Office of the Minister for the Environment

The Chair, Cabinet

Government Response to the Royal Commission on Genetic Modification: Legislative changes for new organisms – Paper 1 Overview

Executive summary

1. This paper provides the overview and context for a set of papers recommending legislative changes to several Acts as part of the government's response to the Royal Commission on Genetic Modification. These papers make recommendations on the basis of public consultation on a series of proposals for amendments to the Hazardous Substances and New Organisms Act to improve the operation of the Act for new organisms. This consultation attracted over 1000 submissions from a broad range of stakeholder groups and private individuals and provided a very diverse set of views on the way forward in managing new organisms.

2. The papers in this suite recommend a series of changes to law focused on providing a practical framework for proceeding with caution in the management of new organisms (including genetically modified organisms) while preserving opportunities.

3. Within this overall direction, the changes proposed are:
   - Ensuring comprehensive and strict regulation by addressing any omissions in the regulatory system
   - Streamlining of the process of approving laboratory work
   - Streamlining procedures for assessment and approval of medicines that are or contain new organisms, including approvals to deal with emergency situations
   - Providing for conditional release of new organisms within a cautious and case-by-case framework
   - Strengthening the machinery for enforcement and incentives to comply with HSNO Act in relation to new organisms

In addition, changes to improve the overall effectiveness of the operation of the HSNO Act for new organisms are proposed.

4. This paper also advises on progress towards developing amendments to the HSNO Act to meet the government's stated intention to better reflect the Treaty relationship between Maori and the Crown in the Act.

Introduction and background

5. In late 2001 the government responded to the Royal Commission Report on Genetic Modification (RCGM). A significant element of this response was to direct officials to proceed with amendments to the Hazardous Substances and New Organisms (HSNO) Act and related Acts. Early in 2002 a set of proposals for legislative change were drafted and approved by the government for consultation (CAB Min (01) 33/22 refers). Included were a number of matters not directly related to the government's response to the Royal Commission but intended to improve the overall operation of the HSNO Act as regards new organisms. The

Minister for the Environment was invited to report to POL by 31 January 2003 with proposals for amendments with a view to introducing a Bill in March 2003.

6. This paper provides the overview and context for a suite of 7 papers setting out these proposals for amendments to the HSNO Act and to a number of related Acts including the Medicines Act and Agricultural Compounds and Veterinary Medicines (ACVM) Act.

7. These proposals need to be read in the context of the government's overall response to the RCGM report, including:

- The recent formation of a Bioethics Council Toi te Taiao (CAB Min (02) 32/3A refers)
- Evaluation of the possible economic effects of use of genetic modification in New Zealand production systems (due for report in March 2003)
- The setting up of research programmes to investigate environmental and social effects of genetic modification 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

These items were reported on in detail in the 'stock-take' of the government's response to the Royal Commission considered by Cabinet in September 2002 (CAB Min (02) 24/6 refers) and are scheduled for update on 30 April 2003.

Strategic context

8. In responding to the Royal Commission's report, the government accepted the Royal Commission's overall direction of proceeding with caution while preserving opportunities.[1] This was set out explicitly in the Speech from the Throne, which stated:

> "The Royal Commission on Genetic Modification recommended a precautionary approach which preserved options for the future. My government endorses that approach. For that reason, the existing legislation with respect to the moratorium on the commercial release of GM organisms will not be extended but a strict regulatory framework will be maintained."

9. The government has also agreed a strategic direction for growth and innovation, within which biotechnology is one of the three identified areas of strategic priority. As part of this work the Biotechnology Task force is expected to report in February on reducing the barriers to the growth of the biotechnology sector in New Zealand. In addition, the government has recently agreed to a sustainable development strategy, which includes among its principles:

- Seeking innovative solutions that are mutually reinforcing rather than accepting gain in one area will necessarily be achieved at the expense of another

- Addressing risks and uncertainties when making choices and taking a precautionary approach when making decisions that may cause serious or irreversible damage

10. In most cases implementing the idea of proceeding with caution while preserving opportunities in practice applies generally to new organisms as well as specifically to

[1] The Royal Commission's report states "We favour a strategy of preserving opportunities and proceeding selectively with appropriate care" (Report of the Royal Commission on Genetic Modification Chapter 13 Major Conclusion: Preserving Opportunities)

genetically modified organisms. Accordingly, these proposed changes to legislation reflect that fact.

Overview and key perspectives

11. The Royal Commission reported that the basic regulatory framework for managing GM organisms is appropriate and the key institutions ERMA and ANZFA (now called FSANZ) are carrying out their functions conscientiously and soundly. This present framework for managing genetic modification is summarised in Annex 2. It therefore made no recommendations for changes to the basic structure of the law or the institutions but did recommend some enhancements. The government however chose to put in place a temporary moratorium on the ability to apply for approval to release GM organisms so that it could do the work recommended by the Royal Commission. This restricted period expires in October 2003 and, as noted above, the government has clearly signalled its intention to allow this to happen. In response to the proposals for these enhancements, views in the community vary from those who consider that the present regulatory framework for GM is inhibiting growth and economic development to those who consider that the moratorium on releases should be extended, at least until more is known about the underlying science in general and the environmental effects in particular.

12. The Royal Commission concluded that "there are aspects of genetic modification that we consider positive and useful"[2] and this conclusion is reinforced by recent developments in areas such as medicines (where the products from genetically modified organisms are in routine use (e.g. insulin) and living organisms as medicines are clear possibilities (e.g. recent advances in vaccines)) and in pest resistance for crops (a number of such crops are in common use elsewhere, while many of these particular crops may not be of significant use in New Zealand, others may be) as well as possibilities in areas such as pest control. Recent survey work undertaken for ERMA[3] shows that many in the community see these and other areas including; improved yields, reduced use of chemicals in agriculture, and New Zealand's remaining competitive and innovative in our key biologically based industries as major potential advantages. Many of these advantages were also seen as coming from new organisms generally. (The same survey also identified risks such as: potential impact on organic production; and possible impacts on the New Zealand image.)

13. These factors suggest that the government's position of proceeding with caution while preserving opportunities remains a sound approach. Putting this into practice will require both the opportunity to consider releases with conditions and the necessary strict regulatory framework to evaluate risks and benefits and to impose and enforce those conditions. Accordingly the central theme of the proposed changes to law set out in these papers is to provide a framework for making this critical balancing act work in practice.

14. The key elements of this framework are

a) Addressing omissions in the legislation, which have arisen from increased scientific knowledge since the HSNO Act was passed in 1996. This will ensure effective and precautionary judgements can be made for GMOs and when new organisms are introduced to New Zealand.

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[2] Report of the Royal Commission Ch 13: Major Conclusion

[3] Awareness of New Organisms Issues and ERMA 2002 General Public Survey, Reported August 2002 Conducted for the Environmental Risk Management Authority by Network Communications Australia/New Zealand, Public Relations Consultants. (Available on the ERMA NZ Website)

b) Streamlining the processes for approval of genetic modification work in the fully contained laboratory situation. Much of the basic scientific work involving GM is now well enough understood and containment standards are sufficient to allow for approval of overall project work rather than the present situation under which organisms and modifications must each be examined individually. This change should further improve the ability of researchers to identify and develop new opportunities in biotechnology.

c) Streamlining the processes for approval of new organisms that are also medicines. Such changes should mean better access to new medical technologies while allowing assessment, and if necessary regulation, of the organisms (e.g. vaccines) for their possible impact beyond the patient. Similarly, improving the systems for approval of medicines in emergencies will improve our readiness to deal with these.

d) Providing for conditional release of new organisms. Officials advise that this Royal Commission recommendation be proceeded with, but conditional release be implemented in the Act as an extension of the existing release category rather than a separate approval category as envisioned by the Royal Commission. The HSNO Act amendments would also provide overall direction on the circumstances and conditions under which conditional release can be approved.

e) Strengthening the machinery for compliance and enforcement where new organisms are subject to controls. Firstly officials consider that the powers and responsibilities currently provided in the HSNO Act for enforcement should be explicitly extended to provide for enforcement for new organisms, including explicit consideration of: enforcement for containment, detection and action on unauthorised new organisms, and enforcement of conditions on conditionally released organisms. Secondly, although there is no principled basis for special liability rules solely for GM, incentives to comply with HSNO Act could be strengthened by providing for strict civil liability for harm caused by non-complying activity (complying activities would remain subject to the current law), and a civil penalty regime for certain breaches of the HSNO Act.

f) Extending the Minister's ability to call in specific applications to include significant cultural, ethical and spiritual effects.

g) Improving the operability of the law through a number of provisions including clarifying the circumstances and procedures for protection of confidential supporting information, completing the transfer of controls on animals in zoos and similar facilities, and amending operational details such as providing more realistic time limits and procedures for dealing with containment decisions.

15. A related paper from the Minister of Agriculture will be provided shortly and advise on a number of key issues which need to be addressed in making coexistence between GM and non GM primary production work in practice.

16. Using this framework effectively means both providing sufficient guidance in the legislation and making effective use of those expert bodies already set up (e.g. ERMA, the New Zealand Food Safety Authority (NZFSA) and MedSafe). A balance needs to be struck between providing appropriate guidance to expert bodies while at the same time allowing them the flexibility to implement the legislation in the most appropriate way. This theme is reflected in this suite of policy proposals.

Views in submissions

17. In most cases, submissions to the public discussion document addressed the matters raised in the document. These matters are discussed in detail in the papers that make up this suite. However, several other matters were raised. These matters are briefly set out in the following paragraphs, and detailed further in annex 1.

18. A large number of submissions, many identical or nearly identical, made comments from different perspectives about the need to retain a 'GE free status' for New Zealand. These comments varied from outright rejection of genetic modification through recommendations to prohibit certain uses of genetic modification or permit only certain uses. For example, submissions stated that medical use might be acceptable but that use in food products was not. Another common theme was that genetic modification in the laboratory was acceptable but that the risks of moving any GM organism out of containment were too large.

19. At the opposite end of the spectrum, those involved directly or indirectly in agriculture or the seeds business consider that an outright prohibition on unapproved GM organisms is too strict and may make coexistence impractical. Submissions making these comments pointed to the impossibility with current technology of detecting very low levels of GM contamination. Regardless of whether or not GM crops are grown in NZ, these groups consider the lack of a workable threshold in relation to unintended (adventitious) contamination of imported and domestically produced seeds to be both economically damaging and environmentally unnecessary. In general some form of legislated threshold based on an assessment of environmental risks was requested in place of the current position. These submissions also pointed to trigger levels of GM ingredients used in regulating food elsewhere in the world for support of this concept.

20. Neither of these positions is recommended, and for similar reasons.

21. A blanket prohibition on a whole class of new organisms, especially given the proposed ability to provide controls through conditional release, does not allow for the case-by-case evaluation and management of the risks and opportunities that provides for ***proceeding*** with caution. In reality New Zealand is not 'GE free' in that, while there are no live GM organisms permitted outside contained research situations, living organisms are routinely part of many types of research and the results of genetic modification are approved for use in food and medicines. New Zealand has in place effective and comprehensive systems for management of GM, which will be further strengthened by the proposals in these papers. New Zealand also has set in place an expert body with the ability to deal with the decisions needed for case-by-case consideration of new organisms generally. This body is presently being reviewed to ensure that it is able to deal effectively with the work required of it. Officials were satisfied that coexistence was a practical option, and submissions did not provide justification for rejecting it.

22. On the other hand, allowing some form of acceptable 'threshold' is to accept release without assessment of a new organism. Allowing the release of a genetically modified organism (or a new organism) without the opportunity for case-by-case assessment would be contrary to the fundamental approach in the HSNO Act. The arguments put forward in submissions did not provide sufficient justification for such a fundamental alteration.

23. The issue of the adventitious contamination of seed shipments is an international issue, which will continue to arise as new varieties of GM crop plants are approved and used

around the world. New Zealand will need to maintain an overview of the scale of the issue and the international responses taken by our trading partners to address the problem.

Maori perspectives

24. Most Maori submitters expressed frustration at what they saw as inadequate time and opportunity for consultation, both on these proposals and on GM policy matters in general. Many submissions expressed opposition to genetic modification, or sought extreme caution in its regulation. These submissions also expressed concerns about the risks to New Zealand's biodiversity from GM organisms. Other issues attracted little comment from Maori. Other matters seen as important by Maori included the formation of the Bioethics Council, amendment to Ministerial Call-in and strengthening Treaty of Waitangi provisions in law. This latter issue is being considered by the Ministers' Maori Reference Group.

Treaty of Waitangi provisions in the HSNO Act

25. The government stated, when consulting on the proposed law changes outlined in this paper, that it was appointing a Maori Reference Group to advise it on amendments to the HSNO Act to better reflect the Treaty relationship between Maori and the Crown. This group was appointed in early December 2002 and first met on 17 December 2002. It has expressed extremely strong concerns about the short time available in which to provide advice to Ministers, given the government's intention that these Treaty-related amendments should be in the bill as introduced. The group is working through January 2003, and will provide advice to government by mid-February 2003.

26. I consider that the Maori Reference Group should be provided with the best possible opportunity to provide the advice we have asked them for. Accordingly I recommend that Ministers agree to consider advice from the group in a separate paper in late February 2003. This will require separate instructions to the Chief Parliamentary Counsel for drafting these provisions, but provided the work is accorded high priority and the amount of additional drafting is not large, this should allow a completed bill to be available for introduction by the end of March.

Timetable implications

27. Cabinet previously agreed to consider final proposals for these amendments in January 2003 and agreed an indicative timetable for progressing these amendments (CAB Min (02) 24/4 refers). This indicative timetable has been reworked on the basis of officials' best estimates of the likely minimum time required for the remaining steps. The revised timetable is set out in Annex 3 and indicates that the timeframe for completing this work remains tight, and that in particular the time available to draft a Bill for introduction is extremely limited. As a result, the Parliamentary Counsel Office will need to give drafting of the Bill high priority. A submission for legislative priority for the Bill will be considered shortly as part of the setting the 2003 legislative programme.

Financial implications

28. There are no financial implications associated with this paper. Some papers in the attached suite may have financial implications and these are outlined in the specific papers.

Human rights

29. The proposals need to be assessed for compliance with the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993. This assessment will be possible once the detail of the proposals has been developed and, in particular, once implementing legislation has been drafted. Officials from various agencies responsible for this suite of papers will continue to work with officials from the Ministry of Justice in this regard and these matters will be reported as part of the presentation of a draft bill to LEG.

Legislative implications

30. The proposals in papers 2-7 of this suite are policy for a bill amending several acts with the common objective of improving the management of new organisms to put into practice a way forward which seeks to proceed with caution in dealing with new organisms (including genetically modified organisms) while preserving opportunities for New Zealand. A separate bid for legislative priority for this bill is before LEG for consideration. Legislation will be binding on the Crown.

Regulatory impact and compliance cost statement

31. There is no Regulatory impact and compliance cost statement attached to this paper, as it does not propose any legislative change. However, the detailed recommendations for legislative change set out in other papers will in some cases have compliance cost implications and/or require regulatory impact statements. These are contained in or attached to the particular papers.

Gender implications

32. There are no gender implications associated with this paper.

Disability perspective

33. There are no disability perspective implications associated with this paper.

Publicity

34. There will be considerable interest in the decisions made about changes to legislation. Accordingly I recommend that announcement of these decisions be made by relevant senior government ministers as soon as practicable after these decisions are made. These announcements will be supported by a package of material for interested parties and the release and publication on relevant websites of the papers in this suite, along with the decisions made by the government.

Consultation

35. This paper is based on an extensive public consultation process. Submissions were 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"*. Officials encouraged submissions by attending meetings organised by a wide range of different stakeholder groups. In addition, seven hui were held for Maori and detailed notes taken by officials. Group and individual submissions on the discussion document were also received from the Maori community. All submissions

have been considered in preparing this paper and a detailed summary of submissions is in preparation by an independent contractor for publication.

36. The following agencies were consulted in the preparation of this paper; Ministry of Agriculture and Forestry, Department of Conservation, Ministry of Economic Development, Ministry of Foreign Affairs and Trade, Ministry of Health Ministry of Justice, Department of Prime Minister and Cabinet, Ministry of Research Science and Technology, Te Puni Kokiri, the Treasury, the Environmental Risk Management Authority, and the New Zealand Food Safety Authority.

Recommendations

37. It is recommended that Ministers:

a) **Note** that the Minister for the Environment was invited to report to POL by 31 January 2003 with proposals for amendments to law as a result of public consultation or proposals for public discussion which:

   i) Form part of the government's response to the Royal Commission on Genetic Modification
   ii) Provide for improving the operation of the Hazardous Substances and New Organisms Act for new organisms

b) **Note** that this is the first of 7 papers setting out proposed amendments to the Hazardous Substances and New Organisms and related Acts; other papers in this suite are:

   i) Paper 2: Laboratory Research, Cloning, and Human Cell Lines
   ii) Paper 3: Streamlining the Approval Process for Medicines That Are or Contain New Organisms
   iii) Papers 4: Conditional Release and Enforcement
   iv) Paper 5: Liability Issues for GM
   v) Paper 6: Ministerial Call-in and Confidential Supporting Information
   vi) Paper 7: Improving the Operation of the HSNO Act for New Organisms Including Zoo and Circus Animals

c) **Note** that the Minister of Agriculture will also shortly provide a paper describing the practicalities for coexistence of GM and Non-GM primary production

d) **Agree** that the overall purpose of the amendments to law in these papers is:

   i) To provide a practical framework for proceeding with caution in the management of new organisms (including genetically modified organisms) while preserving opportunities
   ii) To increase the effectiveness and practicality of the HSNO Act for new organisms

e) **Note** that the components of this framework are:

   i) Ensuring comprehensive and strict regulation by addressing omissions in the regulatory system
   ii) Streamlining of the process of approving laboratory work.

iii) Streamlining procedures for assessment and approval of GM organism medicines, including approvals to deal with emergency situations
iv) Providing for and setting out directions for conditional release of new organisms
v) Strengthening incentives to comply with HSNO Act in relation to new organisms
vi) Technical amendments designed to improve the operation of the Act, including enhanced Ministerial call in and improved procedures for management of confidential supporting information

f) **Note** that the government has previously signalled its intention to introduce a Bill based on papers 2-7 of this suite by the end of March 2003 and to complete the necessary legislative changes within the constraint period ending on 29 October 2003, and that the timing to achieve this remains tight

g) **Agree** to the updated indicative timetable for progressing the legislation as set out in Annex 3

h) **Invite** the Minister for the Environment to provide drafting instructions to Parliamentary Counsel covering the agreements from papers 2-7 of this suite with a view to having a Bill available for introduction by the end of March 2003

i) **Note** that following agreement at the time of the government's response to the Royal Commission on Genetic Modification, a Maori Reference Group was appointed in early December 2002 to advise Ministers on amendments to the Hazardous Substances and New Organisms Act 1996 (HSNO Act) to better reflect the Treaty relationship between Maori and the Crown

j) **Agree** that the Maori Reference Group should be provided with the maximum possible time to complete their advice consistent with the need for an amendment bill to contain amendments to better reflect the Treaty relationship between Maori and the Crown

k) **Note** that the Maori Reference Group will report to Ministers by 20 February 2003

l) **Invite** the Minister for the Environment to report to Cabinet Policy Committee by 28 February with proposed amendments in relation to the Treaty relationship to be included in the bill for introduction in March 2003

m) **Agree** that the papers in this suite be made publicly available as soon as practicable after decisions have been taken, and announced by the relevant Ministers

Hon Marian L Hobbs
Minister for the Environment

Annex 1

Key views from stakeholder communities

Submissions received

1011 submissions were received by the closing date for submissions for 15 November 2002. Of these approximately 80% were largely identical 'form' submissions. These appear to have been generated from standard paragraphs on one or more websites and submitted by private individuals, who in some cases added further specific comments. These submissions generally did not directly address the specific issues raised in the discussion document. Rather they expressed opposition to the use of genetic modification outside the laboratory in general and the idea of conditional release in particular. These submissions also sought full and unlimited liability even for unforeseen harm caused by GM organisms.

The remaining submissions for the most part provided specific comment on some or all of the specific matters raised in the discussion document. These submissions can broadly be characterised as coming from the following sources:

- Private individuals
- Universities
- The Science/ Research Community
- Medicines and Veterinary Medicines Supplier
- Agribusiness/ Forestry Sector
- Organics Producers
- Local Authorities
- The Environmental Movement
- Religious and ethics related groups
- The Maori Community

A much more detailed summary of submissions has been prepared by an independent contractor for publication. A brief summary of the key views from various communities is set out below.

Universities

Most universities provided comments on the proposals. These comments generally supported the proceeding with caution while preserving opportunities approach. However, most universities were unhappy with the detail of controls on GM developments in the laboratory and sought less restrictive controls on laboratory work, with some going as far as to suggest separation of regulation of genetic modification from other aspects of new organisms management. This group was also generally concerned about the practical difficulties they face when consulting with Maori and they sought various ways to streamline or remove what was seen as the burden of these requirements.

Science/Research organisations

These organisations also considered that the regulation of laboratory work is presently too restrictive and supported proposals for streamlining such processes (e.g. project based approvals, ability to delegate approval of imports of GM organisms). Organisations in this sector also generally supported the conditional release proposals and recommended no change

to present liability arrangements. Some considered that the regulatory regime could be strengthened to encourage precaution. This group also expressed concerns about the risks of information being inadvertently made available to competitors and sought more protection for information submitted with applications for approval.

There were also general expressions of concern that the present system for regulating GMO developments is over-prescriptive and was discouraging innovation. Accordingly this group sought streamlined approval processes (e.g. for medicines) and the removal of what was seen as artificial constraints on fermentations using new organisms.

Medicines suppliers

Submissions from this group largely focussed on support for various ways of streamlining the approval of medicines and/or veterinary medicines. In general this group favoured less consideration of environmental risks from medicines arguing that such steps were not necessary given the safety of modern medicines.

Agribusiness sector

Submissions from this sector expressed strong views that the present regulation of new organisms is unnecessarily inhibiting economic growth. Accordingly the submissions were in favour of decreased regulation of laboratory work, with one suggestion that such work was by definition low risk and should be unregulated providing it was contained. Submissions in this group also supported streamlining of approval procedures (e.g. for medicines) and the provision of conditional release, but did not consider it necessary to extend liability rules.

In common with the research and medicines supply communities; these submissions recommended that work using human cell lines should be regulated. They also advised that MAF's role as enforcement agency in respect of new organisms be formalised. Submissions in this group also sought further assurances about the protection of confidential information.

Organics producers

Submissions from organics producer groups expressed fears about the effects on their business if GM organisms were permitted out of the laboratory and sought to have the present moratorium extended until these concerns could be dealt with to their satisfaction. These submissions sought measures to allow local authorities to create GE-free zones and recommended extended liability rules to encourage precaution in the use of GM organisms. Some of these views were also shared by beekeepers.

Local authorities

Submissions in this group were largely from territorial authorities. Most sought the ability for local areas to be GE free while generally supporting the concept of strictly controlled conditional release. These submissions also expressed concerns about coexistence between GM and non-GM based agriculture and considered that monitoring was both critical and beyond the resources and skills of local authorities. As a result these submissions generally expressed unwillingness for local authorities to be involved in enforcement with respect to new organisms and recommended that MAF be formally given this role.

Environmental groups

Submissions from environmental groups were opposed to release of GM organisms conditionally or otherwise. This opposition was based on the view that knowledge about GM organisms was insufficient to allow release. In the event that the moratorium was allowed to expire these submissions considered that any release should be preceded by detailed evaluation of environmental effects in the laboratory. These submissions also favoured full and unlimited liability even for unforeseen harm caused by GM organisms and supported compulsory insurance and bonds for those using GM.

Religious and ethics groups

Submissions from these groups presented a number of diverse viewpoints ranging from distrust of the science community to acceptance that scientists should be given greater freedom (i.e. less restrictions) for management of laboratory work and cautious support for conditional release. These submitters drew particular attention to the need to consider cultural and spiritual matters in GMO decisions as well. One submitter considered that stricter liability rules are required to encourage precaution and provide compensation. Submissions in the group also recommended streamlining medicines approval procedure on the grounds that this would maximise the availably of medicines.

Maori community

Written submissions from Maori organisations and records from hui expressed a strong view that the level of consultation and time provided was inadequate given the complexity of the issues raised. This was coupled with a frustration about a paucity of information available to Maori and that Maori community views were not taken seriously or considered early enough either in policy formation or in decision-making about genetic modification. Many submissions expressed opposition to genetic modification and sought strengthening of the obligations in law in respect of the Treaty of Waitangi.

Beyond this, these submissions took the view that any use of genetic modification should be done very cautiously, under strict regulation and in full and early consultation with Maori. Some suggested that liability rules and regulatory mechanisms be extended in order to encourage precaution.

Annex 2

New Zealand's present framework for managing genetic modification

New Zealand currently controls genetic modification by:

1. Treating genetically modified organisms as new organisms under the HSNO Act

Applications to import, release or develop a viable GMO in containment is governed by the HSNO Act, the purpose of which is to protect the environment, and the health and safety of people and communities by preventing or managing the adverse effects of hazardous substances and new organisms. An application for importation, release or development in containment must be made to ERMA. A specific (case by case) approval is required for:

- Developing or importing an organism in a laboratory
- Field-testing an organism; field tests allow the organism to be tested under New Zealand environmental conditions in strict containment. Controls are imposed to prevent the organism, or any viable parts, leaving the location during or at the conclusion of the test
- Any release into the environment. Currently an approved release must be without controls

Application for a contained field test

ERMA can only approve an application if it is satisfied the GMO can be adequately contained. This requires the Authority to consider the organism's ability to escape and establish a self-sustaining population and the ease with which the GMO could be eradicated in the event of an escape. It must be satisfied that the beneficial effects of having the GMO in containment outweigh the adverse effects of the GMO should it escape. ERMA places strict containment controls on an approved field test application to minimise the risk of escape. These controls were further strengthened when the HSNO was amended in May 2002.

Application to release a GMO

An amendment to the Act in May 2002 restricts release of GM organisms to applications for those organisms that are also medicines or veterinary medicines. This provision expires on 29 October 2003. No applications for release have been made to date. An application for release must pass the following tests otherwise ERMA must decline it:

- *Minimum standards:* the organism must not cause any significant deterioration of natural habitats; any displacement of any native species within its natural habitat; any significant adverse effects on human health and safety, or on New Zealand's genetic diversity; and must not cause a disease or become a vector for human, animal or plant disease.
- *Cost benefit analysis:* it must be shown that the positive effects of the organism outweigh the adverse effects.
- *Irreversibility:* as with contained field test applications, ERMA must also have regard to the ability of the GMO to establish an undesirable self-sustaining population, and the ease with which it could be eradicated if such a population was established.

ERMA must have sufficient information to assess all these factors and be satisfied the criteria are met. An application must be declined if this information is not made available.

For all applications, ERMA must take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects as well as the

principles of the Treaty of Waitangi, the relationship of Maori and their culture and traditions with ancestral sites and taonga.

Application process

Release applications must be publicly notified and public submissions called for.

Potential applicants generally enter into discussions with ERMA before making an application. At this time, significant information requirements or gaps in the application are identified. Applicants then have the choice of either not proceeding with the application until the required information is available or to proceed with the application with the knowledge that it is highly likely that the application will be declined.

2. Requiring medicines be approved before general sale

This includes both medicines derived from GM organisms (e.g. insulin or hepatitis B vaccine) and medicines that are live organisms (e.g. some cholera vaccines).

Medicines are assessed for safety and efficacy by the Medicines Advisory Committee (MAAC) using international guidelines. MAAC is supported by Medsafe, a business unit of the Ministry of Health.

3. Pre-sale approval by the Australia and New Zealand Food Regulation Ministerial Council and labelling of all foods with genetically modified content

The sale of foods produced using gene technology is prohibited unless they have been assessed for safety by Food Standards Australia New Zealand (formerly ANZFA) and approved by the Australia and New Zealand Food Regulation Ministerial Council (formerly the Australia New Zealand Food Standards Council). At present, 20 such have been approved for sale in New Zealand and Australia.

In addition, all foods containing genetically modified material DNA or protein, or having altered characteristics must be labelled. There are exemptions for flavours present in 0.1% or less, and for food prepared in restaurants and takeaways. Unlabelled food found to contain 1.0% or less of genetically modified DNA or protein does not breach the food standard if its presence is unintended.

4. Dual approval

Foods or medicines that are themselves viable organisms would require both HSNO Act approval and the requisite usage approval (food, medicine etc). Examples of this would include GM grain imported for processing (e.g. milling to flour), which would require assessment by FSANZ and approval by ERMA, or a GM live vaccine which would require approval both through Medsafe and ERMA.

Annex 3

Indicative timetable for new organisms amendments

Step (in reverse)	Estimated timing	Comments
Amendments in force	By 29 October 2003	
Amendment passed into law (includes 3rd reading, committee of the whole etc)	September 2003	
Select Committee process including: • Submissions period • Hearing of submissions • Consideration, deliberation and report	Mid-April 2003 – end August 2003	Assumes a substantial volume of submissions and the number of people wishing to be heard requiring hearings in several centres.
Bill introduced & referred to select committee	By mid-April 2003	The House is not timetabled to sit in the 3rd and 4th weeks in April 2003
Cabinet approval for introduction of Bill	Early April 2003	
Drafting instructions and Bill drafted	February – March 2003	
Maori reference group reports & decision on providing for the Treaty of Waitangi in the HSNO Act	By end February 2003	Further Cabinet decision required
Cabinet decisions on policy for the Bill excluding Treaty matters	End January 2003	Decisions on these papers
Final amendment proposals developed excluding Maori reference group advice on Treaty matters	November 2002 – January 2003	Papers in this suite
Public consultation on proposed amendments	*30 September – 15 November 2002*	*Completed*
Discussion document distributed	*30 September 2002*	*Completed*
Cabinet approval of proposals for amendment (including coalition consultation)	*Mid-September 2002*	*Completed*