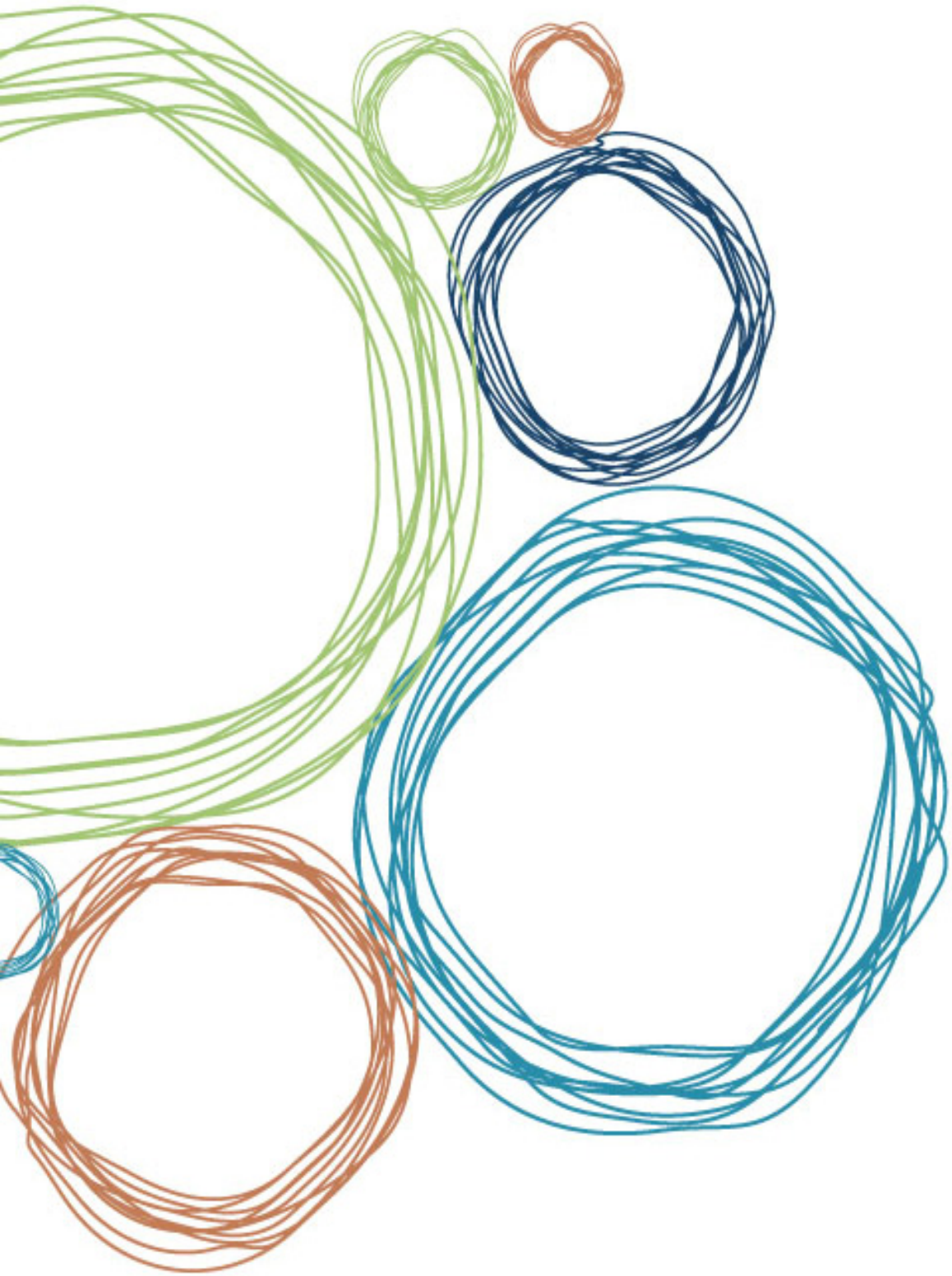

Review of the Forty-Nine Recommendations of the Royal Commission on Genetic Modification

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Exploring a complex world

Review of the Forty-Nine Recommendations of the Royal Commission on Genetic Modification

April 2008

Report *Review of the Forty-Nine Recommendations of the Royal Commission on Genetic Modification*

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Preface

> Having established a model of community consultation and scientific rigour that other nations may consider emulating, the New Zealand government cannot rest on its laurels. Some of the Commission's recommendations require further public resources. It is all too easy to request more funds for research, but the Commission is surely right to highlight the need for publicly funded exploration of the environmental impact of GM crops as well as research into organic and other sustainable agricultural systems. But the report's recommendations are much more wide ranging and, in places, contentious. To consolidate the Commission's good work, the New Zealand government will need to legislate with determination. ('A sound approach to GM debate', *Nature*, 2001: 569)

The editor of *Nature* considered the *Report of the Royal Commission on Genetic Modification* sound but, as can be seen from the comment above, suggested that it contained a number of challenges. The Prime Minister, Helen Clark, and then Environment Minister, Marian Hobbs, welcomed the Commission's inquiry, describing it as 'the most wide-ranging inquiry into genetic modification ever undertaken in any country' (Pockley, 2001: 573). What then has this investment of time and resources delivered to New Zealanders seven years on?

Sustainable Future has undertaken this review to examine the Government's response to the Commissioners' 49 recommendations in order to understand the current framework for the management of genetic modification in New Zealand, and to identify outstanding issues. To our knowledge the implementation of the recommendations has not previously been independently examined.

This report could not have been written without significant support and advice from a wide range of people both inside and outside the public service, and I would like to acknowledge the assistance we have received. In particular, Libby Harrison from ERMA and Sarah Adams-Linton from the Ministry for the Environment have been of invaluable assistance in completing this review.

No independent not-for-profit research organisation could exist without people committed to the wider public good. In our case, we are also fortunate to have external reviewers committed to quality; therefore our sincerest thanks go to Ronnie Cooper, Dr Kerry Grundy, Dr Jack Heinemann, Stephanie Howard, Dr Barbara Nicholas and Dr Sean Weaver. Needless to say, any errors or omissions remain the responsibility of the writers.

Lastly, I would like to thank the team at Sustainable Future, including my co-authors, Miriam White and Steph Versteeg, who never stopped believing in the importance of this research project.

Wendy McGuinness
Chief Executive
Sustainable Future

Executive Summary

> While the Commission has recommended an openness to genetic modification, we have proposed appropriate safeguards to ensure the well-being of the community and the environment. (RCGM, 2001a: 342)

The 'safeguards' mentioned above are contained in the package of 49 recommendations the Royal Commission on Genetic Modification proposed in 2001. The underlying theme of these recommendations was one of 'preserving opportunities'. In effect, the Commission suggested a package of actions designed to enable New Zealand to make better decisions on the use of biotechnology in the future.

This report examines the degree the Commissioners implemented the Warrant, the relevance of the seven shared values and the extent Government implemented the Commissioners' recommendations developed under the Warrant. While acknowledging the breadth of the debate around genetic modification and biotechnology, including their ethical, social, political, cultural, ecological and economic implications, we have endeavoured to keep the focus of this paper on the Warrant, the resulting recommendations and the Government's response to date.

It is important to note that this report does not critically assess the assumptions that underlie the Commissioner's recommendations or provide an overview of the history. A discussion of the wider issues is contained in *The Future of Genetic Modification in New Zealand* (Sustainable Future, in press) and the history to the debate is provided in *The History of Genetic Modification in New Zealand* (Sustainable Future, 2008).

The Commissioners' report made four key findings (see Section 2), which we have used to assess progress over the last seven years. We have adopted these as the basis for developing our methodology (Section 3) and our assessment (Section 5) of the forty-nine recommendations. These are:

1. **The seven shared values of New Zealanders** (see Sections 2.2.1 and 6.2).
2. **The 49 'preserving opportunities' recommendations.** These form the complete package of recommendations proposed by the Commissioners. Each recommendation is discussed in Section 4 (see also a summary in Appendix 1).
3. **The 10 'watershed' recommendations.** This group of recommendations acknowledge that the first genetically modified (GM) crop released in New Zealand would move New Zealand from being a GM-free nation to a GM nation (see Section 5).
4. **The three 'institutional' recommendations**. These were described by the Commissioners as necessary to deliver the capacity to make effective decisions on specific applications and on strategic decisions in the future. These three major proposals are in Chapter 14 of the Commissioners' Report (see Section 5).

We acknowledge that there are many ways to assess progress on the implementation of the recommendations, however after much consideration, we developed the following approach. Firstly we identified two criteria (described below) and then classified each recommendation (as summarised in Tables 1 and 2 below):

1. Level of implementation: Whether action to date has resulted in a recommendation being 'fully', 'partially' or 'not' implemented in accordance with the text used by the Commissioners. Our approach was to determine whether a recommendation was fully implemented or not, and if neither, it was treated as partial.

Our assessment using the first criteria revealed that less than half of the recommendations were implemented in accordance with the text used by the Commissioners. The summary findings are outlined in Table 1 below. More detailed information is contained in Table 12.

Table 1 Level of Implementation

Level of Implementation	Number
Fully Implemented	20
Partially Implemented	12
Not Implemented	17
Total recommendations	**49**

2. Level of Further Policy Work Required: Whether 'significant', 'ongoing' or 'no' outstanding policy work remains in relation to the issue the recommendation was intended to manage or solve. This approach reviews each of the 49 recommendations to assess the extent public policy work remains. A recommendation that has been fully implemented in accordance with the text used by the Commissioners may still have outstanding policy work.

Our assessment of further policy work found that over half of the recommendations require additional policy work. The summary findings are outlined in Table 2 below. More detailed information is contained in Table 13.

Table 2 Level of Further Policy Work

Level of Further Policy Work	Number
No Further Policy Work Required	20
Ongoing	11
Significant	18
Total recommendations	**49**

As part of our analysis, this process resulted in the reclassification of nine recommendations (see Appendix 2). The impacts of the reclassification are significant when reviewed in detail (compare Table 12 with Table 13).

In response to the degree the Commissioners implemented the Warrant, we found the Commissioners met the second *matter,* being reporting on the institutional arrangements, but could have gone a great deal further to reporting on their inquiry into strategic options (being the first *matter)*. In particular, this could have detailed the range of options available to New Zealand that they considered, rather than only describing and reporting on one option. Arguably the Commissioners' major theme of 'preserving opportunities' was a 'strategic pathway' for the Government, rather than a 'strategic decision' itself.

In response to the relevance of the seven shared values, we considered any further discussion and decision-making on the use and application of genetic modification technology in New Zealand should start with consideration of these seven shared values.

In response to the extent Government implemented the Commissioners' recommendations developed under the Warrant, this report concludes that:

- Of the package of forty-nine recommendations only twenty were fully implemented.
- Of the ten watershed recommendations only two were fully implemented.
- Of the three institutional recommendations, although two were arguably fully implemented, considerable policy work remains in order to meet the underlying purpose of all three institutional recommendations.
- In summary, a significant amount of further policy work is necessary regarding recommendations relating to 'Crops and Other Field Uses', 'Te Tiriti o Waitangi', 'Major Conclusion: Preserving Opportunities' and 'The Biotechnology Century' in order to meet the intent of the Commissioners' recommendations.
- New Zealand does not have in place the governance and accountability framework proposed by the Commissioners under their major theme of 'preserving opportunities'. In particular, the Commissioners relied heavily on the development of practical co-existence strategies, the use of sterility technologies, a national strategic 'watershed' decision and effective institutional entities in order to deliver the theme of 'preserving opportunities' and enable co-existence between GM and non-GM producers. To date, these initiatives have not been actioned.
- There is no indication that this situation is likely to change in the short term.

These findings show that the New Zealand Government is not currently pursuing the strategic option of 'preserving opportunities' as proposed by the Commissioners and raise further questions about New Zealand's ability to manage the risks of genetic modification.

1. Introduction

1.1 Purpose

The strategic aim of this report is to:

> Evaluate the current governance and accountability framework for managing genetic modification in New Zealand.

To do this, evidence of government activity in relation to each recommendation is examined in order to assess the level of implementation of each recommendation and the extent to which outstanding policy work remains today.

Importantly, this paper does not discuss or assess:

1. The extent to which the Commissioners' recommendations meet the terms of reference established under the Warrant (see their Appendix 1 for the Terms of Reference).
2. The quality of the Commissioners' analysis and assumptions, including the desirability or practicality of the Commissioners' major theme of 'preserving opportunities'.
3. The extent to which the Commissioners' recommendations could reasonably achieve the goal of 'preserving opportunities'.
4. The quality and effectiveness of the implementation of each recommendation. For example, a recommendation could in our view be implemented fully, but not have been implemented in a way we thought was appropriate, cost-effective or even necessary.
5. Any issues outside those contained in the recommendations. For example, ideas, issues or strategies which are highly relevant to this topic but are not related directly to a recommendation are not discussed in this report.[1]
6. International scientific developments, institutional structures, legislation, market behaviour or surveys unless relevant to the recommendation.

[1] In such instances, the idea, issue or strategy will be discussed in our report, *The Future of Genetic Modification in New Zealand* (in press).

1.2 Sustainable Future

Sustainable Future[2] is a research organisation and independent think-tank on sustainability issues in New Zealand.

In addition to this project on genetic modification, Sustainable Future is currently undertaking a two-year research project called *Project 2058,* which examines how New Zealand will look and feel in 2058. In 2009 we will write up our optimal strategy for New Zealand.

There are connections between *Project 2058*'s objectives and this research, as the challenges identified by the Commissioners are applicable to a context wider than genetic modification. This research also provides useful insights into the tensions and ambitions of New Zealanders through its identification of a shared framework of values. In addition, this topic provides policy makers, consultants and academics a very recent and complex case study for exploring public policy, risk management and participatory democracy.

[2] See http://www.sustainablefuture.info

2. The Shape of the Commissioners' Report

This section looks at the shape of the Commissioners' Report as a whole and offers our interpretation of how the recommendations fit together (RCGM, 2001a-d). The discussion in the early chapters of the report provides the context for proposing the 49 recommendations, namely the ability for New Zealand to 'preserve opportunities' by considering a shared framework of values (RCGM, 2001a: Chapter 2), and taking into account cultural, ethical and spiritual issues (Chapter 3), environmental and health issues (Chapter 4), and economic and strategic issues (Chapter 5).

The recommendations start from Chapter 6 of the Commissioners' Report. Each recommendation relates to a specific chapter, hence recommendation 6.12 is the twelfth recommendation in Chapter 6. The relevant chapters are grouped into four parts:

Part 1: Applications for GMO

Chapter 6: Research (14 recommendations)
Chapter 7: Crops and Other Field Uses (7 recommendations)[3]
Chapter 8: Food (4 recommendations)
Chapter 9: Medicine (6 recommendations)

Part 2: Other Key Issues

Chapter 10: Intellectual Property (7 recommendations)
Chapter 11: Te Tiriti o Waitangi (1 recommendation)
Chapter 12: Liability Issues (2 recommendations)

Part 3: Major Conclusion on Strategic Options

Chapter 13: Major Conclusion: Preserving Opportunities (4 recommendations)[4]

Part 4: Three Major Proposals

Chapter 14: The Biotechnology Century: Three Major Proposals (4 recommendations)

[3] There is not a specific definition of crops and other field uses in the Commissioners' Report, but in this chapter the Commissioners imply that crops are plants, trees and animals grown for food and other commercial purposes (RCGM, 2001a: 137).

[4] Chapter 13 contains four recommendations unique to this chapter (recommendations 13.1 to 13.4) and five earlier recommendations (recommendations 6.8, 7.7, 7.1, 7.3 and 6.13). These nine, plus one from chapter 14 (recommendation 14.1), form the package of what we have called the 'watershed' recommendations. See Section 2.2.3 for further discussion of these recommendations.

2.1 The Warrant

The Warrant[5] establishing the Royal Commission stated the Commissioners should:

> … receive representations[6] upon, inquire into, investigate, and report upon the following matters:
>
> - the strategic options available to enable New Zealand to address, now and in the future, genetic modification, genetically modified organisms, and products; and any changes considered desirable to the current legislative, regulatory, policy, or
> - institutional arrangements for addressing, in New Zealand, genetic modification, genetically modified organisms, and products. (RCGM, 2001b: 158)

In response to the first *matter*, the Commissioners discussed a spectrum with two positions at either end: (i) New Zealand is Free of all GM material; and (ii) Unrestricted use of GM. These positions represented extremes and therefore neither were considered feasible options. The Commissioners state they considered all positions along the spectrum (RCGM, 2001a: 332), but they only reported on one position, what they called 'preserving opportunities'. A short discussion on this option can be found in six pages at the back of the report (RCGM, 2001a: 333-338). It is clear that the Commissioners only identified one strategic option and in so doing, missed the opportunity to report on the 'options' available to New Zealand.

In response to the second *matter*, the Commissioners' report reviewed institutional arrangements in existence, and discussed the establishment of two new institutions: a Parliamentary Commissioner on Biotechnology (which was not pursued by Government); and a Bioethics Council (RCGM, 2001a: 342-348). The Bioethics Council was subsequently established by Government. The Commissioners also reviewed and made a number of recommendations regarding 'genetic modification, GMOs, and products'.

The Commissioners met the second *matter* of the warrant, but could have gone a great deal further in reporting on their inquiry into the first *matter*. In particular, the Commissioners could have detailed the range of options available to New Zealand, rather than describing and reporting on one option, being the 'preserving opportunities' option.

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5 More information on the Warrant can be found in Sustainable Future (2008: Appendix 1).

6 More information on the Royal Commission public engagement process can be found in Sustainable Future (2008: Appendix 4).

2.2 The Four Key Findings of the Royal Commission

The Commissioners' Report is underpinned by four key findings.

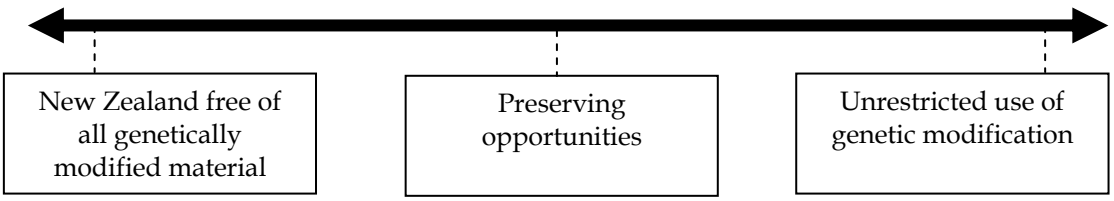
2.2.1 The seven shared values of New Zealanders

Seven shared values were identified by the Commissioners. These values are: the uniqueness of New Zealand, our cultural heritage, sustainability, being part of a global family, the well-being of all, freedom of choice, and participation. These values were used as a platform on which to develop the report's recommendations.

2.2.2 The forty-nine 'preserving opportunities' recommendations

The Commissioners identified a spectrum, being at one end a 'New Zealand free of all genetically modified material' to 'unrestricted use of genetic modification' at the other, as outlined in Figure 1 below. In discussing the extreme position of 'New Zealand free of all GM material', the Commissioners considered this position impractical due to widespread use of GM medicines. Furthermore, the 'economy would contract as skilled scientists emigrated and academic and industry standards ceased to be internationally competitive' (RCGM, 2001a: 332). The other extreme position, 'unrestricted use of genetic modification', they considered was likely to create unacceptable risks to human health, environmental health and cultural heritage, compromise consumer choice and/or reduce our export options. They also state that no submitter supported such an approach (RCGM, 2001a: 333).

Figure 1 The Strategic Spectrum Identified by the Commissioners



The discussion on the strategic decision culminates in Chapter 13, where the Commissioners describe the 'preserving opportunities' option.

> The major theme of the Report is Preserving Opportunities. Our recommendations aim to encourage the coexistence of all forms of agriculture. The different production systems should not be seen as being in opposition to each other, but rather as contributing in their own ways to the overall benefit of New Zealand. (RCGM, 2001a: 2)

In order to progress this preserving opportunities option, the Commissioners provided a package of 49 recommendations.

> The Commission considers that genetic modification technology should be used only in ways that are carefully managed. All opportunities to use the new technology should be seen in terms of the net contribution they will make to New Zealand. This will allow controlled use of genetic modification, the degree of control varying with the situation. (RCGM, 2001a: 331)

In order to implement the strategic option of preserving opportunities, the Commissioners found that management of three of the four types of applications of GMOs (research, food and medicine) did not require a national strategic decision, in other words the status quo was sufficient. However, they did believe a national strategic decision for GM crops and other field uses was necessary (RCGM, 2001a: Recommendation 13.2). A strategic national assessment and political decision – a 'watershed' decision – was considered to be essential once the first application for release or conditional release of a genetically modified crop is received by ERMA.

Additionally, in order to ensure Government has the institutional capacity to consider genetically modified crops and other potential opportunities in the biotechnology century, the Commissioners developed three major 'institutional' proposals.

As a consequence, within the 49 recommendations designed to preserve opportunities, we identified two subgroups of recommendations for additional assessment, which we have called the 'watershed' recommendations and 'institutional' recommendations. We discuss these in turn below.

2.2.3 The ten 'watershed' recommendations

The Commissioners found that use of genetic modification technology in research, food and medicine could (with minimal changes in the framework) continue to be approved by ERMA on a case-by-case basis. The exception was genetically modified crops.[7] The Commissioners in effect placed an additional strategic test on GM crops; they refer to this test as the 'watershed decision', as stated below.

> We make this recommendation because the first release would be very much a watershed decision. At that point we would no longer be a genetic modification-free nation in terms of crops. (RCGM, 2001a: 338)

Importantly, the Commissioners proposed that such a decision requires a strategic and political decision (i.e. by the Minister), rather than a case-by-case decision by the decision-making body (i.e. ERMA), as indicated below.

> **13.2** That before the controlled or open release of the first genetically modified crop, the Minister exercise the call-in powers available under HSNO section 68 in order to assess the likely overall economic and environmental impact on the preserving opportunities strategy. (RCGM, 2001a)

[7] At that time, there had been no commercial releases of GM crops, although outdoor research experiments had been conducted. See Table 6 of *The History of Genetic Modification in New Zealand* (Sustainable Future, 2008: 25).

In the last pages of Chapter 13, the Commissioners briefly discuss whether compatibility between GM and non-GM crops is possible (RCGM, 2001a: 336–38). The central analysis offered by the Commissioners provides little insight into how they arrived at the strategic option for crops, therefore we are left to draw their thinking from the recommendations set out at the end of Chapter 13.

The Commissioners clearly considered that before a conditional or full release of a GM crop can occur, a full strategic assessment must take place. After examining the major recommendations at the end of Chapter 13, we believe the Commissioners were proposing that New Zealand adopt a three-pronged approach to crop and other field uses to support the Minister in making this national strategic assessment. We have grouped the recommendations into three types: those that collect data for the decision, those that identify who should make the decision, and those that enable decision-makers to add controls to a release.

We do this on the basis that the Commissioners have carefully crafted and grouped these first-release recommendations to meet the needs of the 'watershed' decision.

(i) Collecting data for the watershed decision

The Commissioners first provide a plan for Government to collect the information necessary to develop and implement a framework so that decision-makers will be well-informed in advance of the watershed decision. This is based on implementing the eight recommendations that are briefly summarised below:[8]

1. Recommendation 13.1 — That the Methodology: (i) include economic assessment based on a national strategy of 'preserving opportunities' and (ii) allow for the exclusion of GMOs from local districts;
2. Recommendation 7.7 — That MAF establish a code to manage and ensure effective separation distances;
3. Recommendation 13.3 — That MAF develop communication networks between farmers to provide for mediation;
4. Recommendation 13.4 — That sterility technologies be a part of the overarching strategy;[9]
5. Recommendation 7.1 — Development of a Bt[10] Strategy;
6. Recommendation 7.3 — Development of a GE-free honey management strategy;

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8 We note that the purpose of a number of other recommendations (besides the eight listed here) is to collect information in advance of an application to release genetically modified crops and organisms (e.g. Recommendations 6.12 and 6.14). The full text of these recommendations is contained in Appendix 1.

9 The basis for this recommendation is questionable. See *The Future of Genetic Modification in New Zealand* (Sustainable Future, in press) for further discussion of these issues.

10 Bt (Bacillus thuringiensis) is a soil bacterium that produces a protein with insecticidal qualities. (RCGM, 2001a: 59)

7. Recommendation 6.13 — That public research funding adequately support organic and other sustainable agricultural systems;

8. Recommendation 14.1 — That the legal provisions for assessing release applications (Hazardous Substances and New Organisms (HSNO) Act 1996, s68) be extended to include significant cultural, ethical and spiritual issues as grounds for the Minister's call-in powers.[11]

(ii) Making the watershed decision

The Commissioners require the 'watershed decision' to be made by Ministers, rather than ERMA, by recommending:

9. Recommendation 13.2 — Ministers are to call-in the decision for first release.

(iii) Adding controls to the watershed decision

Lastly, the Commissioners provide a way of adding controls to the 'watershed decision' by creating a further intermediary step, namely:

10. Recommendation 6.8 — Development of a class of release called 'conditional release'.

2.2.4 The three 'institutional' recommendations

The last chapter of the Commissioners' Report recognises that in order to 'preserve opportunities', New Zealand would need new and improved institutional capacity. It makes three major proposals to this end: the creation of a Bioethics Council, a Parliamentary Commissioner on Biotechnology, and a Biotechnology Strategy.[12]

2.2.5 Public expectations

There is no onus on Government to adopt all, or indeed any, of the recommendations of any Royal Commission, but the Government did create a public expectation:

> The Government's conclusion is to accept this overall strategy of preserving opportunities … However, we have come to some different conclusions from the Royal Commission as to how the overall strategy of preserving opportunities should best be implemented. The differences are in two main areas:
>
> 1. The first is the extent to which commercial use or release of live genetically modified organisms (or GMOs) should be possible in the immediate future.

---

11 As discussed in footnote 4, we have included recommendation 14.1 in the 'watershed' recommendations as its purpose was to extend the breadth of the Minister's call-in powers.

12 The Commissioners actually make four recommendations, but refer to three major proposals. We consider the first, 'That HSNO section 68 be extended to include significant cultural, ethical and spiritual issues as grounds for the Minister's call-in powers' (Recommendation 14.1), relates to the discussion in Chapter 13; therefore we have taken the liberty of treating Recommendation 14.1 as a 'watershed' recommendation. See Section 2.2.3 (i) 8.

2. The second area is the conditions under which contained field testing of GMOs should be able to proceed. (New Zealand Government, 2001)

Overall, the Government's response to the Commissioners' report was largely positive. Over the next few years a number of cabinet papers were released by Government (see Government's Response MfE, 2001a-f; 2002a-b; 2003a-i).

Given this, we had some anticipation that the recommendations would be enacted. The next section outlines the methodology used to investigate how well the recommendations were actually implemented.

3. Methodology

The methodology has been developed both to examine the 49 recommendations individually (see Section 4), to complete a detailed assessment (see Section 5) and draw conclusions (see Section 6).

3.1 Our Approach

In this report, we have endeavoured to make the distinction between facts, our analysis of the facts and our conclusions. We consider this is critical, as it is a very complex topic that requires the reader to be able to review the facts, understand our interpretation of those facts, and also to make their own assessment based on their own values and ethics.

We have therefore endeavoured to explain our reasoning, rather than propose that our view is the only interpretation. We are also acutely aware that although we have made every endeavour to obtain all the facts, given the considerable territory the paper covers, some details may nevertheless be omitted.

3.2 Information Collection

This research primarily focused on gathering specific information about the current status of each of the Commissioners' recommendations and the action that has been taken by the Government since the Commissioners' Report was published. Although the Government provided an initial detailed response to the Commissioners' Report in 2001, we found limited publicly available information on the Government's progress over time.

In August 2006, Sustainable Future sent letters to relevant government agencies requesting information specific to each of the recommendations of the Commissioners' Report. A reply, dated 1 November 2006, was received from the Ministry for the Environment on behalf of the agencies contacted. Individual agencies also replied to questions that were specific to them.

As a result of both the initial Government response and of further investigation, additional issues emerged. Consequently, a second set of letters was sent requesting further information from both government agencies and Crown Research Institutes. In many cases, this correspondence led to additional phone calls, emails and meetings.

Additional information was sourced from other national and international organisations, and existing information held in the Sustainable Future archives. Interviews, inquiries and feedback of public servants and external reviewers were also integral to completing this assessment. All formal correspondence is available on our website (except that which is classified as confidential) and email correspondence is available on request.

3.3 Method of Analysis of the Warrant

As noted in Section 2.1, the Warrant clearly sets out two *matters* the Commissioners must report upon. Our method is to review each *matter* in terms of the Commissioners' Report. This discussion occurs in Section 6.1.

3.4 Method of Analysis of the Seven Shared Values

As noted in Section 2.2.1, these values were developed by the Commissioners and considered when formulating their recommendations. It is beyond the scope of this paper to do a comprehensive assessment of the relevance of these values today; however we do consider whether, while completing this review, we have come across evidence that is contrary to the values articulated by the Commissioners in 2001. This discussion occurs in Section 6.2.

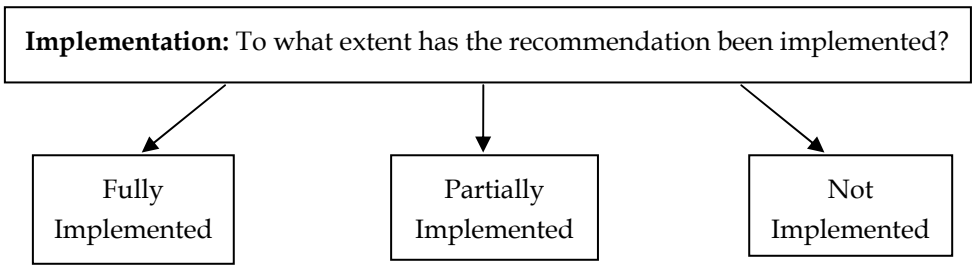
3.5 Method of Analysis of the Forty-Nine Recommendations

We take a bottom-up approach by first examining in detail the level of implementation of each recommendation (Section 4), assessing the overall package (Section 5) and summarising the findings in Section 6.3.

For each recommendation, we assess:

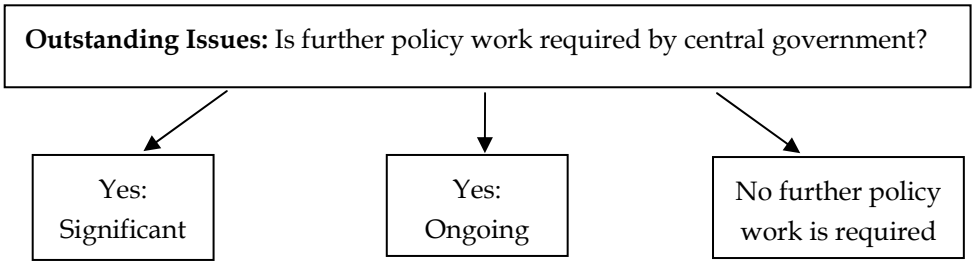
1. **Level of Implementation:** Whether a recommendation has been 'fully', 'partially' or 'not' implemented in accordance with the word of the Commissioners. Our approach was to determine whether a recommendation was fully implemented or not, and if neither, it was treated as partial.

Figure 2 Level of Implementation



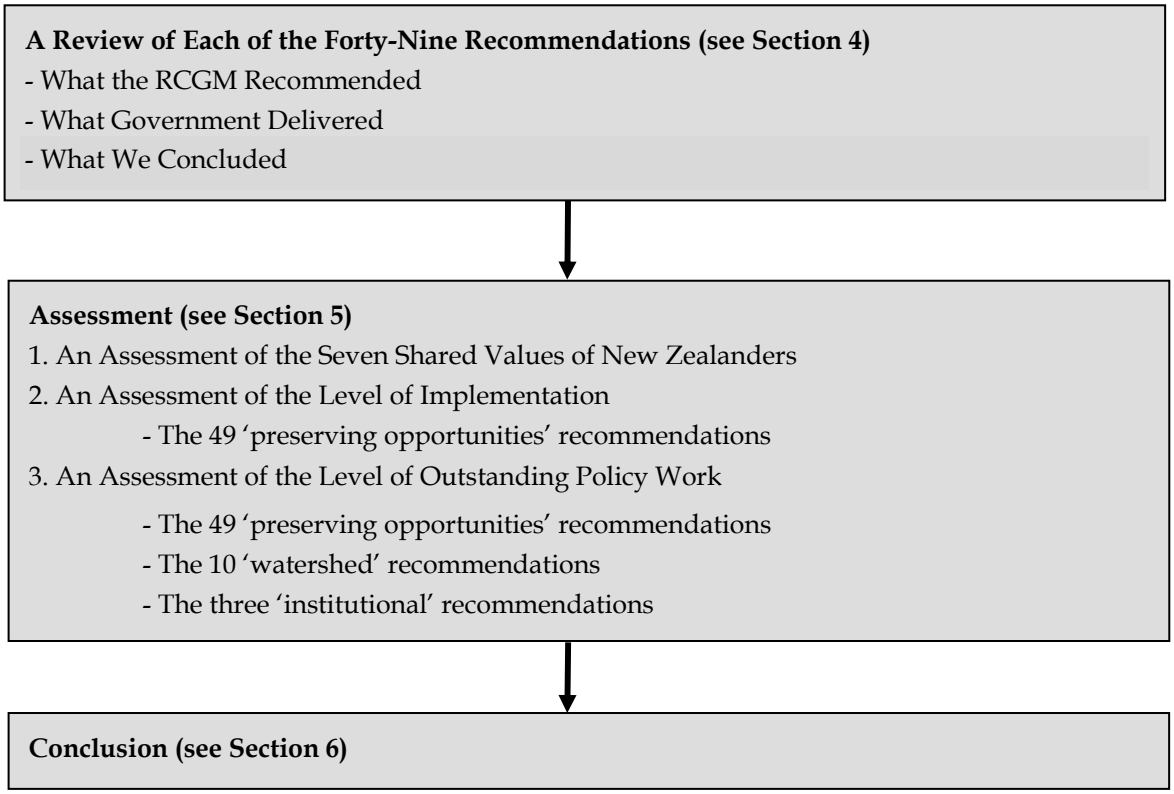
2. **Level of Further Policy Work Required:** Whether 'significant', 'ongoing' or 'no' policy work remains outstanding in relation to the issue the recommendation was intended to manage or solve. This approach reviews each of the 49 recommendations to assess the extent public policy work remains. See Appendix 2 for the nine recommendations that were reclassified.

Figure 3 Level of Further Policy Work Required



How this process has been adopted is outlined in Figure 4 below.

Figure 4 Process of Analysis



3.5.1 An examination of each of the forty-nine recommendations

Each recommendation is examined in Section 4, in the order presented in the *Report of the Royal Commission on Genetic Modification* (2001a). Where we have been unsure about the interpretation of a recommendation, we have referred back to the specific section in the Commissioners' Report for clarification. Each recommendation is dealt with in three parts - see Figure 5.

Figure 5 Analysis of Each Recommendation

What the RCGM Recommended
The actual text of the Commissioners' recommendation.

What Government Delivered
Government response and key actions are listed by date. This information is gained from public records, interviews and correspondence with key stakeholders, and feedback from external reviewers.

What We Concluded
Two assessments are made: the extent to which the recommendation has been implemented (see Section 3.5.2) and the degree to which further policy work remains (see Section 3.5.3).

3.5.2 An assessment of the level of implementation

Our assessment in Section 5 analyses the extent to which each recommendation has been (i) implemented, (ii) partially implemented or (iii) fully implemented.

For the purpose of analysis we have developed a system for coding the level of implementation. A recommendation must be 100% executed to be considered 'fully implemented'. In contrast, a recommendation that has not progressed towards achievement is considered to have been 'not implemented'. Any recommendation that falls between these two extremes has been classified as 'partially implemented'. We have taken this approach to ensure we minimise any subjective interpretation at this early stage.

3.5.3 An assessment of the level of further policy work

After comparing what has happened in the last seven years against the intention of the original recommendations, we make a judgment as to whether each recommendation requires significant further policy work, ongoing policy work or no further policy work. These are summarised in Section 5; the 49 'preserving opportunities' recommendations (Table 13), the 10 'watershed' recommendations (Table 14) and the three 'institutional' recommendations (Table 15).

Significant issues that are raised through this assessment are discussed in greater detail in *The Future of Genetic Modification in New Zealand* (Sustainable Future, in press).

4. Examination of the Forty-Nine Recommendations

Progress on each of the 49 recommendations, from the Government's initial response until today, is examined in this section.

4.1 The Government's Initial Response 2001 - 2003

The Government's official response was released in three phases, with the first phase being a general statement in July 2001; agreeing:

- to thank the Commissioners for their work,
- to characterise the report as measured, balanced, and inclusive of the many values that New Zealanders hold, and to acknowledge the report's major theme of preserving opportunities; and
- not to comment on the individual recommendations until the whole report has been considered (a report back is due by October 31 2001).
(Hobbs, 2001: 4)

Phase two included setting up a group of officials from across a broad range of agencies to look at the report in detail and provide advice to enable the Government to decide on the way forward.[13] The Government's conclusion was to broadly accept the overall strategy of preserving opportunities. The Government released six papers, dated October 2001 (MfE, 2001a-f) which are summarised below. Government agreed to:

- Carry out essential research, recommended by the Royal Commission, to understand better the issues involved in managing GM, if we were to go down that road; for example marketing and soil ecology.
- …explore coexistence and conditional release frameworks as far as is practicable in the absence of releases.
- Put in place many of the amendments to the HSNO Act, which the Royal Commission recommended. This includes the legal parts of the conditional release framework, and importantly streamlining of the system for approving work in secured laboratories.
- Establish Toi Te Taiao or the Bioethics Council to advise, provide guidelines and promote dialogue on the cultural, ethical and spiritual issues associated with biotechnology.

[13] This core group, coordinated by the Ministry for the Environment, included officials from: Ministry of Agriculture and Forestry; Ministry of Economic Development; Ministry of Foreign Affairs and Trade; Ministry of Health; Ministry of Research, Science and Technology; Te Puni Kokiri — Ministry of Māori Development; Treasury, and the Department of Prime Minister and Cabinet. Others included Customs, the Department of Conservation, and the Ministries of Consumer Affairs, Fisheries and Justice. Crown agencies were also involved, including in particular the Environmental Risk Management Authority and the Foundation for Research, Science and Technology.

- Further investigate the liability system for genetic modification related issues. Specifically the Government will be looking at how to include this in the Law Commission's work programme. This will ensure that any potential problems with the existing liability system are identified and addressed proactively, and more importantly visibly and transparently.
- Develop a biotechnology strategy. The strategy will ensure that New Zealand keeps abreast of developments in biotechnology, with a mechanism to ensure ongoing balance between benefits and risks.

On the other hand some of you may be aware that the Royal Commission recommended the setting up of a Parliamentary Commissioner for Biotechnology: We do not intend to do this although we do think that some of the tasks envisaged for the Commissioner are useful and we will be considering other ways to do these. (New Zealand Government, 2001)

In regard to the second point, Cabinet decided to direct officials to explore the work involved in developing coexistence frameworks, which in effect postponed the coexistence decision:

> 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. (MfE, 2001a: 9)

The third phase is when officials reported back to Cabinet, resulting in a further eight papers (MfE, 2003: a-h). All fifteen papers guided our examination of the forty-nine recommendations.

4.2 Recommendations One to Forty-Nine

What follows is an examination and analysis of the implementation of each of the 49 recommendations in the years since 2001. See Tables 3 to 11.

Table 3 Research

What the RCGM Recommended	**6.1 That applications to develop genetically modified organisms in PC1 and PC2 containment be assessed by the Institutional Biological Safety Committees (IBSCs) on a project rather than organism basis.**
What Government Delivered	**2001**: In the initial Government response, this recommendation was accepted by Government as it stood (MfE, 2001b). When the Commissioners' Report was released, much of the necessary policy work to fulfil this recommendation had already been completed by MfE and ERMA. Issues such as the best way to group the organisms, what process to follow if there was a change of circumstance within a project, and the best way to ensure compliance with the HSNO Act were all discussed. **2002:** Submissions were called for in 2002 as part of a plan to amend the HSNO Act. It was established that the HSNO Act needed to be simplified and amended to distinguish between low-risk and high-risk organisms (MfE, 2002; 2003j). **2003**: An amendment was made to section 42A of the HSNO Act to include the phrase 'on a project basis' in relation to low-risk approvals (NZ Govt, 2003a). Another amendment was made to the HSNO Act to ensure comprehensive prior notification of intentions from the researcher in their application to ERMA, approval of the proposal by IBSC or ERMA, and provision of progress reports as specified by IBSC or ERMA (MfE, 2003b). See Appendix 3 for reference to current policy requirements and processes for IBSCs.
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **No**

Table 3 Research cont.

What the RCGM Recommended	**6.2 That all approval forms, standards and regulations relating to the development of genetically modified organisms in containment be reviewed and updated.**
What Government Delivered	**2001**: The intent of this recommendation was accepted by the Government. At the time of the Commissioners' Report, work was already underway to update these forms (MfE, 2001b). **2003:** Under the HSNO Amendment Act (2003), ERMA now has the power to update all approval forms, standards and regulations relating to the development of genetically modified organisms in containment (NZ Govt, 2003a).
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **No**

Table 3 Research cont.

What the RCGM Recommended	**6.3 That a separate, simplified form be developed for low-risk (Categories A and B) applications to IBSCs.**
What Government Delivered	**2001**: The implementation of this recommendation was under development in 2001, so no further action was required (MfE, 2001b).
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **No**

Table 3 Research cont.

What the RCGM Recommended	**6.4 That the Hazardous Substances and New Organisms Act 1996 (HSNO) be amended to allow for the efficient importation of low-risk genetically modified organisms, through delegation of the approval process to the IBSCs.**
What Government Delivered	**2001**: This recommendation was accepted by the Government, with the intention that it would enable New Zealand researchers to better take advantage of and collaborate with international research (MfE, 2001b). **2002**: This issue was included in a discussion paper released by the Government and submissions were called for as part of a plan to amend the HSNO Act (MfE, 2002; 2003j). **2003**: Officials recommended that the HSNO Act be amended (i) to permit IBSCs to approve the importation of low-risk GMOs and (ii) to include a definition of low-risk organisms for the purposes of importation (MfE, 2003b). In the HSNO Amendment Bill 2003, an amendment was made to section 19(2)(a): > that the Authority [ERMA] may delegate, on such terms and conditions as the Authority thinks fit, the power to conduct a rapid assessment to any person, whether or not that person is a member of the Authority [S42B] (NZ Govt, 2003a). This amendment would also apply to the rapid assessments of genetically modified organisms for importation into containment.
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **No**

Table 3 Research cont.

What the RCGM Recommended	**6.5 That approval to develop or import genetically modified organisms be deemed to cover their holding and breeding**.
What Government Delivered	**2001:** The intent of this recommendation was supported by the Government (MfE, 2001b). No action was taken as breeding was deemed to be a normal part of development approvals and ERMA was already dealing with the issue of holding in the amendments to the HSNO Act (MfE, 2001b).
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **No**

Table 3 Research cont.

What the RCGM Recommended	**6.6 That HSNO be amended to clarify that research involving genetic modification of human cell lines or tissue cultures is covered by the Act.**
What Government Delivered	**2001**: The intent of this recommendation was to ensure that appropriate regulatory oversight of research involving the genetic modification of human cell lines or tissue cultures in the laboratory was supported (MfE, 2001b). **2002:** This issue was included in a discussion paper released by the Government, and submissions were called for as part of a plan to amend the HSNO Act (MfE, 2002; 2003j). **2003:** Under the New Organisms and Other Matters (NOOM) Bill, section 50A of the HSNO Act was amended to regulate the genetic modification of human cell lines or tissue cultures in registered containment facilities (NZ Govt, 2003a). In addition, the definition of 'organism' in section 2(1) was amended to include human cells (defined as 'human cells, cell lines, tissues, reproductive cells or embryonic cells being grown or maintained outside the human body') (NZ Govt, 2003a). This amendment applies only to human cells in culture and not to therapeutic procedures involving people; this is covered under section 7A of the Medicines Act (NZ Govt, 1981).
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **No**

Table 3 Research cont.

What the RCGM Recommended	**6.7 That approval for development of genetically modified animal cell lines be delegated to the IBSCs.**
What Government Delivered	**2001:** The intent of this recommendation was supported by the Government. This resulted in an amendment to the Low-risk Genetic Modification Regulations of the HSNO Act (see Recommendation 6.1) (MfE, 2001b). In section 5 of the HSNO (Low-risk Genetic Modification) Regulations 2003, the development of genetically modified animal cell lines is classified as category B, and therefore low-risk and able to be delegated to IBSCs for approval (NZ Govt, 2003d).
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **No**

Table 3 Research cont.

What the RCGM Recommended	**6.8 That HSNO be amended to provide for a further level of approval called conditional release.**
What Government Delivered	**2001:** This recommendation was accepted as the Government felt it reflected the general theme of 'preserving opportunities' in the Commissioners' Report (MfE, 2001c). MfE was directed to report back on the best way to implement conditional release. **2002:** This issue was included in a discussion paper, and submissions were called for in 2002 as part of a plan to amend the HSNO Act (MfE, 2002; 2003j). **2003:** The New Organisms and Other Matters (NOOM) Bill (NZ Govt, 2003a) amended the HSNO Act 1996 in multiple areas (specifically sections 34A and 38A-L) to create a new category called conditional release (in contrast to a full release without controls). Importantly, a conditional release is not a compulsory stage required for the release of a new organism. ERMA is given broad discretion to determine appropriate conditions in regard to each separate application for release (MfE, 2003d).
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **No**

Table 3 Research cont.

What the RCGM Recommended	**6.9 That HSNO be amended to cover procedures used in mammalian cloning, such as nuclear transfer or cell fusion.**
What Government Delivered	**2001**: The Government accepted that all new organisms should be subject to the HSNO Act (MfE, 2001b). **2002:** This issue was included in a discussion paper released by the Government. Submissions were called for as part of a plan to amend the HSNO Act (MfE, 2002; 2003j). **2003:** It was established that the most straightforward method of meeting this recommendation was to amend the definition of 'develop' to encompass all forms of regenerating a new organism from tissues, cells or other genetic material. This would ensure that new species of mammals (or other animals) cannot be imported as tissues, subsequently regenerated by cloning and released without an appropriate HSNO Act approval (MfE, 2003b). This was included in the 2003 amendments to the HSNO Act (NZ Govt, 2003a).
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented** Note: Many of these modifications were also necessary to harmonise New Zealand legislation with the Protocol on Biosafety.
	Is further policy work required by central government? **No**

Table 3 Research cont.

What the RCGM Recommended	**6.10 That IBSCs include at least one Māori member, appointed on the nomination of the hapū or iwi with manawhenua in the locality affected by an application.**
What Government Delivered	**2001:** The intent of this recommendation was to help ensure appropriate and timely consultation with Māori about low-risk research applications that are approved by IBSCs. This was supported by the Government, although it was noted that this may not provide the best means for achieving the required consultation and other avenues would be looked into by officials during a wider review of relevant processes (MfE, 2001b). **2003:** It was noted by the Government that a network of Māori IBSC members was developing. ERMA was directed to further investigate how this network could be supported (MfE, 2003h). **Nov 2004:** The policy document *Incorporating Māori Perspectives in Part V Decision-making* was published, and included reference to appointing Māori to decision-making committees (ERMA, 2004). **2007:** ERMA's current policy with regard to Māori membership of IBSCs is that there should be at least one Māori member appointed to each IBSC. This person must be nominated through the iwi or hapū with manawhenua in the locality covered by the application (MfE, 2006).
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **No**

Table 3 Research cont.

What the RCGM Recommended	**6.11 That the funders of resource portfolios be resourced to include the cost of compliance with HSNO.**
What Government Delivered	**2001:** The intent of this recommendation — to ensure that the cost of an application to ERMA doesn't limit the amount of research that can be funded — was accepted by the Government. It was noted, however, that all government agencies that fund research portfolios already include the application cost in their funding, and that as recommendations 6.1 to 6.5 are implemented, the cost of applications should go down (MfE, 2001b). MoRST notes, in a written response received by Sustainable Future through ERMA, that: > Government funding of research though Vote Research, Science and Technology operates under a full cost funding model which means that the full costs of research (including costs for regulatory approvals) should be included in research proposals. There have been no increases in funding that are specifically allocated for costs associated with regulatory approvals. (ERMA, 2007a: 13)
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented.** Note: This was already common practice.
	Is further policy work required by central government? **No**

Table 3 Research cont.

What the RCGM Recommended	**6.12 That the Environmental Risk Management Authority (ERMA) require research on environmental impacts on soil and ecosystems before release of genetically modified crops is approved.**
What Government Delivered	**2001:** The Government agreed with the intent of this recommendation, which was to ensure that necessary research is undertaken so that ERMA has sufficient information on environmental impacts on soil and ecosystems before making decisions about the release of GM crops. It noted that applicants seeking approval to test or release GM organisms, including crops and forest trees, were already required to provide ERMA with appropriate data on the likely impacts on soil and ecosystems (MfE, 2001c).
What We Concluded	To what extent has the recommendation been implemented? **Not Implemented** Is further policy work required by central government? **Yes: Significant** **Discussion** We understand this recommendation was referring to increasing knowledge on impacts specific to New Zealand (RCGM, 2001a: 133), for example: > While international research will increase our knowledge in this area, there is also a need for research specific to the New Zealand environment. (RCGM, 2001a: 133) However, we concluded that there was a difference between 'require research', as in recommendation 6.12 (a generic approach), and 'request data' from applicants on likely impacts on soil and ecosystems as part of the application process (using a control in a case-by-case approach). Therefore in our view the recommendation has not been implemented. This recommendation raises four additional issues, namely: **(i) The role of ERMA as both a control body and as a way of actively pursuing public-good research** The Commissioners' note that pursuing this recommendation offers associated benefits for the public good, such as increased public understanding of genetic technologies (RCGM, 2001a: 133). However, the authority argues it cannot create controls for purposes beyond the management of immediate negative effects. Therefore, in order to add controls that monitor public-good outcomes, the legislation would need to be changed.

Table 3 Research cont.

	(ii) If not ERMA, who will research the environmental impacts on soil and ecosystems? Under the 'Sustaining New Zealand's Economic and Technological Development' portfolio, FRST agreed to invest up to $1.463 million per annum from 2002 to 2005 on three research projects specifically relating to the environmental impacts of GMO release on soil and ecosystems.[14] In 2006 and 2007 only the third project continued, at a cost of $370,000 per annum (FRST, 2007a). The relevant research projects and their outputs are as follows:[15] 1. 'Bio Diversity and Threatened Species' (Landcare Research NZ Ltd) ($418,000 p.a., excluding 2005, when it was $202,000 p.a.). 2. 'Horizontal Gene Transfer in the NZ Environment' (Institute of Environmental Science and Research Ltd) ($675,000 p.a.).[16] 3. 'The Role of Indigenous Pollinators as New Zealand Specific Mechanisms for Transgene Flow' (Crop and Food) ($370,000 p.a.) (FRST, 2007a).[17] **(iii) The need for quality information and robust debate before the first application to release a genetically modified crop is received by ERMA** We believe this is the key purpose of this recommendation, and consider the strategic option of 'preserving opportunities' was all about gathering information 'specific to the New Zealand environment' (RCGM, 2001a: 133). We consider this recommendation was designed to support the effective application of Recommendation 13.2 (as part of the 'environmental impact' information that would be needed in order for the Minister to make an assessment on the first application to release a GMO crop) under section 68 of the HSNO Act. In 1998, Monsanto discussed with ERMA the first draft of an application to import and plant canola (GMR98001). After feedback on the requirements of the HSNO Act, the draft application was withdrawn. However, this demonstrates the intention to commercially grow GM crops in New Zealand, and that as such, we need to be prepared to manage this risk when the situation arises.

[14] More information about the 'Sustaining New Zealand's Economic and Technological Development' portfolio can be found at http://www.frst.govt.nz/research/SET.cfm

[15] Research reports for all of these projects are available on the FRST website (FRST, 2007a)

[16] More information about the project 'Horizontal Gene Transfer in the NZ Environment' can be found on the Institute of Environmental Science and Research website at http://www.esr.cri.nz/competencies/populationhealth/genetransfer.htm

Table 3 Research cont.

	(iv) Lack of public engagement and transparency Also at a strategic level, the Biotechnology Research Roadmap (MoRST, 2007a) has been prepared as a direction-setting document; direction 8 in the Roadmap states: > The Government will continue to support research to inform quality decision-making on the environmental impacts and societal implications of emerging biotechnologies in the New Zealand context. (MoRST, 2007a) As part of implementing this direction MoRST held a workshop in 2007 involving researchers, policymakers, regulators and FRST representatives, to discuss research needs and capabilities. This workshop helped inform FRST's Request for Proposals for its 'Sustaining New Zealand's Economic and Technological Development' portfolio (ERMA, 2007a). We consider it would be advantageous for direction-setting to involve more public engagement. We note that ERMA, MoRST and FRST liaise informally about research needs and outputs in this area. ERMA is on the Advisory Group for the FRST 2007/08 SET investment round, and an end-user of FRST-funded research programmes such as the non-target impact research led by HortResearch (ERMA, 2007a). However, we have concerns about how strategic (e.g. comprehensive, cost-effective and useful) and independent public-good research has been to date. Without characteristics like public consultation, an independent body to peer review work, and a culture where conclusions and findings are made public, many people may remain sceptical about this.

[17] More information about the project 'The Role of Indigenous Pollinators as New Zealand Specific Mechanisms for Transgene Flow' can be found on the Crop and Food website at http://www.crop.cri.nz/home/research/land-water/research-programmes.php

Table 3 Research cont.

What the RCGM Recommended	**6.13 That public research funding be allocated to ensure organic and other sustainable agricultural systems are adequately supported.**
What Government Delivered	**2001:** The Government agreed with this recommendation but decided that this research would benefit from a more formalised, overarching direction (MoRST, 2003a: 7). It recommended that FoRST and the organic and sustainable farming community, in consultation with research providers, develop a research strategy to inform the prioritisation of public research in this area (MfE, 2001c). **2003:** MoRST reported that research specifically supporting the organic sector had increased by approximately $0.8 million p.a. to a total of $3 million p.a. It was also noted that this sum was supplemented by primary production research into sustainable agriculture of approximately $50 million p.a. (MoRST, 2003a). **April 2003:** A development strategy for the organics sector, contracted by MAF, was released. This is not specifically a public research funding strategy (a strategy for developing research by, for and with the organics sector to support their development). However, it does aim to develop a more cohesive, focused and productive industry with greater capacity to be involved in research.[18]
What We Concluded	To what extent has the recommendation been implemented? **Partially Implemented**
	Is further policy work required by central government? **Yes: Ongoing** **Discussion** This recommendation has arguably been implemented, but it is unclear to what extent the level of funding was sufficient, delivered value and followed due process. We were also unsure how outcomes are assessed (value for money) and by whom. Lastly, we were unsure how the process for allocating funds will be updated and managed. We therefore question whether the needs of the organic and wider sustainable farming community are being adequately supported by current levels of research. These considerations are critical for non-GM farmers.

[18] The Organic Sector Strategy is available from http://www.maf.govt.nz/mafnet/rural-nz/sustainable-resource-use/organic-production/organic-strategy/organic-strategy.pdf

Table 3 Research cont.

What the RCGM Recommended	**6.14 That public research funding portfolios be resourced to include research on the socio-economic and ethical impacts of the release of genetically modified organisms.**
What Government Delivered	**2001:** The intent of this recommendation was accepted by the Government; it was initially thought that funding of $1.5 million p.a. would be needed to implement it (MfE, 2001c). **2002:** In the 2002 budget, the Government allocated funding through FoRST to go towards research that addresses the socio-economic and ethical impacts of biotechnologies, including genetically modified organisms.[19] **2002–2006:** Under the 'Sustaining New Zealand's Economic and Technological Development' portfolio (SET),[20] $842,000 of funding per annum has been provided to three projects which specifically address this recommendation (FoRST, 2007b). The relevant research projects (available on the FoRST website) are as follows: [21] 1. 'The Fate of Biotechnology' (Lincoln University) ($142,000 p.a.). 2. 'Socially and Culturally Sustainable Biotechnology in New Zealand' (Waikato University) ($500,000 p.a.).[22] 3. 'Clarification and Evaluation of Māori beliefs and Perspectives Concerning Genetic Biotechnologies' (Otago University) ($200,000 p.a.).

[19] FoRST was provided with an additional $1 million in 2002/03 (rising to $2.5 million p.a. from 2003/04) to support 'multidisciplinary research aimed at an improved understanding of the socio-economic, ethical and environmental impacts of genetic modification and other emerging biotechnologies' (MoRST, 2003b: 7). The reference to research on 'other emerging biotechnologies' was added to widen the context of the new research and go beyond the consideration of impacts specific to GM.

[20] More information about the 'Sustaining New Zealand's Economic and Technological Development' portfolio can be found at http://www.frst.govt.nz/research/SET.cfm

[21] A FoRST reply to Sustainable Future did not include the project 'Constructive Conversations: Biotechnologies, dialogue and informed decision-making', undertaken by the University of Canterbury (2003–2008, with a total contract value of $2,992,500) as a research project specifically addressing this recommendation, however we note its contribution to the field. More information about the project is available from http://www.conversations.canterbury.ac.nz/index.htm and http://www.frst.govt.nz/Public/Reporting/reports06/Report.cfm?Report=2

[22] More information about Waikato University's 'Socially and Culturally Sustainable Biotechnology in New Zealand' project can be found at http://wms-soros.mngt.waikato.ac.nz/NR/exeres/D4172EE7-AEA2-4EBB-BAD3-2B18808F23EC.htm

Table 3 Research cont.

What We Concluded	To what extent has the recommendation been implemented? **Partially Implemented**
	Is further policy work required by central government? **Yes: Ongoing** **Discussion** We consider the Commissioners' strategic option of 'preserving opportunities' aimed to gather and utilise information from a range of areas, including the broader 'social and economic context', in order to make a strategic decision around the use of GM in New Zealand (RCGM, 2001a: 135). We consider this recommendation was intended to support 'economic impacts' (Recommendation 13.2), and 'cultural, ethical and spiritual issues' (Recommendation 14.2) as grounds for the Minister's call-in powers under section 68 of the HSNO Act. We note that: (i) While $1.5 million p.a. was expected (see 2001 above), the actual amount used to date is significantly less, at just $842,000 p.a. (the total p.a. amount from the 2002–2006 figures above). In addition, although it is clear that research is being produced, it is not clear how its findings are being fed back into the industry and influencing the development of GM in New Zealand. (ii) There has been some economic analysis of genetic modification, including some preliminary research on the economics of biopharming (AERU, 2007).[23] Our conclusion that this recommendation is 'partially implemented' is based on the premise that although 'cultural, ethical and spiritual issues' and 'economic issues' have been researched, there remains insufficient research to meet the needs of a strategic decision on release. In our view, without further research there will be insufficient information for ERMA (or a Minister under s68) to make an assessment of the socio-economic and ethical impacts of the release of a genetically modified organism in New Zealand. Part of the challenge will be ensuring research is relevant, transparent, peer reviewed and conducted independent of final decision-makers.

[23] Economic research includes: *Assessment of Economic Risks, Costs and Benefits: Consideration of impacts on the market economy* (ERMA, 2005); *Modelling the Trade Impacts of Willingness to Pay for Genetically Modified Food (*Kaye-Blake *et al*., 2004); *Economic Impacts on New Zealand of GM Crops: Result from partial equilibrium modelling* (Saunders et al., 2003), and *Briefing on Genetic Modification Economic Analysis Paper* (Treasury, 2003).

Table 4 Crops and other field uses

What the RCGM Recommended	**7.1 That, prior to the release of any Bt-modified crops, the appropriate agencies develop a strategy for the use of the Bt toxin in sprays and genetically modified plants, taking into account:** **a. The concept of refugia;[24]** **b. Limitations on total planted area, and** **c. Home gardener use.**
What Government Delivered	**2001:** The intent of this recommendation was accepted by the Government. It felt that it would be most successful if it were implemented on a case-by-case basis for organisms under conditional release. However, home-gardener use of Bt was not considered significant enough to be included in this practice (MfE, 2001c). **Oct 2002:** The report *Towards a Strategy for Using Bt Toxins in New Zealand* (MAF, 2002) provides guidelines for the development of an appropriate strategy. It states that: In summary, the Government should consider the following questions/issues: • The amount of Bt used by home gardeners and commercial farmers should be estimated and assessed for its potential to accelerate the development of resistance. • Similarly, a decision to regulate Bt crops to delay resistance should be justified by assessing whether selection pressure applied to pests from the Bt crops is sufficiently different from other methods of controlling those pests, including the use of Bt sprays. The assessment should take account of the numbers of Bt plants being used, as well as their characteristics. • If regulation is considered, the usual process of evaluating costs and benefits should be followed. In particular, monitoring and enforcement will be critical issues. For example, there may need to be some sort of third-party audit system, and a way of collecting data about the amount and location of Bt crops being grown or Bt spray being used. • The Government should continue to consider the potential for resistance when using Bt sprays for biosecurity operations. (MAF, 2002: 14)

[24] In the context of pest control, the word 'refuge' is used to mean an area of habitat where susceptible pest populations can survive in numbers that will sufficiently dilute any resistance that arises in the target populations (MAF, 2002).

Table 4 Crops and other field uses cont.

	2003: MAF advised that although generic research had been undertaken in preparation for managing future applications, no actual strategy had been developed. Instead, for each relevant application for conditional release, the applicant may be required to develop their own insect resistance management strategy specific to the crop in question, which complies with a standard determined by MAF. MAF suggest the three concepts the Commissioners note above should be taken into account and managed on a case-by-case basis (MAF, 2003). MAF continues to monitor international developments (MAF, 2003).
What We Concluded	To what extent has the recommendation been implemented? **Not Implemented**
	Is further policy work required by central government? **Yes: Significant** **Discussion** The Commissioners were trying to put in place a national strategy based on proactive strategic thinking and quality information, but instead the Government has delivered a reactive response delegated to ERMA.

Table 4 Crops and other field uses cont.

What the RCGM Recommended	**7.2 That the appropriate agencies develop a labelling regime to identify:** **a. genetically modified seed;** **b. nursery stock; and** **c. propagative material** **at point of sale.**
What Government Delivered	**2001:** This recommendation was accepted by the Government (MfE, 2001c). The Government directed MAF, following consultation with the industries involved, to develop options for the introduction of a labelling regime for propagative plant material. There was some deliberation over whether the regime should be voluntary or mandatory, and it was noted that organisms for conditional release may be required to comply with this system (MAF, 2003; MfE, 2001c). **Nov 2004**: The draft code was published by MAF, with the intention that the labelling regime would be voluntary (see MfE, 2006). If the draft code becomes final, it will be enforceable through the Fair Trading Act 1986 (MAF, 2007a). MAF notes that the code (or parts of it) could become mandatory in specific instances if labelling was required under conditional release to manage a risk identified in ERMA's risk assessment (MAF, 2007a). However, to date there have not been any applications to ERMA for the release of GMOs, for sale or otherwise.
What We Concluded	To what extent has the recommendation been implemented? **Not Implemented** (for a, b and c).
	Is further policy work required by central government? **Yes: Significant** **Discussion** We are unsure how, when or by whom the voluntary draft code will be finalised. We are also of the view that the Commissioners were proposing a comprehensive mandatory labelling regime, rather than case-by-case control via the ERMA application process.

Table 4 Crops and other field uses cont.

What the RCGM Recommended	**7.3 That the Ministry of Agriculture and Forestry (MAF) develop a strategy to allow continued production of genetic modification-free honey and other bee products, and to avoid cross-pollination by bees between genetically modified and modification-free crops, that takes into account both geographical factors (in terms of crop separation strategies) and differences in crop flowering times.**
What Government Delivered	**2001:** Initially this recommendation was rejected by the Government in its original form. It felt a strategy to limit the exposure of bees to GM plants would only be needed once flowering crops were released from containment, and that even then such a strategy would be unlikely to be successful in the long term (MfE, 2001c). **April 2003:** MAF was directed to investigate the use of a register for GM plants based on a Geographic Information System, whereby information would be made available to the bee-keeping community (MAF, 2003). The findings of this investigation were passed on to the bee-keeping community (MAF, 2007a). **Nov 2004:** MAF officials reported to Ministers on the need to strike a balance between bee-keepers wanting to have full knowledge of locations of GM crops and the danger of these crops being sabotaged when considering relevant approvals. MAF was directed to monitor developments and report back on issues to be further considered by the Government (MFE, 2006). Ministers have noted that the impact of flowering GM crops on bee products could be mitigated through conditions that could be set under a conditional-release approval (MAF, 2007a).

Table 4 Crops and other field uses cont.

What We Concluded	To what extent has the recommendation been implemented? **Not Implemented**
	Is further policy work required by central government? **Yes: Significant** **Discussion** A strategy has not been developed. We find the MAF solution advocated above to be contrary to the strategic recommendation of preserving opportunities. The MAF solution places the onus of managing the risk on bee-keepers rather than the GM-crop producers. In summary, the industry remains very vulnerable to the release of certain GM crops.

Table 4 Crops and other field uses cont.

What the RCGM Recommended	**7.4 That, in connection with any proposal to develop genetically modified forest trees, an ecological assessment be required to determine the effects of the modification on the soil and environmental ecology, including effects on soil micro-organisms, weediness, insect and animal life, and biodiversity.**
What Government Delivered	**2001**: This recommendation was accepted, however, the Government understood that HSNO legislation already gave ERMA the authority to require this information before an application for release was approved (MfE, 2001c). The HSNO Act and the HSNO (Methodology) Order 1998 provide the statutory requirements and methods for carrying out a risk assessment. There are also supporting technical guides and protocols that provide policy guidance (ERMA, 2007a). No applications for the release of GM trees have been submitted to date, but ERMA has the power to uphold this recommendation if there are future applications (MfE, 2006). However, ERMA did approve two applications for field tests in 2000, from the Crown Research Institute now called Scion.[25]

[25] Scion is a Crown Research Institute, formerly known as Forest Research, which is undertaking research and development in the area of plantation forestry and biomaterial development.

Table 4 Crops and other field uses cont.

What We Concluded	To what extent has the recommendation been implemented? **Not Implemented** Is further policy work required by central government? **Yes: Significant** **Discussion** We have taken the view that the Commissioners were expecting this requirement to be mandatory practice by ERMA on receipt of an application to develop, field test or release GM forest trees in the outdoors. This was based on the view that being 'required to determine the effects' (as proposed in the above recommendation) implied that a full ecological assessment 'must' occur before forest trees could be planted in the outdoors, and must be completed independently of the applicant and ERMA. This raises four issues: (i) Should this happen retrospectively? We note that Scion applied to carry out two field tests in 2000, and ERMA gave approval, but to our knowledge, did not complete a comprehensive ecological assessment. (ii) The HSNO legislation does not require an independent ecological assessment. We note that the current legislation suggests ERMA should require research into effects when considering an application for GM organisms, but this is not necessarily an ecological assessment. We would like to see independent ecological assessments made mandatory, and prepared and made public in advance of any applications to 'develop, test or release' forest trees in the outdoors. (iii) We consider forest trees to be too narrow a category, and that all plants and animals placed in the outdoors should, as part of the application process, have a complete and full assessment report prepared by a third party. This report should be prepared independent of the applicant and ERMA, and should be made available to ERMA and the public before public hearings take place. This is above and beyond the current ERMA report on an application. Due to the small number of outdoor applications, and the benefits of a precautionary and transparent approach, we consider a lot could be gained at minimal cost. (iv) Keeping in mind the increased application and demand for 'ecological assessments', we consider the Government should put forward an 'ecological assessment protocol or standard' for application across all aspects of government (much like the standard the EU currently has in place).[26]

[26] See http://ec.europa.eu/environment/eia/sea-legalcontext.htm for details on this standard.

Table 4 Crops and other field uses cont.

What the RCGM Recommended	**7.5 That, wherever possible, non-food animals, or animals less likely to find their way into the food chain, be used as bioreactors rather than animals that are a common source of food.**
What Government Delivered	**2001**: The intent of this recommendation — to ensure that GM animals and animal products do not unintentionally enter the human food chain — was accepted by the Government (MfE, 2001b). The Government decided no further action was required as the current legislative and regulatory requirements under the HSNO Act 1996, the Food Act 1981 and the Animal Products Act 1999 would already prevent bioreactors entering the food chain unintentionally. It was also considered acceptable for animals such as cows and sheep to continue to be commonly used as bioreactors because they are easy to manage, well-researched and produce a significant quantity of milk. It was also felt that conditional release would address this issue (MfE, 2001b). **Aug 2003 to Aug 2004**: The Bioethics Council conducted a detailed investigation into the ethical issues surrounding human genes in other organisms, and concluded that the Government should adopt this recommendation (Bioethics Council, 2004a; 2004b; NFO, 2004).
What We Concluded	To what extent has the recommendation been implemented? **Not Implemented** Is further policy work required by central government? **Yes: Significant** **Discussion** The Commission was attempting to put a safety net around this issue, one that the Government has continued to consider unnecessary. For example, we note that the Government has continued to fund AgResearch's use of GM cattle as bioreactors to produce biopharmaceutical proteins, and that Crop and Food is proposing to develop potatoes to produce therapeutic proteins (AERU, 2007). Now that the Bioethics Council has, after considerable public consultation, released a report that supports the Commissioners' recommendation, we consider the Government can no longer ignore the advice of the two expert bodies it has established and funded. We await the Government's response.

Table 4 Crops and other field uses cont.

What the RCGM Recommended	**7.6 That, wherever possible, synthetic genes or mammalian homologues of human genes be used in transgenic animals to avoid the use of genes derived directly from humans.**
What Government Delivered	**2001:** The Government felt that in making this recommendation the Commission was assuming that ethical concerns about the use of copies of human genes in animals would be reduced if synthetic or closely related genes from other mammals were used instead. However, the Government disagreed with this idea as it considered it unlikely that the ethical concerns of people who are opposed to aspects of gene technology would be lessened by the subtleties of how that genetic modification is done (MfE, 2001b). The Government asked the Bioethics Council to address the ethical issues raised by this recommendation. **Aug 2003 to Aug 2004:** The Bioethics Council conducted a detailed investigation into the ethical issues surrounding human genes in other organisms. The Council concluded that the Government should adopt this recommendation (Bioethics Council, 2004a; 2004b; NFO, 2004).
What We Concluded	To what extent has the recommendation been implemented? **Not Implemented**
	Is further policy work required by central government? **Yes: Significant** **Discussion** As with Recommendation 7.5, now that the Bioethics Council has, after considerable public consultation, released a report that supports the Commissioners' recommendation, we consider the Government can no longer ignore the advice of the two expert bodies it has established and funded. We await the Government's response.

Table 4 Crops and other field uses cont.

What the RCGM Recommended	**7.7 That MAF develop an industry code of practice to ensure effective separation distances between genetically modified and unmodified crops (including those grown for seed production), such a code:** **a. to be established on a crop-by-crop basis** **b. to take into account:** – **existing separation distances for seed certification in New Zealand;** – **developments in international certification standards for organic farming;** – **emerging strategies for coexistence between genetically modified and unmodified crops in other countries** **c. to identify how the costs of establishment and maintenance of buffer zones are to be borne.**
What Government Delivered	**2001**: This recommendation was accepted in principle by the Government, though it was felt that there could be practical difficulties with implementation. It was acknowledged that the development of a strategy would involve a cost to Government, and could mean increased compliance costs to farmers if their practices were restricted. However, it was seen that such issues might be outweighed by the strategy's benefits in the long term. In view of this, MAF was directed to investigate the issue (MfE, 2001c). **2003**: MAF's investigation included assessing relevant literature, discussing the issues with a range of practitioners, and seeking submissions on the practicality of a code of practice. MAF discovered that the main practical difficulty in implementing an industry code of practice would most likely be the difficulty of guaranteeing absolute purity. The views of submitters differed as to whether this was actually possible. **2003:** It was decided that in the short to medium term, under the proposed new conditional-release amendment to the HSNO Act, the case-by-case conditions placed by ERMA on an applicant or delegated user would amount to specific controls for the management of each organism. These would have legal standing and be enforceable under the HSNO Act. Officials recommended that MAF continue to monitor the situation and report back on issues around development of a generic code of practice (MAF, 2003).

Table 4 Crops and other field uses cont.

	Nov 2004: MAF reported that a generic industry code of practice would be impractical as each primary industry has different concerns and requirements. This difficulty is amplified as it is not known which GM organisms are likely to be used in New Zealand. However, it was agreed that a code could possibly be developed once this became clear. In the meantime ERMA could choose to require the recommended practices as conditions under conditional release, and MAF could work with relevant industries or producers on a case-by-case approach to develop best practice in achieving coexistence (MAF, 2007a; MfE, 2006).
What We Concluded	To what extent has the recommendation been implemented? **Not Implemented**
	Is further policy work required by central government? **Yes: Significant** **Discussion** No code of practice has been developed. This was a key strategy in support of the option of 'preserving opportunities', therefore MAF's inability to produce a cost-effective and practical code must raise questions as to whether the Commissioners' strategic option is now feasible. In addition, the ad hoc case-by-case industry approach proposed by MAF could place a disproportionately large share of the burden of ensuring non-contamination on non-GM producers and reduce their ability to press for costs if harm occurs. Once again (like the bee-keepers) this proposal could be seen as New Zealand pursuing GM crops at the cost of non-GM producers, rather than 'preserving opportunities'.

Table 5 Food

What the RCGM Recommended	**8.1 That the Food Administration Authority:**[27] **a. monitor research studies on stock feed; and** **b. act on any that indicate a need for stock feed to be assessed in relation to human health.**
What Government Delivered	**2001**: This recommendation was accepted by the Government, subject to adequate available resourcing (MfE, 2001d). MAF was directed to plan a programme to monitor research into the health aspects of GM stock and to assess what action might be required in the future. The NZFSA, which is currently responsible for monitoring the science in this area, has currently contracted this work to Environmental Science and Research Services (NZFSA, 2007a)[28]. **2006:** No food safety or human health issues have been identified in the course of MAF's monitoring of international and domestic information sources (MfE, 2006). Currently there is no legislative mechanism in the Agricultural Compounds and Veterinary Medicines Act 1997 to support this recommendation. However, any new organism included in animal feeds must be recognised as safe for inclusion, which would require relevant ERMA approval for the release of the organism in New Zealand (MfE, 2001d; 2006).
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **No** **Discussion** In making this assessment, we have assumed that the monitoring and assessment practices noted above would have been independently reviewed in the past seven years and any recommendations for improvement adopted.

[27] Now the New Zealand Food Safety Authority (NZFSA).

[28] See http://www.nzfsa.govt.nz/science/current-awareness/gm/index.htm for the latest report, which includes a study of the safety of food derived from animals given GM feed.

Table 5 Food cont.

What the RCGM Recommended	**8.2 That Government facilitate the development of a voluntary label indicating a food:** **a. has not been genetically modified;** **b. contains no genetically modified ingredients; and** **c. has not been manufactured using a process involving genetic modification.**
What Government Delivered	**2001:** This recommendation was accepted by the Government, and the Ministry of Consumer Affairs (MCA) was directed to further investigate the requirements of such a label (MfE, 2001d). **2002**: In terms of general labelling under the ingredients of a product, since December 2002 all approved genetically modified foods or foods containing genetically modified DNA or protein must be labelled according to Standard 1.5.2 of the Australian New Zealand Food Standards Code (MfE, 2006). Genetically modified material in flavourings making up less than 0.1% of a final food, and the unintentional presence of trace amounts of GM material (less than 1%) in ingredients are exempt from this requirement (MfE, 2006). **April 2003:** A discussion document was released by MCA and NZFSA on the development of a voluntary GM-free labelling system for food (NZFSA, 2007b). **Nov 2003:** MCA and NZFSA convened a stakeholder working group to consider submissions on the discussion paper and to generally develop a way forward (NZFSA, 2007b). A GM-free label was deemed not practicable due to the interpretation under the Fair Trading Act 1986 of 'free' as an absolute term. To this end, there are also difficulties in conducting accurate testing. These technical difficulties led to a recommendation that companies should be free to label their products GM-free on their own if they are confident that this is correct, but that in the immediate future a label for this purpose will not be developed by the Government (MfE, 2006). **2004:** A Cabinet Policy Committee directed MCA to work in cooperation with the Commerce Commission to facilitate the development of a guideline for industry regarding requirements for labelling products GM-free, to provide suppliers with an opportunity to minimise adverse outcomes of an accidental breach of the Fair Trading Act and to strengthen consumer confidence that GM-free claims are well founded (MfE, 2006). As of 2006, this work was ongoing.

Table 5 Food cont.

What We Concluded	To what extent has the recommendation been implemented? **Not Implemented**
	Is further policy work required by central government? **Yes: Significant** **Discussion** No GM-free label has been developed.

Table 5 Food cont.

What the RCGM Recommended	**8.3 That, as a matter of priority, the Food Administration Authority[29] disseminate information on:** **a. the labelling regime for genetically modified foods; and** **b. consumer rights** **in relation to foods made available for consumption at restaurants and take-away bars.**
What Government Delivered	**2001:** The Government accepted the informal intent of this recommendation, which it interpreted as being to effectively implement the GM Food Standard and a communications strategy (MfE, 2001d). Initially the Government explored a number of alternative strategies to develop an effective consumer communication regime for the labelling of GM food. **2002:** The Government agreed to a communications strategy involving media statements, television and radio interviews, newspaper advertisements, pamphlets, mail drops and local/iwi radio advertising. It also planned a two-year audit programme of existing New Zealand food businesses. **2002:** An information pack produced by MfE, MoH, MAF and MoRST was released to consumers explaining how GM is used in foods and how it is controlled (MfE, 2006). **2003:** NZFSA published the report *Assessment of Compliance with Standard 1.5.2: Food produced using gene technology* (NZFSA, 2003). The survey examined the level of compliance with Standard 1.5.2 of the Australian New Zealand Food Standards Code and assessed the systems food businesses have in place to ensure ongoing compliance. Under current GM labelling requirements, foods prepared for immediate consumption and sold from restaurants, vendors, caterers, self-caterers and takeaways are exempt from the labelling regulations, and if the consumer wishes to know of GM content they must enquire at the point of sale.

[29] Now the New Zealand Food Safety Authority.

Table 5 Food cont.

What We Concluded	To what extent has the recommendation been implemented? **Partially Implemented**
	Is further policy work required by central government? **Yes: Ongoing** **Discussion** We note that this recommendation was considered a 'matter of priority' by the Commissioners but that: (i) No labelling regime for foods prepared for immediate consumption has been developed. Thus information about a labelling regime cannot be disseminated, and as such, this part of the recommendation cannot be fully realised. (ii) It is unclear whether the Government has undertaken any work regarding consumer rights in this area.

Table 5 Food cont.

What the RCGM Recommended	**8.4 That the Food Administration Authority[30] produce and distribute consumer information on the use of gene technology in the production of food.**
What Government Delivered	**2001**: This recommendation was accepted. It was proposed to update existing web-based MoH and MAF GM-food fact sheets to avoid the need to obtain further funding (MfE, 2001d). **2002:** An information pack produced by MfE, MoH, MAF and MoRST was released to consumers explaining how GM is used in foods and how it is controlled. In a general sense, the Government directed MOH, MAF and NZFSA (once established) to update existing web-based information for consumers. This has been done, and the information will be updated periodically. Information about GM food has also been included in the communication strategies under the broader umbrella of biotechnology (MfE, 2006).
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **No**

30 Now the New Zealand Food Safety Authority.

Table 6 Medicine

What the RCGM Recommended	**9.1 That all gene therapy, whether in the public or the private sectors, require formal medical ethical oversight.**
What Government Delivered	**2001:** The intention of this recommendation, to ensure that gene therapy should be introduced into a clear legislative and ethical framework, was accepted by the Government (MfE, 2001d). Under section 30 of the Medicines Act, researchers are required to apply to the Director-General of Health for permission to conduct any trial involving gene therapy in humans (NZ Govt, 1981). This involves applying for an exemption from the controls of the Act. Advice would have to be sought from the Health Research Council, and the study protocol approved by an HRC-accredited ethics committee before consent can be given. The Minister of Health has set up and funded six regional health and disability ethics committees and one multi-regional committee under section 11 of the New Zealand Public Health and Disability Act 2000. Clinical trials involving gene therapy require multiple ethical approvals (MfE, 2006).
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **No**

Table 6 Medicine cont.

What the RCGM Recommended	**9.2 That Toi Te Taiao: The Bioethics Council develop ethical guidelines for xenotransplantation involving genetic modification technology.**
What Government Delivered	**2001:** The broader interpretation of this recommendation was accepted. The Government identified that, until the Bioethics Council had fully considered this issue and the Medicines Act been changed, the introduction of xenotransplantation technology involving humans must not proceed (MfE, 2001d). **2001**: Xenotransplantation was regulated under Part 7A of the Medicines Act 1981 (NZ Govt, 1981). An amendment was passed that allows xenotransplantation trials to be considered and approved by the Minister of Health, but requires strict criteria to be met before approval is given — currently Part 7A is set to expire on 31 December 2008 (MfE, 2006). We are unsure what happens after this point. **Jan 2005:** The Bioethics Council was commissioned by the Government to consult on the cultural, ethical and spiritual considerations around xenotransplantation. It was not to explore the public health or scientific issues around the technology, nor how these should be regulated. The Council subsequently released a discussion document on xenotransplantation (Bioethics Council, 2005a). **Aug 2005:** The Bioethics Council released a final report on xenotransplantation (Bioethics Council, 2005b) in which it made eight recommendations to support the ethical guidelines that it identified for xenotransplantation in New Zealand. The Council recommends that xenotransplantation be allowed to develop in New Zealand but that an appropriate regulatory and decision-making framework be implemented by the Government. **Sept 2007:** The Gene Technology Advisory Committee (under Medsafe) has adopted revised guidelines for assessing applications for clinical trialling of xenotransplantation (GTAC, 2007).

Table 6 Medicine cont.

What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **Yes: Ongoing** **Discussion** Although the Bioethics Council has produced the recommended guidelines, which have fed into GTAC's development of guidelines for clinical trialling, we consider the public still needs to know the Government's response in relation to the wider aspects of the regulatory and decision-making framework within which these guidelines operate. We are also unsure what happens after December 2008 when section 7a of the Medicines Act expires (see 2001 above).

Table 6 Medicine cont.

What the RCGM Recommended	**9.3 That products be clearly defined in legislation as medicines, pharmaco foods, functional foods or dietary supplements.**
What Government Delivered	**2001:** The intent of this recommendation was accepted by the Government, but due to the lack of internationally recognised definitions the use of specific terminology was rejected (MfE, 2001d). The Government directed that this issue be addressed as part of the Trans-Tasman Therapeutic Goods Project and the planned development of a functional foods standard by ANZFA (MfE, 2001d). **16 July 2007:** The New Zealand Government announced that the proposed Therapeutics Products and Medicines Bill was to be postponed, and that 'The Government is not proceeding at this stage with legislation that would have enabled the establishment of a joint agency with Australia to regulate therapeutic products.' The reason given was that 'The [New Zealand] Government does not have the numbers in Parliament to put in place a sensible, acceptable compromise that would satisfy all parties at this time. The Australian Government has been informed of the situation and agrees that suspending negotiations on the joint authority is a sensible course of action.' (ANZTPA, 2007)
What We Concluded	To what extent has the recommendation been implemented? **Not Implemented**
	Is further policy work required by central government? **Yes: Significant** **Discussion** As this Bill and the proposed joint standard have been put on hold, this recommendation has not been implemented. We are unsure what other avenues are available to pursue this recommendation?

Table 6 Medicine cont.

What the RCGM Recommended	**9.4 That imported medicines and pharmaco foods that include live genetically modified organisms be approved for use by Medsafe without a requirement for additional approval from ERMA.**
What Government Delivered	**2001:** This recommendation was accepted in principle, but it was felt that further analysis was required to determine the appropriate environmental risk assessment process (MfE, 2001d). **From 2001:** MfE was directed to investigate this, and the issue was noted in the 2002 HSNO Act amendment discussion document which called for submissions on the changes planned for the HSNO Act (MfE, 2002; 2003j). Currently all new live organism medicines require both HSNO Act and the relevant Medicines or ACVM Act approvals. If the medicine fulfils the requirements of a qualifying organism (section 38I), ERMA may delegate its power to assess and approve the application to the CE of Medsafe or NZFSA (where appropriate) or the CE of ERMA New Zealand. So far this delegation power has not been used, and no applications for live GMO medicines have been received (ERMA, 2007a).
What We Concluded	To what extent has the recommendation been implemented? **Partially Implemented**
	Is further policy work required by central government? **No** **Discussion** We have treated this as partially implemented as ERMA is still required to approve applications. This being said, we consider the current policy is adequate.

Table 6 Medicine cont.

What the RCGM Recommended	**9.5 That, in respect of applications for approval as Animal Remedies of genetically modified organisms or products manufactured by processes using genetic modification techniques, the specified information which the Director–General of Agriculture and Forestry requires to be contained in applications under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM) include:** **a. full information on the efficacy and the form of the genetic modification used in manufacture; and** **b. that such information be included as one of the categories of relevant risks and benefits under section 19 of the Act.**
What Government Delivered	**2001:** This recommendation was accepted by the Government (MfE, 2001d). **2002:** This issue was included in the 2002 HSNO Act amendment discussion document which called for submissions on the planned changes to the HSNO Act (MfE, 2002; 2003j). It was decided that, since assessment of risks associated with genetic modification is ERMA's responsibility, it was not appropriate to repeat these requirements in applications under the ACVM Act. However, the operational arrangements under section 19 of the ACVM Act were altered in 2003 to reflect the intent of this recommendation. NZFSA must be notified of every application for registration of a trade-name product if a GMO is present. This application is then forwarded to ERMA and cannot proceed without a full HSNO Act approval (MfE, 2006).
What We Concluded	To what extent has the recommendation been implemented? **Partially Implemented** Is further policy work required by central government? **No** **Discussion** Although the recommendation has not been fully implemented as intended, we understand its purpose is being achieved through ERMA.

Table 6 Medicine cont.

What the RCGM Recommended	**9.6 That, as protocols identify useful therapeutics for serious disease control, approvals through ERMA and Medsafe be sought in advance for the importation of live genetically modified organisms in the form of vaccines.**
What Government Delivered	**2001:** The concerns of the Commission and the intent of this recommendation — to be prepared for infectious disease emergencies — were accepted by the Government (MfE, 2001d). **2003:** It was determined that advance pre-approval was not possible or practical, but in 2003 the HSNO Act (sections 46–49) and the Medicines Act (section 24) were amended to allow rapid emergency approval in certain defined circumstances (Medsafe, 2006).
What We Concluded	To what extent has the recommendation been implemented? **Partially Implemented**
	Is further policy work required by central government? **No** **Discussion** Although the recommendation has not been fully implemented as intended, we understand its purpose is being achieved through ERMA.

Table 7 Intellectual property

What the RCGM Recommended	**10.1 That the New Zealand Plant Variety Rights Act 1987 be amended to introduce the concept of essential derivation.**
What Government Delivered	**2001:** This recommendation was accepted in principle by the Government. It agreed to carry out a review of the Plant Varieties Act in tandem with Stage 3 of the review of the Patents Act, with a view to introducing the concept of essential derivation (MfE, 2001e). **March 2002:** A discussion paper published by MED on the review of the Plant Varieties Act was released. This paper included a discussion of the inclusion of the concept 'essential derivation' (MED, 2002a). **July 2005:** The Plant Variety Rights Act Amendment Bill was passed; under sections 17 and 18 it included the concept of 'essentially derived genetically modified varieties' (NZ Govt, 2005). This essentially means that a grantee now has the same rights over a derived variety as over the original protected variety, and other persons cannot take advantage of the investment put into developing the original variety.
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **No**

Table 7 Intellectual property cont.

What the RCGM Recommended	**10.2 That the Patents Act 1953 be amended by adding a specific exclusion of the patentability of human beings and the biological processes for their generation, in line with section 18 of the Patents Act 1990 (Commonwealth).**
What Government Delivered	**2001**: The principle of this recommendation was accepted by the Government. It was felt that although the Intellectual Property Office of New Zealand (IPONZ) does not grant patents for human beings as a matter of policy, this could conceivably be challenged in a court of law. It was determined that this question would be addressed as part of Stage 3 of the review of the Patents Act (MfE, 2001e). **March 2002:** A discussion document entitled *Boundaries to Patentability* was released as part of Stage 3 of the review of the Patents Act (MED, 2002b). By November a summary of submissions had also been released (MED, 2002c). **Sept 2003:** Cabinet papers seeking policy approval for changes to the Patents Act 1953 were released (MED, 2003a). **Nov 2004:** A draft Bill was released for public consultation. In this, human beings and the biological processes for their generation are specifically excluded from patentability under clause 15 (NZ Govt, 2004).
What We Concluded	To what extent has the recommendation been implemented? **Partially Implemented**
	Is further policy work required by central government? **No** **Discussion** The final changes to the Patent Act have not yet come into effect, but we understand that the Bill was intended to be introduced to the House by early 2008. If the terminology in the current Bill remains, the above recommendation will be implemented and will not require further work by central government.

Table 7 Intellectual property cont.

What the RCGM Recommended	**10.3 That a Māori Consultative Committee be established by the Intellectual Property Office of New Zealand to develop procedures for assessing applications, and to facilitate consultation with the Māori community where appropriate.**
What Government Delivered	**2001:** The principle of this recommendation was accepted by the Government. It was agreed to determine the scope and role of a Māori Consultative Committee through Stage 3 of the review of the Patents Act (MfE, 2001e). **March 2002:** A discussion document entitled *Boundaries to Patentability* was released as part of Stage 3 of the review of the Patents Act (MED, 2002b). A summary of submissions was released in November (MED, 2002c). **Sept 2003:** Cabinet papers outlining the new policy relating to the Patents Act 1953 were released. One of these was entitled *Māori Consultative Committee for the Intellectual Property Office of New Zealand* (MED, 2003b). **November 2004:** A draft Bill was released for public consultation. Under clauses 283–86, a Māori Consultative Committee would be established. > Clause 284 … the committee's function is to advise the Commissioner (on request) on whether an application is derived from Māori traditional knowledge or from indigenous plants and animals and, if so, whether the commercial exploitation of that invention is likely to be contrary to Māori values. That advice must be considered by the Commissioner but is not binding (clause 285) (NZ Govt, 2004). Submissions on the Bill closed in March 2005 and a summary of submissions was made public shortly afterwards.
What We Concluded	To what extent has the recommendation been implemented? **Partially Implemented** Is further policy work required by central government? **Yes: Ongoing** **Discussion** We note that the powers in the Bill are much narrower than those recommended by the Commissioners; in particular, they do not include 'to develop procedures for assessing applications' or 'to facilitate consultation'. The Bill was intended to be introduced in the House by early 2008.

Table 7 Intellectual property cont.

What the RCGM Recommended	**10.4 That New Zealand be proactive in pursuing cultural and intellectual property rights for indigenous peoples internationally.**
What Government Delivered	This recommendation was accepted by the Government. It noted that New Zealand is already active in contributing to international standards in relation to this issue through a variety of global organisations, and that Recommendation 10.4 has been implemented as a guiding principle for participation in international forums (MFE, 2001e; 2006).
What We Concluded	To what extent has the recommendation been implemented? **Not Implemented**
	Is further policy work required by central government? **Yes: Significant** **Discussion** The application of this recommendation goes beyond genetic modification. Although the Government stated that the recommendation has been implemented (see above), questions remain as to the extent to which this is actually the case. For example, New Zealand is not a signatory to the United Nations Declaration on the Rights of Indigenous People (UNDRIP) (UN, 2007) nor has the New Zealand government officially acknowledged the Mataatua Declaration (Commission on Human Rights, 1993).

Table 7 Intellectual property cont.

What the RCGM Recommended	**10.5 That New Zealand pursue the amendment of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights and associated conventions to include a reference to the avoidance of cultural offence as a specific ground for exclusion or reservation.**
What Government Delivered	**2001:** The Government disagreed that TRIPS did not already address this issue, but felt that section 27(2) did, in fact, provide scope for exclusions from patentability on the basis of avoidance of cultural offence. The section currently provides for this where it is necessary to protect 'public order or morality'. The Government felt that while it might be beneficial to gain greater legal certainty in this area, the pursuit of an amendment offered a poor chance of success and would possibly be injurious to New Zealand's wider trading interests (MfE, 2001e). **2006:** The Government agreed with the intent of this recommendation. As a result government officials have been directed to support the concept of 'exclusion or reservation on the basis of cultural offence' in work being progressed through the World Intellectual Property Organization, and the development of a new system for the protection of Māori 'cultural and intellectual property' (MfE, 2006: 19). They are also directed to be alert for opportunities which may arise through the World Trade Organization and TRIPS (MfE, 2006). The World Trade Organization is currently reviewing Article 27.3b of the TRIPS agreement (WTO, 2007). Following recommendations in the *Doha Declaration 2001*, this has been broadened to include the protection of traditional knowledge and folklore. There is some evidence that New Zealand has been involved to a limited extent (WTO, 2007).

Table 7 Intellectual property cont.

What We Concluded	To what extent has the recommendation been implemented? **Not Implemented**
	Is further policy work required by central government? **Yes: Significant** **Discussion** We are pleased the Government changed its position on this issue between 2001 and 2006. Although the Government says it is mindful of the Cabinet's directive in this respect and is pursuing the intention through a wider, more strategic work programme, we have found little evidence to suggest that New Zealand has been promoting the recommended amendment (MED, 2007; MFAT, 2007).

Table 7 Intellectual property cont.

What the RCGM Recommended	**10.6 That all parties concerned work to resolve the WAI 262 and WAI 740 claim currently before the Waitangi Tribunal as soon as possible.**[31]
What Government Delivered	**2001:** The Government disagreed that there is a critical link between the WAI 262 claim, GM and the Government's intellectual law reform because it felt ownership of flora and fauna and the associated intellectual property rights was an issue broader than the Commission's terms of reference (MfE, 2001e). The Government agreed with the intent of this recommendation, which was that the claims be resolved as soon as possible. However, it noted that the complex nature of the WAI 262 claim and the tribunal itself limits the possibility of speeding up the process (MfE, 2001e). **2006:** A statement of issues was released in July 2006 (Waitangi Tribunal, 2006). **2007:** Closing submissions were heard for the WAI 262 claim in June 2007 and the Tribunal has now entered its report-writing phase (Waitangi Tribunal, 2007).
What We Concluded	To what extent has the recommendation been implemented? **Partially Implemented** Is further policy work required by central government? **Yes: Ongoing** **Discussion** We note that the final ruling on the WAI 262 claim has not yet been announced. The WAI 740 claim has since been subsumed within the WAI 262 case. The Tribunal's report is currently in preparation and is expected to be released in 2008, at which time the Government will have the opportunity to officially respond. Notably, the reform of the Patents Act has proceeded more rapidly than the WAI 262 claim, which clearly has a bearing on the claim. We are of the view that WAI 262 claim does have a direct link with genetic modification, in that the flora and fauna under discussion may be at risk of potential contamination and debates over property rights.

[31] The Wai 262 claim was brought against the New Zealand Crown in 1991 by the members of six iwi (Ngāti Kuri, Ngāti Wai, Te Rarawa, Ngāti Porou, Ngāti Kahungunu and Ngāti Koata). There are four statements of claim for Wai 262, which generally assert exclusive and comprehensive rights to flora and fauna, cultural knowledge and property as taonga protected by Article Two of the Treaty of Waitangi. The Wai 740 claim was lodged by Frederick C. Allen, of Te Atiawa, and relates to the right to collect fruit, seed and spores from Crown and regional authority land in the Wellington region, and the preservation of native flora and fauna (MfE, 2001e).

Table 7 Intellectual property cont.

What the RCGM Recommended	**10.7 That the HSNO and ACVM Acts be amended to give appropriate protection to all commercially sensitive or confidential supporting information provided with applications for approval.**
What Government Delivered	**2001:** This recommendation was accepted by the Government, who subsequently directed MAF and MfE to consult with key stakeholders to determine the appropriate level of protection for submitted information (MfE, 2001e). **2002:** This issue was included in a discussion paper regarding potential amendments to the HSNO Act, and feedback on this topic was sought in a call for submissions in 2002 (MfE, 2002; 2003j). **2003:** Amendments tightened the protection surrounding the release of supporting information received with applications in: a. sections 55 and 57(4) of the HSNO; and b. section 12(4) of the ACVM Act. The dual aim of these amendments was to ensure that confidential supporting information could not be released without the permission of the supplier unless it was in accordance with section 9 of the Official Information Act 1982. The Government agreed to amend the HSNO Act to ensure special protection for confidential supporting information in applications for approval to ERMA that are also the subject of innovative agricultural compounds or medicines (MfE, 2003f; 2006).
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **No**

Table 8 Te Tiriti o Waitangi

What the RCGM Recommended	**11.1 That section 8 of HSNO be amended to provide that effect is to be given to the principles of the Treaty of Waitangi.**
What Government Delivered	**2001:** The Government did not accept this recommendation (MfE, 2001f). It interpreted its intention as being to ensure that the views of Māori are appropriately incorporated into decision-making under the HSNO Act. It was also noted that amending section 8 of the HSNO Act could possibly be problematic as it may raise compliance costs for applications and issues around Māori being satisfied with the new wording (MfE, 2001f). **December 2002:** A Māori reference group was established by the Minister for the Environment to give advice on the amendment of the HSNO Act to 'more appropriately' reflect the Treaty of Waitangi partnership (MfE, 2003h: 2). The reference group presented its final report on this issue in March 2003 (see MfE, 2003h: Appendix 1). **2003:** A Cabinet paper was released outlining the Government's proposal in response to the report of the Māori reference group (MfE, 2003h). It was concluded that three main points needed to be addressed: 1. The effective involvement of Māori in the preparation and consideration of applications under the HSNO Act; 2. Extending the knowledge and experience of Māori values of those involved in decision-making; and 3. Increasing the weighting given to Māori perspectives and values in decision-making. Four amendments to the HSNO Act were proposed by the Māori reference group in relation to giving effect to Māori values and the Treaty of Waitangi. These amendments included a change to section 8 of the HSNO Act, where it was recommended that the words 'take into account' should be changed to shall 'give effect to' in relation to the principles of the Treaty of Waitangi (MfE, 2003h). The Government did not accept the reference group's recommendations. The HSNO Act was amended in 2003 to make Ngā Kaihautū Tikanga Taiao (ERMA's Māori Advisory Committee) a statutory committee. ERMA New Zealand was also provided with additional funding to build the capacity of Māori to engage with the HSNO Act process (ERMA, 2007a). **November 2004:** An ERMA policy document, *Incorporating Māori Perspectives in Part V Decision-making*, was published, detailing ERMA policy for giving consideration and effect to relevant Māori perspectives (ERMA, 2004).

Table 8 Te Tiriti o Waitangi cont.

What We Concluded	To what extent has the recommendation been implemented? **Not Implemented**
	Is further policy work required by central government? **Yes: Significant** **Discussion** Currently the proposed amendments to section 8 of the HSNO Act have not been passed. Therefore, although a lot of activity has taken place, it is critical to establish practical ways of implementing and monitoring the direction to 'give effect to the principles of the Treaty of Waitangi'.

Table 9 Liability Issues

What the RCGM Recommended	**12.1 That Toi Te Taiao: the Bioethics Council, in association with the Human Rights Commission, address the issue of genetic discrimination.**
What Government Delivered	**2001:** The intent of this recommendation was accepted by the Government (MfE, 2001f). However, it felt that the recommendation was better addressed as part of a broader investigation into New Zealand's human rights, specifically as part of the Human Rights Commission's (HRC) plan to develop a national plan of action for the protection of human rights in New Zealand (MfE, 2001f). **September 2004:** The HRC released the status report *Human Rights in New Zealand Today: Ngā Tika Tangata o te Motu*, which discussed the potential for genetic discrimination in New Zealand, particularly as it relates to disabled people (HRC, 2004). **March 2005:** The HRC published the *New Zealand Action Plan for Human Rights: Mana ki te Tangata*. The action plan identifies key human rights outcomes and what must be done over the next five years so that the human rights of everyone in New Zealand (including in relation to genetic discrimination) are better recognised, protected and respected (HRC, 2005). **July 2006:** An inter-agency meeting, which included the HRC and the Bioethics Council, took place for the purposes of information-sharing and cooperation. The Bioethics Council and the HRC have had multiple meetings to discuss their joint interests in this issue (HRC, 2006a). **October 2006:** The HRC released a discussion document, *Review of the Guidelines on Insurance and the Human Rights Act 1993*, which deals with genetic discrimination (HRC, 2006b). Submissions responding to this document were accepted until December 2006. **2007:** The Bioethics Council began a process of public deliberation around the genetic discrimination as it relates to Pre-Birth Testing.[32] **July 2007:** The HRC released a *Draft of the Revised Guidelines for Insurance and the Human Rights Act 1993*; this was open for public comment until 27 July 2007. The final revised guidelines for insurance and the Human Rights Act were released in early December 2007 (HRC, 2007).

[32] See http://nzbioethics.dialoguecircles.com/ for more information.

Table 9 Liability Issues cont.

What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **Yes: Ongoing** **Discussion** It is unclear whether the Human Rights Commission will further address issues relating to genetic discrimination, such as employment issues and the human rights implications of biotechnologies for disabled people.

Table 9 Liability Issues cont.

What the RCGM Recommended	**12.2 That for the time being there be no change in the liability system.**
What Government Delivered	**2003:** After reviewing the current liability system the Government concluded that the existing liability rules would not always operate effectively in relation to GM (MfE, 2003i). However, it was agreed that there would be no immediate change. It was felt that to devise a liability regime only for GM was not sound, as existing liability rules would require future adjustment in a range of areas (MfE, 2003i). **2003:** Changes have been made to the HSNO Act (NZ Govt, 1996) which enable new-organism users to be penalised for non-compliance and allow for claims by any who are harmed by a genetic modification activity in the event of a breach of the Act (MfE, 2006).
What We Concluded	To what extent has the recommendation been implemented? **Partially Implemented**
	Is further policy work required by central government? **Yes: Ongoing** **Discussion** We have noted that some minor adjustments to liability rules have occurred (such as in 2003 above), but consider significant gaps in the regime remain See Simon Terry Associates (2004) and Simon Terry Associates & Mitchell Partnerships (2005) for thorough coverage of these issues. These issues are also considered further in Sustainable Future's report, *The Future of Genetic Modification in New Zealand* (Sustainable Future, in press).

Table 10 Major Conclusion: Preserving Opportunities

What the RCGM Recommended	**13.1 That the methodology for implementing HSNO section 6(e) be made more specific to:** **a. Include an assessment of the economic impact the release of any genetically modified crop or organism would have on the proposed national strategy of preserving opportunities in genetically modified and unmodified agricultural systems.** **b. Allow for specified categories of genetically modified crops to be excluded from districts where their presence would be a significant threat to an established non-genetically modified crop use.**
What Government Delivered	**2001:** This recommendation was not accepted by the Government. In the case of the first point, the Government considers that the HSNO (Methodology) Order 1998 already requires ERMA to consider these issues and that there is no need to make it more specific as this would put undue weighting on them. However, further policy work was recommended to assess the possible changes that could be made to the methodology in respect of this issue. With regard to the second point, the Government considered that location controls are better considered as part of conditional release (MfE, 2001c). **November 2001:** ERMA announced a review of the HSNO (Methodology) Order 1998 (ERMA, 2001). **March 2002:** An ERMA consultation document on the review of the HSNO (Methodology) Order 1998 was released and a draft circulated for submissions. **August 2002:** *Summary of Submissions on the Review of the Methodology* was released by ERMA (2002a). **December 2002:** ERMA released *Position Paper on The Approach to Risk, Methodologies for Dealing with This, and the Techniques and Community Information Required for Implementation* (ERMA, 2002b).

Table 10 Major Conclusion: Preserving Opportunities cont.

	April 2003: A Cabinet paper on *Economic Analysis Results and HSNO Act Implications* was released by the Government (MfE, 2003i). This paper analysed the issue of the economic impact of GM crops in New Zealand. It emphasised both the direct and indirect economic impacts that ERMA considers may result from the release of a GM organism in New Zealand. The paper recommended that no further change be made to the HSNO Act or to the HSNO (Methodology) Order 1998, but outlined methods that ERMA should use when assessing economic risks. ERMA was pronounced capable of dealing with this. It commented that the proposed changes for conditional release under the HSNO Act would support this issue (MfE, 2003i). **June 2003:** A commentary on submissions for the review of the HSNO decision-making Methodology was released (ERMA, 2003a). **September 2003:** ERMA released an explanatory note on the revision of the ERMA New Zealand Methodology (including another call for submissions by 3 October 2003) (ERMA, 2003b). In the same month ERMA released a consultation draft of the proposed Methodology to incorporate the implications of the HSNO Amendment Act 2003 and to provide flexibility in assessing applications (ERMA, 2003c).
What We Concluded	To what extent has the recommendation been implemented? **Not Implemented**
	Is further policy work required by central government? **Yes: Significant** **Discussion** This recommendation has not been implemented as the methodology for implementing section 6(e) of the HSNO Act has not been updated. In addition, MfE and ERMA are still conducting their review of the HSNO (Methodology) Order 1998, which we are told aims to align the methodology with recent HSNO Act changes. We do have concerns, based on past experience, that this review may be used as a mechanism for watering down the substance of the risk management currently contained in the HSNO (Methodology) Order 1998. We have been advised that this review is on the ERMA/MfE work programme for the 2007/08 financial year and is due to be addressed in early 2008.

Table 10 Major Conclusion: Preserving Opportunities cont.

What the RCGM Recommended	**13.2 That before the controlled or open release of the first genetically modified crop, the Minister exercise the call-in powers available under HSNO section 68 in order to assess the likely overall economic and environmental impact on the preserving opportunities strategy.**
What Government Delivered	**2001:** This recommendation was not accepted by the Government. It was felt that ministerial call-in is not an appropriate mechanism to implement a 'proceed with caution' approach to GM. If a call-in was predetermined this might leave the Government open to legal proceedings (MfE, 2001c). > If the Government had signalled its intention to call in the first application for release of a GMO before it was received and without assessing whether it meets the relevant criteria in the HSNO Act, there was risk the call-in decision would be challenged through judicial review on grounds of predetermination. Legal proceedings would cause uncertainty, delay in the decision making process, additional expense to the Government and would attract international attention (MfE, 2001c: 6). **2003:** The HSNO Act was amended to extend the call-in period to the end of the public submissions period, to give more opportunity for the Minister to seek advice and consider important matters where the application is for approval to release any new organism from containment (MfE, 2003f).
What We Concluded	To what extent has the recommendation been implemented? **Not Implemented**
	Is further policy work required by central government? **Yes: Significant** **Discussion** We believe that the first GM conditional or full release is a significant and strategic national decision, that should be made with due consideration of these wider factors, rather than solely within the typical case-by-case decision-making framework. Therefore there is considerable room to argue that this decision should, whilst upholding quality process and public participation, be made by a Minister rather than ERMA.

Table 10 Major Conclusion: Preserving Opportunities cont.

What the RCGM Recommended	**13.3 That MAF develop formalised local networks to encourage constructive dialogue and communication between farmers using different production methods, and to provide for mediation where necessary.**
What Government Delivered	**2001:** The intent of this recommendation — to build upon existing informal networks — was accepted by the Government. They then directed MAF to investigate further, and proceeded to seek submissions on this subject (MfE, 2001c). **From 2001:** Following the submissions process, it was concluded that a nationwide network to facilitate cooperation was unnecessary at that stage. It was noted that neither submitters in favour of a GM-free New Zealand nor those against, strongly sought the establishment of a network (MAF, 2003). Already available mechanisms were deemed to be suitable for the mediation of any disputes. **April 2003:** Ministers agreed that no further work was needed on this issue, but that MAF should continue to monitor the situation (MAF, 2003; 2007).
What We Concluded	To what extent has the recommendation been implemented? **Not Implemented**
	Is further policy work required by central government? **Yes: Significant** **Discussion** Currently, no formal network exists. If Government wishes to pursue the development of GM crops in the outdoors, it is likely to struggle without good communication between all stakeholders.

Table 10 Major Conclusion: Preserving Opportunities cont.

What the RCGM Recommended	**13.4 That sterility technologies be one tool in the strategy to preserve opportunities, especially in the case of those genetically modified crops most likely to cross-pollinate with non-genetically modified crops in the New Zealand context (e.g. brassicas, ryegrass, ornamentals).**
What Government Delivered	**2001:** This recommendation was accepted as a feasible solution by Government (MfE, 2001c). **Background** In May 2000, the conference of the Parties to the United Nations Convention on Biological Diversity (CBD) adopted a resolution on the field trialling and commercialisation of a class of GM sterility traits (often referred to as terminator technology or more technically as Genetic Use Restriction Technologies (GURT)). The UN defines GURT as: > A set of proposed technological means that rely on genetic transformation of plants to introduce a genetic switch mechanism which prevents unauthorised use of either particular plant germplasm, or traits associated with that germplasm (UN, 1999: 13). The resolution below is widely understood by CBD member states to place a moratorium on the field trialling and commercial cultivation of GMOs which carry GURTs: > Recommends that, in the current absence of reliable data on genetic use restriction technologies, without which there is an inadequate basis on which to assess their potential risks, and in accordance with the precautionary approach, products incorporating such technologies should not be approved by Parties **for field testing** until appropriate scientific data can justify such testing, and for commercial use until appropriate, authorized and strictly controlled scientific assessments with regard to, *inter alia*, their ecological and socio-economic impacts and any adverse effects for biological diversity, food security and human health have been carried out in a transparent manner and the conditions for their safe and beneficial use validated. In order to enhance the capacity of all countries to address these issues, Parties should widely disseminate information on scientific assessments, including through the clearing-house mechanism, and share their expertise in this regard [bold added] (UN, 2000: Decision V/5: Para 23).

Table 10 Major Conclusion: Preserving Opportunities cont.

	2007: The New Zealand Government has not developed a stance on 'sterility technologies' (ERMA, 2007a) but ERMA advises us that 'inducible genetic switches': (i) may be being used in containment as tools for research, but (ii) are not currently being used in outdoor experiments. ERMA notes that: 'While genes controlling reproductive development have been investigated in contained outdoor experiments, these do not use an "inducible" gene switching technology that allows a gene (and the trait it confers) to be switched on and/or off during the life of the organism in a controlled fashion to do so (i.e. is not a GURTs technology as defined above)' (ERMA, 2007a). The outdoor experiments referred to above by ERMA appear to be GMF 99001 and GMF 99005. These approvals were granted to the Forest Research Institute, now called Scion, in 2000.[33]
What We Concluded	To what extent has the recommendation been implemented? **Partially Implemented** Is further policy work required by central government? **Yes: Significant** **Discussion** We have six concerns about this recommendation and the Government's response. (i) Currently there is no New Zealand definition of sterility technologies (ERMA, 2007a), therefore by default, we consider the internationally accepted definition should be adopted by both MfE and ERMA in all decision-making and policy documents. (ii) In determining this recommendation, the Commissioners relied upon a so-called UK report, which in fact was only a discussion paper. The final report was significantly less positive about the use of this technology, and indicated that sterility technology required further development and research before it could be effectively utilised (McGuinness, 2001). (iii) As a result, the Commissioners decided that a 'case-by-case' assessment by ERMA was sufficient, as already determined under the HSNO legislation. We consider this view was flawed, and that the use of GURT technology requires a national strategic decision and should be called-in by the Minister, as the Commissioners recommended for the first conditional or open release of GM crops (as in recommendation 13.2).

[33] See http://www.scionresearch.com/

Table 10 Major Conclusion: Preserving Opportunities cont.

	(iv) Depending on the definition of 'sterility technologies' (be it the United Nations definition or the ERMA interpretation quoted above), it could be argued that New Zealand is currently using GURT technologies in the outdoors. Therefore, our understanding is that New Zealand, through two Scion field tests, may be in breach of the United Nations Convention on Biodiversity: that is, the research currently undertaken by Scion is a GURT, and as it is not in a physical structure (as per the definition of containment above) it is a breach of the moratorium on GURTs. (v) We find it difficult to understand how FoRST could argue it is in the best interests of the public to fund experiments like Scion's, which are internationally acknowledged to be risky. It can be argued that not only could public funds be better spent on internationally acceptable and commercially viable technology , but that the funding of those experiments may case public harm, both in terms of New Zealand's clean green reputation and the cost of cleaning up pollution (or managing the effects) resulting from such experiments. (vi) We also note that responsibility for collating up-to-date data on 'sterility technologies' does not fall to one agency. Numerous agencies have an interest in this area in relation to their differing and overlapping legislative, policy and operational responsibilities, both domestically and internationally (MfE, 2006).

Table 11 The Biotechnology Century: Three Major Proposals

What the RCGM Recommended	**14.1 That HSNO section 68 be extended to include significant cultural, ethical and spiritual issues as grounds for the Minister's call-in powers.**
What Government Delivered	This recommendation was accepted in principle by the Government. It was noted that because cultural, ethical and spiritual issues could already be considered to be covered under section 68 of the HSNO Act, adopting this recommendation would not necessarily change the basis of decision-making, though it would encourage public trust in the HSNO Act (MfE, 2001f). **2002:** This issue was included in the discussion documents released and the submissions called for in relation to the planned amendments to the HSNO Act (MfE, 2002; 2003j). **2003:** The HSNO Act section 68 (NZ Govt, 1996) was amended to include significant cultural, ethical and spiritual issues as grounds for the Minister's call-in powers, although it was still noted that this was not a method to 'include cultural, spiritual and ethical matters in decision-making on specific applications' (MfE, 2003f: 2). The terms used are not defined, as that would legally bind ERMA to recognise and provide for the spiritual and ethical issues of GM in their day-to-day consideration of applications (MfE, 2003f; 2006). HSNO Act section 68: Minister's power to call in applications with significant effects (1) The Minister may direct that he or she will decide an application under this Act if the Minister considers that the decision on the application will have — (a) significant cultural, economic, environmental, ethical, health, international, or spiritual effects; or (b) significant effects in an area in which the Authority lacks sufficient knowledge or experience.

Table 11 The Biotechnology Century: Three Major Proposals cont.

What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **Yes: Ongoing** **Discussion** We have two concerns: (i) Although the recommendation is fully implemented regarding 'call-in', we note that the Minister has never 'called-in' an application and this raises further concerns. We explore these concerns in light of AgResearch's GM cows: (a) We consider there should be more clarity over what denotes 'significant effects' and a lack of 'sufficient knowledge or experience', as we consider past field test applications should have already triggered the use of section 68. In our view, the application to create the first GM cow using a human gene (being GMF98009 (iii) and GMD02028) met the 'call-in' criteria in that the effects were 'significant' and the authority must have lacked the necessary 'experience' as the first application was both strategic to New Zealand and novel to the world. (b) We also consider this the timing of effects must be reconsidered. For example, we consider that 'significant cultural, ethical and spiritual effects' existed at the point of creation, being when the human gene was first placed into a cow embryo in the laboratory. (c) We also question the case-by-case approach. For example, the applicant, when pursuing new applications could argue that because 'GM cows containing a human gene' are no longer novel (due to past applications such as GMF98009 (iii) and GMD2028), the 'cultural, ethical and spiritual effects' of subsequent applications either no longer exist or a significantly reduced. Such an approach raises questions about the practicality of the case-by-case approach contained in the legislation. We consider a rule based approach is more appropriate e.g. it is illegal to insert a human gene into animals or plants. We consider the Minister/s must consider this point before further applications are received by AgResearch. In our view, the status quo will result in ERMA approving all future applications that create GM cows inserted with human gene/s.

Table 11 The Biotechnology Century: Three Major Proposals cont.

	(d) There is often a belief that the final stage in the application process is the full release and that it is at this point that the most robust decision-making will occur. However some applicants can meet their end goal without needing to make a final application for release to ERMA. This means that the only opportunity for a Minister to 'call-in' (or ERMA 'to-hear') an application is at the 'field test' stage. For example, AgResearch does not need to make a further application to ERMA to export milk from GM cows (containing a human gene) as the 'milk' from a GM cow is not an organism. Therefore, while the milk is from a GM approved cow undergoing a field test, no further application to ERMA for release is necessary. Therefore the applicant receives the benefits of a release, without ever needing to apply for a conditional or full release. Hence the only opportunity for a Minister to 'call-in' (or ERMA 'to-hear') the application is at the 'field test' stage. (ii) Our second key concern is that there remains no specific requirement for decisions to 'include cultural, spiritual and ethical matters in decision-making on specific applications before ERMA' (MfE, 2003d: 2) or as part of the decision-making called-in by the Minister. We consider this is poor law. section 68 implies that 'significant cultural, economic, environmental, ethical, health, international, or spiritual effects' must be considered in deciding whether to 'call-in' a decision, but does not require ERMA or the Minister to take these effects into account in making approval or decline decisions. We would like to see these effects being clearly stipulated in the HSNO legislation.

Table 11 The Biotechnology Century: Three Major Proposals cont.

What the RCGM Recommended	**14.2 That Government establish Toi Te Taiao: The Bioethics Council to:** **a. Act as an advisory body on ethical, social and cultural matters in the use of biotechnology in New Zealand.** **b. Assess and provide guidelines on biotechnological issues involving significant social, ethical and cultural dimensions.** **c. Provide an open and transparent consultation process to enable public participation in the Council's activities.**
What Government Delivered	This recommendation was accepted by the Government. It was agreed to establish the Bioethics Council and to follow the suggested guidelines for its activities. The Government also decided to disestablish the Independent Biotechnology Advisory Committee (IBAC) (MfE, 2001a; 2003e). **December 2002:** The Bioethics Council was established by the Cabinet Minute [POL (02) 117] (MfE, 2007). Importantly, it was established to advise Ministers only. Therefore ERMA has no formal relationship with the Council, although ERMA does obtain ethical advice through its own Ethics Advisory Panel (EAP).[34] The Council's Terms of Reference are to: 1. Provide independent advice to Government on biotechnological issues involving significant cultural, ethical and spiritual dimensions. 2. Promote and participate in public dialogue on cultural, ethical and spiritual aspects of biotechnology, and enable public participation in the Council's activities. 3. Provide information on the cultural, ethical and spiritual aspects of biotechnology. (Bioethics Council, 2007) **2005:** The Council was independently reviewed by the State Services Commission in 2005. The resulting report, titled *Bioethics Council Review Report*[35], found the purpose of the Council to be valid and that it had become a trustworthy vehicle for education and public discourse on emergent biotechnology issues. The report made a number of recommendations that endorsed the Council's current role and structure but suggested changes aimed at strengthening accountability and communication between the Council and key stakeholders, and the Council and key Ministers (SSC, 2006: 21). It also suggested the formation of an *ad hoc* Ministerial Coordination Group on Bioethics to inform the Council's work programme, to receive and discuss reports and coordinate any appropriate response.

[34] Information about the EAP is available on ERMA's website http://www.ermanz.govt.nz/about/eap.html. An Ethics Framework document is also available at http://www.ermanz.govt.nz/resources/publications/pdfs/ER-PR-05-1.pdf.

[35] This report was not made public and was requested under the Official Information Act.

Table 11 The Biotechnology Century: Three Major Proposals cont.

	To date, the Bioethics Council has covered or is currently covering the following issues in terms of their ethical, social and cultural implications: 1. Pre-birth testing; 2. Māori responses to biotechnologies; 3. Animal-to-human transplantation (xenotransplantation); 4. Human assisted reproduction; 5. Human genes in other organisms; and 6. The New Organisms and Other Matters Bill. For each issue public dialogue is utilised to develop ethical guidelines. All publications from the Bioethics Council are available on their website (Bioethics Council, 2007).
What We Concluded	To what extent has the recommendation been implemented? **Partially Implemented**
	Is further policy work required by central government? **Yes: Ongoing** **Discussion** Although the Ministerial Coordination Group on Bioethics was established in November 2006 (as discussed in the SSC review above), there has been no government response to the previous Bioethics Council reports or any new reports published since that date. We consider the work of the Bioethics Council is important and must continue. We are less clear about how Government will consider and adopt its recommendations**.** Questions as to the extent to which the work and recommendations of the Council inform government management of biotechnologies with ethical implications (see Recommendations 7.5, 7.6, 9.2 and 12.1) are discussed further in Sustainable Future's report, *The Future of Genetic Modification in New Zealand* (Sustainable Future, in press).

Table 11 The Biotechnology Century: Three Major Proposals cont.

What the RCGM Recommended	**14.3 That Government establish the office of Parliamentary Commissioner on Biotechnology to undertake futurewatch, audit and educational functions with regard to the development and use of biotechnology in New Zealand.**
What Government Delivered	**2001:** It was agreed that the futurewatch, audit and educational functions in relation to biotechnology needed attention (MfE, 2001a). The Government felt that its criteria to determine the need for a Parliamentary Commissioner were not met by the proposal of the Royal Commission on Genetic Modification. Instead the intended function of the Parliamentary Commissioner would be incorporated into the existing institutional structure for addressing biotechnology issues (MfE, 2001a). The futurewatch function of this recommendation is being covered by MoRST under their *Futurewatch* work programme, which 'aims to build Government's alertness to new scientific knowledge and technologies and the sort of implications, opportunities and risks that they present to New Zealand' (MoRST, 2007b). **January 2005:** MoRST published the *Biotechnologies to 2025* report (MoRST, 2003b) which provides an overview of national and international trends in biotechnology with reference to their surrounding social and business context and ways in which biotechnology may impact on New Zealand in the future. The educational aspect of this recommendation could be considered to be covered by the development of a Biotech Regulatory WayFinder. This was developed by MoRST and provides detailed information on what is involved in the regulation of biotechnology in New Zealand, as well as links to more information. This resource provides both the public and researchers with easy access to information surrounding biotechnology. Following this, MoRST contracted the establishment of a futurewatch network called the Navigator Network, which operated from 2005–2007. The Biotechnology Strategy notes the need to 'conduct periodic independently contracted audits to assess whether the regulatory regime and its operation are achieving an appropriate balance between assurance and innovation' (MoRST, 2003c). In 2005, MoRST commissioned a *Biotechnology Regulatory System Baseline Study — Landscape Report* (MoRST, 2005) to identify key factors and drivers of interactions within New Zealand's biotechnology regulatory system.

Table 11 The Biotechnology Century: Three Major Proposals cont.

What We Concluded	To what extent has the recommendation been implemented? **Not Implemented**
	Is further policy work required by central government? **Yes: Significant** **Discussion** As no Parliamentary Commissioner has been established, this recommendation has not been actioned. It remains unclear whether any other roles have been created to address the independent audit functions of biotechnology within the existing institutional structure. Additionally, the question remains as to whether a ministry or department operating within the boundaries set by its Minister or by Cabinet is able to achieve the same outcomes as a Parliamentary Office independent of the government. One of the key outcomes of the status quo is that members of the public who have concerns about this technology have no independent body with which to lodge concerns. This has led to a number of high-profile court cases. As a result, court cases funded by private funds are progressing public good issues, and public funds (due to FoRST funding of CRI) are being used to progress private good issues (i.e. commercial objectives). We consider the roles and functions proposed by the Commissioners in regard to the Parliamentary Commissioner on Biotechnology to be sorely lacking and that the Government should reconsider its decision regarding this recommendation. We believe there are significant benefits to be obtained from Government providing an independent entity to hear public concerns and complaints. For example, such an approach may ensure better decisions are made, better controls are put in place, less sabotage of crops occurs and lower legal costs are incurred (due to fewer legal actions being brought against ERMA and CRIs). We think many New Zealanders consider the benefits of GM crops have been overstated, the risks understated, and that there are more effective ways to spend public money. Therefore we consider that without an independent body to undertake the functions recommended by the Commission, the continued development of genetic modification, in particular GM crops, will continue to trigger public protests in the short to medium term.

Table 11 The Biotechnology Century: Three Major Proposals cont.

What the RCGM Recommended	**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.**
What Government Delivered	**2001:** The recommendation to develop a biotechnology strategy for New Zealand was accepted by the Government (MfE, 2001a). **October 2002**: A public discussion paper on a New Zealand biotechnology strategy was published (MoRST, 2002). **May 2003**: *The Biotechnology Strategy for New Zealand* was published (MoRST, 2003a). MoRST funded the Navigator Network (2005–2007) and the Regulatory WayFinder to aid the implementation of the biotechnology strategy.
What We Concluded	To what extent has the recommendation been implemented? **Fully Implemented**
	Is further policy work required by central government? **Yes: Ongoing** **Discussion** The Government needs to clarify the requirements around review, and the process for modifying this strategy in the light of new science and research outcomes or changes in the international arena. It also needs to share with the public what (if any) mechanisms are in place to ensure relevant agencies are acting in line with this strategy. In addition, while MoRST is the agency with primary responsibility for the biotechnology strategy, it is not clear to what extent cultural, ethical and spiritual dimensions, and cross-agency policy areas, are currently being taken into account.

5. Assessment of the Forty-Nine Recommendations

In this section, the information collected in Section 4 is used to assess the Government's response to date.

5.1 The Level of Implementation of the Recommendations

From our first assessment of the recommendations, we found that some chapters, or what the Commissioners called issues (being groups of recommendations), had been implemented while others had not. To explore these gaps we ranked these groups of recommendations by the extent to which they were fully implemented (see Table 12). Although this does not necessarily reflect the importance of one group relative to another, it does indicate where the Government has supported the Commissioners' findings and where it has not.

Our significant findings include:

- Only 20 (41%) of all recommendations have been fully implemented. The highest number of fully implemented recommendations was in the area of 'Research'.
- Of the 29 (59%) partially or not implemented, three specific groups of recommendations were least implemented: 'Crops and Other Field Uses', 'Te Tiriti o Waitangi' and 'Major Conclusion: Preserving Opportunities'.

What is of significant concern is that those recommendations that have not been fully implemented are not only highly complex but are in many ways central to the problem the Commissioners were contracted to solve. Notably, the failure to implement the recommendations in relation to 'Crops and other field uses', 'Te Tiriti o Waitangi' and 'Major Conclusion: Preserving Opportunities' remains a significant barrier to delivering a 'preserving opportunities' strategy for New Zealand.

The findings also raise questions as to why none of the 'Crops and other field uses' recommendations were implemented, in contrast with so many of the 'Research' recommendations? Is this a logical approach, considering the Government's support for GM research is likely to result in an increase in commercial applications for GM crops? Could it be that the Government could not design practical and cost-effective strategies and practices that delivered 'co-existence' without risks of GM contamination?

Table 12 Extent to which the Recommendations have been Implemented

	No.	Not Implemented	Partially Implemented	Fully Implemented	Ranking of Fully Implemented
Chapter 6: Research	14	1 (6.12) **7%**	2 (6.13, 6.14) **14%**	11 (6.1–6.11) **79%**	1st
Chapter 7: Crops and Other Field Uses	7	7 (7.1–7.7) **100%**	0 - **0%**	0 - **0%**	5th equal
Chapter 8: Food	4	1 (8.2) **25%**	1 (8.3) **25%**	2 (8.1, 8.4) **50%**	2nd equal
Chapter 9: Medicine	6	1 (9.3) **17%**	3 (9.4, 9.5, 9.6) **50%**	2 (9.1, 9.2) **33%**	3rd
Chapter 10: Intellectual Property	7	2 (10.4, 10.5) **29%**	3 (10.2, 10.3, 10.6) **43%**	2 (10.1, 10.7) **29%**	4th
Chapter 11: Te Tiriti o Waitangi	1	1 (11.1) **100%**	0 - **0%**	0 - **0%**	5th equal
Chapter 12 : Liability	2	0 **0%**	1 (12.2) **50%**	1 (12.1) **50%**	2nd equal
Chapter 13 : Major Conclusion: Preserving Opportunities[36]	4	3 (13.1-13.3) **75%**	1 (13.4) **25%**	0 - **0%**	5th equal
Chapter 14 : The Biotechnology Century	4	1 (14.3) **25%**	1 (14.2) **25%**	2 (14.1, 14.4) **50%**	2nd equal
Total [%]	49 **100%**	17 **35%**	12 **24%**	20 **41%**	

[36] Chapter 13 contains four recommendations that are unique to this chapter (recommendations 13.1 to 13.4) and five earlier recommendations (6.8, 7.7, 7.1, 7.3 and 6.13). These nine, plus one from chapter 14 (recommendation 14.1), form the 'watershed' recommendations. See Section 2.2.3 for a detailed discussion of these recommendations.

5.2 The Level of Further Policy Work Required

We made an additional assessment of the extent to which further policy work remain in relation to each recommendation. We categorised these according to whether the recommendation required 'significant', 'ongoing', or 'no' further policy work by central government. To explore these gaps we also ranked these groups of recommendations by the extent to which they did not require further work by central government (see Table 13).

The result of the reclassification is significant (compare total percentages in Table 12 with Table 13, and see the reclassified recommendations in Appendix 2). In comparison to the three groups of recommendations least implemented in Table 12, Table 13 shows five groups of recommendations require further policy work of an 'ongoing' or 'significant' degree; namely 'Crops and other field uses' , 'Te Tiriti o Waitangi', 'Liability', 'Major conclusion: Preserving Opportunities' and the three major proposals for the 'Biotechnology Century'.

Therefore, to deliver the 'preserving opportunities' strategy envisaged by the Royal Commission in 2001, the Government would need to invest a significant amount of time and public money.

Table 13 Extent to which the Recommendations Require Further Policy Work

	No.	Significant Work Required	Ongoing Work Required	No Further Policy Work Required	Ranking of No Further Policy Work Required
Chapter 6: Research	14	1 (6.12) **7%**	2 (6.13, 6.14) **14%**	11 (6.1–6.11) **79%**	1st
Chapter 7: Crops and Other Field Uses	7	7 (7.1–7.7) **100%**	0 - **0%**	0 - **0%**	5th equal
Chapter 8: Food	4	1 (8.2) **25%**	1 (8.3) **25%**	2 (8.1, 8.4) **50%**	3rd
Chapter 9: Medicine	6	1 (9.3) **17%**	1 (9.2) **17%**	4 (9.1, 9.4-9.6) **67%**	2nd
Chapter 10: Intellectual Property	7	2 (10.4, 10.5) **29%**	2 (10.3, 10.6) **29%**	3 (10.1, 10.2, 10.7) **43%**	4th
Chapter 11: Te Tiriti o Waitangi	1	1 (11.1) **100%**	0 - **0%**	0 - **0%**	5th equal
Chapter 12 : Liability	2	0 - **0%**	2 (12.1, 12.2) **100%**	0 - **0%**	5th equal
Chapter 13 : Major Conclusion: Preserving Opportunities	4	4 (13.1-13.4) **100%**	0 - **0%**	0 - **0%**	5th equal
Chapter 14 : The Biotechnology Century	4	1 (14.3) **25%**	3 (14.1, 14.2, 14.4) **75%**	0 - **0%**	5th equal
Total [%]	49 **100%**	18 **37%**	11 **22%**	20 **41%**	

5.2.1 The ten 'watershed' recommendations

In our analysis of the watershed recommendations (see Table 14 below), only one [10%] of the ten 'watershed' recommendations could be considered completed by central government. As a result, we believe New Zealand could not legitimately make a well-considered decision if a conditional release or release application of a GM crop was received today.

Table 14 Extent to which the Watershed Recommendations have been Implemented or Require Further Policy Work

Number	Recommendation	To what extent has the recommendation been implemented?	Is further policy work required by central government?
1[37]	**6.8** That HSNO be amended to provide for a further level of approval called conditional release	Fully Implemented	No
2	**13.1** That the methodology for implementing HSNO section 6(e) be made more specific to: • Include an assessment of the economic impact the release of any genetically modified crop or organism would have on the proposed national strategy of preserving opportunities in genetically modified and unmodified agricultural systems. • Allow for specified categories of genetically modified crops to be excluded from districts where their presence would be a significant threat to an established non-genetically modified crop use.	Not Implemented	Yes: significant
3	**13.2** That before the controlled or open release of the first genetically modified crop, the Minister exercise the call-in powers available under HSNO section 68 in order to assess the likely overall economic and environmental impact on the preserving opportunities strategy.	Not Implemented	Yes: significant

[37] The recommendations are in the order discussed at the end of Chapter 13 of the Commissioners' Report.

Number	Recommendation	To what extent has the recommendation been implemented?	Is further policy work required by central government?
4	**7.7** That MAF develop an industry code of practice to ensure effective separation distances between genetically modified and unmodified crops (including those grown for seed production) such a code: • to be established on a crop-by-crop basis • to take into account: existing separation distances for seed certification in New Zealand; developments in international certification standards for organic farming; emerging strategies for coexistence between genetically modified and unmodified crops in other countries • to identify how the costs of establishment and maintenance of buffer zones are to be borne.	Not Implemented	Yes: significant
5	**13.3** That MAF develop formalised local networks to encourage constructive dialogue and communication between farmers using different production methods, and to provide for mediation where necessary.	Not Implemented	Yes: significant
6	**13.4** That sterility technologies be one tool in the strategy to preserve opportunities, especially in the case of those genetically modified crops most likely to cross-pollinate with non-genetically modified crops in the New Zealand context (e.g. brassicas, ryegrass, ornamentals).	Partially Implemented	Yes: significant

Number	Recommendation	To what extent has the recommendation been implemented?	Is further policy work required by central government?
7	**7.1** That, prior to the release of any Bt-modified crops, the appropriate agencies develop a strategy for the use of the Bt toxin in sprays and genetically modified plants, taking into account: • The concept of refugia; • Limitations on total planted area; and • Home gardener use.	Not Implemented	Yes: significant
8	**7.3** That the Ministry of Agriculture and Forestry (MAF) develop a strategy to allow continued production of genetic modification-free honey and other bee products, and to avoid cross-pollination by bees between genetically modified and modification-free crops, that takes into account both geographical factors (in terms of crop separation strategies) and differences in crop flowering times.	Not Implemented	Yes: significant
9	**6.13** That public research funding be allocated to ensure organic and other sustainable agricultural systems are adequately supported.	Partially Implemented	Yes: ongoing
10	**14.1** That HSNO section 68 be extended to include significant cultural, ethical and spiritual issues as grounds for the Minister's call-in powers.	Fully Implemented	Yes: ongoing

5.2.2 The three 'institutional' recommendations

From our analysis in Table 15 below, we conclude that New Zealand does not yet have the institutional capacity required for the new century if it wishes to 'preserve opportunities' for GM and non-GM producers. In particular we note:

(i) The Bioethics Council only exists as a result of a Cabinet Minute [POL (02) 117], which means it remains unmanaged and not linked into the current system. This can be a strength, but if the Council remains unheard and its recommendations continue to lack a response from the Government, the problem it was created to fix will not be resolved.

(ii) We are also a strong advocate of an office of Parliamentary Commissioner on Biotechnology, in that currently there is no body to go to, other than the courts, to make complaints or raise issues independent of the Ministry of the Environment and ERMA (neither of which are independent of the process).

(iii) Lastly, ongoing work is required to monitor, consult and rework the strategy, to ensure it is relevant, effective and aligns with wider national goals.

Table 15 Extent to which the Institutional Recommendations have been Implemented or Require Further Policy Work

Number	Recommendation	To what extent has the recommendation been implemented?	Is further policy work required by central government?
1	**14.2** That Government establish Toi Te Taiao: The Bioethics Council to: • Act as an advisory body on ethical, social 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.	Partially Implemented	Yes: Ongoing
2	**14.3** That Government establish the office of Parliamentary Commissioner on Biotechnology to undertake futurewatch, audit and educational functions with regard to the development and use of biotechnology in New Zealand.	Not Implemented	Yes: Significant
3	**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.	Fully Implemented	Yes: Ongoing

6. Conclusion

In this section, we conclude by revisiting the degree the Commissioners implemented the Warrant (see Section 2.1), the relevance of the seven shared values (see Section 2.2.1) and the extent Government implemented the Commissioners' recommendations developed under the Warrant (see Sections 4 and 5).

6.1 The Implementation of the Warrant

In response to the first *matter* in the Warrant, the Commissioners were to inquire into, investigate, and report upon the strategic options (see Section 2.1). The Commissioners discussed a spectrum with two positions at either end: (i) New Zealand is Free of all GM material; and (ii) Unrestricted use of GM. These positions represent extremes and therefore neither were considered options. The Commissioners state they considered all positions along the spectrum (RCGM, 2001a: 332), but they reported on only one position, 'preserving opportunities', which sits somewhere between the extremes. It is clear that the Commissioners only identified one potential strategic option and, in so doing, missed the opportunity to report on all the 'options' available to New Zealand.

In response to the second *matter*, the Commissioners' report reviewed institutional arrangements in existence, and discussed the establishment of two new institutions: a Parliamentary Commissioner on Biotechnology (which was not pursued by Government); and a Bioethics Council (RCGM, 2001a: 342-348). The Bioethics Council was subsequently created by Government, though it requires further work in order to meet the purpose the Commissioners intended. The Commissioners also reviewed and made a number of recommendations regarding 'genetic modification, GMOs, and products'.

The Commissioners met the second *matter* of the warrant, but could have gone a great deal further in reporting on their inquiry into the first *matter*. In particular, this could have detailed the range of options available to New Zealand, rather than only describing and reporting on one option. Importantly, the Commissioners emphasised the need for Government to make a national strategic decision when ERMA receives the first application to release a GMO crop or other field use. They refer to this as the 'watershed' decision, the defining moment when New Zealand's GM status would change from being a 'GM-free' to a 'GM nation' in terms of crops (RCGM, 2001a: 338).

Rather than reporting on one strategic option, what the Commissioners produced can better be described as a 'strategic pathway'. Essentially, the Commissioners designed a package of recommendations that allowed the Government the time and space to make a strategic decision about GM in New Zealand, but did not, themselves, make a strategic decision. This possibly explains why the Commissioners talk about 'preserving opportunities' as a 'major theme' rather than as a 'strategic option' (RCGM, 2001a: 2). As part of this approach, the Commissioners envisaged a national strategic decision would need to be made by Government at that 'watershed' moment. Consequently, the Commissioners' package left little direction for ERMA when it receives its first application for release of a GMO as a crop or other field use. For many New Zealand citizens, creating this direction was the crux of the Commission's task.[38] Arguably, the very decision the Royal Commission was created to solve was in fact postponed for some future point in time.

6.2 The Relevance of the Seven Shared Values

In completing our assessment, we have reconsidered the seven shared values discussed in Chapter 2 of the Commissioners' Report and found them robust and relevant to today. These values are: the uniqueness of New Zealand, our cultural heritage, sustainability, being part of a global family, the well-being of all, freedom of choice and participation.

To do a complete assessment of the relevance of these values is beyond the scope of this paper, but we do believe the values remain of use seven years after the Commissioners' Report. Importantly, we have encountered no evidence that suggests the Government disagrees with the shared values, but equally we have not found any discussion that indicates any level of support, reflection or wider discussion. We consider this is a missed opportunity.

In our view, any further discussion and decision-making on the use and application of genetic modification technology in New Zealand should start with consideration of these seven shared values.

[38] In their introduction, the Commissioners advise that at their public meetings, and in public written submissions, the great majority of the views expressed opposed any general release of GMOs, and particularly their introduction to the food chain (RCGM, 2001a: 7).

6.3 The Implementation of the Recommendations

There is no onus on Government to adopt all or indeed any of the recommendations of any Royal Commission, but the Government did create a public expectation (see Section 2.2.5). However, the Government's positive reception of the Commissioners' Report, and the strength with which it accepted the Commissioners' central theme of 'preserving opportunities' led the public to believe the resulting recommendations would be substantially implemented (see Section 4.1). This, combined with the fact that the Government established the Royal Commission, called for extensive stakeholder engagement, appointed experts and funded the Commission, implies a high level of trust and commitment to the Commissioners' findings.

We had therefore anticipated that the majority of the Commissioners' recommendations would have been 'fully implemented' in the seven-year period following their report. For the minority of the recommendations that remained 'not implemented' or 'partially implemented', we expected there to be a detailed public explanation of the reasons why this was so and, where appropriate, either an explanation of how a particular problem had been resolved using other mechanisms or a recent update of the remaining work programme. What we did find was a substantial gap between our expectations and reality.

From the analysis in sections four and five above, we found that:

- Of the package of forty-nine recommendations only twenty were fully implemented.
- Of the ten watershed recommendations only two were fully implemented.
- Of the three institutional recommendations, although two were arguably fully implemented, considerable policy work remains in order to meet the underlying purpose of all three institutional recommendations.
- In summary, a significant amount of further policy work is necessary regarding recommendations relating to 'Crops and Other Field Uses', 'Te Tiriti o Waitangi', 'Major Conclusion: Preserving Opportunities' and 'The Biotechnology Century' in order to meet the intent of the Commissioners recommendations.
- New Zealand does not have in place the governance and accountability framework proposed by the Commissioners under their major theme of 'preserving opportunities'. In particular, the Commissioners relied heavily on the development of practical co-existence strategies, the use of sterility technologies, a national strategic 'watershed' decision and effective institutional entities in order to deliver the theme of 'preserving opportunities' and enable co-existence between GM and non-GM producers. To date, these initiatives have not been actioned.
- There is no indication that this situation is likely to change in the short term.

6.4 Implications

The Commissioners identified a spectrum of strategic options, from a 'New Zealand free of all genetically modified material' to 'unrestricted use of genetic modification' and reported on one option, which they called the 'preserving opportunities' option. As the package of forty-nine recommendations originally designed to progress this option has not been implemented (particularly those relating to crops, Te Tiriti o Waitangi, and the 'Major conclusion: Preserving Opportunities', as outlined in Table 12), it can be argued that New Zealand is now positioned further along the spectrum towards the 'unrestricted use of genetic modification'. Such a move appears in contrast with the original intent of the Commissioners' findings, in particular the 'seven shared values of New Zealanders'.

This position is not readily apparent to the wider public due to the absence of an application for conditional or full release. As such, New Zealand's strategy of protecting the GM-free food producer has not been put to the test, which suggests the first application to ERMA for conditional or full release of a GM crop is likely to ignite public concern – a true watershed moment.

This movement along the spectrum towards the 'unrestricted use of genetic modification' would have been more obvious if an independent review had taken place. We believe an independent review mechanism could have been incorporated into the Terms of Reference of this and any future Royal Commission, in order to revisit how Government has responded. Royal Commissions are the highest level of response available to the New Zealand Government to investigate a *matter* of major public importance (RCGM, 2001b: 49) and as such, we believe the public deserve to understand what the Government implemented, what they did not and why.

These findings show that the New Zealand Government is not currently pursuing the strategic option of 'preserving opportunities' as proposed by the Commissioners and raise further questions about New Zealand's ability to manage the current and future risks of genetic modification. It leaves open questions about how well New Zealand can manage risks associated with current outdoor developments and field tests. It leaves untested and unclear how New Zealand will cope on the first application to ERMA for GM release (including conditional release), and provides little confidence that this will be done in a robust manner. Perhaps most importantly, it leaves unanswered whether the current framework meets the expectations of New Zealanders. It may therefore be timely for New Zealand to reconsider its strategic options in dealing with the highly complex debate over the future of genetic modification in New Zealand.

Abbreviations

ANZFA	Australia New Zealand Food Authority
CRI	Crown Research Institute
ERMA	Environmental Risk Management Authority
FRST	Foundation for Research, Science and Technology
HSNO	Hazardous Substances and New Organisms
GM	Genetic Modification
GMF	Genetic Modification Field (Test) — an outdoor experiment of either a project or a specific GMO as defined under the HSNO legislation
GMO	Genetically Modified Organism
GTAC	Genetic Technology Advisory Committee
IBAC	Independent Biotechnology Advisory Committee
IBSC	Institutional Biological Safety Committee
MAF	Ministry of Agriculture and Forestry
MCA	Ministry of Consumer Affairs
MED	Ministry of Economic Development
MfE	Ministry for the Environment
MOH	Ministry of Health
MoRST	Ministry of Research, Science and Technology
NFO	Now TNS (formerly known as NFO New Zealand). A market research company
NOOM	New Organisms and Other Matters
NZFSA	New Zealand Food Safety Authority
PC	Physical containment
RCGM	Royal Commission on Genetic Modification
UN	United Nations

Glossary

Biopharming
'The production of pharmaceutical compounds from genetically modified crops and livestock' (Lincoln University, 2007).

Bioreactors
'The use of genetically modified micro-organisms, plants or animals to produce medicines or specific proteins' (RCGM, 2001a: 158).

Biotechnology
'Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use' (RCGM, 2001b: 204).

Containment
'Relates to an approval granted for a hazardous substance or new organism in containment. Containment means restricting organisms or hazardous substances to a secure location or facility to prevent escape. In respect of genetically modified organisms, includes field testing and large-scale fermentation. Controls on containment for both hazardous substances and new organisms are derived from the Third Schedule of the HSNO Act' (MfE, 2001b: 94).

Controls
'Controls encompass any obligations or restrictions imposed on any hazardous substance or new organism, or on any person involved with any hazardous substance or new organism, by the HSNO Act (and other legislation). Controls also encompass any regulation, rule, code or other document made in accordance with the provisions of the HSNO Act (or any other legislation) for the purpose of controlling the effects of hazardous substances or new organisms on people, property and the environment' (MfE, 2001b: 94).

Corrective Action Requests (CARs)
A request for a corrective action to remedy a non-compliance (MAF, 2007b).

Critical Non-Compliance
A critical non-compliance is defined as a major failure in an operation or system that caused, or could have caused, a serious risk to biosecurity, the environment, or the health and safety of people and communities. It can lead to cancellation of the facility and/or Operator approval. Examples of critical non-compliances include, but are not limited to:

- releasing organisms from a transitional facility without biosecurity clearance
- releasing organisms from a containment facility without a HSNO Act Approval
- breaches in containment
- a significant failure in the structural containment provisions of a facility
- operating a facility without an Operator
- Operator allowing uncleared good to be transferred to non-approved premises

- making major modifications to buildings or facility services (e.g. air handling systems) without MAF approval
- using a HSNO Act Approval specific to another facility
- In the event of a critical non-compliance, the Operator must:
- notify the Inspector as soon as practicable and within 24 hours
- discontinue any activity related to the critical non-compliance that presents a biosecurity risk
- take immediate corrective action to safeguard the environment, the health and safety of people and communities and restore compliance (MAF, 2007b: 8.12).

Developing GMOs in Containment
'Where a GMO such as a transgenic mouse or genetically modified micro-organism is completely developed within a containment facility in New Zealand' (RCGM, 2001a: 120).

Field Test (outdoor experiment)
'Field test means, in relation to an organism, carrying out 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 arising from it, could be retrieved or destroyed at the end of the trials. It includes large-scale fermentation of micro-organisms' (MfE, 2001b: 96).

Genetically Modified Organisms (GMOs)
'GMOs are plants, animals or micro-organisms that have had their genetic material altered using genetic engineering techniques; for example, plants that produce bacterial or insecticidal toxins, or micro-organisms that produce human insulin are genetically modified organisms' (MfE, 2001b: 96).

Genetic Modification Development (GMD)
An indoor or outdoor experiment of either a project or a specified GMO as defined under the HSNO legislation (ERMA, 2007b: 11).

Genetic Modification Field (Test) (GMF)
An outdoor test of a GMO 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 arising from it, could be retrieved or destroyed at the end of the trials (ERMA 2007g: 11).

Field Release
The term is no longer in use. It came into existence with the creation of the Field Release Working Party, and reflects a combination of field test and release. (RCGM, 2001a: 105)

Importing GMOs into Containment
'Where a GMO such as a transgenic mouse or genetically modified micro-organism is developed overseas and imported into New Zealand for use in a containment facility' (RCGM, 2001a: 120).

Institutional Biological Safety Committees (ISBCs)
'Committees that sit within scientific institutions or research organisations which have been appointed by ERMA New Zealand as delegated decision making bodies. IBSCs are authorised to make decisions on approvals for low-risk genetically modified organisms'
(ERMA, 2006b: 49).

Major Non-Compliance
A major non-compliance is defined as a major failure in an operation or system that may cause, or lead to, a biosecurity risk. It may be a specific non-compliance or a system with multiple non-compliances having a cumulative effect. Major non-compliances may be created by escalation of outstanding issues from previous audits and include, but are not limited to:

- failure of the Operator to detect significant and obvious non-compliances
- failure of the Operator to action CARs from previous audits
- activities conducted outside the scope of a HSNO Act Approval
- failure to operate the facility to meet the requirements of this standard
- imports not recorded in register
- restricted material not stored in appropriately identified area
- In the event of a major non-compliance, the Operator must:
- notify the Inspector as soon as practicable and within 24 hours
- take immediate corrective action to restore the facility and/or operations to a compliant condition
- discontinue any activity related to the major non-compliance that presents a biosecurity risk (MAF, 2007b: 8.12).

Minor Non-Compliance
A minor non-compliance is defined as a situation that does not represent a major failure of an operation or system but results in a decrease in confidence in the management of the facility that may not immediately cause or lead to a biosecurity risk. Minor non-compliances include, but are not limited to:

- QMS not up to date
- transfers and inventory not accurate
- boxes on the floor
- failure to maintain staff training records
- missing signage
- lab coats not being worn (MAF, 2007b: 8.12).

Low-risk GMOs
'Organisms that are classified under PC1 or PC2 containment and are contained within a registered containment facility such as a laboratory or glasshouse. By virtue of the nature of the organism and the modifications made to it, they are seen as presenting minimal risk to both people and the environment. They are not expected to survive outside of containment or would have minimal impact in the event of release' (RCGM, 2001a).

New Organism (NO)
Any organism that:
- was not legally present in New Zealand immediately before 29 July 1998
- is prescribed as a risk species in HSNO regulations
- is present in New Zealand but is found only in containment – for example, some organisms found only in zoos or laboratories
- has been genetically modified
- has been eradicated from New Zealand (ERMA, 2006b: 46).

New Organism Conditional Release (NOCR)
Means a NO 'release approval with controls' (NZ Govt, 1996: s38c).

New Organism Release (NOR)
Means a NO release (see release below).

Release
Means to allow the organism to move within New Zealand free of any restrictions other than those imposed in accordance with the Biosecurity Act 1993 or the Conservation Act 1987 (NZ Govt, 1996: Interpretation)

Notified Decision
If the application is for a field test or release then it must be publicly notified. If the application is for a development the Authority has discretion to publicly notify or not. The test in the Act for the exercise of this discretion is that of public interest. This test will be applied by the Authority on a case-by-case basis but in the context of a set of predetermined criteria (ERMA, 2007c).

PC1, PC2, PC3
Level of containment in a containment facility approved in accordance with section 39 of the Biosecurity Act for holding organisms that should not, for the time being or ever, become established in New Zealand (NZ Govt, 1993).

Rapid Assessment
Development of organisms that meet the requirements of Category A or B of the HSNO (Low-Risk Genetic Modification) Regulations may be rapidly assessed under section 42 of the HSNO Act and dealt with by Institutional Biological Safety Committees (IBSCs). Development of new organisms that are "not low-risk" according to the Low-Risk Genetic Modification Regulations, are not eligible for rapid assessment. Such applications must be considered by the Authority and cannot be delegated to IBSCs. Fermentations involving "not-low risk" GMOs may be publicly notified if there is likely to be significant public interest (ERMA, 2007d).

Appendix 1 List of all 49 Recommendations of the Royal Commission

Recommendation	To what extent has the recommendation been implemented?[39]	Is further policy work required by central government?
6.1 That applications to develop genetically modified organisms in PC1 and PC2 containment be assessed by the Institutional Biological Safety Committees (IBSCs) on a project rather than organism basis.	Fully Implemented	No
6.2 That all approval forms, standards and regulations relating to the development of genetically modified organisms in containment be reviewed and updated.	Fully Implemented	No
6.3 That a separate, simplified form be developed for low-risk (Categories A and B) applications to IBSCs.	Fully Implemented	No
6.4 That the Hazardous Substances and New Organisms Act 1996 (HSNO) be amended to allow for the efficient importation of low-risk genetically modified organisms, through delegation of the approval process to the IBSCs.	Fully Implemented	No
6.5 That approval to develop or import genetically modified organisms be deemed to cover their holding and breeding.	Fully Implemented	No
6.6 That HSNO be amended to clarify that research involving genetic modification of human cell lines or tissue cultures is covered by the Act.	Fully Implemented	No
6.7 That approval for development of genetically modified animal cell lines be delegated to the IBSCs.	Fully Implemented	No
6.8 That HSNO be amended to provide for a further level of approval called conditional release	Fully Implemented	No
6.9 That HSNO be amended to cover procedures used in mammalian cloning, such as nuclear transfer or cell fusion.	Fully Implemented	No
6.10 That IBSCs include at least one Māori member, appointed on the nomination of the hapū or iwi with manawhenua in the locality affected by an application.	Fully Implemented	No

[39] Appendices 4 to 6 list recommendations fully, partially and not implemented.

Recommendation	To what extent has the recommendation been implemented?[39]	Is further policy work required by central government?
6.11 That the funders of resource portfolios be resourced to include the cost of compliance with HSNO.	Fully Implemented	No
6.12 That the Environmental Risk Management Authority (ERMA) require research on environmental impacts on soil and ecosystems before release of genetically modified crops is approved.	Not Implemented	Yes: significant
6.13 That public research funding be allocated to ensure organic and other sustainable agricultural systems are adequately supported.	Partially Implemented	Yes: ongoing
6.14 That public research funding portfolios be resourced to include research on the socio-economic and ethical impacts of the release of genetically modified organisms.	Partially Implemented	Yes: ongoing
7.1 That, prior to the release of any Bt-modified crops, the appropriate agencies develop a strategy for the use of the Bt toxin in sprays and genetically modified plants, taking into account: • The concept of refugia;[40] • Limitations on total planted area, and • Home gardener use.	Not Implemented	Yes: significant
7.2 That the appropriate agencies develop a labelling regime to identify: a. genetically modified seed; b. nursery stock; and c. propagative material at point of sale.	Not Implemented	Yes: significant

[40] In the context of pest control, the word 'refuge' is used to mean an area of habitat where susceptible pest populations can survive in numbers that will sufficiently dilute any resistance that arises in the target populations (MAF, 2002).

Recommendation	To what extent has the recommendation been implemented?[39]	Is further policy work required by central government?
7.3 That the Ministry of Agriculture and Forestry (MAF) develop a strategy to allow continued production of genetic modification-free honey and other bee products, and to avoid cross-pollination by bees between genetically modified and modification-free crops, that takes into account both geographical factors (in terms of crop separation strategies) and differences in crop flowering times.	Not Implemented	Yes: significant
7.4 That, in connection with any proposal to develop genetically modified forest trees, an ecological assessment be required to determine the effects of the modification on the soil and environmental ecology, including effects on soil micro-organisms, weediness, insect and animal life, and biodiversity.	Not Implemented	Yes: significant
7.5 That, wherever possible, non-food animals, or animals less likely to find their way into the food chain, be used as bioreactors rather than animals that are a common source of food.	Not Implemented	Yes: significant
7.6 That, wherever possible, synthetic genes or mammalian homologues of human genes be used in transgenic animals to avoid the use of genes derived directly from humans.	Not Implemented	Yes: significant

Recommendation	To what extent has the recommendation been implemented?[39]	Is further policy work required by central government?
7.7 That MAF develop an industry code of practice to ensure effective separation distances between genetically modified and unmodified crops (including those grown for seed production), such a code: • to be established on a crop-by-crop basis • to take into account: – existing separation distances for seed certification in New Zealand; – developments in international certification standards for organic farming; – emerging strategies for coexistence between genetically modified and unmodified crops in other countries • to identify how the costs of establishment and maintenance of buffer zones are to be borne.	Not Implemented	Yes: significant
8.1 That the Food Administration Authority:[41] a. monitor research studies on stock feed; and b. act on any that indicate a need for stock feed to be assessed in relation to human health.	Fully Implemented	No
8.2 That Government facilitate the development of a voluntary label indicating a food: a. has not been genetically modified; b. contains no genetically modified ingredients; and c. has not been manufactured using a process involving genetic modification.	Not Implemented	Yes: significant

[41] Now the New Zealand Food Safety Authority (NZFSA).

Recommendation	To what extent has the recommendation been implemented?[39]	Is further policy work required by central government?
8.3 That, as a matter of priority, the Food Administration Authority disseminate information on: a. the labelling regime for genetically modified foods; and b. consumer rights in relation to foods made available for consumption at restaurants and take-away bars.	Partially Implemented	Yes: ongoing
8.4 That the Food Administration Authority produce and distribute consumer information on the use of gene technology in the production of food.	Fully Implemented	No
9.1 That all gene therapy, whether in the public or the private sectors, require formal medical ethical oversight.	Fully Implemented	No
9.2 That Toi Te Taiao: The Bioethics Council develop ethical guidelines for xenotransplantation involving genetic modification technology.	Fully Implemented	Yes: ongoing
9.3 That products be clearly defined in legislation as medicines, pharmaco foods, functional foods or dietary supplements.	Not Implemented	Yes: significant
9.4 That imported medicines and pharmaco foods that include live genetically modified organisms be approved for use by Medsafe without a requirement for additional approval from ERMA.	Partially Implemented	No
9.5 That, in respect of applications for approval as Animal Remedies of genetically modified organisms or products manufactured by processes using genetic modification techniques, the specified information which the Director–General of Agriculture and Forestry requires to be contained in applications under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM) include: a. full information on the efficacy and the form of the genetic modification used in manufacture; and b. that such information be included as one of the categories of relevant risks and benefits under section 19 of the Act.	Partially Implemented	No

Recommendation	To what extent has the recommendation been implemented?[39]	Is further policy work required by central government?
9.6 That, as protocols identify useful therapeutics for serious disease control, approvals through ERMA and Medsafe be sought in advance for the importation of live genetically modified organisms in the form of vaccines.	Partially Implemented	No
10.1 That the New Zealand Plant Variety Rights Act 1987 be amended to introduce the concept of essential derivation.	Fully Implemented	No
10.2 That the Patents Act 1953 be amended by adding a specific exclusion of the patentability of human beings and the biological processes for their generation, in line with section 18 of the Patents Act 1990 (Commonwealth).	Partially Implemented	No
10.3 That a Māori Consultative Committee be established by the Intellectual Property Office of New Zealand to develop procedures for assessing applications, and to facilitate consultation with the Māori community where appropriate.	Partially Implemented	Yes: ongoing
10.4 That New Zealand be proactive in pursuing cultural and intellectual property rights for indigenous peoples internationally.	Not Implemented	Yes: significant
10.5 That New Zealand pursue the amendment of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights and associated conventions to include a reference to the avoidance of cultural offence as a specific ground for exclusion or reservation.	Not Implemented	Yes: significant
10.6 That all parties concerned work to resolve the WAI 262 and WAI 740 claim currently before the Waitangi Tribunal as soon as possible.	Partially Implemented	Yes: ongoing
10.7 That the HSNO and ACVM Acts be amended to give appropriate protection to all commercially sensitive or confidential supporting information provided with applications for approval.	Fully Implemented	No
11.1 That section 8 of HSNO be amended to provide that effect is to be given to the principles of the Treaty of Waitangi.	Not Implemented	Yes: significant
12.1 That Toi Te Taiao: the Bioethics Council, in association with the Human Rights Commission, address the issue of genetic discrimination.	Fully Implemented	Yes: ongoing

Recommendation	To what extent has the recommendation been implemented?[39]	Is further policy work required by central government?
12.2 That for the time being there be no change in the liability system.	Partially Implemented	Yes: ongoing
13.1 That the methodology for implementing HSNO section 6(e) be made more specific to: • Include an assessment of the economic impact the release of any genetically modified crop or organism would have on the proposed national strategy of preserving opportunities in genetically modified and unmodified agricultural systems. • Allow for specified categories of genetically modified crops to be excluded from districts where their presence would be a significant threat to an established non-genetically modified crop use.	Not Implemented	Yes: significant
13.2 That before the controlled or open release of the first genetically modified crop, the Minister exercise the call-in powers available under HSNO section 68 in order to assess the likely overall economic and environmental impact on the preserving opportunities strategy.	Not Implemented	Yes: significant
13.3 That MAF develop formalised local networks to encourage constructive dialogue and communication between farmers using different production methods, and to provide for mediation where necessary.	Not Implemented	Yes: significant
13.4 That sterility technologies be one tool in the strategy to preserve opportunities, especially in the case of those genetically modified crops most likely to cross-pollinate with non-genetically modified crops in the New Zealand context (e.g. brassicas, ryegrass, ornamentals).	Partially Implemented	Yes: significant
14.1 That HSNO section 68 be extended to include significant cultural, ethical and spiritual issues as grounds for the Minister's call-in powers.	Fully Implemented	Yes: ongoing

Recommendation	To what extent has the recommendation been implemented?[39]	Is further policy work required by central government?
14.2 That Government establish Toi Te Taiao: The Bioethics Council to: a. Act as an advisory body on ethical, social and cultural matters in the use of biotechnology in New Zealand. b. Assess and provide guidelines on biotechnological issues involving significant social, ethical and cultural dimensions. c. Provide an open and transparent consultation process to enable public participation in the Council's activities.	Partially Implemented	Yes: ongoing
14.3 That Government establish the office of Parliamentary Commissioner on Biotechnology to undertake futurewatch, audit and educational functions with regard to the development and use of biotechnology in New Zealand.	Not Implemented	Yes: significant
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.	Fully Implemented	Yes: ongoing

Appendix 2 List of 9 Reclassified Recommendations

Number	Fully Implemented But Requires Further Ongoing Policy Work
1	**9.2** That Toi Te Taiao: The Bioethics Council develop ethical guidelines for xenotransplantation involving genetic modification technology.
2	**12.1** That Toi Te Taiao: the Bioethics Council, in association with the Human Rights Commission, address the issue of genetic discrimination.
3	**14.1** That HSNO section 68 be extended to include significant cultural, ethical and spiritual issues as grounds for the Minister's call-in powers.
4	**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.
Number	**Partially Implemented but Requires No Further Policy Work**
1	**9.4** That imported medicines and pharmaco foods that include live genetically modified organisms be approved for use by Medsafe without a requirement for additional approval from ERMA.
2	**9.5** That, in respect of applications for approval as Animal Remedies of genetically modified organisms or products manufactured by processes using genetic modification techniques, the specified information which the Director–General of Agriculture and Forestry requires to be contained in applications under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM) include: **a.** full information on the efficacy and the form of the genetic modification used in manufacture; and **b.** that such information be included as one of the categories of relevant risks and benefits under section 19 of the Act.
3	**9.6** That, as protocols identify useful therapeutics for serious disease control, approvals through ERMA and Medsafe be sought in advance for the importation of live genetically modified organisms in the form of vaccines.
4	**10.2** That the Patents Act 1953 be amended by adding a specific exclusion of the patentability of human beings and the biological processes for their generation, in line with section 18 of the Patents Act 1990 (Commonwealth).
Number	**Partially Implemented But Requires Significant Policy Work**
1	**13.4** That sterility technologies be one tool in the strategy to preserve opportunities, especially in the case of those genetically modified crops most likely to cross-pollinate with non-genetically modified crops in the New Zealand context (e.g. brassicas, ryegrass, ornamentals).

Appendix 3 IBSC Policy Requirements and Processes

Source: ERMA, 2007a

Information on current policy requirements and processes for IBSCs is provided as follows:

- Institutional Biological Safety Committees and Low Risk Genetically Modified Organism Decision-making
  at: http://www.ermanz.govt.nz/no/applications/ibsc/
- Māori Membership of Institutional Biological Safety Committees (IBSCs) and Consultation Requirements with the Māori Community
  at: http://www.ermanz.govt.nz/resources/publications/policy/no/mmibsc.html
- Interpretation and Explanation of Key Concepts Protocol
  at: http://www.ermanz.govt.nz/resources/publications/pdfs/ER-PR-03-18.pdf (see 'Low-risk genetic modification' (page 46) and 'Project' (page 51))
- Decision form for development in containment of a genetically modified organism by rapid assessment under section 42 or 42A
  at: http://www.ermanz.govt.nz/resources/publications/pdfs/ER-AF-02-3-IBSC.pdf
- Decision form to import a genetically modified organism into containment by rapid assessment under section 42B
  at: http://www.ermanz.govt.nz/resources/publications/pdfs/ER-AF-03-3-IBSC.pdf
- Criteria for Delegating Power to Conduct Rapid Assessments of Applications for the Development in Containment and Importation into Containment of Low Risk Genetically Modified Organisms to External Organisations, August 2005
  at: http://www.ermanz.govt.nz/resources/publications/pdfs/ibsc-criteria-delegation.pdf
- Requirements for Delegation of Power to Conduct Rapid Assessments of Applications for Development in Containment and Importation into Containment of Low Risk Genetically Modified Organisms, June 2007
  at: http://www.ermanz.govt.nz/resources/publications/pdfs/ibsc-delegated-contain.pdf
- User Guide to Making an Application for rapid assessment to develop in containment a project of low-risk GMOs, November 2007
  at: http://www.ermanz.govt.nz/resources/publications/pdfs/ER-UG-NO3P-2.pdf
- User Guide to Making An Application for rapid assessment to import into containment low-risk GMOs
  at: http://www.ermanz.govt.nz/resources/publications/pdfs/ER-UG-NO2R-1.pdf
- Hazardous Substances and New Organisms (Low-Risk Genetic Modifications) Regulations 2003

Appendix 4 List of 20 Recommendations Fully Implemented

Number	Recommendation
1	**6.1** That applications to develop genetically modified organisms in PC1 and PC2 containment be assessed by the Institutional Biological Safety Committees (IBSCs) on a project rather that organism basis.
2	**6.2** That all approval forms, standards and regulations relating to the development of genetically modified organisms in containment be reviewed and updated.
3	**6.3** That a separate, simplified form be developed for low-risk (Categories A and B) applications to IBSCs.
4	**6.4** That the Hazardous Substances and New Organisms Act 1996 (HSNO) be amended to allow for the efficient importation of low-risk genetically modified organisms, through delegation of the approval process to the IBSCs.
5	**6.5** That approval to develop or import genetically modified organisms be deemed to cover their holding and breeding**.**
6	**6.6** That HSNO be amended to clarify that research involving genetic modification of human cell lines or tissue cultures is covered by the Act.
7	**6.7** That approval for development of genetically modified animal cell lines be delegated to the IBSCs.
8	**6.8** That HSNO be amended to provide for a further level of approval called conditional release.
9	**6.9** That HSNO be amended to cover procedures used in mammalian cloning, such as nuclear transfer or cell fusion.
10	**6.10** That IBSCs include at least one Māori member, appointed on the nomination of the hapū or iwi with manawhenua in the locality affected by an application.
11	**6.11** That the funders of resource portfolios be resourced to include the cost of compliance with HSNO.
12	**8.1** That the Food Administration Authority: **a.** monitor research studies on stock feed; and **b.** act on any that indicate a need for stock feed to be assessed in relation to human health.

Number	Recommendation
13	**8.4** That the Food Administration Authority produce and distribute consumer information on the use of gene technology in the production of food.
14	**9.1** That all gene therapy, whether in the public or the private sectors, require formal medical ethical oversight.
15	**9.2** That Toi Te Taiao: The Bioethics Council develop ethical guidelines for xenotransplantation involving genetic modification technology.
16	**10.1** That the New Zealand Plant Variety Rights Act 1987 be amended to introduce the concept of essential derivation.
17	**10.7** That HSNO and ACVM Acts be amended to give appropriate protection to all commercially sensitive or confidential supporting information provided with applications for approval.
18	**12.1** That Toi Te Taiao: the Bioethics Council, in association with the Human Rights Commission, address the issue of genetic discrimination.
19	**14.1** That HSNO section 68 be extended to include significant cultural, ethical and spiritual issues as grounds for the Minister's call-in powers.
20	**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.

Appendix 5 List of 12 Recommendations Partially Implemented

Number	Recommendation
1	**6.13** That public research funding be allocated to ensure organic and other sustainable agricultural systems are adequately supported.
2	**6.14** That public research funding portfolios be resourced to include research on the socio-economic and ethical impacts of the release of genetically modified organisms.
3	**8.3** That, as a matter of priority, the Food Administration Authority[42] disseminate information on: **a.** the labelling regime for genetically modified foods; and **b.** consumer rights in relation to foods made available for consumption at restaurants and take-away bars.
4	**9.4** That imported medicines and pharmaco foods that include live genetically modified organisms be approved for use by Medsafe without a requirement for additional approval from ERMA.
5	**9.5** That, in respect of applications for approval as Animal Remedies of genetically modified organisms or products manufactured by processes using genetic modification techniques, the specified information which the Director–General of Agriculture and Forestry requires to be contained in applications under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM) include: **a.** full information on the efficacy and the form of the genetic modification used in manufacture; and **b.** that such information be included as one of the categories of relevant risks and benefits under section 19 of the Act.
6	**9.6** That, as protocols identify useful therapeutics for serious disease control, approvals through ERMA and Medsafe be sought in advance for the importation of live genetically modified organisms in the form of vaccines.
7	**10.2** That the Patents Act 1953 be amended by adding a specific exclusion of the patentability of human beings and the biological processes for their generation, in line with section 18 of the Patents Act 1990 (Commonwealth).

Number	Recommendation
8	**10.3** That a Māori Consultative Committee be established by the Intellectual Property Office of New Zealand to develop procedures for assessing applications, and to facilitate consultation with the Māori community where appropriate.
9	**10.6** That all parties concerned work to resolve the WAI 262 and WAI 740 claim currently before the Waitangi Tribunal as soon as possible
10	**12.2** That for the time being there be no change in the liability system.
11	**13.4** That sterility technologies be one tool in the strategy to preserve opportunities, especially in the case of those genetically modified crops most likely to cross-pollinate with non-genetically modified crops in the New Zealand context (e.g. brassicas, ryegrass, ornamentals).
12	**14.2** That Government establish Toi Te Taiao: The Bioethics Council to: • Act as an advisory body on ethical, social 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.

Appendix 6 List of 17 Recommendations Not Implemented

Number	Recommendation
1	**6.12** That the Environmental Risk Management Authority (ERMA) require research on environmental impacts on soil and ecosystems before release of genetically modified crops is approved.
2	**7.1** That, prior to the release of any Bt-modified crops, the appropriate agencies develop a strategy for the use of the Bt toxin in sprays and genetically modified plants, taking into account: • The concept of refugia; • Limitations on total planted area; and • Home gardener use.
3	**7.2** That the appropriate agencies develop a labelling regime to identify: **a.** genetically modified seed; **b.** nursery stock; and **c.** propagative material at point of sale.
4	**7.3** That the Ministry of Agriculture and Forestry (MAF) develop a strategy to allow continued production of genetic modification-free honey and other bee products, and to avoid cross-pollination by bees between genetically modified and modification-free crops, that takes into account both geographical factors (in terms of crop separation strategies) and differences in crop flowering times.
5	**7.4** That, in connection with any proposal to develop genetically modified forest trees, an ecological assessment be required to determine the effects of the modification on the soil and environmental ecology, including effects on soil micro-organisms, weediness, insect and animal life, and biodiversity.
6	**7.5** That, wherever possible, non-food animals, or animals less likely to find their way into the food chain, be used as bioreactors rather than animals that are a common source of food.
7	**7.6** That, wherever possible, synthetic genes or mammalian homologues of human genes be used in transgenic animals to avoid the use of genes derived directly from humans.

Number	Recommendation
8	**7.7** That MAF develop an industry code of practice to ensure effective separation distances between genetically modified and unmodified crops (including those grown for seed production) such a code: • to be established on a crop-by-crop basis • to take into account: – existing separation distances for seed certification in New Zealand; – developments in international certification standards for organic farming; – emerging strategies for coexistence between genetically modified and unmodified crops in other countries • to identify how the costs of establishment and maintenance of buffer zones are to be borne.
9	**8.2** That Government facilitate the development of a voluntary label indicating a food has: **a.** not been genetically modified; **b.** contains no genetically modified ingredients; and **c.** has not been manufactured using a process involving genetic modification.
10	**9.3** That products be clearly defined in legislation as medicines, pharmaco foods, functional foods or dietary supplements.
11	**10.4** That New Zealand be proactive in pursuing cultural and intellectual property rights for indigenous peoples internationally.
12	**10.5** That New Zealand pursue the amendment of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights and associated conventions to include a reference to the avoidance of cultural offence as a specific ground for exclusion or reservation.
13	**11.1** That section 8 of HSNO be amended to provide that effect is to be given to the principles of the Treaty of Waitangi.
14	**13.1** That the methodology for implementing HSNO section 6(e) be made more specific to: • Include an assessment of the economic impact the release of any genetically modified crop or organism would have on the proposed national strategy of preserving opportunities in genetically modified and unmodified agricultural systems. • Allow for specified categories of genetically modified crops to be excluded from districts where their presence would be a significant threat to an established non-genetically modified crop use.
15	**13.2** That before the controlled or open release of the first genetically modified crop, the Minister exercise the call-in powers available under HSNO section 68 in order to assess the likely overall economic and environmental impact on the preserving opportunities strategy.
16	**13.3** That MAF develop formalised local networks to encourage constructive dialogue and communication between farmers using different production methods, and to improve for mediation where necessary.

Number	Recommendation
17	**14.3** That Government establish the office of Parliamentary Commissioner on Biotechnology to undertake futurewatch, audit and educational functions with regard to the development and use of biotechnology in New Zealand.

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