The History of Genetic Modification in New Zealand

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Report *The History of Genetic Modification in New Zealand*

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Contents

Tables

Figures

Appendices

Preface

> If you would understand anything, observe its beginning and its development.
>
> Aristotle, 384 BC – 322 BC

History provides the opportunity to reflect on the past in order to consider the future. This paper is a chance to reflect on the history of genetic modification in New Zealand, in order to consider the next steps regarding policy and practice in what has been one of the more complex and publicly engaging debates of the last ten years.

This paper could not have been written without significant support and advice from a wide range of people both inside and outside the public service. I would therefore like to acknowledge the assistance of many stakeholders, including both government departments and civil society organisations. Libby Harrison (ERMA), in particular, has provided invaluable supporting data for the tables.

No not-for-profit independent 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 two 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

Reflection is an excellent skill, but one that needs to be supported by facts. This paper provides an opportunity not to get tangled in the issues, but to view the overall landscape without the rhetoric or value judgements underlying the debate. Our purpose is therefore to reflect on the past in order to understand the current landscape of genetic modification in New Zealand.

We hope this paper provides a useful background for policy-makers and the wider public who are interested in exploring ways of tackling complex issues with diverse social, cultural, economic and environmental impacts. This paper forms the backdrop for two others: *Review of the Forty-Nine Recommendations of the Royal Commission on Genetic Modification* (Sustainable Future, 2008) and *The Future of Genetic Modification in New Zealand* (Sustainable Future, in press).

We have set the boundaries of our analysis by defining genetic modification (see Section 2). We have kept the analysis to New Zealand; therefore the paper does not review what is happening internationally. In Section 3, we discuss chronologically the events from the development of genetic modification technology in the 1970s through the rise of use of the technology. The rise of public understanding and concern in response to this technology ultimately led to the establishment of the Royal Commission on Genetic Modification in 2000.

The Royal Commission's purpose was to explore the strategic options and institutional arrangements available for managing genetic modification in New Zealand. In Section 4, we briefly outline the Royal Commission and the package of 49 recommendations that underpin their overarching strategy of 'preserving opportunities'. In Section 5, we present an overview of the government's stated response and subsequent implementation of these recommendations (also see Sustainable Future, 2008 for further analysis of the government's implementation of these recommendations) and the wider public response following the Royal Commission.

In Section 6, we then take a step back and present an overview of the current landscape by identifying and discussing key elements, such as genetic modification (GM) experiments, legislation, institutions, strategies, international agreements, economic analysis and research into ethics and public attitudes. The landscape remains dynamic and continues to be negotiated by diverse stakeholders.

In keeping with the rigour of focusing on the facts, this paper summarises the history of genetic modification in New Zealand and therefore does not discuss or formulate any recommendations. However, the history does provide a comprehensive case study for reviewing the challenges of applying integrated long-term thinking and an inclusive participatory approach to a complex problem. To this end, our intention is that this paper will provide a common history upon which to develop a common view as to how we shape and create a sustainable nation in the future.

1. Introduction

1.1 Purpose

The strategic aim of this paper is:

> To explore the past in order to understand the current landscape of genetic modification in New Zealand.

1.2 Sustainable Future

Sustainable Future is a research organisation and think-tank specialising in sustainability issues that affect New Zealand. We have a strong interest in governmental transparency, accountability and sustainability. The organisation is a registered charitable trust, titled New Zealand Sustainable Future Foundation Trust. For more information, see our website.[1]

Our interest in this debate is at many levels. We consider the genetic modification debate is an excellent case study to assess:

- New Zealanders' values;
- Participatory democracy in New Zealand;
- Alignment between vision and practice. For example, the delivery of the Prime Minister's vision of New Zealand being the 'first sustainable nation' (Clark, 2007);
- Reconciling short- and long-term objectives;
- Solving complex problems that take time and reflection;
- How integrated current policy is becoming;
- The value of and need to manage our national 'green and clean' brand (an external marketing perspective);
- Public-good risk assessments in practice;
- Modern-day ethics;
- The use and application of language; for example, use of the term 'risk' instead of 'hazard' (i.e. that the use of the term 'risk' instead of 'hazard', may increase the appetite for experiments, because risk also implies benefit).

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

2. Defining Genetic Modification

Modern biotechnology techniques have only been around for about thirty years (MfE, 2007a), but they have given us the power to manipulate biological processes in a distinctly new way. During this time the technology and the possibilities it presents have grown at a rapid pace.

Within this paper we do not explore the technicalities of the science's origins and directions, the intricacies of the debate around the potential impacts, or the diversity of stances and perspectives — cultural, ethical, scientific, commercial and otherwise — in relation to biotechnology. However, we do provide a definition of genetic modification for the purposes of forming a context and boundary for this report.

Genetic modification involves the alteration of genetic material (for example, DNA). Genetic modification can be carried out in any kind of organism from viruses to unicellular organisms (such as bacteria) to species such as humans. The principles of the process of genetic modification are the same regardless of the organism modified. The fundamental intention of this manipulation is also the same — to alter one or more hereditary characteristics of an organism.

The Warrant for the Royal Commission on Genetic Modification (see Appendix 1) specifically defines genetic modification as:

> the use of genetic engineering techniques in a laboratory, being a use that involves:
>
> a. the deletion, multiplication, modification, or moving of genes within a living organism; or
>
> b. the transfer of genes from one organism to another; or
>
> c. the modification of existing genes or the construction of novel genes and their incorporation in any organisms; or
>
> d. the utilisation of subsequent generations or offspring of organisms modified by any of the activities described in paragraphs (a) to (c)
>
> For the purposes of the inquiry, this excluded the generation of organisms using standard breeding techniques, including cloning, hybridisation or controlled pollination (as these do not involve modification of existing genes) and mutagenesis not involving genetic engineering techniques (RCGM, 2001b: 157).

In brief, the Royal Commission identified products of modern biotechnology as being within their terms of reference. Modern biotechnology is defined by international consensus in the United Nations Convention on Biological Diversity (CBD),[2] as:

> The application of:
>
> a. in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
>
> b. fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection (UN, 1992a).

[2] The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding. See http://www.cbd.int/convention/ for more information.

3. The Journey Towards the Royal Commission: 1973 - 2000

It is possible to see clear stages in the debate around the use of genetic modification. What follows is our interpretation of the stages New Zealand has gone through. In this paper we have purposely not identified the names of key stakeholders in the debate, rather we have provided a general context for reflecting on the past. A timeline of key events is contained in Appendix 2.

3.1 The New Tool: 1973–1990

By the early 1970s, scientists internationally were developing applications for a new tool; the first recombinant bacteria, which was developed in a laboratory in 1973. By the early 1980s, these technologies began to be applied in laboratories in New Zealand, largely for biological and medical research purposes (RCGM, 2001b), and have become increasingly widely used since.

In the mid-1970s in New Zealand, institutional management of genetic modification technologies began to emerge at a government level. In 1978 the government placed a moratorium on field releases[3] that remained in place for ten years and an Advisory Committee on Novel Genetic Techniques (ACNGT) was established to oversee contained laboratory and glasshouse genetic manipulation work.[4]

In 1987, a Field Release Working Party recommended that Ministry for the Environment (MfE) establish an Interim Assessment Group (IAG) for the field testing and release of genetically modified organisms. This recommendation was implemented and the IAG came into existence in 1988. The purpose of the IAG was to assess all applications to field-test genetically modified organisms (GMOs) and perform large-scale fermentations involving GMOs. At this point, the moratorium on field release was lifted. The IAG operated independently of the ACNGT, which continued to have responsibility for experiments contained in glasshouses and laboratories.

Neither the ACNGT nor the IAG had any legislative authority, and from 1988 the government began moving towards what was to become the Hazardous Substances and New Organisms Act 1996 (HSNO) (RCGM, 2001a: 105). The IAG dealt with 60 applications between 1988 and 1998 (ERMA, 2007d).

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3 The term is no longer in use. It is a combination of the term field test and release. (RCGM, 2001a: 105)

4 Enforcement of the committee's recommendations lay with the research institution, which was required to appoint a biological safety officer and an Institutional Biological Safety Committee (IBSC). From 1982, IBSCs could approve low-risk experiments (RCGM, 2001a: 104).

3.2 The Development of HSNO: 1990–1996

GMOs began to be developed within New Zealand for possible use in agriculture and food production. At this time, GM technologies were being used in Crown Research Institutes (CRIs), private companies, universities and medical institutions. The IAG began approving applications to field-test GM organisms, and increasingly information on tests filtered into the press. The heightened profile of GM field tests led to the demand for better legislation.

The Environment Minister, Simon Upton, who sponsored the HSNO Bill (read on 8 November 1994, 19 December 1995 and 16 April 1996), also backed a call from IBAC for a hold-off period on the release of genetically modified plants. Simon Upton (who was also Minister for Crown Research Institutes) showed considerable foresight ('Opening Address: Risk, politics and practice', 1998). He likened the controversy around the possible field production of genetically modified crops to the debate about the decision to keep New Zealand nuclear-free (Samson, 1999).

In 1996, the Hazardous Substances and New Organisms (HSNO) legislation became law, although it was not officially in operation for a further two years. In the interim, considerable work was completed in order to develop the appropriate methodology. Politicians, policy analysts and legislators showed considerable foresight and leadership by directing users of the legislation to adopt a risk-management, precautionary and consultative approach.

The HSNO Act 1996 also established the Environmental Risk Management Authority New Zealand (ERMA), which is the institution primarily responsible for the management of novel genetically modified organisms (GMOs) imported into or developed in New Zealand.[5] ERMA is required to work closely with many other government agencies, such as MfE, Ministry of Agriculture and Forestry Biosecurity New Zealand (MAF), Department of Conservation (DoC), New Zealand Food Safety Authority (NZFSA) and others. Importantly, once ERMA has approved a full release, ERMA is no longer involved and the GMO is treated like any other organism, under the overview of MAF and others.[6]

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[5] A range of other existing legislation also has instruments relevant to the management of genetic modification (see Appendix 3). These include the Resource Management Act 1991, the Environment Act 1986, the Agricultural Compounds and Veterinary Medicines Act 1997, the Medicines Act 1981, the Food Act 1981, the Animal Products Act 1999, the Health Act 1956, the Animal Welfare Act 1999, the Animals Protection Regulations and a number of other pieces of conservation, intellectual property, consumer protection and research legislation or regulation.

[6] At this point the Biosecurity Act 1993, Conservation Act 1987 or the Health Act 1956 would apply.

One of ERMA's key aims is to prevent or manage any adverse effects of new organisms. Its key function is to grant or withhold approval, and set controls for:

- Importing GMOs into containment;
- Developing GMOS;
- Conducting contained field tests;[7]
- Releasing any contained or imported GMOs (ERMA, 2007a).

ERMA's structure comprises: the Authority, an autonomous Crown entity that functions as a quasi-judicial decision-making body of up to eight members appointed by the Minister for the Environment; Ngā Kaihautū Tikanga Taiao, a body that advises the Authority on taking into account the principles of the Treaty of Waitangi and Māori perspectives[8]; and the Agency, which carries out operations on behalf of, or in support of, the Authority.

3.3 The Public Protest: 1996–2000

By the late 1990s there was growing recognition that although this legislative framework was in place, many were questioning whether it was in New Zealand's best interests to take the environmental, social and cultural risks associated with the use of this novel and rapidly developing technology. The public reaction was fuelled by ethical concerns and health risks from inserting human genes into cattle, international concerns about the health effects of GM foods, and the potential environmental impacts of GM crops and other field uses (e.g. weedy pine trees).

For a country reliant on agriculture, with a unique indigenous culture to protect and a 'clean, green' image to promote, this was definitely a question that needed an answer. In addition, there were some significant concerns being raised about the ability of the HSNO legislation and ERMA to manage the level of rapid industry growth and technological advances being promised by some Crown Research Institutes. Internationally, the science went from one breakthrough to another, giving the public a more comprehensive view as to what this science was capable of (e.g. green rabbits[9]). In addition, these technological advances raised further issues that had been unforeseen when the HSNO legislation was originally developed.

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7 We have replaced the word *trial* with the term *test*, as the latter is the term used in the HSNO legislation. There has always been considerable debate about the meaning of a field test as compared with a field trial, which is increasingly becoming blurred, both in New Zealand and overseas. In this paper, we use the term 'field test' as defined by the HSNO legislation.

8 Although they were established by the first schedule of the HSNO Act 1996, Ngā Kaihautū Tikanga Taiao were only made a statutory body by a 2003 amendment to the Act.

9 Artist Eduardo Kac created a GM green rabbit in 2002.
See http://www.ekac.org/grahamphillips.html.

Rapid industry growth was being promoted by some scientists and industry representatives (including Federated Farmers, New Zealand Crown Research Institutes such as AgResearch and Crop and Food Research, and international corporations such as Monsanto). At the same time, other scientists and industry representatives (e.g. the organic industry), NGOs and the wider public were pushing for a moratorium on field tests until the full risks and opportunities of genetic modification in New Zealand had been assessed.

Over time, the debate became increasingly lively at community, local government and industry levels.[10] 'GE-free' zones were widely promoted and occasionally established[11] and large demonstrations took place in major cities. A strongly networked movement developed in civil society in response to the perceived risks of genetic modification. The government's response included the establishment of the Independent Biotechnology Advisory Committee (IBAC) in May 1999 to assess and provide independent advice on the use of this technology.

The wider public concern culminated in a petition calling for the establishment of a Royal Commission to investigate and establish a way forward for genetic modification in New Zealand. The petition, signed by 92,000 New Zealanders, was presented to Parliament by the Green Party in October 1999 (RCGM, 2001b: 50). This solidified the government's understanding of the level of public concern on genetic modification research and development, and sealed the incoming Labour government's decision to form the Royal Commission on Genetic Modification.

On 21 December 1999, in the Speech from the Throne at the Opening of Parliament, the government announced its decision to establish the Royal Commission on Genetic Modification. In March 2000, the Minister for the Environment was appointed Minister in charge of the inquiry and a voluntary moratorium was put in place (see Section 6.1.1).

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[10] For example, see *Caught in the Headlights* (PCE, 2000) for an exploration of the range of perceptions, views and values of the New Zealand public, tangata whenua and sector groups about the use of biocontrol methods to control possums.

[11] Many territorial authorities were active in this debate at this time. See RCGM for a list (RCGM, 2001b: 49).

4. The Royal Commission: 2000 - 2001

The Royal Commission existed for just over twelve months, producing a report in mid-2001 (RCGM, 2001a-d). It was the key mechanism for New Zealand to develop a more comprehensive understanding of the risks and opportunities in relation to the introduction and use of genetically modified organisms and technologies in New Zealand.

The Commissioners describe a Royal Commission as:

> [the] highest level of response available to the New Zealand Government when considering an inquiry into a particular issue. Royal Commissions are convened to investigate any matter of major public importance that is of concern to the government of the day, such as matters of considerable public anxiety or where a major lapse in government performance appears to be involved (RCGM, 2001b: 49).

4.1 The Purpose

The Warrant[12] establishing the Royal Commission stated the Commissioners should:

> … receive representations[13] 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).

4.2 The Establishment of the Royal Commission

The Warrant establishing the Royal Commission was published on 11 May 2000, and the Commission was given until 1 June 2001 to complete its inquiry. By Order of Council on 14 May 2001 this timeframe was extended until 27 July 2001. Cabinet allocated a provisional budget of $4.8 million on 17 April 2000, which was increased to $6.2 million on 7 August 2000 (RCGM, 2001b).

Four Commissioners were appointed: the Right Honourable Sir Thomas Eichelbaum GBE, of Wellington, formerly Chief Justice of New Zealand; Dr Jacqueline Allan, medical practitioner, of Auckland; Dr Jean Sutherland Fleming, scientist, of Dunedin; and the Right Reverend Richard Randerson, of Auckland, Bishop of the Anglican Church (See Figure 1).

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12 More information on the Warrant can be found in Appendix 1.

13 More information on the consultative process is provided in Appendix 4.

Figure 1 The Four Commissioners

From left to right: Bishop Richard Randerson, Sir Thomas Eichelbaum, Dr Jacqueline Allan and Dr Jean S. Fleming.

4.3 The Process

The Commissioners' consultative process involved background papers, scoping meetings, formal hearings for 'Interested Persons' and consultation with Māori, youth and the wider public (this is described in further detail in Appendix 4).

4.4 The Four Key Findings

The Commissioners' Report is underpinned by four key findings. These findings are discussed below. For more detailed analysis, see *Review of the Forty-Nine Recommendations of the Royal Commission on Genetic Modification* (Sustainable Future, 2008).

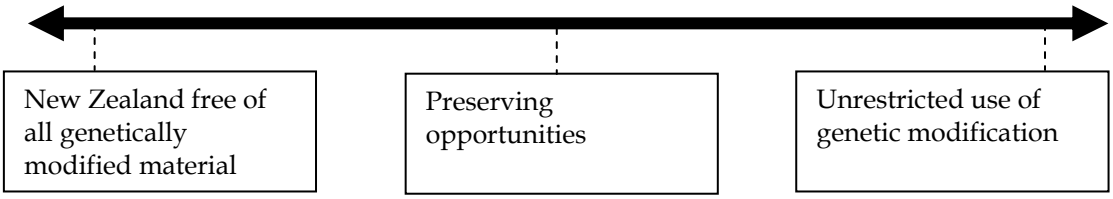
4.4.1 The seven shared values of New Zealanders

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.

4.4.2 The forty-nine 'preserving opportunities' recommendations

The Commissioners identified a spectrum of options, 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 2 below. In discussing the extreme position of 'New Zealand free of all genetically modified material', the Commissioners considered this position impractical due to GM medicines and that 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 2 The Strategic Spectrum Identified by the Commissioners



The discussion on the strategic decision culminates in Chapter 13, where the Commissioners decide on a middle option, which they call 'Preserving Opportunities'.

> 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 strategic option, the Commissioners provided a package of 49 recommendations. [14]

> 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)

[14] This paper does not review how these recommendations were arrived at following the Commissioners' consultation process or how representative they are of the information obtained through this process.

The Commissioners found that the use of genetic modification technology in research, food and medicine should (with minimal changes in the framework) continue to be approved on a case-by-case basis. The exception was genetically modified crops.[15] The Commissioners in effect placed an additional strategic test on GM crops, and 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)

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 (see Table 1).

In addition, in order to ensure the government has the institutional capacity to consider genetically modified crops and other potential opportunities in the future, the Commissioners developed three major proposals (see Table 2 on page 16).

For the remainder of this paper, we refer to these two subgroups of recommendations as the ten 'watershed' recommendations (see Table 1) and the three 'institutional' recommendations (see Table 2).

4.4.3 The ten 'watershed' recommendations

The Commissioners discuss the 'watershed' decision in the last pages of Chapter 13 of their report under the heading 'Is Compatibility 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 obtain some insight into their thinking based on the recommendations set out in Table 1 below. However, what is clear is that the Commissioners considered that before a conditional or full release of a GM crop can occur, a national strategic assessment should take place.

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[15] At that time, there had been no commercial releases of GM crops, although outdoor research experiments had been conducted.

Table 1 List of the Ten Watershed Recommendations
Source: RCGM, 2001a: 338-39, 345

The Ten Watershed Recommendations
6.8 That HSNO be amended to provide for a further level of approval called conditional release.
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.
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.
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.
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.
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).

The Ten Watershed Recommendations continued…
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;[16] • Limitations on total planted area, and • Home gardener use.
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.
6.13 That public research funding be allocated to ensure organic and other sustainable agricultural systems are adequately supported.
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.[17]

4.4.4 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. To this end it makes three major proposals[18] (see Table 2): the creation of a Bioethics Council, a Parliamentary Commissioner on Biotechnology, and a biotechnology strategy.

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16 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).

17 We have included Recommendation 14.1 as part of the 'watershed' recommendations, as it relates directly to the Minister's powers in making this 'watershed' decision and was clearly not an institutional recommendation, as discussed by the Commissioners in chapter 14 (RCGM, 2001a).

18 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.

Table 2 List of the Three Institutional Recommendations
Source: RCGM, 2001a: 342–350

The Three Institutional Recommendations
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.
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.
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.

5. The Response to the Royal Commission: 2001 - 2008

Below we discuss the breadth of the response to the findings of the Royal Commission. We first outline the government's initial response[19] and then summarise the outcomes of the Royal Commission 'seven years on'.

5.1 The Government's Initial Response: 2001

In 2001, the government's response was to accept the Commissioners' overall strategy of 'preserving opportunities' and announce a number of key decisions. The Hon. Marian Hobbs stated the government would:

- 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.
- 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… 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. (Hobbs, 2001)

Over the next few years a number of cabinet papers were released by government, many of which are discussed further in this and other Sustainable Future papers (MfE, 2001a-f; 2002a-b; 2003a-i).

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[19] The government's initial response is discussed in more detail in the *Review of the Forty-Nine Recommendations of the Royal Commission on Genetic Modification* (Sustainable Future, 2008: 18).

5.2 The International Science Community's Response: 2001

A detailed review of the international science community's response is also outside the scope of this paper, but we felt an editorial in *Nature* in 2001 highlighted some interesting insights into the challenges ahead:

> 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', 2001: 569)

5.3 The Public Response: 2001 - 2008

A detailed review of the public response to the Royal Commission is outside the scope of this paper, however those interested in gaining an insight into the national and international response may like to access the archives on the Sustainable Future website (for example, see McGuinness, 2001a; 2001b). We have also attached an August 2001 press release by the New Zealand Society for Risk Management (2001) in Appendix 5. Over this time there have been a number of public responses which are described below.

5.3.1 Public marches

There were numerous marches in response to the findings of the Royal Commission and the government's response. Two of the more significant were the 'GE-free hikoi', both of which traveled from Northland to Wellington.

The first began in October 2001, with over two hundred people arriving at Parliament on 1 November (Bennett, 2001). This was specifically in response to the GM tamarillo field tests by HortResearch in Kerikeri, and the lifting of the voluntary moratorium on GM applications which was officially announced the day before the group's arrival in Wellington. The group also called for the resignation of Māori MPs, saying that they had failed to stop the government allowing GM field tests. This march was accompanied by a 'sit in' at ERMA's offices in Wellington on 1 November 2001, in which 15 Māori protesters from the Tino Rangatiratanga movement refused to leave for half an hour (Bradford, 2001; Frizzel, 2001). In addition, in late August 2001 the Auckland GE-Free Coalition organised a rally up Queen Street in which 10,000 protesters participated. The intention of the march was to generate anti-GM pressure at a time when the government was making decisions about its response to the recommendations of the Royal Commission (Green Party, 2001).

The second GE-free hikoi began on 22 August 2003 and ended with hundreds of protesters gathering at Parliament on 23 October (RSNZ, 2003). This hikoi called for a complete ban on GM in New Zealand, and was in response to the planned lifting of the moratorium on the release of genetically modified crops which coincided with the group's arrival in Wellington. The hikoi named itself the 'Seed Carriers', and the participants collected seeds as they traveled the length of the North Island in protest at the harm GM could cause to New Zealand's seed varieties, including native plants (Fitzsimons, 2003); these were presented to the government on their arrival in Wellington. Both GE-free hikoi were predominantly organised and participated in by Māori, but many New Zealand Europeans and other ethnic groups also took part.

5.3.2 GE-free zones

Discussion in many communities and regions focused on the creation of GE-free zones as a local way to manage this risk (see RCGM, 2001b:49). Many regional and district councils considered such a move, and some made this decision to become GE-free (for example, Northland District Council[20]). A GE-Free Register was created, which now lists 5693 properties covering a total of 360064 acres.[21]

5.3.3 Wilful Damage

Over the last seven years, a few members of the public have resorted to intentionally damaging GM crops and other field uses. A recent example is the chopping down of trees at Scion ('GE protesters chop down trees at research institute', 2008).

5.4 The Government's Response Seven Years On: 2008

In the years following the Commissioners' report, there has not been a thorough government review of action undertaken to improve New Zealand's national framework for the management of genetic modification. With this in mind, Sustainable Future has undertaken an independent assessment of the implementation of the Commissioners' recommendations, titled *Review of the Forty-Nine Recommendations of the Royal Commission on Genetic Modification* (Sustainable Future, 2008).[22] This reviews the government's response to each of the recommendations and draws conclusions on the outstanding issues. The paper found:

- Of the package of forty-nine recommendations only twenty were fully implemented.
- Of the ten watershed recommendations only two were fully implemented.

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[20] GE-Free Northland has been an active promoter of GE-free zones. See http://www.gefreenorthland.org.nz/.

[21] Retrieved on 5 February 2008 from the GE-Free Register, see http://www.gefreeregister.org.nz.

[22] Available from http://www.sustainablefuture.info.

- 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. (Sustainable Future, 2008: 94)

These findings show that the New Zealand government is not currently pursuing the strategic option of 'preserving opportunities' as proposed by the Commissioners and raises further questions about New Zealand's ability to manage the current and future risks of genetic modification. For example, can New Zealand manage the risks of our current outdoor developments and field tests? To what extent is New Zealand capable of deciding our first application for conditional or full release and is co-existence a realistic option? Lastly, and most importantly, does the current framework meet the expectations of New Zealanders, and if not, is it now timely for New Zealand to reconsider its strategic options. The answers to these questions are explored in our report, *The Future of Genetic Modification in New Zealand* (Sustainable Future, in press).

6. The Current Landscape: 2008

Taking into consideration our findings in Section 5, we outline below our understanding of the current genetic modification landscape under the headings of GM experiments, legislation, institutions, strategies, international agreements, economic analysis and research into ethics and public attitudes.

6.1 Genetic Modification Experiments

Within ERMA, a GMO is categorised according to its location and purpose, as indicated in Table 3 below (see Glossary and Abbreviations as necessary). Although there is a continuum of options for applicants, there is no need for an application to go through each step along the process (i.e. an applicant can apply for full release without a field test).

Table 3 The Types of GMO Applications
Source: Sustainable Future

Location	Indoor	Outdoor	Outdoor	Outdoor
Purpose	Mainly Research	Can be Research or Commercial[23]	Mainly Commercial	Mainly Commercial
Types of GMO	Developments (GMD) in indoor containment facilities[24]	Development (GMD) in the outdoors or GM Field Tests (GMF)[25]	Conditional Release (NOCR)	Full Release (NOR)
Current status	Figures are not available[26]	Only six field tests are currently in operation (see Tables 6 and 7)	To date there have been no applications in this category	To date, one inquiry has been received[27]
Decision-maker	IBSCs (Delegated by ERMA)	ERMA	ERMA	N/A[28]
Policing of controls	MAF	MAF	MAF	MAF, DOC

[23] For example, AgResearch could apply to ERMA for milk from GM cows (created under a GMD or GMF) to be exported for commercial use.

[24] These experiments are contained in a physical structure, called a PC1, PC2 or PC3 laboratory.

[25] An application license number (e.g. GMF98001) represents the application type (e.g. GMF), the year of application (98) and the application number (001).

[26] This information is not collected by a central agency at this time, so obtaining this figure would require requesting this information directly from each of 135 containment facilities. However, looking at Tables 4 and 5 does provide an indication of the quantity of applications approved each year by ERMA and IBSCs.

[27] In 1998, Monsanto made inquiries to ERMA but decided not to proceed with the application. See Appendix 6.

[28] Once released the GMO is treated as any other organism unless it has a negative effect (e.g. similar to gorse) that requires management in the future by MAF or DOC (i.e. there are no controls).

6.1.1 Moratoriums

In order to interpret the following tables, we outline below the three moratoriums that have occurred to date. As discussed in Section 3, the first moratorium on field tests occurred during the years 1978 to 1988. Two further moratoriums have occurred in recent years.

(i) A voluntary moratorium

From 14 June 2000 to 29 October 2001, there was a *voluntary* moratorium on:

- all applications for release, and
- the field testing of GMOs (with defined exemption) (ERMA, 2007b).

This moratorium was negotiated between the government, industry and other research groups. During this period any field test already approved under the HSNO Act 1996 was able to continue.

(ii) A mandatory moratorium

Following the release of the Commissioners' Report a *mandatory* moratorium was put in place from 29 October 2001 to 29 October 2003. Under this moratorium ERMA was not able to consider or approve applications to:

- import GMOs for release; or
- release genetically modified organisms from containment (ERMA, 2007f).

Under this second moratorium, there were exemptions if the application was for:

- a medicine and the Minister of Health gave consent to the application;
- the release of an organism involved in a clinical trial approved by the Director-General of Health;
- the release of a veterinary medicine register under the Agricultural Compounds and Veterinary Medicines Act 1997 and the veterinary medicine was to be used for therapeutic or prophylactic purposes;
- the release of a genetically modified organism in an emergency (ERMA, 2007f).

6.1.2 Approved experiments

Below we list the applications that have been approved by ERMA. Importantly, there is no requirement on applicants to publish the results of their experiments; hence it is difficult to assess the benefits of the public risks being taken by pursuing these experiments. Using the framework developed in Table 3, we discuss the applications in terms of indoor and outdoor experiments.

(i) Indoor experiments

Approvals of GMOs for indoor containment and development between 1998 and 2007 (by financial year) are briefly outlined in Tables 4 (ERMA) and 5 (IBSCs) below. The number of organisms approved by ERMA declined from a high of nearly 1100 in 2000/01 to 213 the following year; since then they have continued to decline steadily, down to only 44 in 2006/07. We also note that the applications approved during the 2000/01 period were twice the expected number due to the investigation into unauthorised GMO developments in 2000 and the brief suspension of delegated authority to Institutional Biological Safety Committees (IBSCs) to approve low-risk applications (ERMA, 2001).

Table 4 ERMA Decisions: Indoor GMO Approvals by Financial Year
Source: ERMA, 2005a; 2006a; 2007d; 2008a; 2008b; 2008c

Approval Type	Quantity approved[29]	1998/99	1999/00	2000/01	2001/02	2002/03	2003/04	2004/05	2005/06	2006/07
Importing GMOs into containment	Applications	0	7	32	11	7	3	5	3	5[30]
	Organisms	0	70	1029	73	23	3	24	4	5
Developing GMOs in containment	Applications	0	7	28[31]	14	15	15	12	27	15[32]
	Organisms	0	53	70	140	72	89	47	90	39
Total Approvals	Applications	0	14	60	25	22	18	17	30	20
	Organisms	0	123	1099	213	95	92	71	94	44

[29] These numbers are the sum of all applications (notified and non-notified) and rapid assessments approved by ERMA.

[30] This comprises approval of 2 non-notified applications and 3 rapid assessments (ERMA, 2007d: Table 2).

[31] Of the 28 applications to develop GMOs in containment in the 2000/01 year, 21 were approved during the time when all IBSC delegations were suspended (ERMA, 2001).

[32] The 15 applications are reported in the ERMA Annual Report as 1 non-notified application and 14 rapid assessments (ERMA, 2007d: Table 2).

Table 5 IBSC Decisions: Indoor GMO Approvals by Financial Year[33]
Source: ERMA, 2006a; 2007d

IBSC Organisation and Location (2005/2006)	Total Number of Decisions Made 05/06	Total Number of Decisions Made 06/07
AgResearch Ltd — Ruakura	1	0
AgResearch Ltd — Palmerston North	1	10
AgResearch Ltd — Wallaceville	2	15
Genesis Research and Development Corporation Ltd	3	0
Horticulture and Food Research Institute — Auckland and Landcare Research — Auckland (Joint IBSC)	1	7
Lincoln University	8	7
Massey University	22	19
Crop and Food Research Ltd	0	2
University of Auckland	32	15
University of Otago	19	21
University of Waikato	0	7
Total number of decisions	**89**	**96**

(ii) Outdoor experiments

To date, ERMA has not declined an application to place experimental GMOs in the outdoors; it could be argued that this supports the view that the HSNO legislation has in effect made ERMA a control-setting body rather than a true decision-making body. Appendices 5, 6 and 7 provide a detailed list of outdoor experiments by year, by applicant and by amendments to applications (i.e. under section 67A of the HSNO Act).

Since the mandatory moratorium was lifted in 2003, no GMO has been released and there have been only two approvals for outdoor experiments — both to Crop and Food. Currently very few outdoor GM experiments exist, with only six currently operating with controls, as shown in Tables 6 and 7 below.

Recent events include Crop and Food's application to ERMA to establish a 2½ hectare site outside Lincoln for field testing of GM onions, spring onions, garlic and leeks. ('More GM research planned', 2008). In addition, ERMA has also advised the public that AgResearch intends to make applications later this year for a number of new approvals.

> ERMA New Zealand understands that AgResearch intends to make applications this year for a number of new approvals. Among other things, these applications are expected to cover the creation of a number of new secure research facilities (at present, there is only one – Ruakura) and to seek permission to move animals between these facilities. If the Authority approved such an application, these new facilities would then have to be separately approved by MAF before they could be used to hold genetically modified animals. (ERMA, 2008f)

[33] Decisions made include both importing into and developing in containment low-risk GMOs (ERMA, 2006a).

Table 6 ERMA Decisions: Outdoor GMO Approvals by Calendar Year
Source: ERMA, 2005a; 2006a; 2007d

Approval Type By Calendar Year	Pre-HSNO	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Developments in the Outdoors	0	0	0	1[34]	0	1[35]	0	0	0	0	0
Field Tests	50	1	9[36]	0	3[37,38]	0	1	0	0	0	1
Conditional Releases	0	0	0	0	0	0	0	0	0	0	0
Full Releases	0	0	0	0	0	0	0	0	0	0	0
Total	50	1	9	1	3	1	1	0	0	0	1

34 The 2000 approval was for an outdoor development (GMD99003), which was not part of the moratorium (see Section 6.1.1).

35 The 2002 approval was for an outdoor development (GMD02028) which was not part of the moratorium (see Section 6.1.1).

36 GMF98009 appears as an approval in both 1999 (part i and ii) and 2001 (part iii).

37 Same as above.

38 Two of the approvals in 2001 (GMF99001 and GMF99005) were signed in December 2000 but notified in January 2001. Table 6 reflects the dates the approvals were publicly notified, whereas Appendices 6 and 8 reflect the date the decision was made.

Table 7 ERMA Decisions: Active Outdoor GMO Approvals by Description
Source: ERMA, 2007a

Organisation	Application Code	Organism	Date of Decision	Date Approval Expires	Number of Submissions Received
AgResearch	GMF98009	Cattle	Part (i) & (ii) 1999 Part (iii) 2001	Part (i) & (ii) Nov 2008 Part (iii) May 2010	30
Scion[39]	GMF99001	*Pinus radiata*	Dec 2000	Dec 2020	735
Scion	GMF99005	*Pinus radiata* and Norway spruce	Dec 2000	Dec 2009	735
AgResearch	GMD02028	Cattle	Sept 2002	March 2010	863
Crop & Food	GMF03001	Onions	Dec 2003	Dec 2013	1933
Crop & Food	GMF06001	Brassicas	May 2007	10 years after first planting[40]	959

6.1.3 Breaches since 2000

ERMA's Annual reports since 1999 contain a list of incidents and inquiries involving new organisms that either did not comply with regulatory requirements and/or may have caused adverse effects to human health and safety. In 2007, nine incidents involved GMOs. Four of these incidents risked GM contamination in the environment. All four were found to have no significant or no identified effects to the environment or health and safety.[41] For the purposes of this paper, breaches are broken into either legislative breaches (those that breach the word of the law) or non-compliance (those that breach the controls made under the law i.e. ERMA decisions), both of which are discussed below.

(i) Legislative breaches

These have been further broken down into non-approved incidents related to 'GM research' or 'GM imports or exports':

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39 Formerly Forest Research.

40 We understand the Brassicas have either been planted or will be planted in early 2008.

41 These Annual Reports are all available on ERMA's website http://www.ermanz.govt.nz. The four 2006/2007 incidents related to AgResearch (1), Import of GM corn seed (1), HortResearch (1) and Scion (1).

Non-approved GM research

In May 2000, ERMA completed a nationwide check of research institutions to see if any non-approved GM research had been carried out since the passing of the HSNO Act. The survey found that at the time there were:

1. 196 examples of research that were not notified to the Ministry for the Environment when it prepared the Order in Council to gazette existing approvals in July 1998.
2. 113 instances of unauthorised GM work with no proper approval (ERMA, 2000: 1–2).[42]

Non-approved GM imports or exports

Since 2001, there have been eight incidents (MAF, 2007a). These are listed below and are also listed on an international register:[43]

1. **November 2000:** It was discovered that a shipload of GM corn seed had been planted in three regions of New Zealand. After initially intending to destroy the crops, the government reversed its decision and cleared them for harvesting and sale.[44]
2. **August 2001:** Harvested product tested positive for GM material (detected as a result of industry quality assurance (QA)).
3. **August 2002:** The presence of GM maize seeds was detected in crops harvested in Gisborne and Pukekohe earlier in the year (detected as a result of industry QA). In response to this incident the report *A Review of the Handling of the GM Maize Incident at Gisborne and Pukekohe: August–October 2002* (McGregor, 2002) was prepared for MAF and ERMA.
4. **July 2003:** GM was discovered in a sweetcorn product that was exported to Japan from New Zealand (detected as a result of industry QA).

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42 A member of the ERMA and past chair of the Interim Assessment Group was one of a number of scientists found to be carrying out unauthorised GM experiments (Espiner, 2000).

43 http://www.gmcontaminationregister.org contains more details of these breaches. The purpose is to record all incidents of contamination arising from the intentional or accidental release of genetically modified (GM) organisms (which are also known as genetically engineered (GE) organisms). It also includes illegal plantings of GM crops and the negative agricultural side-effects that have been reported.

44 This incident became known as Corngate. See Nicky Hager's book 'Seeds of Distrust' (Hager, 2002) for a detailed investigation of the incident and the government's subsequent response.

5. **March 2004:** A MAF audit of a Biogenetic Services Ltd laboratory (in the US) found significant issues with the way GM test results were reported for seed imported the previous season. Retesting of some imported seed found it to be positive for a GM construct. At the time of detection, the crops were close to harvest and the grain produced was harvested, dried, stored and devitalised under supervision.
6. **July 2005:** GM presence in a shipment of maize was detected. Tests determined that the positive result was caused by accidental mixing of the maize with GM soy. The GM construct in the soy had been approved for human consumption by Food Standards Australia New Zealand (detected as a result of industry QA).
7. **December 2006:** MAF discovered some consignments of corn seed imported into New Zealand during October and November 2006. These had been accompanied by test certificates showing positive results for the presence of GM organisms and had been cleared in error at the border.
8. **July 2007:** MAF officers seized and destroyed 300 tropical fish in raids on two Christchurch pet shops and two private premises in Christchurch. The fish were seized after tests done in Britain confirmed they had been genetically modified with a red fluorescent protein to make them a bright red/pink colour.

In response to the 2006 GM contamination incident, the report *Inquiry into the Circumstances Associated with the Imports of Certain Corn Seeds in Late 2006,* prepared by David Oughton, was released in January 2007. Oughton referred to the findings of the 2006 audit report on the Quarantine Service, in which it is stated that the existing requirement for a joint clearance by two Quarantine Officers for *Zea mays*[45] consignments was not being 'consistently complied with' (Oughton, 2007).

> It would seem to me that a desire to simplify work procedures was allowed to override the need to ensure that no consignment of *Zea mays* containing any GM contamination was granted an import clearance. (Oughton, 2007: 8)

The report also questioned why supervisor checks (where that was possible) were not being carried out. Both of these requirements had been put in place as safeguards after the 2002 incident of GM contamination.

[45] *Zea mays* is the scientific name for maize, corn or sweetcorn.

(ii) Non compliance

Non-compliances are failures to comply with the new organism provisions of the HSNO Act, as well as the requirements of MAF Standards. Some of the standards are joint standards between MAF and ERMA because MAF cannot approve standards for containment facilities (where all GM organisms are held), only ERMA can do this.

There are a suite of six containment facility standards. One new standard is called the Microorganism & Cell Culture Standard, which will not become fully implemented until well into 2009. This standard covers both transitional facilities and containment facilities for microorganisms and cell cultures which may be risk goods, including unwanted organisms and new organisms. The Microorganism & Cell Culture Standard is a very radical standard in comparison to the other five. Having just been released, there are a lot of provisions in this standard that are not yet in other standards. This standard introduces a new category, called a 'critical non-compliance'.

Non-compliance is generally identified during the course of audits but may be notified to an Inspector at any time by the Operator. The principles of natural justice will be followed and any non-compliance found during an audit or inspection may be appealed by the Operator to the Inspector. All non-compliances must be reported to the Operator and MAF. Internal and external audit reports must list all non-compliances, corrective action requests (CARs) and the timeframe for these to be completed (MAF, 2007c).

MAF has access to powers under both the HSNO Act and the Biosecurity Act in carrying out its enforcement role. These include powers of entry and inspection, powers to direct that non-compliance be remedied, powers to obtain a search warrant to obtain evidence, and powers to take immediate action in the event that a GM organism has escaped or spread from its intended location. In the case of serious or persistent non-compliance, there are a number of potential charges specified under both the HSNO Act and the Biosecurity Act that could be laid against an offender.

Non-compliances are now classified into critical, major and minor (see detailed definitions in the glossary).

Critical non-compliance

This category requires the Inspector to notify ERMA as soon as practicable. Such events are reported in ERMA's Quarterly Report to the Minister for the Environment. In the event of a critical non-compliance, the Inspector:

- must investigate the critical non-compliance and lodge an investigation report with MAFBNZ[46] as soon as practicable
- may direct that all work using microorganisms or cell cultures cease immediately until the non-compliance is rectified
- Critical non-compliances may require further investigation and possibly lead to prosecution, depending on the nature and circumstances of the event. It is expected that at least one revisit audit will be required to ensure that the critical non-compliance has been effectively resolved and measures have been to taken to prevent its recurrence. (MAF, 2007c)

Major non-compliance
If the major non-compliance involves a new organism, the Inspector must notify ERMA as soon as practicable.

Minor non-compliance
In the event of a minor non-compliance, the Operator must:

- take corrective action to rectify the non-compliance within an acceptable time frame
- record the non-compliance and notify the Inspector on the next audit or visit
- Minor non-compliances involving new organisms are notified to ERMA New Zealand by MAFBNZ through its regular reporting procedures. (MAF, 2007c)

A 'minor non-compliance' is described in a recent MAF report titled *Investigation of Compliance and Monitoring of the Scion GM Field Test* (MAF, 2008). This report was prepared in response to the security breach and GE tree cutting at the Rotorua site in early January.

> MAFBNZ issued a minor non-compliance to Scion following notification of this incident, and recommended that a separate area on site be designated for the drying of tree prunings to prevent future mower access. MAFBNZ graded this as a minor incident, because no serious biosecurity risk/threat has resulted, prunings have not been "disposed" of by mulching and incineration is still the intended final disposal method, and staff had taken measures to remedy the situation and ensure it would not occur again. (MAF, 2008)

MAF does investigate issues, including non-compliances, and produces a variety of reports for different purposes, where they consider it is warranted. MAF does not produce a "report" *per se* on every non-compliance.

[46] MAFBNZ is an abbreviation used by MAF to reflect a part of MAF, called MAF Biosecurity New Zealand.

MAF keeps a register of all CARs to remedy non-compliance. In response to a request for a list of GMO-related CARs, MAF advised that the register records the nature of the non-compliance, the risk involved, how that risk was managed and how to avoid it recurring. CARs are recorded against the requirements of the Standard, not against a specific GMO or a HSNO Approval. While this information could be made available, MAF does not see the benefit in analysing or reporting non-compliances in this way. Rather, it provides an analysis of the types and severity of risks of non-compliances to ERMA so that emerging trends and issues, and how MAF is managing them, are brought to the Authority's attention (Wards, 2008).

Arguably, a public report card on each applicant for non-compliance should be freely available in a public register, as the mere fact that non-compliance is made public acts as a further incentive for applicants to follow the controls set by ERMA. Currently, such a list of non-compliance by GMO applicants would incur an additional expense to a member of the public, and would need to be pursued through an Official Information Act request.

Summary

The above sub-section raises questions about the robustness of the implementation of the legislation and the resulting controls, as well as the public's right to know when implementation fails, all of which we believe are critical for developing public trust in the operation and use of this new technology.

6.2 Legislation

6.2.1 Amendments to legislation

Amendments to four main pieces of legislation took place in 2003: the Hazardous Substances and New Organisms (HSNO) Act 1996, the Medicines Act 1981, the Agricultural Compounds and Veterinary Medicines Act 1997 and the Biosecurity Act 1993. These changes covered the following general areas: contained research using low-risk GMOs, a new category of release for new organisms, strict civil liability and a civil penalties regime, ministerial call-in powers, operational amendments, medicines, and cloning and human cells (see MfE, 2001a: 3). For these and other changes to the HSNO legislation, see Appendix 3. We have also been advised that the Medicines Act is currently undergoing redrafting and the HSNO (Methodology) Order 1998 continues to undergo review.[47]

[47] The review of the HSNO (Methodology) Order 1998 originally started in 2002.

6.2.2 Use of section 67A: minor amendments under HSNO

ERMA has received and approved minor or technical amendments to applications under section 67A[48] of the HSNO Act. This section allows previously approved applications to be amended without public submissions or a public hearing. Concerns have been raised over the extent to which ERMA and AgResearch may have used section 67A to make significant (rather than minor or technical amendments) to previously approved applications. Currently ERMA may be considering a further application.

> AgResearch is also currently considering making an application to amend the GMF98009 approval under section 67A of the HSNO Act. This application would be to align approval GMF 98009 with GMD 02028. It would not cover moving animals around the country. This section 67A application, which would be for a minor or technical amendment to the approval, would not be open to public consultation. (ERMA, 2008f)

See Appendix 7 for an outline of current field test experiments that have applied for and received amendments under section 67A.

6.2.3 Court judgements

There have been three High Court decisions[49] relating to outdoor experiments and a further court case has been heard in regard to ERMA approval GMF06001 for the field testing of GM brassicas (ERMA, 2007d: 9). The three rulings to date are:

- **2001 May**: *Bleakley v ERMA* [AP 177/00]. The ruling was in Bleakley's favour, meaning that the AgResearch approval GMF98009 would be reconsidered by ERMA. ERMA reconsidered the application in private and decided again to approve the application. This case raised the importance of the Treaty of Waitangi and emphasised the need for transparency in ERMA's decision-making.
- **2003 July**: *MAdGE v Minister for the Environment*, *ERMA and AgResearch* [CIV 2003-404-673]. A judicial review was conducted regarding details of approval GMD02028. The ruling was in favour of the Minister for the Environment.
- **2004 December**: *Bleakley v ERMA*, *Minister for Agriculture and Forestry, Minister for the Environment and Whakamaru Farms Ltd* [CIV 2004-485-1042]. A judicial review was held regarding details of approval GMF98001. The ruling was in ERMA, the Ministers' and Whakamaru Farms Ltd's favour, meaning that the decision not to reassess controls on the PPL sheep field test and post-field test monitoring practices would not be reviewed.

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[48] This section was inserted by section 26 of the Hazardous Substances and New Organisms Amendment Act 2000.

[49] The full decisions are available on Sustainable Future's website. See http://www.sustainablefuture.info .

6.3 Institutions

This sub-section outlines the institutions responsible for key aspects in the management of genetic modification in New Zealand.

6.3.1 ERMA

ERMA is the institution responsible for approving (with or without controls) or declining applications for GMOs to be imported, developed, tested, created or released into the outdoors (see Table 3 in Section 6.1). ERMA is responsible for setting controls to manage the potential risks and impacts of a GMO; however once ERMA approves a GMO for full release, the GMO would only be monitored by MAF on receipt of a complaint.

(i) Independent Review

In 2003, government instigated an independent review of ERMA, resulting in a report titled *A Review of the Capability of the Environmental Risk Management Authority (ERMA) Relating to the Risk Management of New Organisms* (ERMA, 2003a).[50] The report made 49 recommendations that included a number of clarifications, improvements and reinforcements in relation to ERMA's fitness for purpose. Recommendations were made on enhancements to:

1. ERMA's decision-making and governing body, referred to as the Authority
2 Methodologies in use in managing risks and benefits
3. Present management and organisational structures
4. Staff qualifications and experience
5. External relationships. (ERMA, 2003a: 10)

We understand from ERMA staff (Harrison, 2007) that all the recommendations have been implemented. A letter to the Minister for the Environment from ERMA in November 2003 states that:

> … action has now either been completed or substantially taken on all the recommendations … in some cases the recommendations involve actions that will be ongoing for some considerable time — for example … on working closely with other agencies dealing with enforcement issues and public awareness training … in some cases, action in line with the review team's findings had been taken either before or during the review, and that in many instances, the changes we have made go considerably beyond the review team's recommendations. (ERMA, 2007e: 6)

ERMA has also advised that:

> there are no current or future external reviews under consideration concerning the operation and management systems and capacity and capability of ERMA New Zealand for new organisms and/or the outcomes of GM outdoor experiments. (ERMA, 2007e: 6)

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[50] This report is frequently called the Nahkie's report, after the Chair.

(ii) ERMA Fees

An ongoing issue, and one also recognised by the Commissioners (RCGM, 2001a: 131), is in relation who should pay the decision-making and compliance costs of ERMA's decisions. To this end, a breakdown of actual expenditure on outdoor GMO applications was sought from ERMA. However, this information was not easily available and could not be provided without ERMA charging and passing on preparation costs. The information that was freely available is contained in Table 8 below. This indicates that the additional costs of processing outdoor applications, including the notification, the public hearing process and the decision making process is significant. Without the expenditure of new GMOs being broken down per type of outdoor experiment, we believe the true costs and benefits of this technology cannot easily be assessed.

Of note in this data is the discrepancy between the true cost of new organism expenditure (column c) and the application fee received from outdoor experiment applications (column d). Although not directly comparable, the comparison indicates that outdoor experiments are likely to cost a great deal more than what applicants are currently being charged. This is surprising when considering that ERMA's pricing principles aim to have an optimal balance between reflecting actual costs (principle 1 below) and other values (principles 2 and 6 below):

1. reflect actual costs
2. do not discourage applications
3. ensure predictability for applicants
4. recognise public benefits
5. enable ERMA to anticipate planned legislative change, and
6. are not a barrier to growth and innovation. (ERMA, 2006c: 5)

This apparent tension raises issues about the extent to which application fees should reflect actual costs, and the types of incentives that may exist and support applicants to pursue the commercial use of GM in the outdoors. These issues are further discussed in our report titled *The Future of Genetic Modification in New Zealand* (Sustainable Future, in press).

Table 8 ERMA Crown Funding, Expenditure and Application Fees
Source: ERMA, 2007c, ERMA, 2007e

	Total Crown Funding (a)	Fees collected from applicants (b)	New Organism Expenditure [51] (c)	Application Fees from Outdoor Experiments (d)	Number of Outdoor Experiments (e)
	Year ended 30 June	Year ended 30 June	Year ended 30 June	Year ended 30 June	Year ended 30 June (See Appendix 8)
1998	$2,435,556	Nil	Nil[52]	Nil	1
1999	$4,000,000	$175,339[53]	$1,062,000	N/A[54]	6
2000	$4,325,278	$183,072	$1,321,000	Nil	5
2001	$4,373,333	$459,038	$1,296,482	Nil	4
2002	$5,111,111	$556,406	$690,771	N/A	0
2003	$5,311,111	$609,050	$864,883	$110,000 (approx)[55]	1
2004	$10,326,000	$719,000	$1,086,000	Nil	1
2005	$11,733,000	$451,000	$1,301,000[56]	Nil	0
2006	$11,699,000	$678,000	$1,615,000	$2,250[57]	0
2007	$9,397,000	$802,000	$1,982,000	$39,375[58]	1

51 Being the true cost of decision-making for New Organisms.

52 No applications were received or considered because the HSNO Act 1996 did not become operational until 1998.

53 In 1999 and 2000 the fees collected from applicants only include new organisms not hazardous substances.

54 This information was not available at time of print.

55 Being the application fee for GMF03001 (Onion field test).

56 From 2005 forward, the amount spent on new organism decision-making includes oversight of compliance systems (ERMA, 2007e).

57 Minor or technical amendments under section 67A of the HSNO Act.

58 Being the application fee for GMF06001 (Brassica field test).

6.3.2 Bioethics Council

The New Zealand government established Toi Te Taiao: The Bioethics Council[59] in December 2002. The Council's purpose is to:

(i) Enhance New Zealand's understanding of the cultural, ethical and spiritual aspects of biotechnology
(ii) Ensure that the use of biotechnology has regard for New Zealanders' values. (Bioethics Council, 2007)

However, this work is subject to boundaries; these are:

(i) Not to do the work of an existing agency.
(ii) Not to review, approve or offer opinion on specific proposals.
(iii) Not to make recommendations that are binding.
(iv) Not to be a quasi-judicial body. (Bioethics Council, 2007)

The Council has produced a number of reports and recommendations that, to date, the government has not responded to (see Sustainable Future, 2008: Tables 9 and 11).

The Bioethics Council was independently reviewed by the State Services Commission in 2005, but the resulting report was not made public. The SSC report, titled *Bioethics Council Review Report*[60], found the purpose of the Bioethics Council to be valid and that they had become a trustworthy vehicle for education and public discourse on emergent biotechnology issues. The report made a number of recommendations that endorsed the Bioethics 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). A key recommendation was the formation of an *ad hoc* Ministerial Coordination Group on Bioethics to inform the Bioethics Council's work programme and receive and discuss reports and coordinate any appropriate response. Although the Ministerial Coordination Group on Bioethics was established in November 2006, there has been no government response to the previous Bioethics Council reports or any new reports published since that date.

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[59] The New Zealand government established Toi Te Taiao: The Bioethics Council by Cabinet minute [POL (02) 117] in December 2002 (MfE, 2007b).

[60] This report was requested under the Official Information Act.

6.3.3 MAF Biosecurity New Zealand

MAF Biosecurity New Zealand (MAF) is the lead agency in New Zealand's biosecurity system. It replaced MAF's Biosecurity Authority in November 2004, and has been tasked with a 'whole-of-system' leadership role, encompassing economic, environmental, social and cultural outcomes. It also has international trade and animal welfare responsibilities. MAF Clearance Services identify and manage any potential biosecurity risks at the border, and provide domestic and offshore technical inspection and clearance services. See the discussion on non-compliance in Section 6.1.3 above.

MAF holds two Memorandums of Understanding with ERMA.

The first of these, the *Memorandum of Understanding Concerning the Inter-relationship between ERMA New Zealand and MAF Regulatory Authority 1998* (ERMA & MAF, 1998), covers the general relationship between the two agencies.

The second, the *Memorandum of Understanding between ERMA New Zealand and the Ministry of Agriculture and Forestry Concerning New Organisms 2003* (ERMA & MAF, 2003), relates specifically to new organisms enforcement. With the introduction of the HSNO Amendment Act 2003, MAF is responsible for ensuring that the provisions of the Act with respect to new organisms are enforced. As a result of this there are many overlaps in the responsibilities between these two agencies. The second memorandum establishes mutually agreed intentions to ensure successful cooperation between the two parties in the management of new organisms.

As directed in the 2003 memorandum, MAF's responsibilities in relation to the management of new organisms are as follows:

1. The Administration of the Biosecurity Act — this includes the exclusion, eradication and effective management of unwanted organisms
2. Managing the risks associated with the potential for imported risk goods to bring harmful organisms into New Zealand (Border Control)
3. Ensuring that the provisions of the HSNO Act with respect to New Organisms are enforced. This includes audits and inspections to monitor compliance with controls on New Organism approvals. MAF is also responsible for managing and responding to incursions and non-compliance situations. However, if ERMA New Zealand disagrees with MAF's proposed course of action and these disagreements cannot be resolved ERMA has final decision making power under this Memorandum of Understanding
4. Undertaking prosecutions for conduct that is an offence against the New Organism provisions of the HSNO Act
5. To report to ERMA on the level and nature of inspection to be provided by enforcement officers

6. Both Agencies are responsible for reporting relevant information regarding New Organisms to each other
7. It is also possible for MAF to make an application for the use of a new organism in an emergency; in this case the application must go through the normal ERMA channels. (ERMA & MAF, 2003)

Unlike ERMA, MAF has a role not just in the monitoring of GMOs before release, but also following ERMA approval for full release without controls. In the latter case, MAF would be called in to manage any negative effects of such a release.

MAF is also responsible for overseeing the Animal Welfare Act 1999 and the ethics surrounding the use of animals in research and testing.

As stated in the second memorandum, it is MAF's responsibility to inspect and audit the containment facilities for GMOs. MAF holds records of the number and names of all the containment facilities in New Zealand of which, as of October 2007, there are 135. However, MAF does not keep a record of exactly which approvals are active in each containment facility at any given time, due to the fact that approvals can be activated and deactivated. Containment facilities for plants are inspected annually; all other containment facilities are inspected every six months. The GM-Cattle outdoor research is inspected every three months and GM-plant outdoor research is inspected at times appropriate to stages in the life-cycle of the crop, such as planting harvesting or when flowering structures occur (MAF, 2007b; ERMA, 2008e). Every audit is written up as a formal report, and is available via Official Information Act (OIA) requests (MAF, 2007b).

6.3.4 Institutional Biological Safety Committees (IBSC)

An Institutional Biological Safety Committee (IBSC) is a committee established by a research organisation or group of organisations. ERMA delegates the authority to assess and approve rapid assessment applications for the importation and development of low-risk GMOs to these committees, and checks decisions for accuracy before they are placed on ERMA's website (ERMA, 2008e). IBSCs are audited approximately every three years, to ensure applications are properly prepared and decisions are consistent with the HSNO Act and ERMA's methodology. Reports are available from ERMA via Official Information Act (OIA) requests (Venables, 2007). Table 5 shows the number of decisions that were made in the 2005/06 and 2006/07 financial years. See Appendix 6 in *Review of the Forty-Nine Recommendations of the Royal Commission on Genetic Modification* (Sustainable Future, 2008) for a list of current IBSC policy requirements and processes.

6.3.5 Ministry of Research, Science and Technology

MoRST has prepared a number of reports and strategies, including *Futurewatch Current Work* (MoRST, 2007). An earlier research report *Hands Across the Water,* which was released by MoRST (Cronin & Jackson, 2004), reported on how to advance New Zealand's understanding of the key issues in relation to the GM debate and how we might improve communication about science and technology developments in the future. The report made 24 recommendations in the following areas:

1 Feedback to participants
2. Transfer of learning to other sectors
3. Working with the news media
4. Capacity building for science communication
5. Capacity building for social research on science and technology
6. Future research to support engagement around biotechnology. (Cronin & Jackson, 2004)

6.3.6 The Biotechnology Sector Taskforce

The Biotechnology Sector Taskforce, set up in 2002 under the Growth and Innovation Framework (MoRST, 2003; NZTE, 2007), provided a report back to government in 2003 which consisted of 28 recommendations for action and a 10-year vision for the sector.[61] The work of the taskforce fed into the 'Growing the Sector' goal of *The New Zealand Biotechnology Strategy: A Foundation for Development with Care* (See below). MoRST states that progress on the taskforce's recommendations were evaluated in 2004 and it was found that good progress had been made.[62]

6.3.7 Statistics New Zealand

Statistics New Zealand gathers and analyses a range of information on the biotechnology industry in New Zealand. This information is primarily gained from industry surveys which have been conducted sporadically since 1999, but are now noted as occurring every two years.

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[61] The members of the Biotechnology Task Force in 2002 included Bill Falconer (Chairman), the Hon. Pete Hodgson (Convenor), Professor Garth Cooper, Michael J. Harrington, Professor Diana Hill, Elizabeth Hopkins, Dr Claire McGowan, James McLean , Bruce Munro, Ray Potroz, Dr Max Shepherd and Paul Tocker.

[62] See http://www.morst.govt.nz/current-work/biotechnology/taskforce/.

However, these figures are not yet entirely comparable across time due to reporting difficulties. For example, although the 2007 survey collected figures on biotechnology income, expenditure and export earnings, feedback from some respondents indicated that the requested figures are difficult to distinguish from overall financial figures when bioprocesses are an inherent part of the production process. These issues were also present when attempting to determine staff numbers employed in the biotechnology sector. Due to these difficulties, the 2007 figures were not published. These figures were most recently published in 2005. Statistics New Zealand is working to understand these issues, and the impact they may have on use of financial and employment measures of biotechnology activity (Stats NZ, 2007).

To conclude, although we may have a clear definition of genetic modification, we do not have a way of exploring how genetic modification contributes to the biotechnology sector, or indeed how the biotechnology sector contributes to the wider economy.

6.4 Strategies

6.4.1 New Zealand Biotechnology Strategy

The New Zealand Biotechnology Strategy: A Foundation for Development with Care was released in May 2003. The key theme — 'development with care' — is supported by three primary goals:

1. Building understanding about biotechnology and constructive engagement between people in the community and biotechnology sector
2. Grow New Zealand's biotechnology sector to enhance economic and community benefits
3. Manage the development and introduction of new biotechnologies with a regulatory system that provides robust safeguards and allows innovation. (MoRST, 2003)

6.4.2 Biosecurity Strategy for New Zealand

The Biosecurity Strategy is another key strategy relevant to genetic modification in New Zealand (MAF, 2003). Notably, this strategy does not include discussion of issues relating to genetic modification other than to note a gap in capability that needs to be addressed (see below) and a reference to imported seed (MAF, 2003: 50).

> The strategy does not focus on the framework for managing the intentional introduction of new organisms, including Genetically Modified Organisms (GMOs), because this has been the subject of a separate review process — firstly by the Royal Commission on Genetic Modification, then by the Government in developing its response (which includes the New Organisms and Other Matters Amendment Bill). Nor does this strategy focus on the role and capability of ERMA, which has been the subject of a separate review. The Council is unaware of any scientific basis to treat GMOs as a different class of biosecurity risk, requiring some special approach. The need for appropriate surveillance and response capability to deal with possible GMOs incursions does need to be addressed. (MAF, 2003: 7)

Tensions exist between the New Zealand Biotechnology Strategy and the Biosecurity Strategy for New Zealand. Both strategies demand safety, but one aims to manage the introduction of new organisms while the other demands the protection of current organisms from new (introduced and genetically modified) species.

6.5 International Agreements

The Cartagena Protocol on Biosafety (UN, 2000), an international agreement on trans-boundary movement of living modified organisms, is a supplement to the Convention on Biological Diversity (CBD). It was adopted by the Conference of the Parties to the CBD on 29 January 2000, and after gaining 103 signatories and 50 ratifications (including New Zealand) it came into force on 11 September 2003. The Cartagena Protocol is a treaty designed to enhance biosecurity by providing for prior consent to international shipments of living GMOs — known as 'living modified organisms' (LMOs). It is motivated by concern to protect biodiversity, and also carries significant trade implications.

In February 2006 the Sustainability Council of New Zealand released *Brave New Biosecurity: Realigning New Zealand's Approach to the Cartagena Protocol* (Sustainability Council, 2006), which outlines the Protocol's potential to upgrade two important areas of New Zealand's existing biosecurity management:

1. Requirements for labelling that would identify those LMOs not intended to be a part of a shipment, which could otherwise escape detection; and
2. A new liability regime to provide compensation for any harm resulting from importing an LMO, when redress would otherwise generally not be available (Sustainability Council, 2006: i).

The report concludes that the New Zealand government's actions in negotiations did not support these developments and that our position should be more strongly aligned with these.

6.6 Economic Analysis

The potential economic impacts resulting from the use of GM in New Zealand have received considerable analysis in the past decade and remain an important area to continue to explore.[63, 64] The consideration of economic risks, costs and benefits has become further integrated into the case-by-case approval of GMOs through the ERMA decision-making process. A technical guide for consideration of impacts on the market economy has been developed for Authority and Agency staff, and to provide stakeholders with information regarding the Authority's recommended approach in this area (ERMA, 2005b).

Broader analysis of the potential economic risks, costs and benefits of genetic modification has been undertaken for the Treasury and the Ministry for the Environment (see Treasury, 2003; BERL and AERU, 2003). This reveals that the level of positive or negative impacts from the release or non-release of a GMO on GDP depends upon the assumptions, such as price impacts and productivity gains, built into the economic models. These assumptions are also influenced by factors such as New Zealand's clean green image and the effectiveness of the regulatory framework (*ibid*).

More specific dimensions of this macro picture have also been explored. A recent assessment of biopharming suggests the economic benefits of having a biopharming sector in New Zealand should be treated with caution (Kaye-Blake *et al.*, 2007). Biopharming is notoriously risky, as indicated by the case of PPL Therapeutics (New Zealand) Ltd[65] whose field test (ERMA approval GMF98001) was stopped and approximately 4000 AAT-producing transgenic sheep were subsequently destroyed.

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63 For example: *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).

64 In addition, a submission to ERMA containing an analysis of the economic benefits of GM Onions (GMF03001) also questions economic benefits (McGuinness, 2003). See also the wider discussion in the discussion paper, titled *The Future of Genetic Modification in New Zealand* (Sustainable Future, in press).

65 The PPL Therapeutics press release notes: 'Bayer Biological Products (BP) and PPL Therapeutics plc (PPL) announced a decision to put their recombinant Alpha-1 Antitrypsin (recAAT) development program on hold. Although significant advances have been made since the end of Phase II clinical trials, the resources required to move the project forward, combined with the decision not to build a commercial purification facility because of the financial risk, have led the companies to the decision to place the project on hold' (PPL Therapeutics, 2003).

Over the last ten years much of the debate about GM has been generated by promises of economic gain and improvements in human and environmental health to New Zealanders from outdoor field tests and developments. However, we have not been able to find any proven commercial profit or medical benefit to date nor could we find any indication that this may change in the short-term.

6.7 Research on Ethics and Public Attitudes

This sub-section gives an insight into the body of research on genetic modification that exists in relation to ethics and public attitudes. This is not an exhaustive review of the literature but rather seeks to outline some key themes and findings present in this work. Importantly we acknowledge the extensive amount of research taking place in government bodies, particularly through the Bioethics Council, in universities and civil society.

6.7.1 Ethics Research

Publications have been prepared by the Bioethics Council in support of three recommendations of the Commissioners, namely Recommendations 7.5 (use of non-food animals as bioreactors wherever possible), 7.6 (use of synthetic genes or mammalian homologues wherever possible) and 9.2 (the development of ethical guidelines for xenotransplantation) (See Bioethics Council, 2004a; 2004b; 2005a; 2005b; NFO, 2004). The government has not publicly responded to the Council's findings (see Section 6.3.2).

An Ethics Advisory Panel (EAP) was set up by ERMA in 2005 to provide advice on ethical matters; the panel has developed an Ethics Framework document (ERMA, 2005c). It is of note, that the Bioethics Council is 'not to do the work of an existing agency' (see Section 6.3.2), so there may be potential for tension over clarity of roles and relationships.

Examples of civil society's response include a number of NGO and individual responses. The Nathaniel Centre, an independent body exploring this landscape, has prepared a number of publications that encompass a range of ethical issues in relation to the use of biotechnologies (Nathaniel Centre, 2007). In addition, Paul (n.d.) presents an interesting collection of works that collectively explores the Judaeo-Christian and Western ethical interpretations and implications of genetic modification.

6.7.2 Research on Public Attitudes

In the last decade, a body of work has emerged which explores New Zealanders' understanding and perceptions of and attitudes towards genetic modification. This has been conducted by academics, central government, media and lobby groups, using methods that include digi-polls, surveys and focus groups (See Appendix 9 for a list of recent research). What follows is not a comprehensive summary, but rather a brief discussion on four key considerations that exist within this body of research.

The Agribusiness and Economic Research Unit (AERU) has found that an individual's understanding of genetic modification and biotechnology interacts with their values and worldview to form their stance on the issue (Cook *et al*., 2004). Although an individual's understanding is likely to change over time in response to new information, their values and worldview remain more constant (*ibid*). For many New Zealanders this entrenched nature of their worldview means they are unlikely to change their stance in relation to biotechnology (see Cook *et al*., 2004; Cook and Fairweather, 2005). However, the AERU has also found that greater acceptance of biotechnology has developed over time, though this change has been very slow and is likely to remain so due to deep-seated views on the issue (see Cook *et al*., 2004; Cook and Fairweather, 2005; 2006).

Secondly, an individual's view is not necessarily the same for all applications of GM. As noted in the Royal Commission,[66] individuals attitudes to genetic modification is dependent on the application of the technology. For example, medical use of biotechnology has been found to be more acceptable than use in agriculture (Cook *et al*., 2004). A high level of concern regarding the use of this technology in agriculture is supported by numerous public opinion polls commissioned by the Sustainability Council. The most recent poll found 74.5% of New Zealanders' in favour of New Zealand remaining a GM free producer (Sustainability Council, 2005).

Views are diverse across all sector groups and key stakeholders. AERU has conducted research (see Cook *et al*., 2000; Fairweather *et al*., 2001; 2003) over time which seeks to understand farmer attitudes to genetic modification. For example, just over 40% of farmers were opposed to the use of GMOs for on-farm human or animal food production whereas only one third support this use (Fairweather *et al*., 2003).

It is also important to consider different cultural views and interpretations of the GM debate, and in New Zealand, particularly those that exist within Te Ao Māori. Considerable research discusses these views; Te Momo (2007) presents seven themes through which to interpret Māori communities association with biotechnology. Roberts *et al*. (2004) discuss the importance of the concept of whakapapa within a Māori worldview, and as a framework for interpretation of the potential impacts of the use of genetic modification.

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66 The RCGM noted: Submitters often distinguished between research in containment, and uncontained research and its impacts on the environment (RCGM, 2001a: 103).

7. Conclusion

This paper provides an overview of the history of genetic modification in New Zealand. This complex history continues to be negotiated today by stakeholders in central and local government, iwi, research institutes, industry, civil society, the media, and international companies and organisations.

This paper provides a context to support and assist with interpretation of Sustainable Future's review of the implementation of the recommendations of the Royal Commission on Genetic Modification (see *Review of the Forty-Nine Recommendations of the Royal Commission on Genetic Modification,* 2008) and ultimately, our evaluation of the future of genetic modification in New Zealand (see Sustainable Future, in press). We refer you to these papers to gain a more in-depth and critical understanding of the government's management of genetic modification technology since the Commissioners' report and the resulting challenges for New Zealanders who desire a sustainable nation.

Abbreviations

CAR	Corrective Action Requests
CRI	Crown Research Institute
DOC	Department of Conservation
ERMA	Environmental Risk Management Authority
FRST	Foundation for Research, Science and Technology
HSNO	Hazardous Substances and New Organisms Act 1996
GM	Genetic Modification
GMD	Genetic Modification Development
GMF	Genetic Modification Field (Test)
GMO	Genetically Modified Organism
IBAC	Independent Biotechnology Advisory Committee
IBSC	Institutional Biological Safety Committee
MAdGE	Mothers Against Genetic Engineering
MAF	Ministry of Agriculture and Forestry
MAFBNZ	Ministry of Agriculture and Forestry Biosecurity New Zealand
MfE	Ministry for the Environment
MoRST	Ministry of Research, Science and Technology
NFO	Now TNS, formerly known as NFO NZ (a market research company)
NOCR	New Organism Conditional Release
NOR	New Organism Release
OIA	Official Information Act
PC	Physical Containment
RCGM	Royal Commission on Genetic Modification

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, 2001g: 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, 2001g: 94).

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

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, 2007c: 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, 2001g: 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, 2001g: 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, 2007f: 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 2007f: 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, 2007c: 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, 2007c: 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, 2007e).

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, 2007c).

Appendix 1 The Warrant

Source: RCGM, 2001b: 102-108

1. Appointment and order of reference

Know ye that We, reposing trust and confidence in your integrity, knowledge, and ability, do, by this Our Commission, nominate, constitute, and appoint you, The Right Honourable Sir Thomas Eichelbaum, Jacqueline Allan, Jean Sutherland Fleming, and The Right Reverend Richard Randerson, to be a Commission to receive representations upon, inquire into, investigate, and report upon the following matters:

1. the strategic options available to enable New Zealand to address, now and in the future, genetic modification, genetically modified organisms, and products; and
2. 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:

2. Relevant matters

And, without limiting the order of reference set out above, we declare that, in conducting the inquiry, you may, under this Our Commission, investigate and receive representations upon the following matters:

a. where, how, and for what purpose genetic modification, genetically modified organisms, and products are being used in New Zealand at present:

b. the evidence (including the scientific evidence), and the level of uncertainty, about the present and possible future use, in New Zealand, of genetic modification, genetically modified organisms, and products:

c. the risks of, and the benefits to be derived from, the use or avoidance of genetic modification, genetically modified organisms, and products in New Zealand, including:

   a. the groups of persons who are likely to be advantaged by each of those benefits; and
   b. the groups of persons who are likely to be disadvantaged by each of those risks:

d. the international legal obligations of New Zealand in relation to genetic modification, genetically modified organisms, and products:

e. the liability issues involved, or likely to be involved, now or in the future, in relation to the use, in New Zealand, of genetic modification, genetically modified organisms, and products:

f. the intellectual property issues involved, or likely to be involved, now or in the future, in relation to the use in New Zealand of genetic modification, genetically modified organisms, and products:

g. the Crown's responsibilities under the Treaty of Waitangi in relation to genetic modification, genetically modified organisms, and products:

h. the global developments and issues that may influence the manner in which New Zealand may use, or limit the use of, genetic modification, genetically modified organisms, and products:

i. the opportunities that may be open to New Zealand from the use or avoidance of genetic modification, genetically modified organisms, and products:

j. the main areas of public interest in genetic modification, genetically modified organisms, and products, including those related to:

a. human health (including biomedical, food safety, and consumer choice):
b. environmental matters (including biodiversity, biosecurity issues, and the health of ecosystems):
c. economic matters (including research and innovation, business development, primary production, and exports):
d. cultural and ethical concerns:

k. the key strategic issues drawing on ethical, cultural, environmental, social, and economic risks and benefits arising from the use of genetic modification, genetically modified organisms, and products:

l. the international implications, in relation to both New Zealand's binding international obligations and New Zealand's foreign and trade policy, of any measures that New Zealand might take with regard to genetic modification, genetically modified organisms, and products, including the costs and risks associated with particular options:

m. the range of strategic outcomes for the future application or avoidance of genetic modification, genetically modified organisms, and products in New Zealand:

n. whether the statutory and regulatory processes controlling genetic modification, genetically modified organisms, and products in New Zealand are adequate to address the strategic outcomes that, in your opinion, are desirable, and whether any legislative, regulatory, policy, or other changes are needed to enable New Zealand to achieve these outcomes:

3. Definitions

genetic modification means the use of genetic engineering techniques in a laboratory, being a use that involves:

a. the deletion, multiplication, modification, or moving of genes within a living organism; or
b. the transfer of genes from one organism to another; or
c. the modification of existing genes or the construction of novel genes and their incorporation in any organisms; or
d. the utilisation of subsequent generations or offspring of organisms modified by any of the activities described in paragraphs (a) to (c)

genetically modified organism means an organism that is produced by genetic modification

organism includes a human being

product includes every medicinal, commercial, chemical, and food product that (while not itself capable of replicating genetic material) is derived from, or is likely to be derived from, genetic modification:

4. Exclusions from inquiry

But We declare that you are not, under this Our Commission, to inquire into the generation of organisms or products using modern standard breeding techniques (including cloning, mutagenesis, protoplast fusions, controlled pollination, hybridisation, hybridomas and monoclonal antibodies):

5. Consultation and procedures

And you are required, in carrying this Our Commission into effect,-

a. to consult with the public in a way that allows people to express clearly their views, including ethical, cultural, environmental, and scientific perspectives, on the use, in New Zealand, of genetic modification, genetically modified organisms, and products; and
b. to adopt procedures that will encourage people to express their views in relation to any of the matters referred to in the immediately preceding paragraph; and
c. to consult and engage with Māori in a manner that specifically provides for their needs; and
d. to use relevant expertise, including consultancy and secretarial services, and to conduct, where appropriate, your own research:

And you are empowered, in carrying this Our Commission into effect,

a. to prepare and publish discussion papers from time to time on topics relevant to the inquiry; and
b. unless you think it proper in any case to withhold any evidence or information obtained by you in the exercise of the powers conferred upon you, —
c. to include in any discussion papers prepared and published by you all or any of that evidence or information; and
d. to publish or otherwise disclose in such other ways as you think fit all or any of that evidence or information:

6. Reporting date

And, using all due diligence, you are required to report to His Excellency the Governor-General in writing under your hands, not later than 1 June 2001, your findings and opinions on the matters aforesaid, together with such recommendations as you think fit to make in respect of them:

7. Extending time within which the Royal Commission on Genetic Modification may report

We do by these presents extend, until 27 July 2001, the time within which you are so required to report without prejudice to the continuation of the liberty conferred on you by Our said Warrant to report your proceedings and findings from time to time if you should judge it expedient to do so.

Appendix 2 Timeline of Significant Events and Reports

Key events and documents are noted below in chronological order. More information can be found in Sustainable Future's on-line archives at http://www.sustainablefuture.info.

Date	Significant Event
1978	Cabinet appoints an Advisory Committee on Novel Genetic Techniques (ACNGT)
1978	Moratorium on field release of genetically modified organisms is established
1986	Field Release Working Party established
1987	Field Release Working Party releases final report
1988	Moratorium on field release of genetically modified organisms lifted
1988	Minister for the Environment establishes the Interim Assessment Group (IAG)
1993	Biosecurity Act passed
1996	Hazardous Substances and New Organisms (HSNO) Act passed
1996	The Environmental Risk Management Authority (ERMA) established
1998	IAG disestablished
1998	ACNGT disestablished
1998	HSNO (Methodology) Order
1998	Previous IAG decisions reassessed by ERMA
1999	Radical Green group the 'Wild Greens' trashes a field test crop of GM potatoes at Lincoln University's Crop and Food Research Institute
1999 May	Independent Biotechnology Advisory Committee (IBAC) established
1999 December	Decision to form a Royal Commission on Genetic Modification announced from the throne at the Opening of Parliament
2000 January	Cartagena Protocol on Biosafety to the Convention on Biological Diversity signed
2000 14 June	Moratorium on applications to field-test or release genetically modified organisms announced
2000 November	Discovery that a shipload of GM corn seed had been planted in three regions of New Zealand. After initially intending to destroy the crops, the government reverses its decision and clears them for harvesting and sale
2001 April	Statistics New Zealand releases the report *Modern Biotechnology Activity in New Zealand*

Date	Significant Event
2001 May	High Court decision, Bleakley vs. ERMA, in Bleakley's favour, meaning that the AgResearch approval for GM cattle research would be reassessed by ERMA
2001 May	Press release from AgResearch concerning the High Court decision states that 'The decision … is disappointing and will be frustrating for MS sufferers'
2001 July	Lincoln University Commerce Division releases the discussion paper *Economic Analysis of Issues Surrounding Commercial Release of GM Food Products in New Zealand*
2001 August	Lincoln University Agribusiness and Economics Research Unit releases *Environmental Beliefs and Farm Practices of New Zealand Organic, Conventional and GE Intending Farmers*
2001 August	Harvested crop product tests positive for GM material (detected as a result of industry QA)
2001 October	Moratorium on applications to release GM organisms is extended to 2003, but moratorium on field tests is lifted
2001 October	Government releases a Cabinet Minute of Decision in initial response to the Recommendations of the Royal Commission on Genetic Modification
2001 November	Government releases a series of six Cabinet papers as a response to the Recommendations of the Royal Commission on Genetic Modification
2002	IBAC disestablished to make way for the Bioethics Council
2002 February	AgResearch releases a Statement to the Finance and Expenditure Committee regarding the moratorium on applications to field-test GMO and possible resulting commercial prejudice
2002 February	W McGuinness writes a letter to Mark Peck regarding AgResearch's Statement to the Finance and Expenditure Committee
2002 May	HSNO amendment (Genetically Modified Organisms) Act (2002) passed
2002 July	*Seeds of Distrust* by Nicky Hager is published. It claims there was a cover-up by the government during the 2000 GM corn scare
2002 August	Presence of GM maize seeds detected in crops harvested in Gisborne and Pukekohe earlier in the year (detected as a result of industry QA)
2002 October	MoRST releases a discussion document on the Biotechnology Strategy for New Zealand
2002 October	*A Review of the Handling of the GM Maize Incident at Gisborne and Pukekohe: August–October 2002* (McGregor, 2002) is prepared for MAF and ERMA
2002 December	The government establishes the Bioethics Council

Date	Significant Event
2003	Ministry for the Environment (MfE) releases a series of eight Cabinet papers entitled *The Government's Response to the Report of the Royal Commission on Genetic Modification: Legislative Changes for New Organisms*
2003	Ministry of Agriculture and Forestry (MAF) releases two Cabinet papers entitled *The Government's Response to the Report of the Royal Commission on Genetic Modification: Report on Managing the Effects of GM Organisms in Primary Production*
2003 March	MfE releases *A Review of the Capability of the Environmental Risk Management Authority (ERMA) Relating to the Risk Management of New Organisms*
2003 March	Treasury releases the report *Briefing on Genetic Modification Economic Analysis*
2003 April	MfE and Treasury release the report *Economic Risks and Opportunities from the Release of Genetically Modified Organisms in New Zealand*
2003 May	Cook and Fairweather research report released: *Change in New Zealand Farmer and Grower Attitudes towards New Zealand Biotechnology Strategy Gene Technology: Results from a Follow Up Survey*
2003 May	Fairweather, Maslin, Gossman and Campbell research report released: *Farmer Views on the Use of Genetic Engineering in Agriculture*
2003 May	Biotechnology Taskforce releases the report *Growing the Biotechnology Sector in New Zealand*
2003 May	Ministry of Research, Science and Technology (MoRST) releases *The New Zealand Biotechnology Strategy*
2003 June	PPL Therapeutics 'pulls the plug' on its New Zealand GM sheep field-test after Bayer Healthcare withdraws from the project
2003 July	High Court decision, MAdGE vs. Minister for the Environment, over human genes in GM cattle. Ruling is in the Minister for the Environment's favour
2003 July	GM is discovered in sweetcorn product imported to Japan from New Zealand
2003 August	Report published: *Economic Impacts on New Zealand of GM Crops: Result from Partial Equilibrium Modelling*, by Caroline Saunders, William Kaye-Blake and Selim Cagatay
2003 September	ERMA releases a draft of its proposed revisions of the *ERMA New Zealand HSNO Methodology (1998)* for public comment
2003 September	MoRST releases a report: *Implementing the Government's Response to the Royal Commission on Genetic Modification's Recommendations on Research Priorities*
2003 October	New Organisms and Other Matters Bill is passed, including the HSNO Amendment Act (2003)

Date	Significant Event
2003 October	Moratorium on applications to field-test or release GM organisms lifted
2004 January	Bioethics Council releases *Reflections on the Use of Human Genes in Other Organisms: Ethical, Spiritual and Cultural Dimensions*
2004 March	HSNO Amendment (Transitional Provisions and Controls) Act (2004) passed
2004 March	Duncan E. J. Currie releases *Liability for Damage from Genetic Modification*
2004 March	A MAF audit of Biogenetic Services Ltd Laboratory (in the US) finds significant issues with the way GM test results were reported for seed imported the previous season. Retesting of some imported seed finds it to be positive for a GM construct. At the time of detection the crops were close to harvest and the grain produced was harvested, dried, stored and devitalised under supervision
2004 March	*Community Management of GMOs: Issues, Options and Partnership with Government*, commissioned by the Inter-council Working Party on GMO Risk Evaluation and Management Options and prepared by Simon Terry Associates, is released.
2004 June	MfE releases *Genetic Modification: The New Zealand Approach*
2004 July	Sustainability Council of New Zealand releases *Seeding Purity: Improving Practices to Avoid GM Contamination of Seed Imports*
2004 August	Bioethics Council releases *The Cultural, Ethical and Spiritual Dimensions of the Use of Human Genes in Other Organisms*
2004 October	Government releases the report *Local Government and Environment Committee Inquiry into the Alleged Accidental Release of Genetically Engineered Sweetcorn Plants in 2000 and the Subsequent Actions Taken*
2004 December	High Court decision, Bleakley vs. ERMA, MAF, MfE and Whakamaru Farms Ltd, in favour of ERMA, MAF, MfE and Whakamaru Farms Ltd, meaning the decision not to reassess controls on the PPL sheep field test and post-field test monitoring practices would not be reviewed
2005 January	Bioethics Council discussion document released: *The Cultural, Spiritual and Ethical Aspects of Xenotransplantation: Animal-to-Human Transplantation*
2005 March	Dr R.J. Somerville QC writes a letter to Mr G.J. Mathias regarding Opinion on Land Use Controls and GMOs
2005 May	*Community Management of GMOs II: Risks and Response Options*, commissioned by the Inter-council Working Party on GMO Risk Evaluation and Management Options and prepared by Simon Terry Associates and Mitchell Partnerships, is released.

Date	Significant Event
2005 July	GM presence in a shipment of maize is detected. Tests determine that the positive result was caused by accidental mixing of the maize with GM soy. The GM construct in the soy had been approved for human consumption by Food Standards Australia New Zealand
2005 August	Bioethics Council releases its report *The Cultural, Spiritual and Ethical Aspects of Xenotransplantation: Animal-to-Human Transplantation*
2005 November	Dr Kerry Grundy releases a *Briefing Paper on GE Initiative*
2006 February	Sustainability Council of New Zealand report released: *Brave New Biosecurity: Realigning New Zealand's Approach to the Cartagena Protocol*
2006 June	MoRST report released: *Research and Development in New Zealand: A Decade in Review*
2006 December	MAF discovers contamination in some consignments of corn seed imported into New Zealand during October and November 2006. These had been accompanied by test certificates showing positive results for the presence of GM organisms and had been cleared in error at the border
2007 January	*Inquiry into the Circumstances Associated with the Imports of Certain Corn Seeds in Late 2006* prepared by David Oughton for MAF in response to the 2006 GM corn security breach
2007 July	Whangarei District Council media release 'Responsibility for GE clean-ups would land on local government and local land owners'
2008 January	AgResearch announces intention of applying for new approvals to continue their transgenic cattle research. The existing approvals expire November 2008.
2008 January	'GE protesters chopped down trees at Scion research institute' (2008)

Appendix 3 Summary of Changes to the HSNO Act

Source: Hazardous Substances and New Organisms Act 1996 (NZ Govt, 1996)

The purpose of this appendix is to clarify:

(A) the purpose of the HSNO Act and subsequent amendments, and

(B) the associated regulations.

A: Hazardous Substances and New Organisms Act 1996 and Amendments

Hazardous Substances and New Organisms Act 1996

PART II - Purpose of Act

4. Purpose of Act---The purpose of this Act is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms.

5. Principles relevant to purpose of Act---All persons exercising functions, powers, and duties under this Act shall, to achieve the purpose of this Act, recognise and provide for the following principles:

(a) The safeguarding of the life-supporting capacity of air, water, soil, and ecosystems:

(b) The maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural wellbeing and for the reasonably foreseeable needs of future generations.

6. Matters relevant to purpose of Act---All persons exercising functions, powers, and duties under this Act shall, to achieve the purpose of this Act, take into account the following matters:

(a) The sustainability of all native and valued introduced flora and fauna:

(b) The intrinsic value of ecosystems:

(c) Public health:

(d) The relationship of Māori and their culture and traditions with
   i. their ancestral lands, water, sites, waahi tapu, valued flora
   ii. and fauna, and other taonga:

(e) The economic and related benefits to be derived from the use of a
   iii. particular hazardous substance or new organism:

(f) New Zealand's international obligations.

HSNO Amendment Act 1999

Clarification of definition of New Organism and approval and enforcement processes.

HSNO Amendment Act 2000

Clarification of application process. Also inserts section 67A (which came into operation 1 July 2001).

67A Minor or technical amendments to approvals

The Authority may, of its own motion, amend any approval given by it under this Part if it considers that the alteration is minor in effect or corrects a minor or technical error.

HSNO (GMO) Amendment Act 2002

The purpose of this Act is—

(a) to require the Environmental Risk Management Authority (the Authority) to consider additional matters when considering certain applications in relation to genetically modified organisms and, if it approves the applications, to include particular controls for field tests and certain developments; and

(b) to impose a restriction, from 29 October 2001 to the close of 29 October 2003, on the Authority considering or approving applications to import new organisms for release or to release new organisms from containment if the new organisms are genetically modified organisms; and

(c) to provide exceptions to the restriction; and

(d) to provide transitional provisions for approved applications relating to certain genetically modified organisms.

This amendment also introduced a definition called genetic element.

genetic element, in relation to a new organism, means—

(a) heritable material; and

(b) any genes, nucleic acids, or other molecules from the organism that can, without human intervention, replicate in a biological system and transfer a character or trait to another organism or to subsequent generations of the organism (s10 Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2002)

HSNO Amendment Act 2003

The purpose of this Act is—

(a) to make certain changes to the Hazardous Substances and New Organisms Act 1996, including—

(i) streamlining the approval of the genetic modification of new organisms in laboratories; and

(ii) providing for the approval of the conditional release of new organisms; and

(iii) clarifying enforcement responsibilities; and

(b) to improve the operation of the Hazardous Substances and New Organisms Act 1996 for new organisms.

HSNO (Approvals and Enforcement) Amendment Act 2005

This Act amends the Hazardous Substances and New Organisms Act 1996 in the areas including:

(i) Regulation and controls regarding Hazardous Substances
(ii) Enforcement of the Act
(iii) Codes of Practice
(iv) Approvals

HSNO Amendment Act 2007

This Act amends the Hazardous Substances and New Organisms Act 1996 in the areas of:

(i) Powers, functions, and duties of Authority
(ii) Requirements for containers, identification, disposal, emergencies, tracking, and fireworks
(iii) The omitting of the term Manufacture from the pecuniary penalty order and Civil liability sections

B: Hazardous Substances and New Organisms Act 1996 — Regulations

Hazardous Substances and New Organisms (Methodology) Order 1998

Sets out the Methodology to be used by ERMA for making decisions under part 5 of the HSNO Act.

Hazardous Substances and New Organisms (Personnel Qualifications) Regulations 2001

Sets out regulations for required qualifications for personnel who are handling, enforcing and certifying under the HSNO Act.

Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998

Defines an organism that is not regarded as genetically modified.

Hazardous Substances and New Organisms (New Organisms Forms and Information Requirements) Regulations 1998

Sets out regulations for applications, application forms and processes surrounding these under the HSNO Act.

Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003

(i) Defines 'Low Risk' and categories A and B under 'Low Risk' and the regulations surrounding them.
(ii) Defines host organisms and the categories surrounding them.
(iii) Replaces the HSNO (Low Risk Genetic Modification) Regulations 1998.
(iv) Defines developments that are not low risk.

Appendix 4 The Royal Commission Public Engagement Process

Source: RCGM, 2001b: 157-161

The Commissioners conducted a comprehensive public engagement process, the main facets of which are detailed below.

Background papers: To aid in identifying key questions and issues for the Commission to address, nine background papers were requested on major issues considered relevant to the inquiry.[67] These were presented to the Commissioners in their initial weeks on the job.

Scoping meetings: The public consultation began with a series of scoping meetings. These were held with the intention of gaining an understanding of the potential issues that would be raised in submissions, to help prevent issues additional to those already identified being overlooked in deliberations. The process also provided information to participants; this information was also communicated online.

Interested Persons: A process of formal hearings was established for 'Interested Persons'. Interested Persons were entitled to be heard and able to apply to cross-examine other submitters (RCGM, 2000). Many persons and organisations were excluded on the basis that their interest was no different 'apart from any interest in common with the public'. This was a significant concern to doctors and scientists, and many representatives of iwi and hapū who were not given Interested Person status.

> Organisations wanting to tamper with genes had gained status whereas organisations specifically set up to provide expert advice on gene technology and others with a specific interest in the impacts of gene technology had been denied status (Keown, 2000).

A call for applications for Interested Person status was placed in 22 national newspapers on 29 July 2000. By the closing date six days later (4 August 2000), 265 applications had been received; this later increased to 292. On 14 September 2000, after multiple hearings, 117 applicants were awarded Interested Person status. Submissions and witness briefs were then received. From 16 October 2000, formal hearings took place for 12 weeks during which 107 people gave presentations. In March 2001, legal submissions and new or rebuttal evidence were heard.

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67 These papers were: *Current Uses*, Professor A.R. Bellamy; *Legal Aspects*, Helen Atkins; *Ethical Issues*, Dr Barbara Nicholas; *Public Perceptions*, Joanna Gamble; *Māori Aspects*, Bevan Tipene Matua; *Environmental Aspects*, Dr Lin Roberts; *Economics*, Dr Janice Wright; *Human Health Aspects*, Dr Michael Berridge, and *International Aspects of Genetic Modification*, Ministry of Foreign Affairs and Trade (RCGM, 2001b: 190–93).

Wider public consultation: The Warrant required the Commission to consult with the New Zealand public in a way that allowed them to express their views clearly. Not all people who held a strong view could gain Interested Person status, so a series of less formal public meetings was set up. These meetings consisted of a workshop with an open floor and question time. Fifteen meetings were held in main centres throughout New Zealand between 18 September 2000 and 4 November 2000.

There was also a call for submissions from the public. This was notified via news releases, public notices and through the public meetings, with a closing date of 1 December 2000 stipulated. In total 10,904 submissions were received from members of the New Zealand public. A telephone survey of 1153 New Zealanders was also conducted by BRC Marketing and Social Research between 22 March and 8 April.

Māori consultation: The Warrant specified that the Commission should engage and consult with Māori as part of their inquiry. On 21 July 2000 an initial hui was held to seek input into defining an appropriate consultation process for Māori. This led to a programme of 28 regional workshops, 10 regional hui and one national hui between 24 October 2000 and 10 March 2001. During this time a wide range of views and submissions were heard from Māori.

Youth forum: The Commission wished to consult with youth as part of its strategy to engage with the New Zealand public. It was felt that the outcome of this inquiry would particularly impact on this age group. In Wellington on 5 March 2001, a one-day forum involving role-play, brainstorming, workshops and discussion was attended by 99 young people aged 12–25 years.

Appendix 5 New Zealand Society for Risk Management

Source: NZSRM, 2001. Press Release: 4: 54pm, 3 August 2001.

The New Zealand Society for Risk Management has responded to the report of the Royal Commission on Genetic Modification, expressing disappointment that the inquiry did not follow recognised best practice in risk management.

Formed late last year, and with a membership of over 200 professionals from the private, government and academic sectors, the Society aims to improve the knowledge and practice of risk management in New Zealand. For more details, see the Society's website at http://www.risksociety.org.nz.

The Society's spokesperson Karen Price, says that genetic modification clearly has the potential to deliver benefits to society but there are uncertainties as to the extent of those benefits and the extent and likelihood of adverse effects.

'GM poses risks. As with any risk, it is important to understand the context in which it occurs, which includes the wellbeing of present and future New Zealanders and the environment. There are recognised methods through which those risks can be identified and treated so that socially preferred outcomes are more likely — and less desirable outcomes are avoided or reduced. We are disappointed that an explicit risk management model was not able to be used. This has reduced the potential usefulness of the inquiry — and leaves a range of issues still to be resolved.'

The Society notes that the Royal Commission was an eminent panel and has produced an extensive report; however, it has done so within the constraints of the Terms of the Order in Council provided by the Government. The Society has doubts about how far the principles of risk management were specified in those terms of reference and applied by the Commission.

'It is unfortunate that the Order in Council did not require the Commission to adopt an explicit risk management process, as set down in Australia/New Zealand Standard 4360:1999 for Risk Management. This would have exerted greater rigour in the work of the Commission — for example requiring the panel to state the criteria they were using and the weightings applied to different risks.'

Technological developments, such as GM, are best managed after identifying the full context of possible effects, both positive and negative — and the risks of those effects. In this case, the context is the wellbeing of all New Zealanders and the future viability of our ecological and agricultural systems. It clearly includes a wide spectrum of interests. The Commission has made efforts to evaluate and reflect those viewpoints but it has not identified the extent to which it has captured the full balance of social objectives.

Risks cannot be assessed or treated unless there is a clear understanding of both likelihood and consequences; the uncertainties involved; and how those risks rank with other risks accepted by the community.

The Commission has recorded information from submitters on the risks of GM but has not always provided sufficient analysis of the risks e.g. for the environment and human health.

The Report has discussed one of the more significant risks from genetic technologies, that of legal liability for both foreseeable and unanticipated damage — but the Society considers that there are still many important issues to be resolved.

The Report of the Royal Commission should be seen as a beginning and not an end in this process. It has set ambitions targets for the Government and in fact the whole community.

The Society hopes that in considering the Report the Government will more explicitly adopt a risk management framework.

This would include:

- Identifying the risks posed by different forms and uses of genetic technology.
- Assessing those risks in the light of uncertainty and consequence — and considering levels of social acceptance.
- Prioritising the risks involved, including those that should be either avoided altogether of accepted subject to appropriate management.
- Identifying appropriate treatment for specific risks.
- Actively involving the community in discussion and education on the nature of the various risks and their management.

The Society and its members welcome the challenge presented by the Royal Commission's Report and look forward to playing an active role in encouraging the use of sound risk management practices to underpin development of practical management solutions around the risks of genetic modification.

Appendix 6 Applications for Outdoor Experiments in Date Order: 1997—Today

Source: FRST, 2007; ERMA, 2007c; AgResearch, 2007; Scion, 2007 and Crop and Food, 2007

Application Code	Year decision made by IAG or ERMA	Applicant	Cost to Applicants[68]	Funding from FRST?[69]	FRST contract $ from which funds were derived for this application[70]	FRST Contract Number[71]	Year of Contract
IAG42	1996	Monsanto	Unknown	Not Requested	n/a[72]	n/a	n/a
IAG43	1996	Aventis	Unknown	Not Requested	n/a	n/a	n/a
IAG45	1997	Scion[73]	Unknown	Not Requested	n/a	n/a	n/a
IAG51	1997	HortResearch	Unknown	Not Requested	n/a	n/a	n/a
IAG60	1997	Monsanto	Unknown	Not Requested	n/a	n/a	n/a
GMR98001	Withdrawn	Monsanto	0	Not Requested	n/a	n/a	n/a
GMF98001	1999	PPL Therapeutics (NZ) Ltd	$10,627.25	Not Requested	n/a	n/a	n/a
GMF98002	1999	Crop & Food	$2,563.78	Not Requested	n/a	n/a	n/a
GMF98004	1998	Betaseed Inc	$6,364.86	Not Requested	n/a	n/a	n/a

68 ERMA, 2007c.

69 Sustainable Future only made requests to AgResearch, Scion and Crop and Food for confirmation of funding received from FRST (see AgResearch, 2007; Scion, 2007; Crop and Food, 2007).

70 FRST, 2007a, AgResearch, 2007; Scion, 2007; Crop and Food, 2007. The funding shown in this table is the complete total of each contract. However each contract may fund multiple experiments and therefore each application may only be funded from part of a total contract.

71 FRST, 2007.

72 These have been labelled n/a both when funding was not received by FRST and when this data was not requested by Sustainable Future.

73 Formerly the Forest Research Institute.

Application Code	Year decision made by IAG or ERMA	Applicant	Cost to Applicants[68]	Funding from FRST?[69]	FRST contract $ from which funds were derived for this application[70]	FRST Contract Number[71]	Year of Contract
GMF98005	1999	Pioneer NZ Ltd	$3,275.87	Not Requested	n/a	n/a	n/a
GMF98006	1999	Pioneer NZ Ltd	$3,250.47	Not Requested	n/a	n/a	n/a
GMF98007	1998	Crop and Food	$3,167.77	Yes	$112,449[74] $234,136	CO2X0017 CO2X0212	2001/02 2002/03
GMF98008	1998	Crop and Food	$3,212.77	Yes	$112,449[75] $234,136	CO2X0017 CO2X0212	2001/02 2002/03
GMF98009(i), (ii) and (iii)	1999 and 2001	AgResearch	$15,892.02	Yes	$440,500 $300,300 $1,188,057 $1,259,720	C10X0010 C10X0010 C10X0305 C10X0305	2001/02 2001/02 2003/04 2004/05
GMF98010	1999	AgResearch	$2,513.32	No	n/a	n/a	n/a
GMF98011	1999	Carter Holt Harvey Ltd	$3,994.36	Not Requested	n/a	n/a	n/a
GMD99003	2000	NZ King Salmon Company Ltd	$1,153.46	Not Requested	n/a	n/a	n/a
GMF99003	Withdrawn	Monsanto	$96,524.12	Not Requested	n/a	n/a	n/a
GMF99004	2000	AgResearch	$84,978.60	No	n/a	n/a	n/a
GMF99001	2000	Scion	$74,384.72	Yes	$450,000[76]	CO4X207	2006/07
GMF99005	2000	Scion	$67,582.45	Yes	$450,000[77]	CO4X207	2006/07

[74] See footnote 70.

[75] See footnote 49.

[76] See footnote 70. The total contract is for $2.7 million but only $450,000 is allocated to GMF99001 and GMF99005. This portion of the funding is also for public outreach programmes and Māori engagement activities as well as field trial research on environmental impacts. (Scion, 2007)

Application Code	Year decision made by IAG or ERMA	Applicant	Cost to Applicants[68]	Funding from FRST?[69]	FRST contract $ from which funds were derived for this application[70]	FRST Contract Number[71]	Year of Contract
GMD01194	Withdrawn	AgResearch	$58,921.40	No	n/a	n/a	n/a
GMD02028	2002	AgResearch	$107,043.13	Yes	$1,188,057 $1,259,720	C10X0305 C10X0305	2003/04 2004/05
GMF03001	2003	Crop & Food	$110,000 (approx)	No	n/a	n/a	n/a
GMF06001	2007	Crop & Food	$39,375	No [78]	n/a	n/a	n/a

[77] See footnote 49.

[78] 'The public has misconceptions about funding for the new project, Dr Williams says. "A lot of people say it's coming from the Government. It's not – it's coming from other companies, New Zealand companies" ' ('Dusting off a crop of trouble', 2007).

Appendix 7 Proposals for Amendments under Section 67A

Source: ERMA, 2008d

This appendix provides details on field tests and developments which are (i) currently operating in the outdoors and (ii) ERMA has approved amendments under section 67A of the HSNO Act 1996. This information is publicly available on the ERMA NZ website (ERMA, 2008d).

> 67A Minor or technical amendments to approvals
> The Authority may, of its own motion, amend any approval given by it under this Part if it considers that the alteration is minor in effect or corrects a minor or technical error (NZ Govt, 1996: S67A).

Proposals for amendments under section 67A of the HSNO Act (1996)

Application Code	Approval Holder	Purpose of Application	Date of ERMA Approval of Initial Application	Purpose of Amendment	Date of Amendment Request
GMF98009	New Zealand Pastoral Agricultural Research Institute Ltd (AgResearch)	To field test, in Waikato, genetically modified cattle with extra bovine genes, the insertion of the human myelin basic protein gene, and the deletion of the bovine beta-lactoglobulin gene. Genes will be expressed in the milk of the cattle	18 November 1999	To extend the duration of the approval for a period of three years	4 November 2005
GMF98009 Part II	New Zealand Pastoral Agricultural Research Institute Ltd (AgResearch)	To field test, in Waikato, cattle genetically modified with the human myelin basic protein gene; genes will be expressed in the milk of the cattle	Date decision notified: 23 May 2001	To extend the duration of the approval by four years.	10 May 2006

Application Code	Approval Holder	Purpose of Application	Date of ERMA Approval of Initial Application	Purpose of Amendment	Date of Amendment Request
GMF98009	New Zealand Pastoral Agricultural Research Institute Ltd (AgResearch)	To field test, in Waikato, genetically modified cattle with extra bovine genes, the insertion of the human myelin basic protein gene and the deletion of the bovine beta-lactoglobulin gene. Genes will be expressed in the milk of the cattle	18 November 1999	To extend the duration of the approval for a period of three years	4 November 2005
GMD02028	New Zealand Pastoral Agricultural Research Institute Ltd (AgResearch)	Development in containment by AgResearch of genetically modified *Bos taurus* (cattle) cells and animals that can express functional therapeutic foreign proteins in their milk, and to develop genetically modified cattle to study gene function and genetic performance	30 September 2002	To allow AgResearch to use two functional sequence elements currently excluded by the organism description, namely (i) loxP sites derived from the bacteriophage P1 and (ii) a poly adenylation sequence derived from Simian Virus 40 (SV40 polyA).	October 2007
GMF03001	New Zealand Institute for Crop & Food Research Limited	To field-test onions modified for tolerance to the herbicide glyphosate, and to evaluate their environmental impact; herbicide tolerance; agronomic performance; development as cultivars and equivalency to non-genetically modified onions	18 December 2003	To make amendments to the controls that will allow the test to proceed more efficiently and produce more relevant data	16 August 2005

Appendix 8 Outdoor Experiment Status by Entity: 1997—2007

Source: ERMA, 2007a

Entity	Description of Application					Applications Received By ERMA			Approved Field Tests				
1. Crown Research Institutes	Application Code	GM Organism	Date of Decision	Date Approval Expires	Number of Submissions Received	ERMA Status: Being Assessed	ERMA Status: Withdrawn	ERMA Status: Declined	Recently Approved But awaiting GMO	App roved & Started	Finished But Controls Still Apply	Finished But No Controls Apply	Approved But Never Started
AgResearch	**GMF98009 (i) & (ii)**	Cattle	Nov 1999	Nov 2008	30					✓			
AgResearch	**GMF98009 (iii)**	Cattle (BF)	May 2001	May 2010	30					✓			
AgResearch	**GMF98010**	Hydatids vaccine	June 1999	Not Stated	2								✓
AgResearch	**GMF99004**	Sheep (BF)	Oct 2000	Oct 2005	80								✓
AgResearch	**GMD01194**	Cattle (BF)	Withdrawn	N/A	383		✓						
AgResearch	**GMD02028**	Cattle (BF)	Sept 2002	March 2010	863					✓			
Crop & Food	**GMF98002**	Petunia	March 1999	Feb 2000	8							✓	
Crop & Food	**GMF98007**	Potatoes	Dec 1998	June 2003	17							✓	
Crop & Food	**GMF98008**	Potatoes	Dec 1998	June 2003	17							✓	
Crop & Food	**GMF03001**	Onions	Dec 2003	Dec 2013	1933					✓			
Crop & Food	**GMF06001**	Brassicas[79]	May 2007	10 years[80]	959				✓[81]				

[79] Being GM cabbages, cauliflower, broccoli and forage kale (ERMA, 2007d:9)

[80] 10 years from date of planting.

Entity	Description of Application					Applications Received By ERMA			Approved Field Tests				
1. Crown Research Institutes	**Application Code**	**GM Organism**	**Date of Decision**	**Date Approval Expires**	**Number of Submissions Received**	**ERMA Status: Being Assessed**	**ERMA Status: Withdrawn**	**ERMA Status: Declined**	**Recently Approved But awaiting GMO**	**App roved & Started**	**Finished But Controls Still Apply**	**Finished But No Controls Apply**	**Approved But Never Started**
Scion	**IAG 45**[82]	*Pinus radiata*	Jan 1997	Jan 2003	-							✓	
Scion	**GMF99001**	*Pinus radiata*	Dec 2000	Dec 2020	735					✓			
Scion	**GMF99005**	*Pinus radiata* and Norway spruce	Dec 2000	Dec 2009	735					✓			
Hort Research	**IAG 51**	Tamarillo	Jan 1997	Jan 2001								✓	

[81] We understand the Brassicas have been planted or are to be planted in early 2008.

[82] The Interim Assessment Group was the body that assessed applications before the establishment of ERMA. Under the IAG, public submissions were not called for.

Entity	Description of Application					Applications Received By ERMA			Approved Field Tests				
2. NZ-owned Companies (75+%)	**Application Code**	**GM Organism**	**Date of Decision**	**Date Approval Expires**	**Number of Submissions Received**	**ERMA Status: Being Assessed**	**ERMA Status: Withdrawn**	**ERMA Status: Declined**	**Recently Approved But awaiting GMO**	**App roved & Started**	**Finished But Controls Still Apply**	**Finished But No Controls Apply**	**Approved But Never Started**
The NZ King Salmon Co Ltd	**GMD99003**	Chinook salmon	Feb 2000		See note [83]						✓[84]	✓	
Betaseed Inc[85]	**GMF98004**	Sugar beet	Nov 1998	Dec 2000	9							✓	
Carter Holt Harvey Limited	**GMF98011**	Pine trees	Dec 1999	June 2003	13								✓[86]

[83] The public were not invited to make submissions.

[84] Development stopped but frozen semen remains.

[85] Completed by Kimihia Research Centre on behalf of Betaseed.

[86] However, the shade house part of the experiment continued.

Entity	Description of Application					Applications Received By ERMA			Approved Field Tests				
3. International Companies (less than 25% owned by NZ interests)	**Application Code**	**GM Organism**	**Date of Decision**	**Date Approval Expires**	**Number of Submissions Received**	**ERMA Status: Being Assessed**	**ERMA Status: Withdrawn**	**ERMA Status: Declined**	**Recently Approved But awaiting GMO**	**App roved & Started**	**Finished But Controls Still Apply**	**Finished But No Controls Apply**	**Approved But Never Started**
PPL[87]	**GMF98001**	Sheep[88]	March 1999	Not stated	30						✓		
Monsanto	**GMR98001**[89]	Canola	Withdrawn	N/A			✓						
Monsanto	**GMF99003**	Roundup Ready wheat	Withdrawn	N/A	1411		✓						
Monsanto (CropMark)	**IAG 60**	Roundup Ready canola	Nov 1997	Nov 1998							✓		
Monsanto (CropMark)	**IAG 42**	Roundup Ready canola	Nov 1996	Nov 1997								✓	
Aventis[90]	**IAG43**	Canola	Nov 1996	Nov 1997								✓	
Pioneer NZ Ltd	**GMF98005**	Maize	Oct 1999	[91]	10								✓
Pioneer NZ Ltd	**GMF98006**	Maize	Oct 1999	[92]	9								✓

87 PPL Therapeutics (NZ) Ltd.

88 Being an insertion of an artificial gene based on a gene of human origin (BF).

89 Application to import for GM release canola with resistance to Roundup herbicide. Although an application number was given, a formal application was never received by ERMA.

90 Plant Genetic Systems (PGS), Belgium.

91 Not specified in controls.

92 Not specified in controls.

Appendix 9 Research on Public Attitudes

The following list of research on attitudes towards genetic modification in the New Zealand public or particular demographics is indicative but not exhaustive.

Cook, A., & Fairweather, J. (2003). *Change in New Zealand Farmer and Grower Attitudes towards Gene Technology: Results from a Follow Up Survey.* Retrieved 5 February, 2008 from http://www.lincoln.ac.nz/story_images/604_RR259AC_s2655.pdf

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Cook, A., & Fairweather, J. (2006). *Nanotechnology - Ethical and Social Issues: Results from a New Zealand Survey.* Retrieved 5 February, 2008 from http://www.lincoln.ac.nz/story_images/2679_RR289_s7764.pdf

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