

Chair
Cabinet

ROYAL COMMISSION ON GENETIC MODIFICATION: GOVERNMENT RESPONSE

Executive Summary

1. This paper discusses the government's overall response to the Report of the Royal Commission on Genetic Modification. It recommends that the government support the overall strategy of 'preserving opportunities' suggested by the Commission, but that the government does not accept all of the Commission's proposals on how to implement that strategy.
2. The paper outlines the government's intention to implement the strategy through a constraint period on commercial release, enhancements to the criteria for contained research and through work on other key recommendations.
3. The paper also covers financial implications of the proposals in this paper, an indication of timing and process for next steps, and a communications strategy.

Overview of Royal Commission's proposed direction

4. The Royal Commission's report explicitly rejects both the "New Zealand free of all genetically modified material" and the "unrestricted use of genetic modification" extremes. They note that "genetic modification has been used freely in New Zealand for more than a decade" particularly for research and medical purposes.
5. The major theme of the Royal Commission report is "Preserving Opportunities". The Commission believe it would be unwise to turn our back on the potential advantages on offer from genetic modification but New Zealand should proceed carefully and implement genetic modification selectively and cautiously, minimising and managing risks.
6. The Commission looked closely at the existing institutional structures dealing with GM technologies, and was satisfied that the basic regulatory framework (including the Hazardous Substances and New Organisms (HSNO) Act) is appropriate, but should be fine-tuned to enhance the rigour and integrity of the system and facilitate the proceed with caution approach. To recognise the significance of the first application for commercial release of a GM crop, the Commission recommended that the Minister for the Environment exercise her call in power to assess its economic and environmental impact.
7. The Commission felt that the existing regulatory bodies were not best placed to address ethical issues surrounding genetic modification, particularly those raised

by Maori. To this end they proposed the creation of Toi Te Taiao, the Bioethics Council.

8. The Commission also acknowledged that there were significant gaps in knowledge on the environmental, socio-economic and ethical impacts of the release of genetically modified organisms. It suggested research funding should be directed to these areas.

Overview of Government's response to RC direction

9. The government is primarily concerned about the health and safety of all New Zealanders and their environment. As such I want to take a precautionary approach as to how to proceed with genetic modification. In this context the government supports the Commission's overall strategy of preserving opportunities. I consider the report is a balanced and thorough consideration of the issues.
10. However, I propose that the government should come to different conclusions as to how the Commission's strategy of preserving opportunities should be best implemented. The differences occur in two areas:
 - the extent to which commercial release should be possible in the immediate future; and
 - the conditions under which research should be able to proceed.
11. The Royal Commission has made a series of recommendations concerning research, economic and strategic analysis, amendments to the HSNO Act and the creation of the Bioethics Council. The Commission's approach does not suggest that they considered that applications for the release of GMOs needed to be held up until the work they had recommended has been completed or the research programme established.
12. In accordance with the precautionary approach, I believe that there is a need to constrain the release of genetically modified organisms (with limited exceptions) for a period while the work, analysis and research identified as necessary by the Commission is underway. I do not consider that the Commission's recommended use of the call in provision is the appropriate mechanism to implement a 'proceed with caution' approach. The recommended purpose, scope, duration and implementation of the constraint period are outlined below.
13. The government supports the Commission's conclusion that the regulatory framework governing research involving genetic modification is sound. I believe that the case-by-case approach taken by ERMA, supported by the range of containment provisions provides a strict and rigorous regime. However under the legislation, ERMA has some discretion to determine all the conditions to be applied to approved research. I believe that there is a need to clarify its expectation that all research must meet strict safety standards. To this end, I recommend that legislation be amended to require specific conditions to be applied to any approval to ensure environmental and health safe guards.

Implementation of Government Response

Constraint Period on Commercial Release

14. It is proposed that the government legislate to ensure that no applications for release of GMOs are possible in the immediate future.

Purpose

15. The purpose of the constraint on release of GMOs is, in accordance with the precautionary approach, to allow time to:
 - establish and/or continue research programmes to address areas of socio-economic, ethical, environmental and agricultural research which were identified by the Royal Commission as needing additional work;
 - put in place appropriate amendments to the HSNO Act (and related Acts) and regulations to meet the concerns raised by the Commission;
 - establish a Bioethics Council;
 - complete generic work on the economic impacts of GM crop releases on the strategy of "preserving opportunities";
 - undertake appropriate work on other issues identified by the Commission such as conditional release and coexistence, biotechnology strategy and addressing liability issues.

Scope

16. No applications for release of GMOs may be lodged with ERMA, except those that provide direct benefits to:
 - human health, specifically where the GMO is a medicine under the Medicines Act which has been granted consent to market by the Minister of Health under section 20, 23 and 30, or is the subject of a clinical trial approved by the Director-General of Health under section 30, of the Act; or
 - animal health, specifically where the GMO has been approved as a veterinary medicine under the ACVM Act;
17. A provision will also be included to allow the existing emergency provisions of HSNO Act, to continue to apply (sections 46 -49).
18. Within the exemption it will also be required that:
 - Applicants provide additional information demonstrating that the organism cannot remain viable in the physical environment beyond the target organism.
 - ERMA take account of relative efficacy, safety and ecological effects.
19. The exemption provision outlined in paragraphs 16 to 18 above will allow applications to proceed for any GMO vaccines that might be needed for diseases

such as cholera and rotavirus infections and will at the same time improve safety criteria.

Duration

20. The constraint period will need to be sufficient for the purposes listed in paragraph 15 above to be achieved. Officials estimate that the legislative changes needed to HSNO Act and other acts will take up to two years to be enacted and that this period would also allow the research programmes to reach some conclusions.
21. Consideration has been given to most appropriate way to bring the constraint period to an end. Options considered included: requiring a specific parliamentary vote, with or without earlier formal review procedures. It is highly unlikely that such a piece of legislation would be allowed to lapse without parliament debating the issue therefore it is unnecessary to specifically provide for a vote within the legislation.

Implementation

22. The constraint period will be legislated as separate piece of legislation that amends the HSNO Act.
23. If Cabinet agree to the proposals in this paper then drafting instructions will be sent to the PCO. Legislation could be introduced into the House before the end of November. The legislation could then proceed to Select Committee and could be passed at the earliest before the House rises for Christmas.
24. ERMA is required by the HSNO Act to process any applications lodged with it after the current moratorium ends (31 October 2001). The Minister for the Environment has no power to direct ERMA in its statutory decision making functions (Part 5 of HSNO). The gap between 31 October and passing of legislation for a constraint period can be addressed by inclusion of a clause that would enact the legislation from the date of announcement. A clause could also be included that requires ERMA to cease further processing of any applications it has received until the end of the constraint period. This addresses the gap between 31 October 2001 and the date when legislation could first be introduced.

Officials' advice on a constraint period

25. Officials were asked to comment on the risks of a constraint period. The following provides the combined advice from the Ministries of Agriculture and Forestry, Economic Development, Environment, Fisheries, Foreign Affairs and Trade, Health, Research, Science and Technology, and the Treasury. Officials have identified two implications of a constraint period. These are discussed in turn.

Risks to investment and scientific capacity

26. Comments to officials from industry stakeholders can be summarised as “uncertainty kills investment”. The main risk they perceive is that it creates uncertainty for investors and researchers about whether or when GM products and technology can be commercialised in New Zealand.
27. The proposed constraint would affect primary production sectors, but the extent of this is likely to be slight. There is, however, a slight risk that investment would move offshore to countries with which we compete e.g. Australia, which promotes biotechnology research and has already allowed commercial releases of GM crops and flowers.
28. Industry is concerned that once a constraint is put in place it will be extended indefinitely.
29. If releases were allowed for human and veterinary medicines, investment in this area is unlikely to be affected. However, the mechanism to implement the constraint may have an effect if it is perceived as a new regulatory barrier (such as a new decision step) or increases compliance costs, then investment in these areas could also be affected.

Competitive advantage in biological production systems

30. Most GM activity and research for biological production systems in New Zealand is likely to remain as contained field tests rather than releases for at least two or more years. However if it is assumed that our competitive advantage relies on GM technology as a key input, there is a risk that other countries could get a head start in the use of GM technology developed overseas, and thereby secure a competitive advantage over New Zealand (as the technology could not be used (released) in NZ).

Contained Research

Overview of Current Regime

31. Research involves both laboratory work and contained field research. Field work is essential for some research because it provides the information necessary to understand the characteristics and responses of an organism when exposed to an external environment (as opposed to a laboratory). If the organism was intended for eventual release, field research would also provide information to assess its potential impacts on the environment. Field research of GMOs has been undertaken in New Zealand for 13 years with no known instance of release of the organisms involved.
32. GMO field research presents a much lower risk to the environment than release. This is because of the stringent definition of field test in the HSNO Act, the tight conditions that can be placed on the research, and because of the scale of the work is generally quite small.

33. The definition of field test in the HSNO Act requires that the test is contained: *Field test means, in relation to an organism, the carrying on 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, but from which the organism, or any heritable material from it, could be retrieved or destroyed at the end of the trials; and includes large-scale fermentation of micro-organisms.*
34. Before the current moratorium was in place, under the existing legislation, ERMA made decisions on field research on a case by case basis. To grant the application to research, ERMA must be satisfied that the benefits of having the organism in containment outweigh the adverse effects should the organism escape (s45); and bearing in mind:
- the ability of the organism to escape at all (s44); and
 - the ability of the organism (by implication if it did escape) to form an undesirable self sustaining population (s37); and
 - how easily it could be eradicated if the escape occurred (s37).
35. In addition, the Third Schedule of the HSNO Act gives an extensive list of the matters to be addressed by containment controls for field research and development of genetically modified organisms. These include controls to limit the likelihood of any accidental release of any organism or any viable genetic material. For example:
- requirements for treatment and decontamination to prevent escape by way of expelled air, discharge of water or liquid waste, removal of solid waste or goods, or breaches in facility boundary (1a)
 - requirements for the disposal of any biological material (1e)
 - requirements to secure the facility and openings, including securing against failure in the event of foreseeable hazards (1g)
36. The third schedule also requires that the conditions on a field test approval specify:
- means to exclude unauthorised people from the facility (2)
 - means to exclude other organisms from the facility and to control undesirable and unwanted organisms within the facility (3)
 - means to prevent the unintended release of the organisms by experimenters (4)
 - means to control the effects of any accidental release or escape of an organism (5)
 - inspection and monitoring requirements for containment facilities, including any inspection required before commencement of the development or field testing (6)
37. Controls imposed by an approval may specify:
- the qualifications required of the person responsible for implementing the controls imposed by an approval (7a),
 - the provision of a management plan specifying procedures for implementing controls imposed by an approval (7b).

38. The ERMA must also consider the precautionary approach (section 7 of HSNO Act) when considering any application before it: ERMA must take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.
39. All applications for field tests must be publicly notified (s53d) and members of the public may make submissions on the application, which ERMA then take into account in their decision making process.

Government's expectations of contained research

40. The Royal Commission's report noted that 'rigorous monitoring of field trials is essential and that all material associated with the trial must be removable from the site'. (para 91, pg 123). While the Government is generally satisfied that the current framework for assessing applications for contained research is satisfactory, it considers that it is necessary to clarify its expectation that ERMA shall continue to impose the strictest possible safety standards on granted applications.
41. To that end the Government proposes to require, in addition to the current criteria, explicit conditions for contained research of GM plants and animals to the effect that:
 - (1) *If the application is to field test in containment a genetically modified plant, conditions will be placed on the test to ensure that:*
 - (a) *Once any reproductive structure above the ground reaches the stage where it is capable of releasing heritable material it shall be securely contained or immediately removed, and transported in secure containment if required, and destroyed; and*
 - (b) *Any heritable material beneath the ground is destroyed on site or retrieved and transported in secure containment for destruction once the test is complete; unless the heritable material is required for research purposes in which case it shall be retained in conditions of high security.*
 - (c) *All material associated with the trial must be removable from the site by destruction or otherwise.*
 - (2) *If the application is to field test a genetically modified animal controls will be placed on that field test to ensure that all animals forming part of the test, including their offspring, are:*
 - (a) *Held in secure containment; and*
 - (b) *Clearly identified in case the animal escapes.*
 - (3) *ERMA will be required to take account of relative efficacy, safety, and ecological effects.*
 - (4) *Appropriate inspection and monitoring conditions are compulsory.*
42. The proposed strengthening of the containment provisions outlined in the paragraph above would be achieved by amending Part V of the HSNO Act. The amendment will require that any field test involving plants or animals, which is approved, will be subject to the conditions set out in paragraph above.

Other Key Royal Commission Recommendations

43. All of the Royal Commission's recommendations have been addressed in detailed analysis by officials. Some of the recommendations form significant parts of the enhanced framework for release proposed by the Royal Commission and because of their significance, the analysis on them has been included here for ministers to decide them in advance of the other papers. The balance of the recommendations will be considered at detailed papers at POL on Wednesday 31 October.
44. The seven key issues are:
- Creation of a category of conditional release
 - Development of a strategy for co-existence of GM and other kinds of agriculture
 - Establishment of a Bioethics Council
 - Creation of a Parliamentary Commissioner for Biotechnology
 - Creation of a Biotechnology Strategy
 - Liability for damages arising from GMOs
 - Economic analysis

Conditional Release

Royal Commission recommendation 6.8: that HSNO be amended to provide for a further level of approval called conditional release.

45. This recommendation reflects the wider scope of the Commission's central theme of 'preserving opportunities. In its report, the Commission recognises that the risk analysis regime created under the HSNO Act is generally satisfactory. Since the legislation came into force, however, there have been significant changes not only in gene technology but also to the social and commercial context in which the technology is used. As a result, there is a need to create new tools for managing the technology to preserve the full range of options both of the technology and of alternative technologies.
46. Having heard evidence from a range of submitters including ERMA, research institutes and a number of community groups, the Commission recommended the HSNO Act be amended to allow ERMA to approve the release of a new organism subject to controls or conditions. The Commission called this "conditional release".
47. When discussing the possibility of compatibility between GM and non-GM crops, the Commission comments that the prohibition on post-release controls supports an "*all or nothing approach*": *genetically modified crops may be anywhere or nowhere*" which does not accord with the Commission's recommended strategy of preserving opportunities. The Commission wishes for "*a greater range of options*". Conditions and controls under any new release category would reflect the wide range of uses for GM organisms and the circumstances that merit the conditions and controls.

48. Officials consider that the recommendation should be accepted. Officials note also that such a category could be valuable in managing the release of non-genetically modified new organisms. Significant policy work is required to explore the purpose, scope and criteria for the new conditional release category and enforcement and compliance issues.
49. This recommendation is consistent with the precautionary approach. Given the government's stated objective of giving primacy to health and safety concerns, it is important that in the event that releases are allowed in the future there is an ability within the legislation to impose appropriate conditions.

Development of a strategy for co-existence of GM and other kinds of agriculture

50. The Commission made six recommendations that are aimed at creating a situation in which GM agriculture could co-exist alongside other forms of agriculture. Officials advise that five of these should be accepted (7.1, 7.2, 7.7, 13.3, 13.4) and one rejected on the ground that is impracticable (7.3 relates to managing bees). The details of these recommendations are contained in the papers that will be considered by cabinet committee on Wednesday 31 October. All require further work and some funding to be implemented. In addition, some are dependent on the actual release of GM organisms to be fully implemented.
51. If Cabinet accepts the proposal for a constraint period, no commercial releases of crops will be possible in the next two years. The issues around coexistence do not therefore need to be determined immediately. However I recommend that work should take place to allow frameworks to be developed to complement the creation of the conditional release category. Notwithstanding this, much of the detailed work on coexistence will necessarily have to be done in relation to actual applications on a case by case basis.
52. I propose that officials be directed to explore the work involved in developing co-existence frameworks as far as is practicable in the absence of specific applications for release or conditional release, and use that to complement the development of conditional release policy.

Bioethics Council

Royal Commission recommendation 14.2: that Government establish Toi te Taiao: the Bioethics Council to:

- *act as an advisory body on ethical, social¹ and cultural matters in the use of biotechnology in New Zealand*
- *assess and provide guidelines on biotechnological issues involving significant social, ethical and cultural dimensions*
- *provide an open and transparent consultation process to enable public participation in the Council's activities*

¹ Officials advise that this recommendation was misworded and should have referred to ethical, *spiritual* and cultural matters, not ethical, *social* and cultural matters.

53. The rationale behind the Royal Commission's recommendation is that ethical, cultural and spiritual dimensions of genetic modification are not adequately addressed by current processes and structures. The Royal Commission's view is that the ERMA and the local ethical committees established under various health and animal welfare legislation cannot appropriately address issues of a national or overarching nature. The Commission intended that establishment of a Bioethics Council would provide the appropriate forum for the consideration of ethical, cultural and spiritual dimensions of biotechnology, guide decision-makers on these matters and ultimately make decisions more socially robust and widely acceptable.
54. The scope of the proposed Bioethics Council is intended to extend beyond genetic modification and would provide guidance on the breadth of biotechnological developments, such as cloning and xenotransplantation.
55. Officials propose that a Bioethics Council be established to advise and, where appropriate, provide guidelines on, biotechnological issues involving significant cultural, spiritual or ethical dimensions with a view to preventing or reducing value conflicts. It would also promote and guide public dialogue on these matters. The advice would guide the ethical decision-making of regulatory bodies as well as those involved in the research or application of biotechnology. However, the Bioethics Council would only be an advisory body as opposed to making binding decisions. It is envisaged that Ministers would refer matters to the Bioethics Council for consideration as appropriate.
56. While it is intended that the Bioethics Council would focus on cultural, ethical and spiritual issues as they affect both Maori and non-Maori, it needs to be determined whether it is the appropriate place to deal with a wider range biotechnology-related matters of interest to the public.
57. The role of the existing Independent Biotechnology Advisory Council (IBAC) overlaps to a considerable degree with that proposed for the Bioethics Council and the Parliamentary Commissioner on Biotechnology. The Royal Commission suggested that IBAC be disestablished to make way for proposed new structures or arrangements, which it considered would more adequately fulfil these roles. Officials concur with this view. While this approach could leave a gap in the coverage of biotechnology ethical or expert advice before the new initiatives are implemented, this is not a significant risk as advice could be coordinated on an *ad hoc* basis if required.
58. Further work is required to determine the scope of the Bioethics Council, its relationship with other institutions (including the ERMA) and regulation (e.g. the HSNO Act), appropriate membership (including Maori representation) and institutional structure, as well as the fiscal implications. [*Deleted under section S9(2)(f)(iv) of the Official Information Act*]

Parliamentary Commissioner for Biotechnology

Royal Commission recommendation 14.3: that Government establish the office of Parliamentary Commissioner on Biotechnology to undertake futurewatch², audit and educational functions with regard to the development and use of biotechnology in New Zealand

59. This recommendation arises because the Commission believes that these functions are not adequately covered by existing institutions' terms of reference or could be brought together, particularly the systems' guardian and educational functions.
60. The proposal by the Commission does not meet the criteria for the establishment of a separate Parliamentary Commissioner. The Finance and Expenditure Select Committee (FEC) in 1989 (after the establishment of the Parliamentary Commissioner for the Environment) agreed the following set of criteria for Parliamentary Commissioners:
 - An Officer of Parliament must only be created to provide a check on the arbitrary use of power by the Executive;
 - An Officer of Parliament must only be discharging functions which the House of Representatives itself, if it so wished, might carry out;
 - Parliament should consider creating an Officer of Parliament only rarely.
61. Officials recommend that Ministers do not support the establishment of a Parliamentary Commissioner for Biotechnology, as the role does not meet the FEC criteria for the establishment of a Parliamentary Commissioner and because the functions can be carried out by some extensions to the roles of existing bodies. However, we recommend that Ministers explicitly indicate their support for the functions indicated by the Royal Commission.
62. Further work is required to establish how these functions can be performed most efficiently and effectively without creating another oversight body that will increase compliance and administration costs. This further work will take place within the context of the biotechnology strategy discussed elsewhere in this paper. The Royal Commission indicated that the independence of a Parliamentary Commissioner may be desirable for carrying out these functions. Officials will take this into account when advising on alternative ways of giving effect to the Royal Commission's recommendation.
63. Possible options for existing bodies that may undertake the functions suggested by the Royal Commission include the Parliamentary Commissioner for the Environment, Ministry of Research, Science and Technology, and judicial review by the courts. The Bioethics Council, if established, may also undertake certain educational and futurewatch roles consistent with its terms of reference.

² The Royal Commission indicates the futurewatch function would comprise monitoring and responding to emerging developments in biotechnology in terms of their implications in the New Zealand context.

64. If Ministers did decide to establish a new Parliamentary Commissioner, it is estimated that this would cost around \$2 million per annum, depending on the scope of its operations.

Biotechnology Strategy

Royal Commission recommendation 14.4: that the Ministry of Research, Science and Technology develop on a consultative basis a medium- and long-term biotechnology strategy for New Zealand

65. The Royal Commission recommends the development of a strategy to ensure that New Zealand is kept abreast of developments in biotechnology, and that these are used to national advantage while preserving essential social, cultural and environmental values. The Royal Commission suggests that this strategy should take into account scientific, environmental, economic, cultural, consumer preference and other factors, and the interplay between them. It envisages such a strategy as encompassing, on an ongoing basis, many of the issues debated by the Commission itself.
66. Officials support the need for a strategy and view it as forming the policy framework for addressing biotechnology and GM issues into the future. It is also proposed that the strategy considers the audit, educational and futurewatch functions proposed for the Parliamentary Commissioner on Biotechnology.
67. Biotechnology is complex with long-range uncertainties. It is also much broader than the current focus on genetic modification. Officials consider the need for a strategy as a way of ensuring ongoing balance between the benefits that biotechnology offers and the social, cultural and environmental challenges. Officials also believe the strategy should be cognisant of the overarching theme of preserving future opportunities and the framework of values identified by the Royal Commission.
68. Officials envisage a staged approach to the strategy development. The first stage would be to develop a governance framework that links and integrates scientific, environmental, economic, cultural, consumer preference and other factors, and the interplay between them, to enable New Zealand to keep abreast of developments in biotechnology and use these to national advantage. This framework should:
- Articulate Government's approach to biotechnology and provide principles and processes for making judgements and trade-offs on particular issues now and into the future
 - Consider how the functions of audit, education, public participation and futurewatch (proposed by the Royal Commission to be undertaken by the Parliamentary Commissioner on Biotechnology) could best be delivered
 - Consider other matters outside the Royal Commission response, such as the need for coordination of biotechnology within and outside of Government
 - Have regard for other relevant strategies, in particular the sustainable development strategy.

69. This framework would need to encompass, but extend beyond, the existing regulatory system for GMOs. It would need to be developed in concert with the range of other policy work that will be undertaken in response to the Royal Commission report, such as the proposed establishment of a Bioethics Council and the Maori review of ERMA processes.
70. The second stage of the strategy would be to progress the development and use of biotechnology within the framework. During this stage, officials would expect to oversee (or in some cases initiate) the implementation of a number of agreed actions by a wide range of agencies, community groups and the private sector. By way of example, these could include new processes for the coordination of research on biotechnology, enhanced school and community-based education and dialogue on biotechnology and its impacts, and private sector initiatives to enhance the commercialisation of biotechnology.
71. [*Deleted under section S9(2)(f)(iv) of the Official Information Act*.]

Liability for damages arising from GMOs

Royal Commission recommendation 12.2: that for the time being there be no change in the liability system (but that the matter could be referred to Law Commission for further analysis)

72. The Commission's overall approach to compensation appears to be that the individuals/organisations responsible for causing harm should be responsible for any compensation, not the State. Its emphasis is also on preventing damage or injury in the first place, rather than creating a liability regime additional to that already in place.
73. Officials agree with the Commission's conclusion that for the time being it is unnecessary to recommend legislation providing special remedies for third parties where they may have been affected by the release of a genetically modified organism. The present law of tort, such as negligence and nuisance, is sufficiently flexible and adaptable to meet the issue of civil liability arising from harm caused by genetic modification. There may also be a precedent risk in singling out a particular issue for inclusion in legislation when it is not clear that a separate liability rule is justified.
74. Given the Commission's aim of balancing the need for adequate protection with the need to encourage innovation and progress, its conclusion that it is best to avoid introducing a regime of strict liability seems to be a sensible one. It is also consistent with the weight of international precedent.
75. However, officials consider it is still useful to consider whether the existing liability system is appropriate into the future (within the biotechnology strategy framework outlined below). The matter therefore should be referred to the Law Commission for further analysis. There are two options for further referral: monitoring by the Law Commission as to whether further work is required; or referral for active consideration by the Law Commission.

76. On balance, officials consider that the matter should be referred through appropriate channels for further active consideration by the Law Commission. This will ensure that any potential problems with the existing liability system are identified and addressed proactively.
77. Ministers may also wish to direct the Law Commission to seek analyses from other disciplines (for example economics) in considering this issue.

Economic analysis

78. The Royal Commission did not include detailed analysis of the various economic risks and opportunities that may arise from GM and non-GM technology. Officials believe that to inform further policy work, such as the agricultural co-existence work and the biotechnology strategy, further economic analysis is necessary. Officials will undertake that work in late 2001/early 2002 to inform the further GM policy development. An economic analysis will inform decision-making on the viability and desirability of coexistence of GM and non GM technology.

Financial Implications

79. A number of the recommendations in this paper have fiscal implications. Some of these will be incurred in 2001/02, such as development of the biotechnology strategy. Other costs, such as legislative changes to the HSNO Act, will be incurred in 2002/03. There are also likely to be ongoing costs, such as the Bioethics Council, from 2002/03 onwards.
80. Many of the recommendations are, at this stage, very high level. Until the detail, and in particular the scope, is finalised, it is not possible to finalise the costings for some of the individual initiatives. Therefore the costings for these initiatives should be regarded as indicative only. It is intended that the costings be finalised as part of the report-backs on these individual initiatives, where possible as part of the 2002/2003 budget.
81. In addition to these, the communications programme described in paragraphs 96–98 [*Deleted under section S9(2)(f)(iv) of the Official Information Act*].
82. Based on the indicative costings, it is recommended that Ministers consider a package of funding for the policy response to the Commission. The 2001/2002 component of this package is considered in this suite of papers. The 2002/2003 and outyear components of the package should be considered as part of the 2002 Budget [*Deleted under section S9(2)(f)(iv) of the Official Information Act*].

2001/02 fiscal implications

83. [*Deleted under section S9(2)(f)(iv) of the Official Information Act*].
84. [*Deleted under section S9(2)(f)(iv) of the Official Information Act*].
85. [*Deleted under section S9(2)(f)(iv) of the Official Information Act*].

2002/03 and outyears fiscal implications

86. [Deleted under section S9(2)(f)(iv) of the Official Information Act].
87. These amounts are indicative only, as they are dependent on the final scope and timing of changes agreed. These costs will be finalised as part of the detailed report-backs on the changes, and funding considered as part of established processes, [Deleted under section S9(2)(f)(iv) of the Official Information Act].
88. [Deleted under section S9(2)(f)(iv) of the Official Information Act].
89. The terms of reference and membership of the Bioethics Council are still to be finalised. Accurate costings are not available until these matters are finalised. [Deleted under section S9(2)(f)(iv) of the Official Information Act].
90. The Ministry of Agriculture and Forestry advises that the amount and timing of funding necessary to set up and maintain agricultural co-existence depends on the timing of releases, if any, of GM crops or animals. There are likely to be both one-off costs and ongoing costs. However, the Ministry considers it unlikely that there would be any applications for release of GM crops or animals in 2002/03. [Deleted under section S9(2)(f)(iv) of the Official Information Act].
91. [Deleted under section S9(2)(f)(iv) of the Official Information Act].
92. Implementation of the biotechnology strategy is likely to have fiscal impacts in 2003/2004 and outyears. Details will become clearer as the strategy develops. Examples of initiatives, however, could include international research collaboration, investment in science education, and mechanisms to expedite the commercialisation of biotechnology research.

Timing/Process for next steps

93. There are a number of next steps, which vary in scope and urgency. These are summarised in the table below in order of timing of report back and priority. Details of the steps required for individual recommendations are given in papers to be considered at POL on Wednesday 31 October 2001. The timing of any further steps subsequent to the stated report back is indicative only.

Further major policy work	
Report back by:	
Mid-December 2001 (to Minister of RS&T)	Development of a Biotechnology Strategy (<i>Recommendation 14.4</i>) – on the scope and process for development of the strategy (MoRST lead), with a view to: <ul style="list-style-type: none"> • consultation being completed by April 2002 and • stage 1 of the strategy in place by June 2002 [subject to funding being available]

End of April 2002	<p>Bioethics Council (<i>Recommendation 14.2</i>) - on options for implementation, including terms of reference, membership and institutional structure (SSC lead), with a view to:</p> <ul style="list-style-type: none"> • completing consultation by June 2002 and • establishment second half of calendar 2002. [subject to funding being available] <p>Conditional release (<i>Recommendation 6.8</i>) - on options for implementation, including possible regional exclusions areas (<i>Recommendation 13.1</i>) (MfE/MAF lead), with view to:</p> <ul style="list-style-type: none"> • consultation being completed by June 2002 and • any amendment included in the HSNO Amendment Bill (see below)
End of April 2002	<p>Actions required for amendment to the HSNO Act, with a view to</p> <ul style="list-style-type: none"> • consultation completed by end October 2002 • policy approval by end of February 2003 • drafting and introduction to the House by end of April 2003 • select committee report back by August 2003
Further policy work – no legislative change required	
As and if required	Development and implementation of a management framework and techniques for managing the release of GM organisms, and for co-existence (<i>Recommendations 7.1, 7.2, 7.7, and 13.3</i>) by 30 March 2003
End of February 2002 (to Minister of RS&T)	New research required to address gaps identified by officials in socio-economic, cultural and environmental areas (<i>Recommendations 6.12, 6.13, 6.14 and 7.4</i>).

94. To date the whole of government response to the recommendations of the Commission has been coordinated by the Ministry for the Environment (refer FIN Min 01) 14/9)). A core group of officials was established from the following departments – Department of the Prime Minister and Cabinet, the Ministries of Agriculture and Forestry, Economic Development, Environment (lead), Foreign Affairs and Trade, Health, Research, Science and Technology, Te Puni Kokiri and the Treasury.
95. It is proposed that officials’ core-group (Environment lead) continue, in order to function to ensure a whole of government response. This will be reviewed in June 2002.

Communication of Decision

96. The Ministry for the Environment has developed a communications strategy to communicate the Government’s decisions at the time of their announcement, and preliminary plans for the following months. The Ministry has commissioned market research into what the public understands and wants to know about genetic modification. The results will be available in early

November.

97. Immediate post-announcement communications will need to focus on the Government's decisions and put them into the context of current controls on GM. Officials consider that there is a clear need to provide factual, neutral information for the wider public over the next two years. [*Deleted under section S9(2)(g)(i) of the Official Information Act*].
98. [*Deleted under section S9(2)(f)(iv) of the Official Information Act*]. Officials estimate the total cost for the communication strategy will be \$0.4m in the present financial year. These costs cannot be met from current baselines and additional funding will be required to meet the costs of this strategy.

Consultation

99. This paper was drafted in the Office of the Minister for the Environment.

Recommendations

It is recommended that Cabinet:

Royal Commission's proposed direction

1. **Note** that in July 2001, Cabinet agreed to release the report of the Royal Commission on Genetic modification and noted a report back was due by 31 October 2001 [CAB Min (01) 23/17].
2. **Note** that the major theme of the report of the Royal Commission is 'preserving opportunities', and that the Commission believe that New Zealand should proceed carefully and implement genetic modification selectively and cautiously, minimising and managing risks.
3. **Note** that the Commission considers that the basic institutional structures and regulatory framework (including the Hazardous Substances and New Organisms Act) for dealing with GM technologies is appropriate but should be fine tuned to fit the 'preserving opportunities' strategy.
4. **Note** that the Commission recommended that the Minister for the Environment exercise her call-in power to assess the economic and environmental impacts of the first application for release of a GMO crop.
5. **Note** that the Commission acknowledged there were significant gaps in knowledge on environmental, socio- economic and ethical impacts of the release of GMOs and that it suggested research funding should be directed to these areas.

Government's response to the Royal Commission direction

6. **Agree** to take a precautionary approach as to how to proceed with genetic modification, and in this context support the Commission's overall strategy of "preserving opportunities".
7. **Agree** that the government has come to different conclusions from the Commission as to how the strategy of preserving opportunities should be best implemented, in particular in:
 - The extent to which commercial release should be possible in the immediate future; and
 - The conditions under which research should proceed.
8. **Agree** that the Commission's proposed use of the Ministerial call-in provision is not the appropriate mechanism to implement a 'proceed with caution' approach.
9. **Agree** that in accordance with the precautionary approach there is a need to constrain the release of GMOs (with limited exceptions) for a period while the work, analysis and research identified as necessary by the Commission is underway.
10. **Agree** that in order to clarify the government's expectation that all research involving genetic modification must meet strict safety standards, legislation must be amended to require specific conditions to be applied to any approval to ensure environmental and health safeguards.

Constraint on Release of GMOs

11. **Agree** that the purpose of the constraint on release of GMOs, in accordance with the precautionary approach, is to allow time to:
 - establish or continue research programmes addressing areas of socio-economic, ethical, environmental and agricultural research which were identified by the Royal Commission recommendations, and agreed by Government, as needing additional work;
 - put in place amendments to the HSNO Act (and related Acts) and regulations;
 - establish a Bioethics Council;
 - complete generic work on the economic impacts of any GM crop release on the strategy of "preserving opportunities";
 - undertake appropriate work on other issues identified by the Commission such as conditional release and coexistence, biotechnology strategy and addressing liability issues.
12. **Agree** that during the constraint period no applications for release of GMOs may be lodged with ERMA, except those that provide direct benefits to:
 - human health, specifically where the GMO is a medicine under the Medicines Act which has been granted consent to market by the Minister of Health under section 23 or 20, or is the subject of a clinical trial approved by the Director-General of Health under section 30, of the Act;or

- animal health, specifically where the GMO has been approved as a veterinary medicine under the ACVM Act.
13. **Agree** to a provision will also be included to allow the existing emergency provisions of HSNO Act, to continue to apply (sections 46 -49).
 14. **Agree** that the exemption will also require that:
 - Applicants provide additional information demonstrating that the organism cannot persist viably in the physical environment beyond the target organism.
 - ERMA take account of relative efficacy, safety and ecological effects.
 15. **Agree** that the constraint period shall last for two years.

Contained Research

16. **Agree** that the Government require that, in addition to the current criteria, explicit conditions be imposed on all contained research of GM plants and animals to the effect that:
 - (1) *If the application is to field test in containment a genetically modified plant, conditions will be placed on the test to ensure that:*
 - (a) *Once any reproductive structure above the ground reaches the stage where it is capable of releasing heritable material it shall be securely contained or immediately removed, and transported in secure containment if required, and destroyed; and*
 - (b) *Any heritable material beneath the ground is destroyed on site or retrieved and transported in secure containment for destruction once the test is complete; unless the heritable material is required for research purposes in which case it shall be retained in conditions of high security.*
 - (c) *All material associated with the trial must removable from the site by destruction or otherwise.*
 - (2) *If the application is to field test a genetically modified animal controls will be placed on that field test to ensure that all animals forming part of the test, including their offspring, are:*
 - (a) *Held in secure containment; and*
 - (b) *Clearly identified in case the animal escapes.*
 - (3) *ERMA will be required to take account of relative efficacy, safety, and ecological effects.*
 - (4) *Appropriate inspection and monitoring conditions are compulsory.*
17. **Invite** the Minister for the Environment to request parliamentary counsel to draft a Bill covering the matters specified in recommendations 11 – 16 of this paper which is made effective from the date of announcement of these decisions.

Other Key Recommendations

18. **Note** that all of the Royal Commission’s recommendations have been addressed in detailed analysis by officials.

19. **Note** that some of the recommendations form significant parts of the enhanced framework for release proposed by the Royal Commission and because of their significance, the analysis on them has been included in this paper for ministers to decide in advance of the papers to be considered by POL on Wednesday 31 October.
20. **Note** that the balance of the recommendations will be considered at detailed papers at POL on Wednesday 31 October.

Conditional Release

21. **Agree** that the HSNO Act be amended to allow the ERMA to approve the release of a new organism subject to conditions or controls.
22. **Direct** officials, led by MfE, to report back to Cabinet by 30 April 2002 with advice on implementation of a new category of release, including the purpose and scope of the new category, the criteria for conditions and any compliance and enforcement issues [RCGM 6.8].

Co-existence

23. **Direct** officials to explore the work involved in developing co-existence frameworks as far as is practicable in the absence of releases, and use that to complement the development of conditional release policy.
24. **Note** that more detailed recommendations in relation to developing co-existence work will be considered by POL on Wednesday 31 October.

Bioethics Council

25. **Agree** to establish the Toi te Taiao: the Bioethics Council (the Bioethics Council) to advise, provide guidelines and promote dialogue on the cultural, ethical and spiritual issues associated with biotechnology [RCGM 14.2]
26. *[Deleted under section S9(2)(f)(iv) of the Official Information Act].*
27. *[Deleted under section S9(2)(f)(iv) of the Official Information Act].*
28. **Agree** that the functions of the Bioethics Council together with the functions of education and futurewatch encompass the existing functions of IBAC.
29. **Agree** to disestablish IBAC on the establishment of the Bioethics council and roll over existing IBAC appointments until that time.
30. **Direct** officials (State Services Commission lead) to provide further advice by 30 April 2002 on how to implement the Bioethics Council, including terms of reference, membership (including Maori representation) and institutional structure.

Parliamentary Commissioner for Biotechnology

31. **Agree** that the establishment of a Parliamentary Commissioner on Biotechnology is not the appropriate mechanism for biotechnology futurewatch, audit and educational functions proposed by the Royal Commission [RCGM 14.3].
32. **Agree** that the biotechnology futurewatch, audit and education functions are important and should be incorporated into New Zealand's institutional structure for addressing biotechnology issues.
33. **Direct** officials (Ministry of Research, Science and Technology lead) to report back as part of the Biotechnology Strategy on the appropriate mechanisms for considering the functions in recommendation 14.3.

Biotechnology Strategy

34. **Agree** to the development of a strategy to ensure that New Zealand keeps abreast of developments in biotechnology and has a mechanism to ensure ongoing balance between benefits and risks [RCGM 14.4]
35. **Agree** that the strategy should encompass consideration of the functions of education, audit, public participation and futurewatch proposed for the Parliamentary Commissioner on Biotechnology.
36. *[Deleted under section S9(2)(f)(iv) of the Official Information Act].*
37. *[Deleted under section S9(2)(f)(iv) of the Official Information Act].*
38. *[Deleted under section S9(2)(f)(iv) of the Official Information Act].*
39. **Note** that the implementation of the biotechnology strategy will have further fiscal implications, from 2003/04, which will be identified as part of the strategy development process.

Liability

40. **Agree** that for the time being there be no change in the liability system for GM [RCGM 12.2].
41. **Invite** the Minister Responsible for the Law Commission to report back to Cabinet on whether this work should be included in the Law Commission's work programme by 30 November.

Economic Analysis

42. **Direct** officials (Treasury lead) to report back on economic analysis on the risks and opportunities that may arise from GM and non-GM technologies by end of February 2003.

Financial Implications

43. **Note** the fiscal implications of the GM policy package that is being considered and the suggested management strategy for these costs (paragraphs 79 -92).
44. **Note** the fiscal implications of individual policy proposals are dealt with in the individual policy papers within this suite.
45. *[Deleted under section S9(2)(f)(iv) of the Official Information Act].*
46. *[Deleted under section S9(2)(f)(iv) of the Official Information Act].*
47. *[Deleted under section S9(2)(f)(iv) of the Official Information Act].*

Next Steps

48. **Note** the work programme outlined in paragraph 93.
49. **Note** that the whole of government response to the recommendations of the Commission has been coordinated by the Ministry for the Environment.
50. **Agree** that the officials' core-group (Environment lead) continue, in order to function to ensure a whole of government response.
51. **Agree** that this core-group be reviewed in June 2002.

Communication of Decision

52. **Note** the communications strategy outlined in paragraphs 96- 98.

Hon Marian L Hobbs
Minister for the Environment