, others thought that they should apply all the time. Other comments included:

- sanctions should only apply where conditions have not been complied with or there have been deliberate breaches of the law
- liability should apply in all cases where full containment is breached

- extended liability rules or mechanisms must be enforceable and be applied in all situations but more particularly where there is a possibility for approved release.
- the benefit of private commercial insurance being obtained by an applicant in all cases where use outside containment is contemplated is to end the false-subsidy under 'socialised risk' of speculative uses of GMOs. It introduces a reasonable moderating influence on GM commerce as a legitimate cost of business. There is no risk to scientific advancement in New Zealand as research and GM opportunities can be developed for contained use.

B8.3.7 Application of extended liability to harm caused by third parties and risks, costs and benefits of approach

Opinion was split on whether extended liability or regulatory mechanisms should apply where the harm is caused by the actions of a third party. Views did not follow the usual pattern of responding, with different industry and Māori groups taking different views.

Some submissions tackled the question of extending liability to third parties as illustrated by the following comments.

- It is appropriate the blameworthy are held responsible. It would also serve to protect GM research and commercial GMO release particularly in cases where fervent overzealous protestors attack and damage field trials and plantings.
- Transfer of liability to third parties in cases of deliberate actions by them would deter authorised interference.

B8.4 Achieving an appropriate level of compensation

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?

B8.4.1 Will existing rules result in an appropriate level of compensation?

Few respondents addressed this question directly. An agricultural organisation thought they would and commented that any compensation system would be unable to provide full compensation. Their view was that complications for GMOs are no different to those that exist in other industries. An organics organisation did not think so and suggested that additional mechanisms were needed.

B8.4.2 Appropriate level of compensation

This was responded to by agribusiness/forestry sector and scientific/research organisations. The main point made was that ideally a compensation system should fully compensate the injured. However, as acknowledged in the Law Commission report, no liability regime could fully guarantee that all harm would be compensated. Some socialisation of costs is appropriate. Full compensation would not take this into account and would potentially result in a situation that stifles research and innovation. A balance must be maintained that encourages investment in new business activities in order to obtain social and economic growth.

One submitter pointed out that biotechnology companies in New Zealand tend to be small to medium. Raising the hurdle would make GM development impossible for them and would drive developments into the hands of large multinationals thus reducing the value captured in New Zealand.

B8.4.3 Extended liability rules as a mechanism for achieving appropriate compensation and effectiveness

Agribusiness/forestry and scientific/research organisations against extending liability responded to this question. They made the following points.

- Extending liability rules will not address all the issues raised by the Law Commission.
- A better approach might be to allow the flexible common law regime some time and room to deal with any issues that arise.
- Other factors such as means of an offender to pay, availability of insurance and the ability to prove and quantify loss may influence results and extending liability rules will not alter these factors.
- The feasibility of testing for GM presence will become more difficult and complex as the technology develops (e.g. increases in the number of sequences and use of GM technology in a way that does not use foreign genes.

B8.4.4 Other compensation mechanisms and effectiveness

Insurance and bonds were favoured by an environmental group and many of the individual submissions. Legal and agricultural organisations were against compulsory insurance and bonding as an alternative means of providing compensation. Reasons given included:

- inconsistency with the preservation of opportunity
- may be a disincentive to prevent damage

- may be a damper to innovation if insurance companies are slower to understand risks than ERMA and then unreasonably refuse cover to otherwise feasible approvals
- other countries, with the exception of Germany, have agreed that existing environmental or common law provides adequate protection for compensation.

These organisations favoured a case-by-case approach by ERMA to imposing conditions requiring insurance or a bond in cases of uncertainty. This was seen to satisfy the purpose of the HSNO Act.

B8.4.5 Recoverability of costs of government action

Views on this area were strongly expressed in individual submissions. They were in favour of costs being fully recoverable from the GM company which caused harms and were against any risks been borne against third parties or society (the socialising of risk).

Responses from the agriculture and research community also favoured costs being recoverable from the persons who caused harm and that existing legislation provides for cost recovery. Cost recovery was not seen as appropriate in situations where a person has followed all controls and requirements or the harm was not foreseeable.

This is in contrast with the views of many of the individual submissions. They favoured full and strict liability with compensation payable even for unforeseen damage, without the requirement of proof and recourse to defences such as 'Act of God', deliberate acts by third parties and activities not regarded as harmful according to the state of scientific and technical knowledge at the time.

B8.4.6 Costs and benefits of extension of liability regime to achieve appropriate level of compensation

Of the few submission addressing this, the majority were from the agribusiness/forestry sector and science/research community. These organisations all focussed on the costs of extending the regime. Costs mentioned were:

- the detrimental impact on investment in research and use of new organisms in New Zealand
- the impact on New Zealand's international competitiveness
- the action setting a precedent for the next new technology in New Zealand
- the significance costs and uncertainties would be for little short-term gain
- that there is no guarantee that extended rules would be adequate to achieve appropriate compensation.

A local authority that responded mentioned increased costs as a cost and more caution and certainty concerning the release of GMOs as the benefit.

B8.5 Insurance of GMO liability

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 5–10 years?

Views on the availability of insurance were small and varied. An agribusiness/ forestry sector submitter stated that insurers currently have not specifically excluded liability for GMO-related damage and/or the industry and that existing policies are likely to cover harm. This organisation also thought there was likely to be a change in the next 12 months to specifically exclude liability for GM related damage/injury. Insurers will only provide cover if they think they can cover the loss.

A religious/ethics group distinguished between cover for insurance for contained research and released GMOs. This submission made the point that quantifiable data about risks is needed to undertake a real cost/benefit analysis and to enable the relative merits of alternatives (e.g. containment) to be considered.

Two local authorities doubted that insurance companies would be interested or willing to provide cover for unknown risks and the potential for huge payouts. One of these thought the question of insurance arose when a grower was planning full release. In such cases, assessing risk would be a matter for the grower and the insurer.

B8.6 Overview

In summary there are four basic options for addressing the liability issues raised by GMOs.

- **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?

In favour of retaining the current liability rules and regulatory regime – i.e. the status quo (Option 1): agribusiness/forestry sector; science/research organisations and legal organisation
Reasons • Support the Royal Commission view that GM technology is not so radically different to require new or special remedies. The emphasis should be on the prevention of harm through the regulatory regime. Changes can be made at a later time should experience prove this necessary. • Relying on existing legislation is the only option that would enable research and development to continue in New Zealand. • Existing regime is capable not only of dealing with, but also guarding against actual and potentially adverse effects from the use, development and release of genetically-modified organisms.
In favour of extending liability rules (Option 2): private individuals, local authorities, organics producers, union body, religious/ethics groups, environmental groups
Reasons • Strict or absolute liability is the best protection of the national interest against unreasonable commercial speculation using gene technology in the open environment. Risk assessment by insurance actuaries based on data is a preferred method to introduce commercial influences rather than assessments by ERMA which are flawed and expose the public to unacceptable risk.
In favour of extending new regulatory mechanisms (Option 3): university; organics producers, a religious/ ethics group
Reasons/comments • Existing rules are sufficient, but the modify the regulations to reduce risk. • GMOs may spread into non-GMO areas and create problems. It could be difficult to determine the source of the GMO and to estimate the harm in terms of loss of non-GM status and the time lag before harm becomes evident. Psychological, emotional or cultural harm may be difficult to assess. It may be that the authorities that approve GM have a role regarding liability as well as those that finance and carry out the research and development.
In favour of a mix of new liability rules and regulatory mechanisms (Option 4): a union organisation, organics producer, environmental group and some individuals all indicated Option 4 as a second preference
Reasons have been covered under Options 2 and 3 above.

B8.7 Other issues

A number of submissions raised specific questions about liability, the ability to insure and to be compensated.

- Will beekeepers be held liable (as a third party) for transferring pollen from GM to non-GM plants?
- Will there be an ability to compensate in unforeseen cases – for example bees working a GM crop that was considered to be too far away from hives? What happens if a beekeeper is a certified organic producer and loses organic status? Would sales of organic-certified product be compensated and under which law?
- Who will be liable for loss of exports and loss of markets for imports?
- What insurance can the ordinary citizen take to protect themselves and their family?
- The public should not have to insure for GMO-related harm.
- Who pays for suffering from GM experiments?

The majority of private individuals and environmental groups criticised the Discussion Paper and the Government's neglect of 'polluter pays' principles. Many were also in favour of a full and strict liability regime that addressed unforeseen as well foreseen risks, the burden of proof being with the defendant and there being no socialisation of risk. Comments were also made about the majority of New Zealanders being against the release of GMOs.

Two submissions favoured more debate and discussion about liability. One of these thought that the Discussion Paper revisited issues dealt with by the Law Commission report and that a better approach would have been to focus on the outstanding issues.

Law of nuisance – the obligation of GM users not to do harm to neighbours, the wider community or the environment.

A robust system or border control and biosecurity measures should be introduced to protect New Zealand's 'GE free' environment status.

B9.0 Zoo and circus animals

B9.1 Introduction

Currently 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. These 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 new organism zoo or circus animals. Proposed amendments include:

- giving ERMA the discretion to apply, on a case-by-case basis, containment controls
- 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 of zoos and circuses will need to be replaced with MAF approvals as containment facilities.

B9.2 Controls on animals in existing zoos and circuses

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 under the HSNO Act
- the HSNO 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?

B9.3 Additional 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?

B9.4 Transitional provisions

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?

Few responses were received to this chapter. Key points are as follows.

- Agreement that ERMA be given the discretion to apply containment controls on a case-by-case basis. One submitter proposed a conditional approval process and cited recent cases of animals escaping as demonstrating the need for such controls.
- Special controls were seen to be needed for containment of new organisms eligible for display in zoo or circuses that are genetically modified, needing to be transported or temporarily absent from the containment facility (e.g. for veterinary visits) or for domestic or international travel reasons. These situations either need to be provided for in the Third Schedule or to be included in the containment standard that is currently under development.
- Concern that aspects of the Third Schedule may be unworkable for zoos or circuses, particularly in relation to identification of biological waste.
- Support for the amendments by an industry member on the proviso that there be a) one standard relating to containment b) sufficient resources provided for the amendments to be developed and drafted in a co-operative manner by the crown agencies involved.
- A number of purposes for zoos importing animals are already listed. Additional purposes suggested by the industry include importing for educational purposes (i.e. in classrooms but not on display to general public) and off-display as part of co-operative conservation breeding programmes which may be covered by 'conserving genetic material'.
- A few submissions expressed dismay at their interpretation of the proposed changes as aimed at providing for the display of GMOs.

B10.0 Enforcement agency for new organisms

B10.1 Introduction

Chapter 10 of the Discussion Paper covered issues relating to the powers of agencies responsible for the enforcement of the HSNO Act and discussed options for clarifying the agency responsible for new organism enforcement in containment.

This chapter attracted submissions from a moderate number of organisations and a very small number of individuals. The organisations making submissions on this chapter comprised Māori organisations, local authorities, agribusiness/forestry organisations, research organisations, universities, ethics/religious groups, environmental groups, organics producers, and legal/risk management organisations.

B10.2 Formalisation of MAF as an enforcement agency

The Discussion Paper identified four key issues with the enforcement of the HSNO Act, as follows.

- The provisions of the HSNO Act do not differentiate between enforcement for hazardous substances and enforcement for new organisms.
- No agency is listed as having responsibility for enforcement of new organism provisions in containment, although in practice MAF has been undertaking this role.
- While the Occupational Safety and Health Division of the Department of Labour (OSH) has responsibility for ensuring that the provisions of the HSNO Act are enforced in any place of work, the containment of new organisms (at the importation, development and field-testing stages) is currently enforced by MAF. 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.
- 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 and no agency ensures that HSNO Act procedures are followed.

The Discussion Paper proposed that MAF's enforcement role for new organisms in containment under the HSNO Act should be formalised, and that MAF be given the flexibility to use HSNO provisions in circumstances that do not warrant a Biosecurity Act intervention. The Discussion Paper noted that this may require an extension of MAF's functions beyond the scope of the Biosecurity Act.

The Discussion Paper sought views on this proposal, and also any alternative mechanisms that submitters may wish to propose.

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

Nearly all of the submissions from organisations responding supported the proposal to formalise MAF as an enforcement agency for new organisms in containment. These submissions came from agribusiness/forestry organisations, research organisations, local bodies, universities, ethics/religious groups, legal/risk management organisations and most Māori organisations responding.

This support was based largely on the view that MAF have the resources and expertise to do the job, although some organisations mentioned the need to avoid duplication in enforcement efforts. For ethics/religious and Māori organisations in particular, however, support was dependent on MAF developing sufficient expertise and resources to do the work and being adequately funded for its compliance role.

One submission from an organics producer, which supported the proposal, suggested that it was important that the enforcement agency be independent of any advocacy role in relation to GM technologies to avoid compromising its enforcement position. This submitter suggested that perceived MAF support for the establishment of GM technologies in New Zealand would complicate the use of MAF as an enforcement agency.

One submission from a Māori organisation disagreed with the proposal, but did not specify why.

Two submissions from individuals addressed this issue, both supporting the proposal. One of these submitters noted concerns about past MAF failures, and suggested that MAF should be given clear directions to protect the public interest over commercial pressures. The other submitter made no comment about their support for the proposal.

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.

One submission from a Māori organisation suggested that the Ministry for the Environment be the primary enforcement agency and that OSH, MAF and all other government agencies could have regulatory roles specific to their departments. This submission suggested that OSH could have a defined role for areas not covered by another agency.

One submission from a legal/risk management organisation suggested a process combining MAF enforcement roles with a role for ERMA in auditing, monitoring and examining documentation related to the establishment and approval of the project (including projects approved by IBSCs). Under this process, the Parliamentary Commissioner on Biotechnology recommended by the Royal Commission would oversee MAF and ERMA in regard to their decision-making and their enforcement, monitoring and audit activities. The Parliamentary Commissioner would also oversee the decision-making and audit/monitoring functions of the IBSCs related to low-risk and contained research.

B10.3 Other issues

A number of other issues related to enforcement were raised in submissions on the questions in this section. The other issues raised were as follows.

- MAF's functions under the Biosecurity Act may not be wide enough to cover GMOs given the definition of 'risk goods' or 'unwanted organisms'. The HSNO Act will need to be amended to provide for other circumstances where a GMO was found in New Zealand without an ERMA approval.
- MAF cannot be held responsible for achieving compliance related to controlled organisms, as this is an impossible task.
- OSH oversight may be a useful safeguard, with an OSH role integrated as part of an improved system.
- Boundaries between MAF and ERMA processes will need to be clarified so that duplicate approvals do not need to be sought.

- The Biosecurity Act should be amended to ensure that all GMOs are classed as unwanted organisms unless there has been a specific approval for the organism to exist in this country.
- There currently appears to be no enforcement agency in New Zealand with the will or procedures to ensure enforcement, and no statute providing for one. ERMA should be funded to provide enforcement officers and to enforce the HSNO Act.
- Gaps between approval and enforcement processes cause problems, and proactive information about what is required of the applicant is needed.
- MAF does not appear to have information, skills and resources to control the importation and spread of GMOs.

B11.0 Issues arising from operation of the HSNO Act

B11.1 Introduction

Chapter 11 covered a range of issues that have arisen in light of experience under the HSNO Act. These issues are:

- the time to release a decision
- the definition of 'new organism'
- the definition of 'organism'
- compliance orders
- the time to lay information for a prosecution
- a review of the Second Schedule (prohibited new organisms)
- large-scale fermentation
- clarification of the decision-making criteria for new organisms in containment.

This chapter attracted responses from a small number of organisations and very few individuals. However, most questions in this chapter attracted only a very small number of responses. The organisations represented were chiefly from the research and agricultural/ horticultural sectors, with a smaller number of environmental organisations, ethical or religious organisations, Māori organisations, local authorities and legal organisations.

B11.2 The time to release a decision

It was proposed that this time be extended from 15 to 30 days. The purpose of this proposal is to allow ERMA sufficient time to adequately consider, decide and publicly notify its decisions on significant applications.

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.

Most of the submissions from organisations responding supported the proposal that the time for ERMA to release a decision should be extended to 30 days. These submissions came from most agribusiness/forestry organisations who responded, along with all research organisations, environmental groups, local bodies and ethics/religious groups. One ethics/religious group provided a reason for agreement, which was that ERMA should have the discretion to allow additional time for proper public hearings and to canvass expert advice.

The support of some agribusiness/forestry organisations and research organisations for the extension was, however, conditional on the hearings being closed promptly and ERMA not being able to:

- waive the 30 days without the permission of the applicant
- circumvent the timeframe through an adjournment.

Another agribusiness/forestry organisation suggested that the extended timeframe should only be used when there is a requirement for full hearings and disclosure of evidence.

One individual supported the extension, on the grounds that ERMA needed the opportunity to fully assess the implications of an application, and that even the simplest GM research had more potential for complex issues than the construction of a shed, which takes 20 days to consider.

One agribusiness/forestry organisation opposed the extension on the grounds that the current 15-day timeframe is adequate and that the extension would serve no useful purpose.

Rather than directly agreeing or disagreeing with the proposal, several organisations noted general issues surrounding the setting of timeframes. The issues raised by organisations in this category included:

- the use of 30 days as a minimum hearing time
- the need for a timeframe providing certainty to applicants
- the possibility of a discretionary extension by the Minister if the hearing is complex
- the imperative to ensure decisions are expedited for scientific and commercial considerations.

Rather than directly agreeing or disagreeing with the proposal, one individual noted the need for timeframes to consider the status of the organism the application relates to (e.g. is it a retrospective application for a crop about to release pollen?).

B11.3 Definition of a 'new organism'

There are issues with the identification of organisms at a species level. These arise from the following.

- The non-deliberate introduction of new organisms. A new organism is defined as not being present before July 1998. However, non-deliberate introduction of a new organism may lead to a population being established for some time before the introduction is discovered.
- The identification of new organisms at the species level being not entirely appropriate from a risk assessment perspective for plants and micro-organisms.

B11.3.1 The non-deliberate introduction of new organisms

The HSNO Act defines a 'new organism' in a way that means organisms arriving through natural means or as accidental 'hitchhikers' are still considered new organisms. This means that any deliberate importation of these species requires a HSNO approval.

An amendment to the HSNO Act was proposed to provide a power to declare that an organism established in New Zealand is no longer new, despite the fact that it meets the strict legislated criteria of a 'new organism'.

It was also suggested that criteria may be needed to assess whether an organism should be declared 'no longer new'. Criteria proposed include:

- the organism has formed a self-sustaining population
- the population is not undesirable
- the organism was not deliberately imported or released in contravention of any Act.

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

Most submissions agreed with the statement that there was a need to provide for organisms that arrive by natural means or as accidental 'hitchhikers'. These submissions came from agribusiness/forestry organisations, research organisations and local bodies. Some of these agribusiness/forestry organisations and research organisations considered that this provision was important as a means enabling regulators to keep track of organisms in the environment. Others saw this process as a means of assisting in identifying organisms that were no longer 'new', and raised issues of defining when populations were established in New Zealand. One agribusiness/forestry organisation supported this provision as a means for management of the adventitious presence of GMOs in imports that are not being imported as GM products (e.g. seeds).

A small number of agribusiness/forestry organisations and research organisations did not agree that there was a need for the HSNO Act to provide for organisms that arrive by natural means or as accidental hitchhikers. These organisations considered that the arrival of these organisms is only generally recognised when the population has become established and therefore that the presence of these organisms becomes a biosecurity issue.

B11.3.2 How should organisms be declared established in New Zealand?

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

Of the very small number of submissions from organisations responding, most indicated support for the proposal that ERMA (after consultation with other agencies) should be the agency declaring that an organism is established in New Zealand. These submissions came entirely from agribusiness/forestry organisations and research organisations. These organisations favoured this option because of ERMA's expertise, existing responsibilities and existing communications networks with other organisations involved.

A very small number of submissions from agribusiness/forestry organisations favoured other mechanisms, including an application to the Biosecurity Authority dealt with by ERMA in terms of the normal process and amendments to the definition of 'new organism' to define the details of an 'approved seed'.

B11.3.3 Definition of an organism as 'no longer new'

The Discussion Paper sought views on possible criteria for defining an organism as no longer 'new', and defined three possible criteria as follows:

- self-sustaining populations
- non-deliberate introduction
- the organism being not undesirable.

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.

Most of the very small number of submissions from organisations responding indicated support for the suggested criteria of an organism that is no longer 'new'. These submissions came from agribusiness/forestry organisations, research organisations and universities. A very small number of these organisations supported additional criteria. The additional criteria suggested were that:

- the population established was ineradicable
- the population has been self-sustaining for at least several years (indicating an ability to survive climatic variation)
- the population occupies the majority of its potential distribution in New Zealand
- an undesirable new element (the population of organisms to be defined no longer 'new') is present in another population at or above a threshold level.

B11.3.4 Approval below species level

Identification of organisms at the species level may be less appropriate from a risk assessment perspective for plants and micro-organisms than it is for animals. Issues with identifying plants and micro-organisms at the species level include:

- hybridisation and plant breeding techniques making it difficult to identify the full range of species which some plants (e.g. orchids) may be bred from
- crucial differences between micro-organisms, which are members of the same species, whereby some members of a species are not pathogenic and others are (e.g. *E. coli* bacteria).

The risk species provision in the HSNO Act is intended to enable differentiation between subspecies, infraspecies, varieties and cultivars. This is achieved by allowing prescription of any subspecies, infraspecies, variety or cultivar as a 'risk species', without necessarily also prescribing other members of the same species in the same way. However, using this provision is time consuming because of the statutory processes required and therefore may prove a clumsy response to a risk species event. This provision also requires risk species regulations that have not yet been promulgated.

Adequacy of the risk species provisions

11e Is the risk species process adequate to deal with organisms at a level below the species level? How could it be improved? Please explain your comments as clearly as possible, including examples and referring, where necessary, to the relevant parts of the HSNO Act.

Most submitters who responded commented that the risk species process was not adequate to deal with organisms at a level below the species level. These submissions came from research, agribusiness/forestry and environmental organisations. The risk-species process was considered by a research organisation and an agribusiness/forestry organisation to be a clumsy and inadequate way of dealing with organisms below the species level, and one research organisation commented that it would be unworkable if applied to all organisms.

The suggestion to include the phrase 'any subspecies, infraspecies, variety, strain or cultivar' in the definition of a new organism and to enable any taxon below species level to be declared as a risk organism by *Gazette* notice received support from two research organisations, subjects to:

- unapproved subspecies requiring separate applications for research in containment
- declarations of taxons below the species level as risk species being subject to appeal.

Other mechanisms suggested to improve the risk species process were:

- processes which reduce complexity and detail while increasing ERMA's ability to consider issues broadly and appropriately, subject to that consideration being effectively challenged
- a molecular profile to define organisms and help risk assessment.

HSNO Act Amendments to identify risk species

Two alternative approaches to amending the HSNO Act were proposed to take account of these issues. These were to amend the HSNO Act to:

- allow approval at a level below the species level. This would involve allowing a declaration by *Gazette* notice that a particular species or subspecies was a risk species, so a declaration could be made at any time. Criteria to be used by ERMA in making the declaration would need to be defined, and consultation processes identified
- include the phrase 'any subspecies, infraspecies, variety, strain or cultivar' in the definition of a new organism.

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.

A small number of submissions from organisations identified problems with the inclusion of the phrase 'any subspecies, infraspecies, variety, strain or cultivar' in the definition of 'new organism'. These submissions came from research organisations, agribusiness/forestry organisations and universities. Nearly half of these organisations expressed concern that treating each subspecies, infraspecies, variety, strain or cultivar as a new organism may increase the burden of identifying whether an organism is in fact a 'new organism' requiring approval from ERMA for its importation. A smaller number of organisations raised other issues, including:

- the technical difficulties of identifying which subspecies, infraspecies, etc an organism belonged to
- difficulty applying the terminology used to some organisms (e.g. bacteria), and the tendency to regard each isolate of a bacterium as a new strain
- difficulty of determining which taxons of which species were present in New Zealand prior to the introduction of the HSNO Act, or which do not meet the criteria of 'new organisms' for some other reason.

Submissions from a small number of research and agribusiness/forestry organisations expressed a preference for this option to only be applied when there is a scientific reason to believe that particular taxa could pose a risk to New Zealand. One agribusiness/forestry organisation suggested that assessment of such organisms would involve consultation with the relevant experts.

Submissions from a small number of organisations and individuals proposed a range of mechanisms for addressing issues related to the identification of risk species. The mechanisms proposed by organisations were:

- assessment of a micro-organism being related to the phenotype and genotype of the micro-organism, not to its strain
- use of ERMA's risk assessment regarding the organism as a means of identifying whether the organism poses a risk or not
- use of a simplified application to import, which includes assessment of risk factors
- assessment of containment facilities to manage the risk posed by new organisms
- ERMA defining which organisms they are concerned about, and only requiring those to be specified to more than the species level
- have ERMA approve or not approve a species, and then allow MAF Biosecurity to assess whether particular strains within that species pose a risk
- a molecular profile which helps define the new GM organisms and aids risk assessment.

The mechanisms proposed by individuals were:

- a molecular profile which helps define the new GM organisms and aids risk assessment
- a multi-layered system based on risk, with low risk species approved in a 'single-desk' process and more scrutiny for medium and high risk species.

B11.3.5 Assessment at the genus level

The option of allowing ERMA the flexibility to consider plant organisms at a higher classification than species was considered.

Cases where assessment at genus level is appropriate

The Discussion Paper discussed issues related to classification of organisms at the species level. One particular difficulty was identifying the species from which hybrid organisms (particularly plants) are bred. Orchids were cited as an example of this difficulty.

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

A small number of submissions from organisations offered examples in addition to orchids of which it might be appropriate to have approvals at a level above the species level. These examples were:

- plants that cannot form a self-sustaining population and persist only by continued human cultivation (e.g. types of frangipani)
- micro-organisms (including environmental bacteria) which often cannot be described at the species level
- fungi where not all strains have been allocated to a species level (e.g. Neurospora)
- ornamental plants such as rhododendrons and crop hybrids.

One research organisation objected to generic and family-level applications because the species/genera included in the higher ranges depend on the taxonomic treatment that is followed. A zoological organisation supported consideration of both plants and animals at higher taxonomic levels. This organisation cited the example of two approvals being required to import two very closely-related species of iguana when the risks of both species were seen by the submitter as being virtually identical.

Other mechanisms for classifying organisms

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.

A very small number of submissions from research organisations offered other mechanisms for addressing assessment at the levels above that of species. These included:

- description at phenotypic property for micro-organisms
- approvals at higher taxonomic levels (e.g. genus) with the ability to exclude particular species, subspecies, etc as risk species, if species within the genus differ in their potential to cause harm
- a system where applications were made at a generic level, but could be reduced to species level by ERMA (through consultation with the applicant) if insufficient evidence is presented that the risks of all members of the taxonomic group are the same.

One university questioned how a 'kind' of organism would be defined in relation to changes affected by GM technology. This organisation raised the question of whether, for example, once one corn cultivar expressing the *Bt* gene is approved, would all corn cultivars expressing this gene be approved.

B11.4 Including prions as organisms

Prions are small, infectious protein particles that can cause fatal neuro-degenerative diseases in animals. These particles do not contain genetic material and are not self-replicating but induce changes in the host organism that result in disease.

Currently, the Biosecurity Act includes prions as organisms while the HSNO Act does not. It was proposed that the infectious nature of prions means that consideration should be given to including prions derived from both animals and humans as organisms under the HSNO Act.

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

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

About half of the small number submissions of organisations responding to the issue stated that prions should be included in the HSNO Act definition of an organism. These submissions came from environmental organisations, agribusiness/forestry organisations, research organisations and legal/risk management organisations. Of the two submissions providing reasons for this view, one indicated that prions should be treated as a special case in this respect (on what grounds was not made clear), while the other sought consistency with the Biosecurity Act.

Of the remaining submissions responding to this issue, about half disagreed with the proposal. These submissions came from research organisations, universities, and agribusiness/forestry organisations. Reasons given for disagreeing with the proposal were as follows.

- As proteins, prions are not organisms (they are unable to reproduce and do not contain genetic code) and may better fit the hazardous substances category.
- The Biosecurity Act already provides adequate protection.
- Including prions as organisms raises the potential for:
  - requirements for ERMA to approve research with other proteins
  - inconsistency between treatment of prions and treatment of other vectors of disease or genetic fluctuation (e.g. pesticides).

Rather than directly stating agreement or disagreement, the remaining organisations responding to the issue outlined concerns with the proposal. These included that:

- prions are not organisms
- some prions may be beneficial
- the proposal may result in the restriction of future options to work with prions which do not in fact pose risks
- HSNO low-risk regulations already regulate experiments that generate infectious particles pathogenic to plants, animals and humans
- prions have already been found in fungi and yeast as well as animals, and the 'prion phenomenon' may spread further.

One individual stated that it was 'obvious' that prions should be included as new organisms.

B11.5 Compliance orders

B11.5.1 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 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 was 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.

Most of the very small number of submissions from organisations responding agreed with the proposal to amend the HSNO Act so that compliance notices come into effect at a period stated on the notice and that the period on the notice must be a reasonable one in which to take the action required or to cease the action in the circumstances. These submissions came from environmental groups, agribusiness/forestry organisations, research organisations, Māori organisations and a health organisation.

The support of a number of these organisations was, however, conditional on the processes that would be followed in setting the timeframe for compliance. Comments suggested that organisations supported the proposal if:

- the precautionary approach was adopted in setting the timeframe for compliance
- at least four days notice was given for compliance
- clearer guidelines were offered about how to set a 'reasonable' period for compliance.

One submission from an individual supported the proposal as long as a precautionary approach was used in setting the time period.

Rather than directly stating agreement or disagreement with the proposal, one submission from a research organisation stated that the present time limit should be changed if it is unsuitable. Similarly, one submission from an individual suggested that time periods should be set on a case-by-case basis using common sense as to what fits the case. This submission noted the view that a period too long to destroy an organism already shedding pollen may be unnecessarily short to destroy the unexpected product of a fully-contained laboratory experiment.

B11.5.2 Last day of notice for 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.

It was proposed to delete from the HSNO Act 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.

Most of the very small number of submissions from organisations addressing this issue agreed with the proposal. These submissions came from agribusiness/forestry organisations and research organisations. The two organisations giving a reason for agreeing with this proposal cited consistency with the Resource Management Act.

One submission from an agribusiness/forestry organisation stated that it was important that people realise that there is a deadline to appeal and are aware of the timeframe. This submission stated a preference that a reference to the District Court rules be given on the compliance order.

Rather than state agreement or disagreement with the proposal, one submission from a research organisation suggested that the time limit should be removed if there was no advantage in setting it.

B11.6 Time to lay information for prosecutions

There are several issues under this heading.

- Differences across legislation in the period during which information can be laid.
- Differences in the point at which the period begins in which information can be laid.
- Offences related to hazardous substances and offences related to new organisms being covered by different legislation.

B11.6.1 Changes in the period to lay information

The HSNO Act currently 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'. Because of the time required to obtain specialist legal advice, this restriction has apparently prevented some offences for new organisms being pursued under the HSNO Act. It has therefore been proposed that the Act be amended to lengthen the 120-working day period.

The current 120-day 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). However, it is not in line with the Biosecurity Act 1993 nor with the ACVM Act, which both specify a period of two years from 'time of knowledge'.

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 focuses on the time of knowledge that there has been an offence, rather than the time of the offence itself.

It was proposed to amend the HSNO Act to lengthen the 120-day period and to alter the starting time of this period 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?

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

Most of the very small number of submissions from organisations responding indicated support for a change in the start time from 'time of knowledge' to 'time of offence'. These submissions came from environmental, research, agribusiness/forestry and Māori organisations. These submissions gave varying reasons for this preference, including public interest, difficulty proving time of knowledge, and alignment with the Biosecurity Act.

Submissions from a very small number of ethics/religious groups and a health organisation opposed the proposed change in start time. These submissions suggested that 'time of knowledge' had better potential to protect the public interest through considering the long-term nature of GMO impacts, and through allowing consideration of historical factors.

Most of the very small number of submissions from organisations responding indicated support for a change in the period of 120 working days allowed to lay information. These submissions came from ethics/religious groups and from research organisations. Organisations giving reasons for this preference indicated that they considered a longer time frame would be reasonable, with one organisation suggesting a period of two years.

One submission from a university considered that no extension in the time to lay information was necessary if the time to lay information began at the time of knowledge, not at the time of the offence. One individual supported this change.

B11.6.2 Alignment of legislation on times to lay information

11o Should these times be aligned with those in the Health and Safety in Employment Act or the Biosecurity Act? Please explain your comments as clearly as possible, referring, where necessary, to the relevant parts of the HSNO Act.

The very small number of submissions from organisations responding were divided over whether times should be aligned with the Health and Safety in Employment Act or with the times in the Biosecurity Act. One health organisation considered the HSNO Act should be aligned with the Health and Safety in Employment Act, while a research organisation considered it should be aligned with the Biosecurity Act. A university considered that the HSNO Act, the Biosecurity Act and the Health and Safety in Employment Act should be

aligned, and a Māori organisation suggested the alignment of all three of these Acts with the Resource Management Act.

B11.6.3 Differentiation of offences involving new organisms and offences involving hazardous substances

Enforcement of new organisms is carried out under the Biosecurity Act, while enforcement for hazardous substances is carried out under the Health and Safety in Employment Act. It was suggested that, as a result of this situation, offences involving new organisms and those involving hazardous substances may need to be differentiated.

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.

Of the very small number of submissions from organisations responding, most stated that it was not necessary to differentiate between offences for hazardous substances and offences for new organisms. These submissions came from universities, research organisations and a health organisation. The submission from the health organisation suggested that differentiation would unnecessarily confuse the enforcement regime. Other submissions stating that differentiation was unnecessary did not give a reason for this view.

One submission from a Māori organisation suggested that offences involving hazardous substances and offences involving new organisms should be differentiated, but did not give a reason for this view.

B11.7 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 and some were explicitly approved by MAF under previous legislation before the HSNO Act commenced.

Specific amendments to the list of organisms in the Second Schedule were proposed as well as a change in the way the Second Schedule is presented.

B11.7.1 Amendments to list of organisms

It was 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)
- *Echinacea 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.*

11q Do you agree or disagree with the proposed changes? Please give your reasons.

Most of the very small number of submissions from organisations responding agreed with the proposed changes. These submissions came from agribusiness/forestry organisations and research organisations. One university-based researcher wanted the cane toad *Bufo marinus* to be removed from the schedule of prohibited new organisms for use in amphibian-related research/teaching applications. One other submission from a research organisation supported most of the proposed changes, but noted a spelling error in the proposed list of corrections. This submission suggested that the correct spelling of the second scientific name being corrected is '*Rham**n**us purshiana*'.

B11.7.2 Amendments to layout of Second Schedule

It was also proposed to list the organisms in the same manner in terms of the order of common and scientific names.

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

One submission from a research organisation proposed that organisms be listed by scientific name including the authority. This submission suggested that ambiguity arose when common names and many scientific names are cited without authorities.

B11.8 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.

B11.8.1 The need for new criteria and containment requirements

It was proposed that 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 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.

Most of the submissions from the very small number of organisations responding supported the proposal. Reasons given for this support were that:

- the proposal better reflects the risks of the developments
- the proposal recognises changes in technology which allow for safe containment of volumes much larger than 10 litres
- criteria other than container size may be more relevant in the management of developments involving fermentation.

Submissions from one agribusiness/forestry organisation and one research organisation opposed the proposal on the grounds that the 10-litre figure was at least clearly defined, whereas the proposal did not offer a clear definition of what 'large-scale' fermentation is. These organisations supported continued application of the current criteria for large-scale fermentation.

B11.8.2 Other mechanisms for management of large-scale fermentation

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

A very small number of submissions from organisations outlined other mechanisms for the management of large-scale fermentation. Submissions from a very small number of research organisations, universities and agribusiness/forestry organisations suggested that large-scale fermentation should be removed from the definition of field trials and assessed on the likelihood and consequences of escape of the GMOs concerned from containment. Submissions from most of these organisations considered that IBSCs should have the authority to consider large-scale fermentation, although one university considered that industrial-scale fermentation may need ERMA approval. One of these research organisations noted that the ability to put in place a code of practice negates the need to develop separate criteria for large-scale fermentation.

One university organisation suggested giving ERMA directions to amend the 'Interpretations and Explanations of Key Concepts' to allow incubations of under 50 litres to be assessed by IBSCs where low-risk GMOs are involved. This organisation noted that IBSCs have the power to impose additional controls to minimise risk involved in larger-scale experiments, and often exercise this power.

B11.9 Clarification of the decision-making criteria for new organisms in containment

Section 45(1) of HSNO Act sets out the criteria to be used in making decisions on applications involving new organisms (including GMOs) in containment. There are two main criteria in section 45:

- 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.
- ERMA must be satisfied that the organism can be adequately contained.

ERMA's approach is to consider as one question the ability of the organism to escape from containment and the adequacy of containment. This approach reflects a view 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 they should be able to influence the weighing-up process directly.

It was proposed to amend section 45 of the HSNO Act so that it is clear that in the 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
- 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.

Most submissions from the small number of organisations responding supported this proposal. These submissions came from research organisations, universities, local bodies, and agribusiness/forestry organisations. Reasons given for this response mentioned the importance of:

- an integrated approach
- considering the containment and risk of the hazard as well as considering the hazard.

Rather than directly stating agreement or disagreement with the proposal, one individual suggested that containment of a whole organism does not obviate the need for containment of parts and products of that organism as a biosecurity measure.

B11.10 Other issues

A number of other issues about the operation of the HSNO Act issues arose in submissions. These issues concerned:

- the general approach of the HSNO Act
- specific proposals for amendments to the HSNO Act.

B11.10.1 Issues raised about general approach of the HSNO Act or regulations

Issues about current operation of the HSNO Act

Some elements of the current operation of the HSNO Act and regulations attracted comment. These were:

- the cost burden:
  - overall
  - on 'first-movers' compared to that faced by other organisations or individuals performing similar work later
  - of approval for field trials
  - from ERMA charging hourly fees rather than fixed fees for service
  - from public hearings (one submitter saw these as a public good to be funded by the state, while another saw early hearings as costly but inefficient)
- the level of regulation of activity
- the level of public consultation involved in approving low-risk activity.

Issues submitters considered should affect the operation of the HSNO Act

Some issues that submitters considered should, but did not, affect the operation of the HSNO Act or regulations related to:

- preserving other opportunities/proceeding with caution:
  - minimising risks or barriers to developing a sustainable, commercially viable and certified organic products exporting industry
  - simplifying the Act to preserve opportunities
- involvement of and obligations to Māori:
  - revamping the HSNO framework to allow full Māori participation
  - providing a more comprehensive link to the Treaty of Waitangi and any fiduciary duty or obligation to Māori
  - developing an adequate pre-application processes involving iwi, which should allow ERMA to have adequate time to consider and decide on an application
- risk assessment:
  - considering the extent to which changes to section 45 may weaken the focus on full containment including trials of GM animals
  - developing an approach for management of low levels of contamination by GMOs in some imports
  - considering environmental risk as arising when a self-perpetuating population is established which is capable of detrimental environmental effects or detrimental change to other organisms

  - focusing on protecting the public from GMOs
  - recognising and providing for biodiversity, public health and international obligations
  - recognising that containment cannot be guaranteed, so every application has environmental, health and economic risks
  - assessment of what is 'low risk' research based on the safety record of the organisation or individual concerned
  - balancing environmental, health, social and economic issues
- processes and delegations:
  - public hearings should occur in the area where releases are to occur, and involve real participation and exchange of information
  - allowing IBSCs to approve contained experiments above low risk level
  - ERMA should document approval decisions more fully.

B11.10.2 Specific suggestions for amendments to the HSNO Act

A range of suggestions were made concerning amendments to the HSNO Act. These suggested amendments covered:

- scope of the HSNO Act:
  - separate treatment of hazardous substances, new organisms and gene technology
  - 'new organism' only defined as such when release into environment is being contemplated
- processes and delegations:
  - delineate the roles of agencies
  - streamline processes
- involvement of and obligations to Māori:
  - amendment to give effect to the principles of the Treaty of Waitangi rather than only taking these principles into account
  - early and ongoing consultation with Māori
- risk assessment:
  - including the 'precautionary principle' which is contained in the Rio Declaration on climate change
  - defining benefits and risks of applications, especially economic risks
  - consider benefits to New Zealand only
  - separate public and private benefits
  - balance release against alternative means of getting the same outcomes/benefits
  - consider ability of researchers to dispose safely of waste products from research
  - distinguish hazard (potential of harm) and risk (likelihood of harm)
  - base management of imports and lab research on phenotypic and practical considerations rather than classification as 'new organisms'.

In addition, some comments suggested processes to be followed before further amendment to the HSNO Act. These comments suggested that:

- liability issues should be resolved prior to amendments to the HSNO Act
- a revision of the definition of 'animal' being undertaken by national animal welfare organisations may be relevant to the review of the HSNO Act
- ensure that reviews of legislation in this area keep pace with technical developments.

PART C:
General Comments made by Submitters

This section of the report summarises the general comments made by submitters that do not directly relate to questions in the Discussion Paper.

The first chapter in this section outlines comments concerning the Discussion Paper and the consultation process used to gather responses to it. These comments concerned the:

- scope of the Discussion Paper
- information provided in the Discussion Paper
- process followed in preparing and distributing the Discussion Paper
- timeframe for the consultation.

The second chapter outlines other comments made and issues raised by submitters about GM technology in New Zealand. These comments concerned:

- economic impacts
- environmental impacts
- food supply impacts
- health impacts
- administrative, process and legislative issues
- risks and benefits, including who takes risks and who benefits
- precautionary approach to implementation
- the future development of New Zealand
- political considerations.

C1.0 The Discussion Paper and consultation process

C1.1 Introduction

These comments addressed a range of issues about the Discussion Paper and about the process undertaken by Ministry for the Environment in seeking input on it. These comments concerned the:

- style of the Discussion Paper
- scope of the Discussion Paper
- information provided in the Discussion Paper
- process followed in preparing and distributing the Discussion Paper
- timeframe for the consultation.

C1.2 Style of the Discussion Paper

One submission from a local body organisation criticised the Discussion Paper as overly complex, while another described it as 'bad' without being more specific.

C1.3 Scope of the Discussion Paper

C1.3.1 Assumptions and approach

One submission from a legal/risk management organisation criticised the Discussion Paper for false or questionable assumptions that GM raised different questions than other new technologies and that contamination could only go one way (i.e. from transgenic to conventional crops). This submission also criticised an overemphasis on regulation as a solution to issues raised by GM technology.

One submission from an individual criticised reliance on the recommendations of the Royal Commission on Genetic Modification, on the grounds that new information had since become available which affected the value of those recommendations.

One submission from an individual questioned why the Resource Management Act appears to be ignored when land use and environmental impacts are fundamental questions arising from the introduction and release of GM technology.

C1.3.2 Ethical and cultural issues

One submission from an individual criticised the attempt to seek answers to the questions in the Discussion Paper when an ethical and cultural base for dealing with GM technology had not been established and criticised the Discussion Paper for not asking 'the right questions'.

One submission from a Māori organisation suggested that the Discussion Paper should have considered the appointment of the Bioethics Council.

C1.3.3 Treaty of Waitangi/Māori issues

Submissions from Māori organisations voiced concerns that the Discussion Paper did not address, or ignored, issues relating to the Treaty of Waitangi. The following specific comments about the Discussion Paper were made by Māori in their submissions, stating that it should have considered:

- the involvement of Māori in the HSNO Act processes
- the formation of the Māori Reference Group
- the ability of the Bioethics Council to represent Māori values
- engagement with Māori over the use of native flora and fauna in GM developments, and over field research
- the integration of the Māori Land Court Act with the HSNO, Resource Management and Biosecurity Acts so that Māori could track applications and their impact.

One submission from a Māori organisation stated that Māori issues in general received little attention.

C1.3.4 Threshold levels for GM contamination

One submission from a research organisation commented that the Discussion Paper did not address the accidental presence of low levels of GMOs in commodities developed or imported as 'GE free'.

C1.3.5 Environmental impacts

One submission, from an individual, expressed concern that the Discussion Paper did not discuss the environmental impacts of GM technology.

C1.3.6 Recommendations of the Discussion Paper

One submission from a research organisation expressed support for the proposed changes to improve the HSNO Act, while another suggested that the recommendations in the Discussion Paper 'patched up' the situation and did not address fundamental flaws in the HSNO legislation.

C1.4 Information provided in the Discussion Paper

One submission from a medicines/veterinary medicines supplier suggested that the Discussion Paper should have detailed the environmental impact information needed for an application to approve a medicine because of the potential cost disincentives for applicants under any of the options proposed.

C1.5 Process of preparing and distributing Discussion Paper

One submission from a Māori organisation suggested that the Māori Reference Group should have been established prior to any consultation process.

One submission from a Māori organisation stated that an active consultation process, which recognised tribal structures, was necessary while another criticised an absence of a 'partnership approach' in the consultation, which the submitter suggested constituted a breach of the Treaty of Waitangi.

One submission from a Māori organisation commented that the lack of involvement of Māori during the consultation process would lead to Māori having reservations about GM technology.

One submission from an individual suggested that the consultation process was public 'window-dressing' to cover the fact that GM development will go on in New Zealand.

C1.6 Timeframe for the consultation

Four environmental organisations, one Māori organisation and three individuals stated that the timeframe for consultation was too short, while one other Māori organisation requested an extension to the deadline for consultation.

One submission from an individual suggested that cautious change and deadlines for consultation 'do not go well together'.

C2.0 GM technology

C2.1 Introduction

These comments covered a range of issues, as follows:

- economic impacts
- environmental impacts
- food supply impacts
- health impacts
- administrative, process and legislative issues
- risks and benefits, including who takes risks and who benefits
- precautionary approach to implementation
- the future development of New Zealand
- political considerations.

The following sections of the report outline comments that were made on each of these issues.

C2.1 Economic impacts

C2.1.1 Trade impacts

A small number of submissions from individuals and one submission from an environmental organisation noted that the introduction of GM technology threatens:

- New Zealand's 'clean, green' image used in marketing agricultural or horticultural produce and tourist destinations
- the organic farming industry, due to loss of organic certification as a result of contamination by GM organisms. Many of these individuals considered that the organic export market was large and that the economic costs of losing this market would be serious
- conventional 'GE free' agriculture or horticulture, due to loss of certification that produce (e.g. meat) is fit for export following contamination of crops or feed.

A very small number of submissions from individuals suggested that the prominence of agriculture and horticulture in New Zealand's economy made the economic threat from GM technology particularly acute. Some of these submissions suggested that New Zealand's economy as a whole could collapse as a result of GM contamination and the loss of export markets, while others suggested only that New Zealand should be more cautious with GM because of economic reliance on agricultural/horticultural produce.

Submissions from one research organisation, one organics producer organisation and a small number of individuals (including a qualified scientist) suggested that markets for GM food were poor. Submissions from one research organisation and one individual considered GM technology an economic failure, due to lower than anticipated demand and prices for outputs combined with high costs. One submission from an individual suggested that GM technology created more economic costs than benefits because of ongoing and unpredictable mutations in the environment.

One submission from an environmental organisation pointed to a conflict between trade and biosecurity without specifying what factors were in conflict.

C2.1.2 Competitive advantage and production processes

One submission from a legal organisation suggested that the loss of a biotechnology industry in New Zealand would disadvantage New Zealand compared to other economies.

One submission from an individual suggested that the world did not need the higher levels of food production promised by GM technology but a more conducive environment for balanced distribution of the food that is produced.

C2.2 Environmental impacts

Submissions from a small number of individuals and one environmental group suggested that the introduction of GM technology threatens the New Zealand environment or the biodiversity of New Zealand ecosystems. One of these individuals stated that remaining 'GE free' would assist in maintaining New Zealand's biodiversity.

Submissions from a very small number of individuals suggested that care should be taken when attempting to change natural systems and processes that have evolved over millennia. One individual referred to DDT as an example of ongoing environmental contamination arising from the use of chemicals/technology considered safe by scientists for many years.

One submission from a Māori organisation considered that New Zealand was particularly vulnerable to environmental contamination from GM technology given the number of endemic plant and animal species in New Zealand. However, a submission from a legal/risk management organisation considered the fact that the economic species liable to application of GM technology were imported means there is less environmental threat in the event of GM escaping into the environment after release.

One submission from an individual suggested that the use of viruses as vectors in GM technology raises risks of viruses threatening the wider environment, while another expressed particular concern about damage to soils with a flow-on effect to agricultural production.

C2.3 Food supply impacts

C2.3.1 Food safety

A small number of submissions from individuals expressed concerns about the safety of GM food, while a very small number expressed a preference for 'GE free' or organic food. One of these individuals suggested there was no desire in developing countries to receive GM food as food aid.

Submissions from a very small number of individuals suggested that it would be impossible to have both GM food and 'GE free' or organic food.

Submissions from a very small number of individuals (including two practising health practitioners) suggested that the consumption of GM food threatens the health status of New Zealanders and the ability of health workers to identify or manage illness.

One submission from a practising health practitioner suggested that the criteria of 'substantial equivalence' was an unscientific way of establishing the safety of GM food. This individual also criticised as unscientific the argument that GM food was safe because Americans had consumed it for 10 years without apparent ill effects.

One submission from an individual suggested that GM technology was important to deliver quality food. However, another suggested that poor food quality arose from inadequate cultivation practices and that adding more chemicals by using GM technology would not increase food quality.

One submission from a Māori organisation summarised issues for many indigenous peoples (including Māori) arising from the consumption of GM foods as concerning:

- the nutritional value of such foods
- the mixing of whakapapa in violation of natural and spiritual laws.

One submission, from an individual, expressed confidence that GM food is as safe as 'GE-free' food. This individual suggested that insistence on total safety of food would mean that nothing was approved as safe to eat or drink.

C2.3.2 Security of food supply

Submissions from three individuals suggested that the release of GM food intensifies the monopoly of global corporations over the world's food supply, while another submission from an individual suggested that introducing GM technology into the food chain would leave no choice about consuming GM food.

One submission from an individual suggested that 'terminator' seed technology may lead to famine if contamination results in the unintended sterility of conventional seeds.

C2.3.3 Approval of foods for consumption

One submission from an individual suggested that the Food Authority should not be allowed to release GM food into the food chain following identification of safety or environmental risks through the HSNO process. Another submission from an individual argued for case-by-case testing of the safety of GM foods before they are released for consumption.

C2.4 Health impacts

C2.4.1 General health implications

Submissions from a very small number of individuals, including two health practitioners, suggested that GM threatens the health status of New Zealanders and/or the ability of health workers to identify and manage illness.

Submissions from two individuals suggested that breaking genetic barriers using viruses as vectors for GM may lead to health risks (e.g. interspecies transmission of altered genes). Another submission from an individual pointed to the possibility of currently unknown health risks arising from the release of GM/GE technology in New Zealand.

C2.4.2 Occupational safety and health

Submissions from one union body, one medicines industry participant and one individual expressed concerns about the safety of workers exposed to the development or testing of GM organisms. The union body suggested that health workers should be kept informed about which workers are being exposed to these processes, to assist with treatment.

C2.5 Administrative, process and legislative issues

C2.5.1 Labelling of foods

Submissions from one Māori organisation, one environmental organisation and a small number of individuals suggested that current food labelling standards are inadequate to enable consumers to exercise real choice about what they are eating (e.g. not labelling goods already on shelves, not including GMOs below a threshold level).

C2.5.2 Consultation processes

Two submissions from individuals, including one practising researcher, suggested that a new consultation process be established, involving:

- initial discussions with Māori, to engage them as partners, develop a process with them, identify their concerns, and establish parameters for future research (e.g. species needing special protection)

- IBSCs and ERMA using the information gathered in their decision-making
- researcher participation in the consultation processes being used.

Submissions from two Māori organisations, one research organisation and a very small number of individuals suggested that consultation processes were needed which respected the Treaty of Waitangi and/or established Māori as partners in the consultation process.

One submission from a Māori organisation suggested that establishing the Māori Reference Group breaches the Treaty of Waitangi in excluding most Māori as partners, and subjugates fundamental belief systems of the Māori world.

One submission from a researcher suggested that the consultation with Māori currently required delivers little response.

C2.5.3 Decision-making processes

One submission from a Māori organisation suggested that a longer-term focus than that taken at present would be appropriate in making decisions about research applications. Another submission from a Māori organisation suggested that the statutory Māori body set up to advise ERMA is not a partnership, and proposed a Māori agency equivalent to ERMA, which would function as a partner in future decision-making.

Two submissions from individuals expressed concerns that regulators do not appear to be concerned about the risks arising from the release of GM technology in New Zealand and that regulators appear to have a 'pro-GE' bias. One submission, from an individual, expressed concerns about the integrity and openness of the companies involved in development and implementation of GM technology.

One submission from a Māori organisation noted concerns that the evidence produced before the Royal Commission on Genetic Modification appeared to be largely ignored. One submission from an environmental organisation expressed concern that the process ERMA uses in public hearings does not appear to balance applicant and public interests, and suggested a need for a balanced process which conforms to the principles of natural justice.

One submission from an individual suggested that it was important for new technologies to be implemented without arguments based on emotion, while one submission from a research organisation expressed support for an open and transparent public debate about the presence and use of GMOs. One submission from an individual suggested that the debate on GM technology has highlighted social issues that suggest that New Zealanders are not mature enough to handle scientific questions that raise major environmental and ethical issues.

C2.5.4 National mechanisms for decision-making

One submission from a research organisation suggested a social charter for the sustainable implementation of GM technology on a case-by-case basis, and expressed support for the development and implementation of a national biotechnology strategy. One submission from an individual suggested that a national policy statement on factors to be considered in decisions on GM applications would be appropriate.

One submission from an environmental group suggested that the Government was trying to achieve its biotechnology strategy without considering community values, ethics or Māori issues.

Submissions from one environmental organisation and one individual suggested that the Government could achieve its current biotechnology strategy by approving only contained research.

C2.5.5 Resourcing of parties involved in processes

One submission from a Māori organisation expressed concern about a lack of funding for Māori to engage in research related to traditional use of flora and fauna for medicinal and other purposes (e.g. for the Wai262 claim).

C2.5.6 Patents and ownership/control of products

One submission from a Māori organisation indicated concern that the system for patenting of GM organisms means that Māori lose kaitakitanga rights over native species traditionally used for medicinal or other uses.

C2.6 Risks and benefits of GM technology

C2.6.1 Balance of evidence on risks and benefits

Submissions from one Māori organisation and a very small number of individuals (including one individual professionally involved in import and export) suggested that the benefits claimed for GM technology were not being realised or that achievement of the claimed benefits was uncertain. On the other hand, submissions from a small number of individuals considered that GM posed major risks or threats to New Zealand, with one suggesting that new evidence already meant that the approach adopted by the Royal Commission on Genetic Modification was inadequate.

Submissions from a very small number of individuals suggested that the risks of GM technology outweigh the benefits. Submissions from two other individuals suggested that GM technology offered no significant benefits but posed significant issues or risks, with one of these individuals suggesting that the detrimental impacts of GM technology are being overlooked for a perceived benefit. One other submission from an individual suggested that New Zealand would gain no advantage from putting its environment at risk through the use and release of GM technology.

One submission from an individual considered that a risky venture should only be undertaken for a good profit and following consideration of all the opportunity costs. This submission suggested that neither the consideration of opportunity costs nor the realistic prospects of a good profit applied in the case of the introduction of GM technology into New Zealand.

C2.6.2 Unclear nature of risks posed by GM technology

Submissions from one environmental group and a small number of individuals suggested that scientific knowledge is inadequate to determine what the risks of GM technology are. Submissions from two other individuals suggested that divisions in the scientific community about the safety of GM technology should suggest that the risks of GM technology are not well understood.

One submission from an individual pointed to the imprecise techniques used to insert genetic material into host organisms as a source of unpredictability about the future development of the host organism, while another submission from an individual considered that the impacts of GM technology are unpredictable, uncontrollable and irreversible.

Two submissions from individuals suggested that the risks of GM technology are broader than that of other technologies, with one suggesting that the risks of other technologies are purely local events in a picture that we broadly understand. One of these individuals also considered that the risks of GM technology also occur over a longer (evolutionary) time frame than the risks posed by other technologies.

C2.6.3 Who benefits and who bears the risks?

Submissions from one Māori organisation and a very small number of individuals suggested that the benefits of GM technology were confined to a small group connected to (largely overseas) corporations.

One submission from an individual suggested that New Zealand was an ideal laboratory for overseas corporations interested in testing GM/GE technology, as it had a well-developed scientific infrastructure yet was isolated enough for contamination or other failures not to impact on their major markets.

C2.7 The precautionary approach to implementation

C2.7.1 Adoption of a precautionary approach

Submissions from two Māori organisations and one local body organisation supported adoption of a precautionary approach on the implementation of GM technology. One submission from an environmental organisation suggested that adherence to the precautionary principle of the Rio Declaration should be mandatory because New Zealand is a signatory to that document.

C2.7.2 What does a precautionary approach involve?

Submissions from a vast majority of individuals expressed a view that implementing GM/GE with caution involved no release of GM organisms into the environment, or restriction of development of GM technology to fully-contained laboratories.

One submission from an individual expressed a view that release of GM organisms into the environment was consistent with proceeding with caution in adopting GM technology.

One submission from an individual expressed a view that New Zealand was taking unfounded risks by treating adoption of GM technology as a 'race' with other countries. This individual and several others stated that New Zealand should adopt an approach of delaying adoption of GM technology and observing the outcomes in other countries of the adoption of that technology.

One submission from an individual expressed concern that a cautious introduction of GM technology would still inevitably lead to contamination of the environment.

One submission from an environmental group expressed concern that current legislation only allowed enforcement when a breach of controls was considered likely to have a negative effect. This submission suggested that this approach was inconsistent with, and outweighed, a precautionary approach to introducing GM technology.

C2.7.3 Preservation of opportunities under the precautionary approach

Submissions from a very small number of individuals suggested that the adoption of GM technology was inconsistent with the preservation of opportunities to produce and market organic or 'GE free' conventional produce, as these opportunities could not co-exist for long without contamination of organic and conventional crops.

C2.8 The future development of New Zealand

C2.8.1 A 'GE-free' future?

Submissions from a Māori organisation, an environmental organisation, two local bodies and a moderate number of individuals supported a 'GE-free' New Zealand and/or the creation of regional exclusion zones which would remain 'GE-free' even if other parts of the country accepted GM technology. Support for a Northland regional exclusion zone was evident in submissions from a Māori organisation, a local body, an environmental group and a moderate number of individuals.

Two submissions from individuals suggested that New Zealand should take the lead in resisting the introduction of GM technology.

C2.8.2 Sustainable development without GM

Submissions from a small number of individuals suggested that New Zealand should take advantage of its natural isolation in building a future in the market for 'GE-free' or organic produce and/or tourism. A very small number of other submissions from individuals suggested that New Zealand build on its experience in agricultural/horticultural production and its 'clean, green' image to develop and tap into markets for 'GE-free' or organic produce. Two submissions from individuals suggested that New Zealand make a concerted effort to develop and study organic produce, with one also suggesting that Government investment in production of 'GE-free' food should be undertaken to capture the potentially huge future markets for such produce.

A very small number of submissions from individuals suggested that New Zealand should begin planning now for a sustainable future that does not involve the use of GM technology, while a similar number suggested that there was no reason for New Zealand to adopt GM technology.

A very small number of submissions from individuals suggested that a 'GE free' future would enable science to be focused on the needs of people, rather than profits from commercial applications of developments. One submission from an individual suggested that laboratory development could continue, to be sold off overseas to the highest bidder on condition that no product of the development ever enters the New Zealand environment or food chain.

One submission from a university suggested that the benefits of being 'GE-free' would be unevenly spread and would not be outweighed by the benefits that would have been gained by supporting GM development.

C2.8.3 Sustainable development with GM

One submission from a research organisation pointed to the need to ensure that farmers have a choice of technology, rather than excluding one branch of technology (GM) entirely. Another submission from a research company suggested that GM should be used responsibly as one available means of adding value, or as one option among many to ensure economic, environmental and social sustainability. One submission from a religious/ethical organisation expressed general support for the development and use of new technologies.

One submission from a legal/risk management organisation expressed concern that overregulation of GM technology would raise the costs faced by developers to the point that development was moved offshore, and that the consequent loss of the biotechnology industry in New Zealand would have serious economic consequences.

Submissions from a very small number of individuals expressed concern that science has come to focus on profits through the opportunity for commercial development and that wider social or environmental impacts may be ignored.

One submission from an individual expressed concern about the social consequences of the introduction of GM technology, particularly social unrest about the introduction of GM technology and the consequences of the wealth gap between rich and poor. Another expressed concern about the inevitability of contamination of the environment and food sources and consequent loss of choice about technology and food sources.

C2.9 Political considerations

C2.9.1 Government responsiveness to public

Submissions from a very small number of individuals noted concerns that the Government does not appear to be listening to public concerns about GM technology or considering information suggesting that the majority of New Zealanders do not want GM technology or organisms in New Zealand. One submission from an individual suggested that the Government had no mandate to authorise the release of GM organisms into the New Zealand environment, while another questioned why the interests of 'a few scientists' were given more weight than the views of the majority of New Zealanders.

C2.9.2 Perceptions of political rights and process

Submissions from one environmental group and two individuals suggested that Governments should respect the rights of New Zealanders to safety, choice, and protection from involvement in experiments without their consent.

One submission from an individual expressed concerns that the Government seemed to avoid political responsibility in the area of implementing GM, while two others considered that regulators appeared to treat with contempt concerns which were later found by the Royal Commission to be substantiated. One submission from an individual objected to being governed by a Government that 'creates a mess for future generations to clean up'.

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.
Phenotype	The observable characteristics of a genetically controlled trait.
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 gametes (i.e. most cells of which an organism is made, other than germ cells).
Taxon	Taxonomic (classification) group or rank.
WTO TRIPs Agreement	World Trade Organisation agreement on Trade-Related Aspects of Intellectual Property Rights.

Appendix 1: The Aim of this Discussion Paper

The following text can be found on pages 5 and 6 of the Discussion Paper.

The aim of this Discussion Paper

The 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.

The main areas covered

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 Māori Affairs and the Associate Minister of Māori Affairs, the Minister of Research, Science and Technology and the Minister in charge of Treaty of Waitangi Negotiations to appoint a Māori Reference Group to assist in addressing this issue.

The Government is appointing a Māori 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.

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 may be required.

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.

Appendix 2: Methodology for Summarising Submissions

- An independent contractor with experience in research and preparing summaries of submissions and other consultation processes had prime responsibility for preparing the summary of submissions.

- A Microsoft Access database was designed to capture information from the submissions. It provided for the capture of details provided by submitter about their interest and expertise as well as for the process that they had used to develop the submission. The remainder of the database was based on questions included in the Discussion Paper and allowed a summary of text to be entered for each question. Additional fields were provided to capture key points relating to questions not specifically mentioned in the Discussion Paper.

- The content of proforma and shorter submissions was captured by hand and the number of submitters making these points tallied.

- Where content relates to a chapter heading it is included in Part B of the report. Additional points made have been included in Part C.

- Once the data was entered, printouts by chapter were reviewed and main concerns and the range of views held were noted, particularly where views differed by submitter group.

- Steps were taken to ensure the quality and consistency of information captured through training provided on the Discussion Paper and database; briefing with Ministry for Environment staff; and a system whereby content entered was compared with the original submission by a second person and/or the principal.

Appendix 3: List of Individuals who Provided Submissions

Please note: Where more than one submission number is listed by one name generally means that the Ministry for the Environment received more than one submission from the same person. In some cases a faxed version was followed by a posted replica, in others the same person had forwarded more than one submission (e.g. had signed two varieties of a proforma submission).

Neil Abel – 765
G Adamson – 160
John Malcolm Addison – 338
Brenda Agnew – 574
Janette Ajani – 545
Sandy Albisvon – 144
Yvonne Aldridge – 1007
Peter Alexander – 858
Raewyn Altena – 892
Virginia Amaya – 842
Karyn Amoore – 1006
Kirsty Anderson – 630
Bruce Anderson – 223
Brian Anderson – 99
Meg Annan – 831
Margaret Aylward – 16
Pauline and David Bailey – 930
Odile Balas – 509
Rob and Michele Bargh – 947
Valerie Barley – 156
Hillary Baxter – 590
Rachel Bayliss – 493
Susanne Beck – 356
Alison Begg – 266
Heather Bell – 348
Ann Bell – 992
Solange Marie Bely – 353
Milton Berking – 178
Menno Besseling – 186
Karin Bettley – 296
Ross Bicknell – 25
Jocelyn and Paul Bieleski – 685
Perry Bishara – 55
Claudine Susanne Bjorklund – 411
PB Blair – 560
Lynton Blair – 682
Claire Bleakley – 985
Christopher Bone – 464
Rachel Booker – 74
Davina Boreham – 629
John Bostock – 173
Eugene Bradley – 877
Paul Bradley – 604
Emily Bradley – 953
Claire Breers – 772
Bill Brislen – 469
John P Brooks – 963
Jocelyn Brooks – 889
Derek Brown – 454
Jill Brown – 187
Barbara Brown – 191
Bruce Brown – 332
Heather Brown – 271
CD Brown – 677
Paul Bruce – 23
Jarad Bryant – 605
Jane Buchanan – 527
Marie Buchler – 193
Trudy Burgess – 36
Paul Butler – 175
Amy Butt – 380
Jan Byres – 492
Manu Caddie – 833
Belinda Caesar – 273
Glen Callahan – 463
Frances Campbell – 307
Raymond Cannell – 841
Grace Catley – 820
Monica Chapman – 672
Patricia Cheel – 868
Michele Cherry – 442
JH and MA Clapperton – 505
Gary Clarkson – 452
Melanie Closs – 526
Trisha Coates – 180
Louise Coats – 948
Josh Cole – 65
Peter Cooper – 48
Michelle Coppel – 262
Undine Corby – 331
Oliver Johann Corby – 330
Peter Alfred Corby – 329
M Corlet – 297
Pauline Cowan – 936
Mark Craies – 327
J Crawford – 537
Julie Crombie – 616
Hugh Cronwright – 727
Trudi Dahlkamp – 972
Joan Dave – 208
Alex Davidson – 503
Fiona Davidson – 393
Joy Helen Davies-Payne – 888
Derrick Davies-Payne – 1002
Victoria Davis – 673
Colin C Day – 174
Paul deSpa – 457
T Deane – 797
Malcolm Deans – 774
Sarah Delahunty – 235
Walker Dendl-Jaud – 803
Kath Dewar – 28
Stephen Charles Dewsuap – 172
Jan diStefano – 252
Matthew Donaldson – 773
Julie Donaldson – 145
Fiona Farrell and Doug Hood – 446
Fiona Douglas – 378
Mark Douglas – 206
Peter Drabble – 368
Charles Drace – 87
Nadine Driver – 496
Oliver Driver – 138
Graham Dunster – 141
Richard Dunwell – 747
Ratna Dyer – 962
Gaye Dyson – 766
Andrew Earle – 951
Kate Ellis – 30
Paul Elwell Sutton – 552
Marty Ennor – 508
Jean Espie – 726
Hughes-Games Family – 373
Gloria J Forgie – 362
Maike Fichtner – 826
Cath Filer – 633
Patrick Fitzgibbon – 978
Barbara Flavin – 606
Margaret Flux – 886
AW Foley – 980
Andrew Forrest – 219
Riwia Fox – 140
Malcolm France – 428
Caroline Frances – 621
Valerie Freeman – 467
Gemma Freeman – 421
Chantel Freeman – 124
Graham French – 783
Richard Frings – 72
Stacy Garland – 303
Carl Gelling – 500

Justin George – 60
Joe Gibbons – 543
Marilyn Gibbons – 542
Barbara Gillatt – 835
John Glaisyer – 482
Esther Goerig – 439
Bryonny Goodwin – 433
Alison Goodwin – 684
Peter Gordon – 185
MacDonald Paul Gourlie – 181
Basil Graeme – 709
Marcus Graf – 832
Moira Graham – 491
Zelka Grammer – 1010
Susan Grant – 20
Matt Grant – 928
Don Graves – 1009
Kath Gray – 583
Richard Green – 830
Caroline Greig – 638
Bruce Grenville – 881
Francisca Griffin – 966
Anton Griffith – 334
Lois Griffiths – 312
George Griggs – 945
Verena Gruner – 969
Phyllis Gudgeon – 1
Jan Guerin – 435
Anna Gundesen – 906
John Guthrie – 964
Kathleen Winifred Guy – 915
Irmgard Habl – 649
Linda Haider – 911
Christian Haider – 910
Caryl Haley – 413
Susan Hall – 661
Nancy Hammond – 666
Mary Hansen – 954
Susan Hards – 40
BMB Harris – 164
Helen Haslam – 199
Raewyn Hastie – 109
Zara Hayden – 615
Louise Judith Hayne – 289
Paul Haysom – 595
Arzhela Henton – 578
Hans Herleth – 234
Richard Herrick – 479
Colin Hewens – 39
Margaret Hicks – 755
Terry Higginson – 19
D Hill and A Kleinsman – 965
Darren Hill – 923
Jesse Hinchey – 295
Amy Hindley – 548
AA Hislop – 974
FH Hoffmann – 171
Oliver Hoffmann – 950
GJ and AC Hollis – 477
Victor Holloway – 551
Caren Hopcroft – 603
Jude Horner – 814
Bernard Hornfeck – 432
Gael Hose – 852
John Howe – 462
Steven Howell – 188
Iris Huebler – 668
Hira Hunapo – 130
Jane Hunter – 828
Catherine Jackson – 622
Sandra Jacobs – 983
Darryn James – 222
Max Jobin – 290
Jan Johns – 541
Margaret Johnstone – 335
Kathy Jones – 784
G Jones – 635
Wendy Jones – 363
Dorothy Jones – 189
Peta Joyce – 200
Edwin Junker – 267
Gabrielle Kearney – 293
Mrs Kells – 287
John Kenderdine – 154
Yvonne Kendrick – 443
Megan Kendrick – 415
Rosemary Kennair – 808
LJ Keys – 250
K Khaine and T Higginson – 444
Kristen Khaine – 18
Hendrik Koch – 166
Richard Lamb – 468
Megan Kate Lang – 93
Jacinta Latta – 884
Salvatore Lauria – 204
Lucy Lawless – 317
Jane Lawrence – 564
Robyn Annette Leach – 127
Min Kyoung Lee – 640
Elizabeth Lee – 265
Baerbel Leeker – 925
Susie Lees – 746
Christine Lenk – 96
Ingrid Leproy – 305
Su Leslie – 274
Gloria Lewington – 228
Lisa Lewis – 671
Alan Liefting – 558
Joan Lockett – 932
Ian Robert Logie – 137
DM Low – 31/165
Dr Virginia Lubell – 958
Joanne MacDonald – 571
Anne MacGregor – 767
Kathleen MacLeod – 656
Angie MacNevin – 226
Yvonne Manning – 41
K Mantey-Worrall – 846
Tui Maples – 818
DJ and JM Marley – 982
Suni Marston – 815
Brent Martin – 455
John Massey – 1004
Aileen Matheson – 212
Des Matheson – 216
Jesse Matheson – 215
Roger May – 159
Dianna McAllansmith – 572
Wayne McCarthy – 238
Grant McDonald – 120
Fiona McEwen – 416
Don McInnes – 438
Billy Mckee – 352
Kathryn McKenzie – 8
Margaret McKenzie – 1005
Anna McKnight – 979
Jo McVeagh – 456
Rosemary Menzies – 294
AG Metuamate – 450
Sean Miller – 769
Sarah Millington – 943
W Mockridge – 776
Janet Moen – 275
TES and ACB Molteno – 967
Anna Moonen – 150
David Moorhouse – 569
Alfred Moroz – 288
John K Morris – 322
Valerie Morse – 203
B Mountier – 636
Neil Mountier – 190
Sonyia Moyes – 878
Jennifer Mulcock – 309
AB Murray – 152
Benjamin Naylor – 195
Eva Naylor – 885
Deborah Naysmith – 431
Cath Neale – 211
Ron Neil – 231
Raewyn Nelson – 360
Kim Newlove – 256
Anne Nicolson – 804
Leonard Ninnes – 458
Gaylene Norris – 632
GS and SL Northe – 866
Kaira Ogg – 634
Alicia Oliver – 366
Rachel Olsen – 939

Anthony Opie – 914
June Marie Orr – 502
Anna Orr – 27
Elizabeth G Orwin – 1003
Tracey Osborne – 957
Andrea Paley – 143
Viola Palmer – 229
Zara Louise Park-Eadie – 134
Wayne Parsonson – 511
David Pate – 836
Alan Peard – 161
Suzie Peek – 51
Don Pengelly – 535
June Pengelly – 534
Robyn Pengelly – 533
Jane Penton – 155
JL Peoples – 103
Ross Petersen – 960
Laine Phillips – 449
Joanna Piekarski – 12/71
Joe Polaischer – 32
Andrea Pollard – 489
Roy Powell – 838
Iris J Powell – 998
Gabriel Power – 611
Dieter Proebst – 568
Adrienne Puckey – 768
Christine Rabone – 490
Karin Rae – 516
Yvonne Raffety – 499
John and Pamela Raggett – 513
Rebecca Ranum – 997
Alana Ray – 291
Peter Raynel – 532
Denise Raynel – 531
Barbel Rehfeld – 824
Niklas Rehfeld – 829
Theresa Reihana – 15
Tom Rearton – 608
John Rhodes – 664
Ray and Jenny Ridings – 946
Macushla Rielly – 128
Patrick Riley – 627
CH Robbinson – 777
Martin Robinson – 996
Carl Robinson – 993
AG Robinson – 987
Peter Rodgers – 562
Nicholas Rodgers – 893
Lyn Rodrigue – 519
Janet Rogers – 650
Caroline Rosewood – 536
Gordon Rounthwaite – 995
Gwyenth Rowlands – 501
Sue Rowsell – 934
J Rozencwajg – 3
Amy Russell – 466
Trudy Ryan – 812
Cathy Sage – 209
Radha Sahar – 968
James Sainsbury – 679
BW Scanlen – 989
Ingrid Schloemer – 900
Volker Schloemer – 899
Gretchen Schubeck – 643
Ingrid Schupbach – 370
Jennifer Scott – 931
Patricia Scott – 986
Janine Sculpher – 478
Silvana Scungio – 799
Rhonwen Seager – 825/944
AJ Seager – 938/1011
Vivienne Seiler – 994
Christine Selby – 546
K Seligman – 970
Nina Selwood – 941
Rodney Sharp – 523
Linda Sharp – 242
Sigrid Shayer – 514
Luisa Simmons – 418
Merrill Simmons-Hansen – 205
Eugene Sims – 176
Su Sindeir – 538
Angela Smith – 539
Riuk Soedon – 2
Susan Somerville – 617
S Sontier – 920
Victoire Soochoon – 887
Christiane Sorger – 339
T Te Rangimarie-Speight Blake – 75
Charlotte Squire – 45
Worik Stanton – 350
Yvonne Steinemann – 512
Hayden Stephens – 575
Olivia Stevenson – 264
Rosalie Steward – 10
Karen Summerhays – 678
Michele Surcouf – 14
Peter Sutton – 47
Peter sven-Berger – 485
Grace Swales – 476
Maria Tabuteau – 619
Simon Tannock – 321
Marama Tate – 221
Amber Tate – 224
Stephen Tate – 225
Kelle Taylor – 395
Barbara Theinert-Brown – 557
Neil Thomas – 544
Jo Thompson – 218
Kelly Thurston – 976
Scott Thurston – 940
Anne C Todd – 163
Jill Tong – 793
Gray Treadwell – 800
Lara Treadwell – 381
JC Turnbull – 859
Eric Turner – 956
Raewyn Turner – 198
Graeme Tyree – 1000
Andrew Umbers – 587
Katrina Upperton – 990
James Valley – 843
John and Jeanne van Kuyk – 949
Joke van Staveren – 905
Eloise Veber – 837
Raymond Vogt – 283
Wayne Walker – 801
Jan Walker – 233
Marlene Wallace – 879
Louise Wallace – 550
Ralph Wallace – 261
Scott Walters – 895
Rosemarie Ward – 17
Susan Washington – 530
Mark Watkins – 631
William D Watson – 314
Denis Eric Watson – 89
Kathleen Watzig – 342
Ingrid Weihmann – 447
Sandie Wendt – 794
Betty Wheeler – 778
Fergus Wheeler – 147
Peter White – 158
James Whittaker – 374
Nichola Wilkie – 1008
Bruce Robert Williams – 202
Anna Huia Williams – 136
Melinda James Williams – 146
Mervyn Cole Williams – 981
Bruce Williamson – 139
Craig and Margaret Wills – 153
Prue Wilson – 399
James Wilson – 179
Ira and Geoffrey Wilson – 952
Celia Wilson – 894
Chris Wilson – 754
Colleen Wiltshire – 942
Kevin Withell – 369
Tania Wood – 133
Beverly Ann Woods – 780
Carol Worthington – 341
Graham Wright – 659
Nicholas Young – 43

Appendix 4: Common Text Contained in Form Submissions

Main variation 1

I oppose 'conditional release' of GE/GM organisms. Attempts to stop GM contamination with controls such as buffer zones have failed to protect conventional and organic crops in Europe and North America. No release – 'conditional' or otherwise – of GM crops should be allowed.

Or

I oppose attempts at conditional release of GM organisms. It is unacceptable to set up regulations for conditional release when it is already known that controls do not work in practice. No release – conditional or otherwise should be considered at this time.

I acknowledge the Government's decision that 'New Zealand proceed carefully and implement GM selectively and cautiously'. However release of GMOs into the environment should not be part of this policy. The Government's biotechnology strategy can be achieved through fully contained applications that meet community values and ethical standards but do not require GE organisms to be released into the environment or food chain.

The HSNO Act and regulatory process must be improved to integrate issues of ethics and culture in a decisive way. This should include a regulatory role for the Bio Ethics Council, including a power of veto. I support the inclusion of 'cultural, ethical and spiritual issues' as apart of the criteria for assessing all applications and not just part of the Ministerial 'call-in' powers.

I support a permanent ban on human reproductive cloning and inheritable genetic modification of human beings ('designer humans').

Or

Human reproductive cloning must be permanently banned. Inheritable genetic modification of human beings (designer humans) must be permanently banned.

Human cell lines and genetic modification of human material must be regulated separately from HSNO.

Or

A separate Act from HSNO is needed to regulate genetic modification of human cell lines and human material. An effective and accountable system is needed to regulate other human genetic technologies (e.g. stem cell research, pre-implantation genetic diagnosis and human somatic gene therapy).

The most cost-effective and practicable approach to managing risks is PREVENTION of contamination by approving only contained applications for GM organisms. Due to the irreversible and ongoing nature of GE contamination, no liability regime can adequately ensure full compensation and environmental cleanup. For this reason genetically-modified organisms (GMOs) must not be released into the environment.

Full liability, even for unseen damage is a reasonable way to encourage companies to comply with controls on GMOs in all situations.

Or

There must be full and unlimited liability, even for so-called 'unforeseen' damage, to encourage companies to fully control GE/GM organisms in all situations. Existing liability rules neither encourage precaution nor produce effective compensation.

Or

With respect to GMOs being handled in containment by any person, there must be full and unlimited absolute liability, even for so-called 'unforeseen' damage and damage for pure economic loss, to ensure that companies that control GE organisms are liable for all the consequences of those organisms. The burden of proof must be shifted to the defendant and there should be absolute liability for all damage, without requirement of proof and without recourse to defences such as Act of God, deliberate acts of third parties or activities which were not considered harmful according to the state of scientific and technical knowledge at the time when the activity took place. In all these cases, there is no reason that society or third parties, rather than the company, should have to bear the risk.

Commercial insurance must be required of GM companies as a normal cost of business and a moderating influence. 'Socialising' risk on the public is an unacceptable subsidy of commercial GM users. Under the principle of 'Polluter Pays' the costs of compensation and remedial action must be carried by the user to ensure reasonable standards of caution in commercial GM speculation.

I oppose the government, or the taxpayer, being the insurer of last resort. 'Socialising' risk on the public is an unacceptable subsidy of commercial GE users, unfair on the taxpayers and general public and runs contrary to the 'Polluter Pays' principle. Commercial insurance must be required of GE companies and researchers. Society and the environment should not be asked to assume a risk that commercial insurers will not assume and that industry will not accept.

Main variation 2

We are farmers who wish to make a submission to this discussion paper so that we can contribute to making a better policy for all New Zealanders. We acknowledge the Government's and the Commission's wish to proceed with caution, but believe that the only way to do that safely is in the confines of a laboratory. We hope to show you the steps that we believe necessary to control open air trials so that when and not if they impact on other people's businesses, then all parties involved in such trials should pay for all associated costs for as long as necessary.

We also wish to make it clear that we strongly disagree with our farming leaders who believe we should keep everyone's options open and that ERMA along with current laws are safe to guard all farmers. We see that you are asking for help on a lot of questions, and while we will try to cover most of them, the main ones we wish to cover are:

1. Containment/Co-Existence
2. Liability
3. Compliance
4. Public Rights for Information
5. Prions

Containment/co-existence

If buffer zones do go ahead then a minimum distance of 8 km should be required. Everyone has been concerned about the wind and the bees involvement in spreading pollen, but we are more concerned with soil contamination (i.e. horizontal transfer), where neighbouring plants pick up these new genes and carry on with their breeding processes, thereby spreading out into the buffer zones. Those who have studied the soil and how the plant root interact with the microbiology of the soil, will tell you that this is inevitable because of the exudates that plants feed into the soil where other plants are free to pick them up at will. There has been very little work done through out the world on horizontal gene transfer, but the bits that have been done all seem to confirm this, and warrant further independent studies. Many if not most of our soil scientists will confirm this worry. Can we ask what happens when the Buffer zone becomes fully contaminated with a wide range of plant species, not just those related to the GMO crops as happens with pollen transfer? Does the zone simply get extended again and again. Another containment issue is human era (sic). There are plenty of examples throughout the world of contamination of various substances due to human incompetence. Can procedure be tight enough to stop this?

Our main concern is with crops but would also like to mention GMO stock with regards to the horizontal gene transfer from their urine and dung. Who would guarantee that this can't happen? We believe there is a strong possibility that it can.

The monitoring of these buffer zones should be done by suitably qualified MAF personal (sic) (to eliminate corruption) but paid for buy those doing the experiments. Why should the taxpayer be expected to pay anything towards a private business enterprise (even Universities etc are businesses and will sell their knowledge if successful). After all if a business is able to make a saleable product, the taxpayer will pay for it again on the shelf. If not successful, why should the taxpayer lose money on someone's experiment?

Co-existence

If co-existence becomes necessary, keep in mind that there will be a range of farmers who don't want anything to do with GMO, not just the organic ones everyone is focusing on. Conventional farmers will (not may) also get their land affected or may be required to provide proof of no contamination by markets. With this in mind, we think that is more than enough of a compromise on the part of the non-GMO farmer, so the least the pro-GMO side can do is compensate for any cost incurred.

Liability

This brings us on to liability. The most effective way to make companies and individuals responsible for their actions is to make them fully liable. We need to have laws in place before any field release, setting out clear liability issues.

Remembering that in most cases these crops and experiments are for business, otherwise they wouldn't be patenting the technology, so as well as paying for the development work these businesses should also be responsible for all associated costs including cleaning of contamination no matter how many years later. The regional authorities throughout New Zealand charge companies for various monitoring work now as well as any associated cleanup costs if spills occur. The only difference is this technology is living and no one knows the time limit. They should also be responsible for lost income within a region or country due to markets not wanting contaminated products and that may also be for a number of years.

For those that are able to stay out of the GMO zone, but have to show proof of it to sell their produce, should have all those compliance costs paid for by those responsible. Why should a farmer have to prove at his/her expense that he/she has not participated in these experiments.

Perhaps compulsory insurance may be a pre-requisite to giving out licences for GMO crops and experiments.

Compliance

We think for the sake of national bio-security that a section of MAF should control a register of some sort and monitor that the companies are following procedures etc as with many existing practices. Registration of any GMO work should be compulsory with this agency.

However as stated above, any specific work carried out by the agency over and above procedural work should be charged out to those concerned, as it is a 'user pays' society now.

Public rights for information

There needs to be a very open process in place for all information associated with GMO plots. Closed doors will only create suspicion and innuendoes. We realise that with patent rights some information can be confidential, but we also believe that the PUBLIC GOOD must be put first, so a way must be found to accommodate this view.

The idea of a network of interested parties is a good one, but it needs to be both workable and cost effective. We need to have a forum where opposite views can be aired when the need arises.

Prions

If prions are the vectors used in the application of GMO technology, then yes we think the HSNO Act should include them as an organism if only to bring it into line with the Biosecurity Act.

The use of viruses as vectors in GE technology is in our view a disaster waiting to happen. Viruses are already moving freely among the public without lacing the food supply with more. Once again no one can guarantee that certain conditions won't trigger them into action.

In conclusion we hope you take this submission seriously along with the many others of a similar tone so that we can keep NZ a safer place for the next generations to come. Those of us with a basic understanding of how nature works believe that this technology is unnecessary, and in its current form, very unsafe. **So if it must be thrust upon us then lets put systems in place to protect all of our innocent people.**

Main variation 3

I do not agree that conditional release of genetically-modified organisms should occur.

It is unacceptable to set up regulations for 'conditional release' when there is already evidence available that horizontal gene transfer does occur and that 'buffer zones' do not work.

At the University of Jena, Germany, Prof Hans Hinrich Kaaz of the Institut fur Bienenkunde (bee research) found a gene transferred from rapeseed (canola, oilseed, rape), engineered to resist the herbicide glufosinate, to bacteria and fungi in the gut of honeybees.

There are many other instances of horizontal gene transfer occurring, so we do not need to waste taxpayers money researching it further.

Despite industry assurances that 50 metre buffer zones are adequate, the UK National Pollen Research Unit and the Federal Agency in Austria have shown canola pollen can drift at least 4.5 kilometres. Thus the use of 'buffer zones' between genetically engineered and organic crops mentioned in the recommendations of the Royal Commission on Genetic Modification Report (utilising fencing, plastic sheeting and netting) is deemed unworkable. Human error could easily occur where pollen could escape easily and horizontal gene transfer has been found to occur from plants into soil micro-organisms which cannot be fenced in. Micro-organisms, birds, pollen and bees do not recognise buffer zones.

Research since 1996 has shown pollen from transgenic herbicide resistant canola can cross-pollinate with weeds to create 'superweeds' which require more spraying not less. Knowing this fact, it is unethical to allow this situation to occur. It may well be nice for the spray manufacturers to make more money from selling spray but it is not fair to the farmer who will incur more costs because of having to use ever more hazardous sprays.

I do not agree with any commercial release of GMOs into the open environment because of the risks attached. I only agree with research within the laboratory in a controlled and contained manner.

Insurance companies will not insure against the effects of GE crops and no Government has legislation on liability. Who will pay when mistakes occur as they have overseas? No doubt the taxpayer, and farmer. It is unethical, and irresponsible to allow such a scenario to occur and no person worthy of being a New Zealand citizen would allow it to occur.

Professor Joe Cummins, Professor of Genetics at the University of Western Ontario, London, Ontario, Canada, states the following safety considerations for humans and for the environment:

- spread of virus disease due to cauliflower mosaic virus being used in the process of
- generic engineering which is prone to recombination to produce novel plant viruses
- synthetic genes
- food allergy and autoimmune disease
- antibiotic resistance
- creation of toxins in soil ecology

Due to the above safety issues I regard the use of genetic engineering in the open environment in New Zealand as unacceptable because of both known evidence and unknown dangerous consequences of this technology and New Zealand and New Zealanders should not be used as guinea pigs.

Overall genetically engineered crops have not shown themselves to have higher yields than what we presently have with traditional crops. Our main market is the European Union and they want GE free food. Thus it is stupidity itself to produce GE food that has safety issues attached to it as well as there being no market for it. Even most New Zealanders do not want to eat it.

Human reproductive cloning must be permanently banned.

Inheritable genetic modification of human beings (designer humans) must be permanently banned.

Human cell lines and genetic modification of human material must be regulated separately from HSNO. An effective and accountable system of regulation needs to be developed for all other human genetic technologies, for example stem cell research, pre-implantation genetic diagnoses and human somatic gene therapy etc through widespread consultation.

The most cost-effective and practicable approach to managing risk is PREVENTION of contamination by approving only contained applications for GM organisms.

Full liability even for 'unforeseen' damage is a reasonable way to encourage companies to comply with controls on GMOs in all situations. Existing liability rules will neither discourage precaution nor produce effective compensation.

Commercial insurance must be required of GM companies as a normal cost of business and a moderating influence. 'Socialising' risk on the public is an unacceptable subsidy for commercial GM users. Costs of compensation and remedial action must be carried by the user of the GMO who caused the harm to ensure caution in commercial GM speculation.

Much money is to be made by the production of genetically engineered proteins, enzymes and medicines in containment within the laboratory. Much money is to be lost by letting the technology out into the open environment where both known and unknown consequences will occur and with the loss New Zealand's clean green image (which is worth billions). Liability issues are a nightmare waiting to happen. I therefore consider that common sense should prevail and that this technology should be kept in the laboratory and not allowed out into the open environment.