September 2013

Report 16

2058

An Overview of Genetic Modification in New Zealand 1973–2013

The first forty years

MCGUINNESS INSTITUTE

Project 2058: Report 16

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The first forty years

This report forms part of *Project 2058*, the Institute's flagship project

Title

An Overview of Genetic Modification in New Zealand 1973–2013: The first forty years

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About the Institute

The McGuinness Institute is an independently funded non-partisan think tank. The Institute's flagship project is *Project 2058*. The strategic aim of this project is to promote integrated long-term thinking, leadership and capacity-building so that New Zealand can effectively seek and create opportunities and explore and manage risks over the next 50 years. It is hoped that *Project 2058* will help develop dialogue among government, policy analysts and members of the public about alternative strategies for the future of New Zealand.

About the authors

Wendy McGuinness is the founder and chief executive of the McGuinness Institute. Originally from the King Country, Wendy completed her secondary schooling at Hamilton Girls' High School and Edgewater College. She then went on to study at Manukau Technical Institute (gaining an NZCC), University of Auckland (BCom) and the University of Otago (MBA), as well as completing additional environmental papers at Massey University. As a Fellow Chartered Accountant (FCA) specialising in risk management, Wendy has worked in both the public and private sectors. In 2004 she established the Sustainable Future Institute as a way of contributing to New Zealand's long-term future. Since 2012 the Institute has been known as the McGuinness Institute.

Renata Mokena-Lodge graduated from Victoria University of Wellington with an LLB in 2013. She has worked at the McGuinness Institute as a research analyst since completing her degree in February.

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This report could not have been written without the considerable work of the Institute's research team and ongoing feedback from interested parties. We are particularly grateful for the work of former Institute staff members Miriam White and Steph Versteeg, who assisted Wendy McGuinness with the 2008 report *History of Genetic Modification in New Zealand*.

We would like to thank all those who helped us access information for the report, in particular the Crown Research Institutes; the Environmental Protection Authority; Food Standards Australia New Zealand; GE Free New Zealand; the Ministry of Business, Innovation and Employment, the Ministry for the Environment and the Ministry of Primary Industries.

Lastly, we would like to thank Professor Richard J Wilkins and Dr J. Morgan Williams, two scientists who have worked hard to contribute to the dialogue on genetic modification.

Foreword

Ki te kahore he whakakitenga ka ngaro te iwi

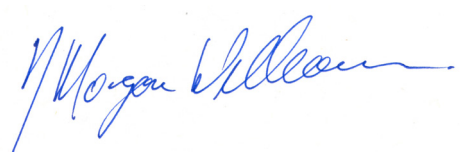
Without foresight or vision the people will be lost

The last forty years of scientific exploration into our genetic foundations could be considered humanity's greatest era of discovery – one that is potentially fundamental to our survival as a species. It has exponentially expanded our understanding of genetic functionality and thus our capacity to modify genes to address some of society's needs and wants. In doing so it has generated major policy challenges in terms of balancing the benefits, costs and risks of emerging genetic technologies. This is at a time when there is an increasing desire by civil society to have a greater say in the application of science and, in some fields, even what science.

The 2001 Royal Commission on Genetic Modification was a valuable response to the policy challenges and societal concerns about gene sciences and emerging technologies. And there are important lessons to be learned from the policies that have been developed over the subsequent 12 years. Being able to look back to gain an understanding of how policy reacts to something new is crucial in developing future strategy. Valuable institutional knowledge is easily lost and mistakes repeated when we do not recognise the importance of hindsight to inform our next decisions. Rigorous analysis of the past is a crucial part of shaping our future.

Despite the value of learning from past applications of science, no science organisation or public agency holding 'Interested Person' status with the 2001 Royal Commission provided any insights from the applications of other sciences that could help inform the Commission. There was agreement by some organisations that it would be useful, but it was not a priority for them. Such thinking does not serve the strategic uses of 21st century sciences – something New Zealand's future prosperity depends on.

There is an emerging debate on the value of institutional knowledge and learning from past experiences in New Zealand, and this report seeks to meaningfully contribute to this debate. Facilitating dialogue on such matters is critical if we are to truly advance policy development and evolution. So too is ensuring that we continue to ask the right questions as we seek to develop better foresight and more robust visions of the future we desire. As the playwright, Eugene Ionesco, renowned for asking questions, has said, 'It is not the answer that enlightens, but the question'. So true – lets not forget this simple observation.



Dr J. Morgan Williams,
Former Parliamentary Commissioner for the Environment, 1997–2007

Executive Summary

It is now 12 years since the report of the Royal Commission on Genetic Modification was released. After considering the options available to New Zealand, the Commissioners endorsed a compromise: a strategy to preserve opportunities and proceed with caution. It is timely to review what has essentially been an expensive and time-consuming exercise in public policy-making. The issue of genetic modification (GM) has provided a particularly interesting case study for policy development in relation to assessing and developing strategies for new technologies where the benefits and risks are uncertain.

The purpose of this report is two-fold. On the one hand it seeks to chronicle the history of GM in New Zealand and provide a record of the available data. On the other, it seeks to consider gaps in the current policy framework and provide a meaningful contribution to the continuing debate. The report consists of seven sections and is split into two main parts; the first part, comprising Sections 1 to 5, describes the historical landscape from the beginnings of the technology in the 1970s to the present day, while the second part, comprising Sections 6 and 7, looks at the Crown Research Institute (CRI) system and, suggests principles to guide its future, and concludes with a set of observations, recommendations and reflections. Importantly the focus of this report is on public policy, it does not aim to report on scientific developments in any detail.

The context of the report and its limitations are outlined in Section 1. Sections 2–5 document the history of GM in New Zealand, breaking it into four eras: the journey to the Royal Commission; the Royal Commission's inquiry; the response to the inquiry, and the current era of institutional change. These sections are supported by 16 appendices in order to provide a factual overview and historical commentary.

The journey toward the Royal Commission (see Section 2) started in the mid-1970s with the emergence and adoption of ground-breaking new technology. As a tool it offered benefits, but arguably it came with considerable risks to an agriculture-based economy. Public concern developed accordingly, and the result was the establishment of the Royal Commission on Genetic Modification in 2000.

The Commission was charged with considering the strategic options available to New Zealand to manage genetic modification, and its conclusions were published in a report in 2001 (see Section 3). During this time a pause was put on the outdoor use of genetically modified organisms (GMOs) while a deeper understanding of the risks and opportunities was developed. The Commission's report included 49 recommendations conceptualised to allow New Zealand to 'preserve opportunities' and retain optionality.

In Section 4 we present an overview of the response to the report of the Royal Commission and consider the subsequent implementation of the Commissioners' recommendations. This era saw both government acceptance of and public protest at the Commission's findings.

The most recent era spans the last five years, during which we have witnessed unprecedented institutional change in New Zealand (see Section 5). As of 2013 only two GM field tests are in operation in New Zealand, but there have been 57 since 1988. Not one of these has resulted in any commercial benefit or tangible return on the public's investment, while all experiments have presented a constant risk. Debates on this subject are often framed as a matter of balancing environmental protection and economic development. Could it be that in this case we have compromised environmental protection for promises of economic development and received neither?

Sections 6 and 7 are the only area of the report to draw conclusions and make suggestions going forward. In Section 6 we take a closer look at the three CRIs that have conducted the majority of GM research in the outdoors since the Royal Commission: AgResearch; Scion, and Plant & Food Research. In this section we also present five principles to drive the current system in order to deliver more effective public investment in the future. These five principles are:

1. Value for money;

2. Robust assessment, decisionmaking and monitoring by regulators;

3. Ethics should drive practice;

4. Timely reporting on controversial experiments is essential, and

5. A culture of due diligence is vital across science.

The overall goal of Section 7 is to assess whether the system fulfils its purpose, and if not, what the government must do to develop a better policy landscape and operational system to manage the benefits, costs and risks of GM in the outdoors. Twelve recommendations are discussed in Section 7, see summary recommendations overleaf. Section 7.1 identifies ten observations that can be made about the current operational framework. Section 7.2 provides our conclusions on the policy process thus far and provides 12 recommendations in response to perceived gaps in the current framework. Lastly, Section 7.3 presents a strategic reflection, bringing the report to a close by providing a narrative and context for future debate.

We found that many initiatives put in place after the Royal Commission have since been disestablished or not progressed. Since 2001, New Zealand has significantly reduced its ability to collect strategic information to make informed decisions on GM. For example, New Zealand has disestablished the Bioethics Council (2009); discontinued Futurewatch, a work programme of the Ministry of Research, Science and Technology (MoRST) (2011); discontinued the Bioscience Survey, a survey undertaken by Statistics NZ (2013); and have not reviewed or updated the Biotechnology Strategy, published in 2003 and due to expire this year.

We also found considerable evidence that the system is showing symptoms of fatigue. Largely due to the significant institutional change that has occurred in the last five years, information is not well collected or reported (see Section 7.2.5 for examples) and institutional knowledge and therefore analytical capability and linkages are likely to be significantly reduced (see in particular Figure 2 and Appendix 16).

Strategically, New Zealand is no further ahead on public policy regarding outdoor use of GMOs than it was when the Commissioners reported their findings in 2001. Indeed, we consider New Zealand is less equipped to make a strategic decision to release GMOs in the outdoors in 2013 than it was a decade ago.

We also identified a number of emerging issues that add to this sense of urgency:

1. Community concerns over the use of GM in food production are growing, that is now putting pressure on councils to address benefits, risks and costs in local plans. This is in line with overseas trends, particularly the European Union (see discussion in Section 7.2.6 and 7.2.11).

2. Food Standards Australia New Zealand (FSANZ) is continuing to approve increasing numbers of GM foods, raising issues over labelling and traceability (FSANZ provides a list of approved GM ingredients, but there is currently no list of food for sale in New Zealand containing those

ingredients). Further, an application for conditional or full release may not necessarily trigger a 'call-in' by the Minister if it is a FSANZ approved GM food.

3. If the Minister did decide to 'call-in' an application (see s 68 of the HSNO Act 1996), the resulting process is unclear. We suggest that the government is not ready to make such a strategic decision on the first release of a GM crop or fibre.

4. There are a range of emerging molecular plant breeding technologies on the horizon that may not come under the HSNO legislation. One that local developers AgResearch and Scion have expressed interest in is zinc finger nuclease (ZFN-1). In April 2013 a decisionmaking committee of the Environmental Protection Authority (EPA), in response to an application by Scion, reached a decision that ZFN-1 was outside of HSNO regulation (despite EPA staff recommending that these techniques should be considered similar to GM techniques, and not exempt from the regulations) (EPA, 2013: 3). This decision may be appealed but, as it currently stands, there would be no assessment of the public benefits, costs and risks as required under the HSNO legislation; nor would outdoor use of food or fibre crops generated by the tecnique be subject to any controls.

5. The upcoming Trans Pacific Partnership Agreement means New Zealand needs to think deeply about its position of GM crops and other uses.

The Royal Commission purposefully created a strategic pathway for New Zealand to follow. Twelve years later, with little evidence that significant commercial benefits exist for New Zealand through outdoor research, it seems timely to revisit the Commission's recommendation of preserving opportunities, and ask whether New Zealand would not be better to remain a GM-free food and fibre producer.

Our approach to GM crops in the outdoors would be threefold:

1. Buy time

Put in place a moratorium or require a field test before any GMO release

2. Undertake a systemic review

Ensure the current system is 'fit for purpose' by implementing the Institute's 12 recommendations

3. Think strategically

Revisit the original question: should New Zealand commit to becoming, a dedicated GM-free food and fibre producer?

Moving Forward

In the closing section of the report, Section 7.3, we reflect on the way forward. In discussing New Zealand's current position, we argue that we have one foot in and one foot out of GM. This is a risky position, particularly when combined with the prevailing belief that we operate one of the most robust regulatory system in the world. Are we putting at risk our global reputation simply because we are failing to critique our own systems? It is crucial that we create durable public policy to deliver the best outcomes for New Zealand. Reactive public policy delivers uncertainty to all stakeholders, creates unnecessary stress within the system for regulators, and is more likely to lead to systematic failure.

The most risk-averse solution would be to close down New Zealand's only two GM experiments (AgResearch and Scion) on the basis that they create unnecessary public risk at little to no public benefit; the science research funds would be better spent elsewhere. In regard to GM crops and other uses, we suggest retaining optionality through buying time, undertaking a systemic review of the current system and thinking strategically about the best way forward. Most importantly we think it is timely to have a conversation on the future of GM crops and other uses. As indicated by the Royal Commission recommendations, this issue remains unresolved; the Commissioners' decided to delay this strategic decision until more information was available. The time for reflection is now.

Recommendations

Recommendation 1: **Investment programmes should be evaluated as a matter of good practice**

Recommendation 2: **Risk management requires a whole-of-government approach**

Recommendation 3: **Compliance costs should be fully recovered from applicants**

Recommendation 4: **Legal liability should be reviewed as coexistence with zero contamination is not possible and definitions of new organisms have become increasingly unclear**

Recommendation 5: **Data management requires urgent attention**

Recommendation 6: **Allow local authorities to regulate GMOs or amend the HSNO framework accordingly**

Recommendation 7: **Before the conditional release of any GMO, a field test should first be undertaken**

Recommendation 8: **Reviews should be tactical and regular**

Recommendation 9: **Memoranda of Understanding should be urgently reviewed and updated**

Recommendation 10: **Strategy should be revisited**

Recommendation 11: **A high-level foresight unit should be established**

Recommendation 12: **Decouple hazardous substances from new organisms, creating separate legislation for both**

The First Forty Years of GM: By the Numbers

In 1988 New Zealand undertook its first outdoor experiment. The following two pages represent GM data from 1988 to June 2013 unless otherwise indicated. There are limitations to this information, as explained in the appendices. Sources: See Appendices 1, 9, 14, 15

46
Plant outdoor experiments

9
Animal outdoor experiments

2
Not specified

57
Total outdoor experiments since 1988 (approved & commenced)

17
Private entities

24
Crown Research Institutes

16
Universities and government departments

Types of animal tested


Mice


Sheep


Goats


Human DNA


Cattle


Salmon

Types of plant tested


Apples


Allium


Wheat


Brassicas


Potatoes


Pine trees

Also tested: Canola, Barley, Kiwifruit, *Lisianthus*, Maize, Norway Spruce Trees, Peas, Petunia, Rapeseed, Sugarbeet, Tamarillo, White Clover

ERA I: The journey toward the Royal Commission

1973
First recombinant bacteria developed in a laboratory

1988
Interim Assessment Group (IAG) on GM established and first GM outdoor experiment in NZ

Inputs

53
Outdoor experiments completed

6
Outdoor experiments approved but not commenced
(2 AgResearch, 2 Pioneer NZ Ltd, 1 Carter Holt Harvey, 1 Plant & Food)

2
Outdoor experiments currently operating
(Scion, AgResearch)

0
Outdoor experiments declined by ERMA/EPA
(from 1998)

2
Outdoor experiment with current approval commenced but not operating
(GMF99001 and GMF99005 are part of the same programme run by Scion. Approval expires in 2020 and 2019 respectively)

Process

11
Incidents of outdoor experiments

52
Reported incidents involving GMOs

1
Outdoor experiment shut down
(Shut down by Plant & Food Research, formerly NZ Institute for Crop & Food Research, two years into a 10-year consent after a biosecurity breach)

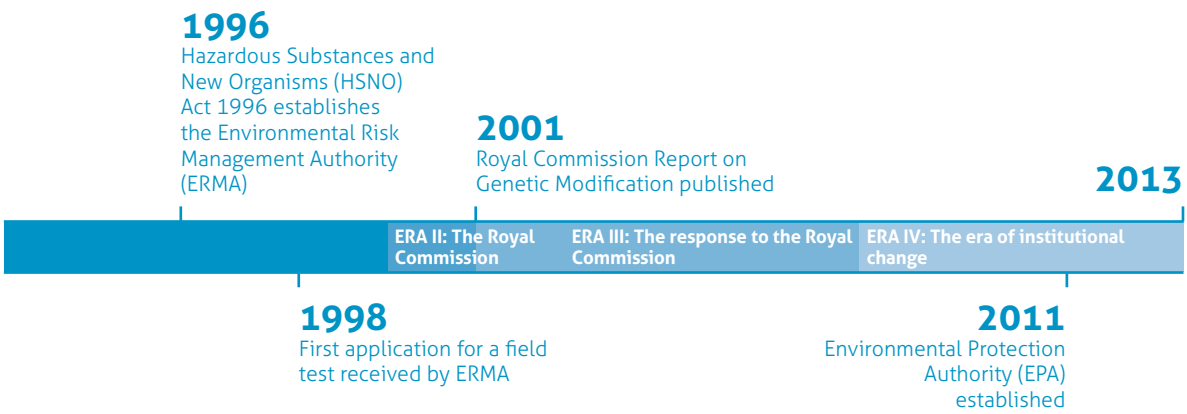
7
Trespasses or acts of vandalism on outdoor experiments

Outputs

59
GM ingredients approved for sale in New Zealand and Australia

0
Commercialised GM crops grown in New Zealand

1
Imported GMO application approved for conditional release
(vaccine for equine [horse] flu – not used to date)



1. Introduction

In 2008 the McGuinness Institute (then known as the Sustainable Future Institute) released two reports on genetic modification in New Zealand. The first was *A History of Genetic Modification in New Zealand* (SFI, 2008a), the purpose of which was to explore the past in order to understand the history of the 2008 policy landscape. The second report, written in response to the 2001 Royal Commission, *Review of the Forty-Nine Recommendations of the Royal Commission on Genetic Modification* (SFI, 2008b). In 2012, the Institute published *Science Embraced: Government-funded Science under the Microscope*. Unlike the earlier reports, the 2012 report looked at the science system from the top down.

This 2013 report updates the initial 2008 *A History of Genetic Modification in New Zealand* to reflect the current position. Its aim is to create a broader narrative for the genetic modification (GM) dialogue in New Zealand. In particular, it discusses the importance of taking a considered and proactive approach, rather than being reactive. While being responsive is important, decisions are best undertaken when all the appropriate information has been collected, analysed and considered; this requires a commitment to collecting relevant, timely and accurate information on the past and undertaking strategic foresight on the future. Only then can lessons be learnt from past experiences, and insights be gained from exploring and engaging with emerging issues (before they become major issues).

In contrast to our 2012 report on the science system, this is a bottom-up report. The 16 appendices, and in particular Appendix 1, record key events in the history of GM in New Zealand. Sections 2 to 4 are broadly taken from the 2008 report, while Section 5 records developments from 2008 to 2013. Sections 6 and 7 are the only areas of the report to draw conclusions and make suggestions: Section 6 provides a review of three of the Crown Research Institutes (CRIs), while Section 7 sets out 10 observations, 12 recommendations, and some reflections on the way forward.

In reading this report it is important to remember that a genetically modified organism (GMO) has never been released in New Zealand,[1] and therefore can be referred to as a 'GM-free food producer' (that is, a country with no commercial production of GM food). Importantly, the 2001 Royal Commission concluded, in response to a discussion on whether compatibility between different food production systems was possible,[2] that the first release of a GMO in New Zealand would be a 'watershed' decision (see Section 3.4.3). At that point New Zealand's food production would no longer be GM-free; this means that for many New Zealanders 'should New Zealand be a GM-free food producer?' and 'should New Zealand release a GMO?' are in practice the same question.

While no GMOs have been released in our environment, it is not correct to say we are 'GM free in the outdoors'; there are currently two GM outdoor experiments running in New Zealand.[3] These experiments confine GMOs to outdoor containment structures,[4] with each experiment having its own tailored set of controls to manage the risks of negative effects. These two GM outdoor experiments – the only such experiments being undertaken in New Zealand – are operated by CRIs, meaning they are partially funded

1 There are two types of release that can occur in New Zealand: a 'conditional release' and a 'release'. In this report, when we use the term release, we are not referring to a conditional release.

2 The Commissioners discuss this in Chapter 13 of their report, where they examine the 'complexity and diversity of the various strategies available to provide for compatibility between genetic modification and non-genetic modification land uses' (RCGM, 2001a: 336). For further discussion see Section 7.2.6.

3 The term 'outdoor experiments' is not a legal definition but for clarity is used in this report to refer to both outdoor developments (GMD) and field tests (GMF).

4 'Containment structure' is defined in the HSNO legislation as 'a containment facility that is a vehicle, room, building, or other structure, set aside and equipped for the development of genetically modified organisms' (e.g. this can include a fence). In contrast, 'laboratory' is defined as 'a vehicle, room, building, or any other structure set aside and equipped for scientific experiments or research, for teaching science, or for the development of chemical or medicinal products'.

by taxpayers.[5] AgResearch is currently undertaking research into GM animals, while Scion is undertaking research into GM Radiata pine. No private companies are currently undertaking GMO research in the outdoors in New Zealand.

Any economic benefits of these experiments, if they exist, would seem to be a long way off. However, risks to our agricultural base, whether they are perceived or real, have the potential to make a significant impact on our economy. Outdoor research is expensive; such sizeable investments must continually be assessed in terms of value produced and opportunity lost, and whether the public dollar would be better spent in other areas of research.

Currently, the Environmental Protection Authority (EPA) has the power to approve an application to release a GMO in the outdoors. At the moment there is no mechanism (for example, a moratorium) to prevent an application for the release of a GMO in the outdoors being considered by the EPA. Any adverse effects from such a release are unlikely to be easily reversed. Further, such a release is likely to impact negatively on our exports and national brand; a brand that currently aims to position New Zealand as '100% Pure'. Therefore the possible benefits of New Zealand staying a GM-free food producer must be considered either before or during an application for the first release. This report looks at whether New Zealand is ready to make such a decision, what institutions and instruments we have in place to collect data, and which institutions have the capability and expertise to synthesise that data so that robust decisions can be made.

There are a number of different components that make up the regulatory system, many of which shouldn't be considered in isolation. For example, the link between GM food production and GM research in the outdoors is not always apparent. However, the EPA (like its predecessor, ERMA) has approved novel applications for research in the outdoors (such as a wide range of GM animals and the placing of human genes in livestock). The possibility that this may become a factor in any decision should the EPA receive an application to release a GM seed already approved for consumption in New Zealand by our food authority FSANZ (such as GM canola, corn or soybean) must be considered. At some time in the near future these two trajectories – food production and food consumption – are likely to meet, and when they do we will need an appropriate public policy framework in place.

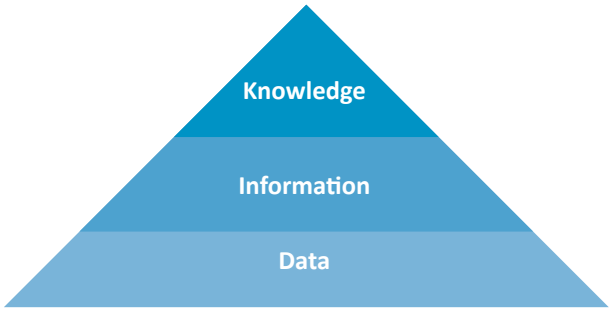
This report focuses on conceptualising ways to strengthen the current policy framework to ensure any decisions made are optimal for New Zealand in the long term. Public interest, transparency and accountability are all crucial to ensuring effective management of any regulatory scheme, and are recurring themes in our analysis. If nothing else, this report seeks to stimulate conversation on the topic in the hope of contributing meaningfully to future public policy that is durable and fit for purpose.

This report does not seek to explore the technicalities of the science nor comment on the debates surrounding potential impacts of genetic modification. Instead our aim is to provide an overview of the research and policy underlying genetic modification in New Zealand over the last forty years, from the years 1973–2013. We have broken the report into four eras: the journey toward the Royal Commission on Genetic Modification (1973–2000), the Royal Commission (2000–2001), the response to the Royal Commission (2001–2008) and the recent institutional changes (2008–2013).

5 CRIs receive a combination of public funding, commercial revenue and private investment. It is therefore not always easily apparent exactly where the funding for any one experiment is coming from. We know that in the past, AgResearch has received private investment for specific GM projects (see Section 7.2.1). If private companies have invested in these ventures it may call into question the ownership of the technology and whether the benefits of New Zealand undertaking these experiments lie with the country itself.

1.1 Differentiating Data, Information and Knowledge

Throughout this report, and even more broadly throughout the Institute, we draw a distinction between data, information and knowledge (see pyramid diagram below). Data in isolation is problematic. However, as more data develops a narrative unfolds, creating information, which in turn creates knowledge. Public policy decisions should be based on knowledge, so public policy systems need to focus on collecting the relevant data to create information, build strategic knowledge and make effective decisions.



1.2 Definition of Genetic Modification

There are varying definitions of what makes an organism a GMO, and in the New Zealand context there can be variance between international agreements to which this country is a party and New Zealand legislation. For example, the *Cartagena Protocol on Biosafety* categorises GMOs as products of modern biotechnology, with the following definition:

> 'Modern biotechnology' means 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, 2000a: 4)

In s 2 of the HSNO Act 1996, a GMO is defined as:

> … any organism in which any of the genes or other genetic material –
> a. have been modified by in vitro techniques; or
> b. are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by in vitro techniques.

When we were preparing our 2008 report, Professor Jack Heinemann advised us to describe genetic modification in the context of it being a tool,[6] and we have used the same definition in 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. (Professor Jack Heinemann, personal communication, 2008)

6 Professor Jack Heinemann is a lecturer in genetics at the University of Canterbury. His research interests are: (1) biochemical and genetic characterisation of horizontal gene transfer, particularly as it relates to the evolution of virulence and antibiotic resistance in microbes and risks of genetically modified/engineered organisms and (2) general yeast, bacteria and bacteriophage genetics.

However, the issue of what is and what is not a GMO, and therefore what is and what is not covered under the HSNO legislation, is an underlying theme of this report (see the discussion in Section 6.2.4). The Royal Commissioners discussed GM in terms of research, medicine, food, crops and other field uses. The latter term, 'GM crops and other field uses', is used broadly and includes any GMO placed in the outdoors. This includes fruits and vegetables, ornamental and nursery plants, forestry, as well as issues relating to bees, bioremediation, bioreactors (plant, cell and animal), pest control, biofuels, and bioprospecting (RCGM, 2001a: 137–178). Throughout this report, when we refer to GM crops we are using this broad definition.

In addition, this report draws a distinction between GMOs in the indoors and those in the outdoors, and refers to outdoor experiments being those developments or field tests that happen outside a containment facility (a closed structure). Discussing GMO experiments as 'indoor' and 'outdoor' is common practice internationally, however describing both indoor and outdoor containments (as we do in New Zealand) as 'contained' is not. In the UK the distinction is drawn between contained use (indoor) and not contained (outdoor). As the UK Health and Safety Executive (HSE) notes:

> The term 'contained use' covers any activity involving GMOs in which measures are taken to limit contact between them and people or the environment. It relates to the actual process of genetic modification, and also to the use, storage, transport and destruction of GMOs. Typical contained use facilities would be microbiology laboratories, animal houses, greenhouses or industrial production facilities. GMOs that are deliberately introduced into the environment for experimental purposes, or placed on the market, for example, as food for medical purposes, are obviously not contained. (HSE, n.d.: 2–3)

1.3 Position Statement

Genetic modification has been and continues to be a controversial topic, and as such there are many stakeholders with a range of positions and perspectives. The Institute, and in particular its chief executive, Wendy McGuinness, were involved early in this debate. McGuinness attended the first Environmental Risk Management Authority (ERMA) hearing on GMF98009 and spoke up about concerns about process, in particular directing the committee to sections within the HSNO Act and Regulations. When the decision was made public in May 2001, McGuinness was invited by other concerned parties at the hearing to join in legal proceedings against ERMA. While this was not a comfortable role, it was one she undertook because she felt strongly that good process was important if New Zealand was to have optimal decisions around GM. Being involved in this case was defining; private funds were being used to raise public concerns, whereas public funds were being used for private purposes (e.g. a joint venture with an overseas company). This was further emphasised when during the pre-hearing stages, AgResearch asked McGuinness to personally provide evidence of $100,000 in cash implying she would need to pay AgResearch's legal costs if the case failed. Although letters of this sort are normal business practice, the experiment being proposed was not; it was a novel and questionable experiment being progressed using taxpayers funds. (personal communication, AgResearch, 2001). See decision in Bleakley v ERMA (2001) in Appendix 7.

McGuinness believes decisions must be well-considered, based on evidence and transparent. As a Fellow Chartered Accountant, transparency is considered critically important both for improving processes and for holding parties accountable if things go wrong. Without such clarity it would be extremely difficult for a new committee member, hearing similar applications, to learn the lessons from past decisionmakers. The second aspect that transparency delivers is accountability; for stakeholders, whether they be applicants, submitters or those suffering harm, transparency provides the ability to hold the decisionmaker responsible if they make poor decisions. Furthermore, it enables the EPA to hold the applicant responsible if they provide misleading or incomplete information that the decisionmakers may have relied upon.

McGuinness's experience provided an insight into how public policy responds to new technology, in this case genetic modification. It showed that public policy must be developed before stakeholders enter the fray with vested interests. The Life Sciences Network (LSN) was another body that entered the debate early, operating in the interests of its members.[7] LSN may have gained additional support from New Zealand scientists, due to the unnecessary over-regulation of low-risk GM experiments in the early years of the HSNO Act 1996. In 2003, the HSNO legislation was amended to enable low-risk experiments to be treated as generic applications; allowing similar experiments to be grouped under one application (see Section 7.2.10). Its actions demonstrated how industry groups join together to lobby decisionmakers to ensure policy is developed for their own interests. This is to be expected, and comment should be welcome, however without a counter narrative such dialogue is one-sided.

In 2000 LSN contracted Infometrics Consulting Ltd to prepare a computable general equilibrium model on the scenarios of the application or non-application of GM in New Zealand. At the time, McGuinness had concerns about the quality of the Life Sciences Network report but also realised government was not resourced to undertake such an assessment. Consequently, she employed BERL to undertake such a review independently in the public interest. BERL found that because of the lack of references to assumptions used in the Infometrics Consulting Ltd model, the statement '"The modelling results present clear empirical support for the pursuit of biotechnology in New Zealand" (paragraph 12, Witness Brief Executive Summary) ... cannot be justified' (BERL, 2000: 3). It was this experience that has reinforced the Institute's drive to provide data and information for the public interest.

1.4 Limitations

This report does not endeavour to assess or address moral, ethical, cultural or religious views in regard to genetic modification. It is, however, important to acknowledge that these issues have formed and will continue to form a key part of this debate, they will be an important part of any future debates surrounding emerging biotechnology issues. In particular, it is beyond the scope of this report to examine the perspective of tangata whenua. Māori cultural perspectives are a key consideration in all policy development in New Zealand, and particularly in areas such as this where conflicting values may arise. We refer those interested in further discussion of Māori perspectives to our 2010 Report 7*: Exploring the Shared Goals of Māori*. Further, this report does not focus on medicine, except in relation to the Bioethics Council, as this was considered outside our brief. In addition, this report does not attempt to comment on global benefits, costs and risks of genetic modification. GM developments are touched on in Section 7 to indicate that this is an area that needs to be strategically reviewed. Foresight on how GM is received globally is important to consider when projecting our 'clean, green' image on a global scale. The Institute intends to undertake a global assessment in an upcoming report on the future of genetic modification in New Zealand within the next few years.

Finally, the authors of this report are not GM scientists; in no way do we purport to be experts in the alteration of genetic material. Similarly, we do not purport to be experts in social science perspectives on GM and this report does not extend to research into public attitudes or actor-network style analysis of this issue.[8] Our expertise is in public policy and research; our interest is in whether the current public policy landscape is fit for purpose. To assess this, it is necessary to understand the past in order to discuss the future.

7 The Life Sciences Network (LSN) was largely an industry group created to lobby government over the period both during the Royal Commission and while government was considering its response to the Commission; see Section 4.3.

8 There exists a considerable and growing body of work in New Zealand and overseas that examines the social and political impact of the GM debate. Sociologist Corrina Tucker's PhD thesis Making resistance politics: The opposition to genetic engineering in Aotearoa New Zealand (Tucker, 2011) is one example, and the work of sociologist Ronnie Cooper at the University of Canterbury is another (University of Canterbury, n.d.). Also see bibliography in Appendix 9: Research on public attitudes, in the report *History of Genetic Modification in New Zealand* (2008).

2. ERA I: The Journey Toward the Royal Commission 1973–2000

The next four sections of the report break the timeline on genetic modification into four distinct eras: the journey toward the Royal Commission; the Royal Commission; the response to the Royal Commission, and the era of institutional change. For a more detailed overview of the last forty years, see Appendix 1: Timeline of key events as at June 2013. Appendices 2, 3 and 4 relate specifically to the Royal Commission. Appendices 5–7 deal with the legal framework, while Appendices 8–12 deal with actual applications. Appendix 13 explores Crown funding and expenditure per year. Appendix 14 deals with incidents and breaches relating to those applications. Appendix 15 outlines approved GM foods. Lastly, Appendix 16 outlines the linkages between central government agencies, by listing existing Memoranda of Understanding.

This section discusses the first era, the journey toward the Royal Commission.

2.1 The New Tool: 1973–1990

By the early 1970s, scientists internationally were developing applications for a new tool: the first recombinant bacteria. In 1973 American scientists Herbert Boyer and Stanley N. Cohen[9] proved that genetically engineered DNA molecules could be inserted in foreign cells by developing recombinant DNA technology. By inserting enzymes that snip out DNA fragments and inserting those fragments into another living organism, they demonstrated the potential for genetic engineering to improve medicine and pharmacology (GNN, n.d.). By the early 1980s, these technologies began to be applied in laboratories in New Zealand, largely for biological and medical research purposes.

In the mid-1970s, institutional management of genetic modification technologies began to emerge at a government level in New Zealand. In 1978 the government placed a moratorium on field releases,[10] which remained in place for 10 years, and an Advisory Committee on Novel Genetic Techniques (ACNGT) was established to oversee contained laboratory and glasshouse genetic manipulation work (RCGM, 2001a: 104–105).[11] See list of moratoria in Appendix 5. In 1987, a Field Release Working Party recommended that the 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 were enacted under legislation, and from 1988 the government began moving toward what was to become the Hazardous Substances and New Organisms Act 1996 (HSNO) (RCGM, 2001a: 105). The IAG assessed 60 applications between 1988 and 1998 (Kahukiwa, 2006: 107).

9 In August 2013 Stanley N. Cohen released a piece on his involvement with DNA cloning since its conception titled *DNA cloning: A personal view after 40 years*, which was published in *Proceedings of the National Academy of Sciences*.

10 Field release is a combination of the term field test and release. The phrase was often used early on in policy discussions.

11 Enforcement of the committee's recommendations lay with the individual research institutions, which were required to appoint a biological safety officer and an Institutional Biological Safety Committee (IBSC). From 1982, IBSCs could approve low-risk experiments.

2.2 The Development of the HSNO Act: 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 Minister for the Environment, Simon Upton (who was also Minister for CRIs), sponsored the HSNO Bill (read on 8 November 1994, 19 December 1995 and 16 April 1996). 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).

> The political reality is that, whatever assurances about the risk, New Zealanders not only want no connection with things nuclear, they have turned the stance to one of positive advantage in promoting New Zealand as a nuclear-free tourist destination and food producer ... Whether that makes any rational sense, [being GM-free] is perceived by some businesses as a real advantage in the marketplace. (Samson, 1999)

In 1996, the HSNO legislation was passed, but it did not come into effect until 29 July 1998. In the interim, considerable work was completed in order to develop the appropriate methodology. Policy analysts and legislators showed considerable foresight and leadership by directing users of the legislation to adopt a consultative approach, embodying risk management principles. A number of consultative reports were produced between 1998 and 1999.

The HSNO Act 1996 also established the Environmental Risk Management Authority (ERMA), an institution primarily responsible for the management of novel GMOs imported into or developed in New Zealand.[12] Importantly, under this legislation if full release was approved, ERMA was no longer involved and the GMO was treated like any other organism, under the overview of the Ministry of Agriculture and Forestry (MAF).[13]

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

- Importing GMOs into containment;
- Developing GMOs;
- Conducting contained field tests,[14] and
- Releasing any contained or imported GMOs (MPI, n.d.[a]).

ERMA's structure comprised: (i) the *Authority*, an autonomous Crown entity that functioned as a quasi-judicial decisionmaking body of up to eight members appointed by the Minister for the Environment; (ii) the *Komiti Māori*, a body to advise the Authority on the principles of the Treaty of

12 A range of other existing legislation also has instruments relevant to the management of genetic modification (see Appendix 6). 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.

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

14 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 report, we use the term 'field test' as defined by the HSNO legislation.

Waitangi and Māori perspectives,[15] and (iii) the *Agency*, which carried out operations on behalf of, or in support of, the Authority (Ministry of Justice, n.d.[a]).

ERMA was required to work closely with many other government agencies, such as MfE, MAF, the Department of Conservation (DOC) and the New Zealand Food Safety Authority (NZFSA) among others. Section 49F of the HSNO Act requires that ERMA must consult with, and have regard to, the views of DOC and any other interested government agency. Section 58 also requires ERMA to have particular regard to any submissions made by DOC on any application for approval to import, develop, field test, conditionally release or release a new organism.

2.3 The Public Protest: 1996–2000

Despite this new legislative framework, by the late 1990s 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 technology. The public reaction was fuelled by ethical concerns and health risks of 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.

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, significant concerns were being raised about the ability of the HSNO legislation and ERMA to manage the rapid industry growth and technological advances being promised by some CRIs. Internationally, the science was racing from one breakthrough to another, giving the public a glimpse into what genetic modification was capable of, one of the more memorable examples being American artist Eduardo Kac's iridescent green rabbit (Phillips, 2002). However, these technological advances raised further issues which were unforeseen when the HSNO legislation was originally developed.

Rapid industry growth was being promoted by some scientists and industry representatives (including Federated Farmers, CRIs such as AgResearch and Crop & Food Research, and international corporations such as Monsanto). At the same time, other scientists and industry representatives (e.g. the organic industry), Non-Governmental Organisations (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.[16] 'GE-free' zones were widely promoted and occasionally established, while large demonstrations took place in major cities.[17] A movement developed 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.

15 Although it was established by the first schedule of the HSNO Act 1996, Ngā Kaihautū Tikanga Taiao only became a statutory body as a result of a 2003 amendment to the Act. Today Ngā Kaihautū Tikanga Taiao is the statutory advisory committee responsible for advising the EPA on matters relating to policy, process and decisionmaking from a Māori perspective. The members seek to provide a broad overview of Māori interests and perspectives. Ngā Kaihautū can have no fewer than four, and no more than eight members at any one time. Their current terms of reference are set by the EPA.

16 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.

17 Many territorial authorities were active in this debate at this time. See RCGM for a list (RCGM, 2001b: 48–49).

2.4 The Birth of the Royal Commission

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 establish a Royal Commission.

On 21 December 1999, 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 (RCGM, 2001b: 104).

3. ERA II: The Royal Commission 2000–2001

The Royal Commission was in place for just over twelve months, producing a three-volume report in mid-2001. It was the key mechanism for New Zealand to develop a more comprehensive understanding of the risks and opportunities in relation to the use of GM technologies.

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)

3.1 The Purpose

The Warrant[18] establishing the Royal Commission stated the Commissioners should:

> … receive representations 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)

3.2 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: 103–104).

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.

3.3 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 3).

18 More information on the Warrant and the resulting consultative process can be found in Appendices 2 and 3.

3.4 The Four Key Findings

The Commissioners' report is underpinned by four key findings, which are discussed below. For more detailed analysis, see *Review of the Forty-nine Recommendations of the Royal Commission on Genetic Modification* (SFI, 2008a).

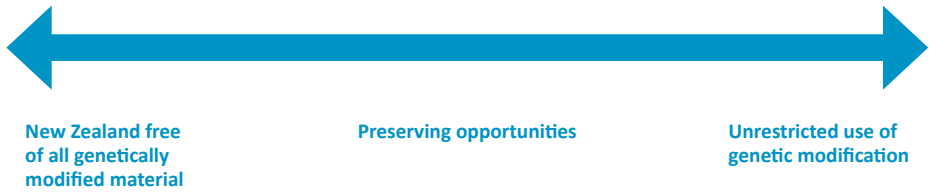
3.4.1 Identification of seven shared values of New Zealanders

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.

3.4.2 The forty-nine 'preserving opportunities' recommendations

The Commissioners identified a spectrum of options, from at one end a 'New Zealand free of all genetically modified material' to the 'unrestricted use of genetic modification' at the other (see Figure 1 below). The extreme position of a 'New Zealand free of all genetically modified material' was considered impractical due to the need for GM medicines and the possibility that skilled scientists would move overseas, meaning academic and industry standards would cease to be internationally competitive (RCGM, 2001a: 332). The other extreme position, 'unrestricted use of genetic modification', was considered likely to create unacceptable risks to human health, environmental health and cultural heritage, compromise consumer choice and/or reduce our export options. The Commissioners' noted that no submitter supported such an approach (RCGM, 2001a: 333).

Figure 1: The strategic spectrum identified by the Commissioners



Discussion on the strategic decision culminates in Chapter 13 of the report, 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)

The Commission considered that GM technology should be used only in ways that are carefully managed. All opportunities to use the new technology should be viewed in terms of the net contribution they would make to New Zealand. This approach would allow controlled use of genetic modification, with the degree of control varying relative to the situation (RCGM, 2001a: 331). The Commission identified 49 recommendations, aiming to bring about this strategic option. Of these 49 Recommendations, some were 'strategic' in nature whilst the others are 'operational'. The 'strategic' recommendations can be further split into two groups; Strategic: GM crops and Strategic: Institutional, these are further explained below.

3.4.3 Strategic decision on research, food, medicine and crops

The Commissioners suggested a strategy that was to preserve opportunities and proceed with care. They assessed genetic modification in terms of four key areas of study: research, food, medicine and crops (see Chapter 13 of the RCGM report). They found that the use of GM 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;[19] the Commissioners placed an additional strategic test on GM crops, referring to the first release as a 'watershed decision':

> 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)

This led to nine strategic recommendations related specifically with crops (these are discussed at the end of chapter 13 of the Royal Commission report). We refer to these recommendations as Strategic: GM crops. These recommendations were designed to delay a decision on GM crops until more information was available and to ensure that once an application was received, a thorough assessment took place. See Table 1 in Section 4.7.1 for the list of nine recommendations.

3.4.4 Strategic decision on building institutional capacity

In chapter 14 of the Royal Commission report, the Commissioners discuss three major proposals needed 'to provide ongoing oversight of biological developments' (RCGM, 2001: 342). They then list three major proposals for New Zealand to build institutional capacity, these proposals consisted of four recommendations related specifically to oversight (these are discussed at the end of the chapter 14). We refer to these recommendations as Strategic: Institutional. See Table 2 in Section 4.7.2 for the list of four recommendations.

For purpose of clarity, we refer to all other recommendations (not mentioned in Chapters 13 and 14) as operational recommendations.

3.5 Going Forward: The Two-pronged Approach

The first approach was about a national strategic decision on GM crops, the Strategic GM crops recommendations. Whereas the second was about building institutional knowledge so that better policy decisions could be made in the future, the Strategic institutional recommendations.

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

4. ERA III: The Response to the Royal Commission 2001–2008

Below we outline the government's initial response to the Commissioners' recommendations and that of other sectors and the general public. We also summarise the Institute's review of the recommendations.

4.1 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. Marian Hobbs, the Minister for the Environment, 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[20] were released by the government, many of which are discussed further in this report.

In response to the findings of the Royal Commission the government commissioned a 2002 Law Commission report called *Liability for Loss Resulting from the Development, Supply or Use of Genetically Modified Organisms*. The following topics were examined:

- Whether liability should lie where it falls in accordance with orthodox liability criteria or whether there should be an alternative compensation scheme.
- The adequacy of current legal approaches to causation in the particular situation of proving the causal link between claimed harm and a genetically modified organism.
- The difficulties of accurate actuarial assessments.
- The problems of enforcement because of the time which may elapse between act or omission and a claim of loss. (Law Commission, 2002: iv)

20 See Appendix 1 (year 2003) for the titles of all eight Cabinet papers.

The Law Commission concluded as a result of this review that 'the current statute and common law will not ensure that all damage that could potentially be caused by GMOs will be compensated. It is unlikely that any liability regime could guarantee this' (Law Commission, 2002: 38).

The Hazardous Substances and New Organisms Amendment Act 2003 was passed in response to the Commissioners' report. The Act came into effect on 30 October 2003, and reflected the Royal Commission's overall conclusion of adopting a precautionary approach[21] while preserving opportunities for the future. The amendments mainly addressed issues concerning GMOs. However, some applied generally to all new organisms. The 2003 amendments covered the following issues:

- civil liability and penalties (now Part 7A of the HSNO Act 1996);
- cloning and the genetic modification of human cells and tissues (s 45 HSNO Act 1996);
- conditional release of new (including GM) organisms (ss 38A to 38L HSNO Act 1996);
- contained laboratory research on GMOs (s 39 HSNO Act 1996);
- improving how the HSNO Act operates;
- medicines made from or containing new organisms (including GMOs) (ss 49A to 49K HSNO Act 1996), and
- Minister's call-in powers (s 68 HSNO Act 1996).

A discussion of legal liability as of 2013 is presented in Section 7.2.4; this issue is still evolving and many stakeholders do not feel that an adequate liability system exists under the HSNO framework (for further discussion see Sections 7.2.4 and 7.2.6).

4.2 The International Science Community's Response: 2001

A detailed review of the international science community's response in 2001 is outside the scope of this paper, but we felt an editorial in *Nature*, a prominent interdisciplinary science journal, 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. (Nature, 2001: 569)

4.3 Industry Response: 2001–2004

Industry was almost exclusively portrayed in the media at the time as being pro-GM, with journalists conceptualising the debate as farmers and scientists versus luddites.

21 This is distinct from the 'precautionary principle' while there are numerous definitions of the precautionary principle the most widely quoted is the one in the Rio Declaration (Principle 15). Under this definition, the triggering factor is the threat of serious or irreversible damage. Once the approach has been triggered, the wording allows but does not require action to be taken and leaves this open for governments to decide on a case-by-case basis. There are similar definitions in various international treaties including: the *1992 Convention on Climate Change*, the *1992 Convention on Biological Diversity* and the *2000 Protocol on Biosafety*' (Treasury, 2006). Section 7 of HSNO directs the authority to take a precautionary approach only where there is scientific and technical uncertainty as to those effects. The requirement does not include the need to exercise caution where there is social or ethical uncertainty: Bleakley v Environmental Risk Management Authority [2001] 3 NZLR 213 (HC): 50. In Bleakley, assistance was not gained from the international concept of the precautionary principle because parliament had intentionally used the word 'approach' rather than 'principle.'

In 2001, the agricultural industry was largely represented in the media by Federated Farmers, which greeted with enthusiasm the Royal Commission's decision to recommend against a ban on field tests (Robson, 2001). It was reported shortly after the Commission's report was released that Federated Farmers president Alistair Polson had stated that 'the recommendation was an important signal to farmers and investors that the economy would be allowed to grow without political interference' (Robson, 2001).

The biotechnology industry was for the most part represented in this period by the Life Sciences Network (LSN), a Wellington-based lobby group that operated between 2000 and 2004, chaired by Dr William Rolleston.[22] The Network was established six months before the Royal Commission on Genetic Modification began its work, and occupied a space in the same building in which the Commission was based. In their submission to the Royal Commission, they stated that they were 'committed to realising the potential of biotechnology to improve the quality of human life' (Life Sciences Network, 2001a: 3). The Network's website no longer exists and it is difficult to source information on the group.

The Network attracted some controversy leading up to the 2002 general election, specifically regarding pro-GM advertisements placed in 21 newspapers three days before the election. AgResearch and Crop & Food Research confirmed that they had contributed $180,000 to an LSN fund that had paid for the advertisements as well as pro-GM 'kits' that were sent to all election candidates, except those from the Green Party or the Alliance Party (Collins, 2002).

Bill English, leader of the National Party opposition at the time, stated that he thought the timing and content of the advertisements were designed to boost Labour's vote at the expense of the Green Party. He described the contributions from the CRIs as 'a gross interference with the democratic process' (Collins, 2002). LSN responded by stating that the advertisements were not motivated by the upcoming election and that they felt confident they had 'made a politically neutral reasoned contribution to an important debate for New Zealand' (LSN, 2002).

Prior to the Life Sciences Network, the key pro-GM lobby group in New Zealand was the Gene Technology Information Trust, commonly referred to as 'GenePool' (Hager, 2008). This group had been based in Wellington since the 1990s and claimed to provide impartial and authoritative information on genetic modification. Among its funding sources were four CRIs ($30,625 in 1999) and the multinational agricultural biotechnology corporation Monsanto ($27,500 in 1999) (RSNZ, 1999).

4.4 New Zealand Society for Risk Management: 2001

In August 2001 the New Zealand Society for Risk Management issued a press release 'expressing disappointment that the inquiry did not follow recognised best practice in risk management' (New Zealand Society for Risk Management, 2001). Further, they stated that:

22 Member organisations of the Life Sciences Network, as listed in their submission to the Royal Commission, include: Agcarm Incorporated (and member organisations), BIOTENZ (and member organisations), Federated Farmers of NZ (Inc), NZ Dairy Board (and subsidiaries), Meat New Zealand (and subsidiaries), Meat Industry Association of NZ (and member organisations), NZ Wool Group (and subsidiaries), Arable Food Industry Council, Auckland Uniservices Ltd, University of Auckland, University of Otago, Egg Producers Federation of NZ, Hamilton City Council, Institute of Molecular Biosciences at Massey University, Malaghan Institute of Medical Research, NZ Agritech Incorporated, NZ Berryfruit Growers Federation, NZ Biotechnology Association ,NZ Feed Manufacturer's Association, NZ Fruitgrowers Federation ,NZ Game Industry Board, NZ Grocery Marketers Association, NZ Vegetable Growers Federation, NZ Veterinary Association, NZ Wool Board (and subsidiaries), and Poultry Industry Association of New Zealand (Inc). (Life Sciences Network, 2001a: 2) The Network also noted close working relationships with the following organisations: Association of Crown Research Institutes, Crop and Food Research (now Plant & Food Research), Horticulture and Food Research, AgResearch, Forest Research Institute (now Scion), NZ Vice Chancellor's Committee, Human Genetics Society of Australasia, Lysosomal Diseases New Zealand/NZ Organisation for Rare Diseases, NZ Association of Scientists, NZ National Commission for UNESCO, NZ Plant Protection Society, NZ Society for Biochemistry and Molecular Biology, NZ Transgenic Animal Researchers and Rural Women NZ. (Life Sciences Network, 2001a: 2-3)

> It is unfortunate that the Order in Council did not require the Commission to adopt an explicit risk management process, as set down in the 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. (New Zealand Society for Risk Management, 2001)

4.5 'Corngate' and the General Election: 2002

The issue of genetic modification and the 'Corngate' scandal played a significant role in the relationships between political parties during the 2002 election campaign. The continual resurfacing of the GM issue has been described as less of an actual issue and played out as more of a 'metacampaign' issue relating to the viability of a Labour–Green coalition (Kriha et al., 2003).

The relationship between the two parties had deteriorated earlier in the year when in May 2002 seven Green Party MPs walked out of the debating chamber in protest at the government's decision to lift the moratorium on GM trials (Miller & Karp, 2004: 137). GM was a central issue for the Green Party in the 2002 campaign – the party pushed it as a central part of its platform with billboards that read 'GE: Keep it in the lab' (Roberts, 2003: 275). The party had made it very clear to the Labour government and the electorate that it was unwilling to compromise.

Tensions between Labour and the Greens escalated following the release of *Seeds of Distrust* only two weeks before the July election. Written by investigative journalist Nicky Hager, the book alleged the Labour government had covered up the accidental planting of a GE corn crop (Hager, 2002). This controversy, which became known as 'Corngate', significantly affected the course of the campaign. Adamantly denying the allegations, Helen Clark accused the media of setting her up and the Greens of playing 'gutter politics' ('"Corngate" could leave a nasty taste', 2002). This issue, combined with tension over the Labour government's support of the American-led war in Afghanistan, effectively ruled out the possibility of a Labour-Green coalition.

4.6 The Public Response: 2001–2008

A detailed review of the public response to the Royal Commission's report is also 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 McGuinness Institute website. Appendices 8–12 provide a detailed overview of indoor and outdoor experiments to date, to which there have been a number of public responses, as described below.

4.6.1 Public marches

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

The first began on October 2001, with over two hundred people arriving at Parliament on 31 October (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, officially announced the day before the group arrived 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 31 October, in which 15 protesters from the Tino Rangatiratanga movement refused to leave for half an hour (Bradford, 2001; Frizzel, 2001). Prior to the hikoi in late August 2001 the Auckland GE-Free Coalition had also organised a rally up Queen Street in which 10,000 protesters participated. The intention of this 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 (Aotearoa Indymedia, 2001).

The second GE-free hikoi began on 22 August 2003 and ended with hundreds of protesters gathering at Parliament on 23 October (Green Party, 2003a). 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 GM crops, which coincided with the group's arrival in Wellington. The hikoi named itself the 'Seed Carriers', and the participants collected seeds as they travelled the length of the North Island in protest at the harm GM could do to New Zealand's seed varieties, including native plants (Fitzsimons, 2003). The seeds they collected were presented to the government when they arrived in Wellington.

4.6.2 Legal cases

There have been multiple cases on the application of the HSNO Act in relation to GM. The first of which was Bleakley v Environmental Risk Management Authority [2001] 3 NZLR in 2001.[23] See Appendix 7.

4.6.3 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 the decision to include GM regulation in their draft plans or policy statements (see Section 5.3.1 for further discussion). A GE Free Register was created online, and in February 2008 listed 5693 properties covering a total of 360,064 acres (GE Free Register, n.d). Residents and businesses were encouraged to 'stake their claim for a GE free environment via a New Zealand GE free environment register and send a legal letter to neighbours within an 8 km radius advising them of the risks of planting GE crops' (Organic Pathways, n.d.). The website no longer exists.

4.6.4 Wilful damage

Over the last few years there have been five instances where members of the public have intentionally damaged GM crops and trees. Examples include the chopping down of GM trees at Scion in January 2008, a plant house being broken into at Plant & Food Research in November 2008, and a containment facility being broken into at AgResearch in May 2009. All 52 incidents are discussed further in Appendix 14.

4.7 The Institute's Review of the Forty-nine Recommendations of the Royal Commission: 2008

There was never an onus on the government to implement the 49 recommendations of the Royal Commission on Genetic Modification. However, there was an expectation that the government would

23 Wendy McGuinness, co-author of this report and chief executive of the McGuinness Institute, was a party to the Bleakley v ERMA appeal (see Section 1.3).

respond to the Commissioners' report, which it did in late 2001 (see Section 4.1). Following the 2003 review of the HSNO Methodology, which produced no changes, and with incidents such as breaches of controls and accidental imports of GM seed continuing to occur, the Institute felt it was time for an independent assessment of the Commissioners' recommendations.

The Institute's work began in 2006, when we wrote to the appropriate government organisations requesting updates on the recommendations. A response from Russell Harding, at the time the Manager of Environmental Stewardship for the MfE, advised that much of the ongoing work arising from the government's decisions following the Commissioners' report was 'both iterative, and ... being undertaken by several different agencies', and that the government would provide a 'coordinated interdepartmental response' to our questions (Russell Harding, MfE, personal communication, 1 November 2006). The response we received in due course was a 21-page document that provided an excellent starting point for our research.

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, the Institute undertook an independent assessment of the implementation of the Commissioners' recommendations, with the results published in its report *Review of the Forty-nine Recommendations of the Royal Commission on Genetic Modification* (SFI, 2008b). The resulting 2008 report reviewed the government's response to each of the 49 recommendations and drew conclusions based on outstanding issues, and found:

- Of the package of 49 recommendations only 20 had been fully implemented.
- Of the nine strategic GM crop recommendations (watershed) only one had been fully implemented (see Table 1).
- Of the four major strategic institutional recommendations, only two had been fully implemented (see Table 2).
- There remains significant policy work in order to meet the underlying purpose of all three groups of recommendation.

4.7.1 The nine strategic GM crop recommendations

The Commissioners discussed the 'watershed' decision in the last pages of Chapter 13 under the heading 'Is Compatibility Possible?' (RCGM, 2001a: 336–338). At this time it was not known if GM crops could cross-pollinate or what the global position would be, which could be significant in terms of trade. Issues such as monopoly ownership of seed stock and the risk of GM crops to the environment were very uncertain. The central analysis offered by the Commissioners provides little insight into how they arrived at the strategic option for crops, therefore we must look to the recommendations (set out in Table 1) in order to gain further insight into their analysis. What is clear is that the Commissioners considered a national strategic assessment should take place, before the conditional or full release of a GM crop.

It is concerning that, as shown in Table 1 overleaf, only one of the nine strategic GM crop 'watershed' recommendations had been fully implemented by 2008.

Table 1: The nine strategic GM crop recommendations of the Royal Commission

Source: RCGM, 2001a: 338–340, 345; SFI, 2008a: 14

	Chapter 13 Recommendations	Extent of implementation by 2008
1	**Recommendation 6.8 (Conditional release)** That HSNO be amended to provide for a further level of approval called conditional release.	Fully implemented
2	**Recommendation 13.1 (Benefit assessment)** That the methodology for implementing HSNO section 6(e) be made more specific to: • Include an assessment of the economic impact the release of any genetically modified crop or organism would have on the proposed national strategy of preserving opportunities in genetically modified and unmodified agricultural systems. • Allow for specified categories of genetically modified crops to be excluded from districts where their presence would be a significant threat to an established non-genetically modified crop use.	Not implemented
3	**Recommendation 13.2 (First release)** That before the controlled[24] or open release of the first genetically modified crop, the Minister exercise the call-in powers available under HSNO section 68 in order to assess the likely overall economic and environmental impact on the preserving opportunities strategy.	Not implemented
4	**Recommendation 7.7 (Separation distance)** 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, and – emerging strategies for coexistence between genetically modified and unmodified crops in other countries. • to identify how the costs of establishment and maintenance of buffer zones are to be borne.	Not implemented
5	**Recommendation 13.3 (Communication networks)** That MAF develop formalised local networks to encourage constructive dialogue and communication between farmers using different production methods, and to provide for mediation where necessary.	Not implemented

24 The category 'conditional release' did not exist when the Commissioners' made their recommendations, it was implemented in 2003. However, we assume the controlled release is referring to a conditional release. See recommendation 6.8 above.

	Chapter 13 Recommendations	Extent of implementation by 2008
6	**Recommendation 13.4 (Sterility technology)** That sterility technologies be one tool in the strategy to preserve opportunities, especially in the case of those genetically modified crops most likely to cross-pollinate with non-genetically modified crops in the New Zealand context (e.g. brassicas, ryegrass, ornamentals).	Partially implemented
7	**Recommendation 7.1 (Bt strategy)** That, prior to the release of any Bt-modified crops, the appropriate agencies develop a strategy for the use of the Bt toxin in sprays and genetically modified plants, taking into account: • The concept of refugia; • Limitations on total planted area, and • Home gardener use.	Not implemented
8	**Recommendation 7.3 (Bees)** That the Ministry of Agriculture and Forestry (MAF) develop a strategy to allow continued production of genetic modification-free honey and other bee products, and to avoid cross-pollination by bees between genetically modified and modification-free crops, that takes into account both geographical factors (in terms of crop separation strategies) and differences in crop flowering times.	Not implemented
9	**Recommendation 6.13 (Research)** That public research funding be allocated to ensure organic and other sustainable agricultural systems are adequately supported.	Partially implemented

4.7.2 The four strategic 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 put forward three major proposals (see Table 2 overleaf): the creation of a Bioethics Council, a Parliamentary Commissioner on Biotechnology, and a Biotechnology Strategy. A fourth recommendation was made that related specifically to changes to the HSNO legislation (see Recommendation 14.1 in Table 2).

As at 2008, two of the four institutional recommendations outlined in Table 2 had been fully implemented. However, since the Bioethics Council has since been disestablished. The framework that the commissioners designed to secure effective public policy decisions in the future has not been implemented.

Table 2: The four major strategic institutional recommendations of the Royal Commission
Source: RCGM, 2001a: 346, 349–350; SFI, 2008a: 16

	Chapter 14 Recommendations	Extent of implementation by 2008
1	**Recommendation 14.1** That HSNO section 68 be extended to include significant cultural, ethical and spiritual issues as grounds for the Minister's call-in powers.	Fully implemented
2	**Recommendation 14.2** That Government establish Toi Te Taiao: The Bioethics Council to: c. Act as an advisory body on ethical, social and cultural matters in the use of biotechnology in New Zealand. d. Assess and provide guidelines on biotechnological issues involving significant social, ethical and cultural dimensions. e. Provide an open and transparent consultation process to enable public participation in the Council's activities.	Partially implemented[25]
3	**Recommendation 14.3** That Government establish the office of Parliamentary Commissioner on Biotechnology to undertake futurewatch, audit and educational functions with regard to the development and use of biotechnology in New Zealand.	Not implemented[26]
4	**Recommendation 14.4** That the Ministry of Research, Science and Technology develop, on a consultative basis, a medium and long-term biotechnology strategy for New Zealand.	Fully implemented[27]

4.7.3 Strategic capacity still outstanding

In summary, our 2008 report noted that a significant amount of further policy work was 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. We concluded:

- 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 coexistence 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 coexistence 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. (SFI, 2008a: 94)

Five years later, and 12 years after the Royal Commission, little progress has been made toward developing the public policy capacity necessary to make effective strategic decisions on GM crops in New Zealand.

25 The Bioethics Council was established in 2002, but disestablished in 2009 (see discussion in Section 5.2.1).

26 The proposal to establish a Parliamentary Commissioner on Biotechnology was never progressed. Although other institutions may have picked up some of these functions, they are dissipated and difficult to trace.

27 The biotechnology strategy was published in 2003 with a 10-year perspective that has now expired. We are unaware of any recent reviews of the 2003 strategy other than a 2004 evaluation (see discussion in Section 5.7).

4.7.4 Response to the Institute's 2008 report

In preparing our original report, the Institute worked with officials to try to ensure that any actions undertaken by the government were reported accurately and in accordance with the report's methodology, and an effort was made to separate fact from opinion. Furthermore, in the interests of informed dialogue, the final report was embargoed but made available to government officials and MPs. However the only detailed response we received from any government official was a document written in response to a third party's OIA request. This document, which questions the Institute's conclusions and methodology, was sent to us by the third party who made the request.[28] On reflection, the Institute regrets not having had the opportunity to address their concerns directly.

28 In correspondence between the Minister for the Environment and Jon Carapiet of GE Free in September 2008 the Minister notes that 'his officials had come to quite different conclusions to the authors [of the Sustainable Future report] and question the authors' conclusions', and that as a result he considers them 'based on flawed assumptions and inaccurate conclusions'. Mr Carapiet forwarded a copy of the Minister's reply to the Institute along with a five-page letter comparing the Institute's and the government's responses, along with a 15-page table attached outlining all 49 recommendations. Officials used the categories (i) fully implemented, (ii) fully implemented but ongoing, (iii) ongoing, (iv) substantively addressed and (v) substantively addressed but ongoing, rather than the Institute's three (i) fully implemented, (ii) partially implemented and (iii) not implemented; there was agreement over 15 of the recommendations. Officials considered that all 49 recommendations had been addressed to some extent, however, their methodology was very different to that used by the Institute. For example, the Institute considered the establishment of a Parliamentary Commissioner on Biotechnology (Recommendation 14.3) was not implemented, whereas the officials argued it was substantially addressed even though the government considered it was not an appropriate mechanism and instead directed officials to report to the Cabinet Policy Committee on the appropriate mechanisms as part of the biotechnology strategy (Trevor Mallard, personal communication to Jon Carapiet, September 4 2008).

5. ERA IV: Institutional Change 2008–2013

While Section 4 discusses the gap between what existed in 2008 and the Commissioners' view of what was necessary to deliver the option of preserving opportunities, this section tracks how the 2008 framework has undergone significant institutional change. In order to describe how the current system has evolved, we discuss the eight key components that make up the system: legislation, central government institutions, local government institutions, CRIs, NGOs, review bodies, strategy bodies and international treaties.

5.1 Legislation

Legislation is a key instrument in bringing about long-term change. Appendix 6 contains a full list of recent developments; forthcoming developments and emerging issues are discussed briefly below. We recommend a legislative review of the current liability system, an issue that is discussed further in Section 7.2.4.

Food Bill 160-2 (2010)
If passed, this Bill would replace the Food Act 1981, and eventually the Food Hygiene Regulations 1974 and the Food (Safety) Regulations 2002. The Bill was introduced to Parliament in May 2010 and at the time of writing was awaiting its second reading. The phrase 'the genetic modification of food' was removed from s 346(3)(i) by the Primary Production Committee; s 346 is the section that allows the minister to set standards to 'ensure that food is safe and suitable'. There was concern from anti-GM groups that this level of ministerial discretion could potentially act as a 'back door' entrance for GM food without it having to comply with HSNO requirements (Organic NZ, n.d.).

Hazardous Substances and New Organisms (Methodology) Order 1998
This Order was written to sit alongside the 1996 HSNO Act, the logic being that the methodology could be improved over time in line with best practice without requiring a change through Parliament.

This risk-management methodology is critical to ensuring effective and transparent decisionmaking under the HSNO. The Institute has always considered this to be an important component of the system, designed to manage the benefits, costs and risks of GMOs in New Zealand. In 2003 ERMA released a draft of its proposed revisions to the 1998 methodology; in 2011 the methodology was described as 'out of date' in the EPA's *Briefing to the Incoming Minister* (EPA, 2011a: 9). When asked to confirm the situation, Minister for the Environment Amy Adams commented that the methodology does not require updating in the short term:

> There are no plans at this time to develop a new methodology in place of the existing order … The public comment on the 2003 discussion document issued by ERMA, and on another discussion document issued in 2008, was fully considered in making decisions not to review the methodology. I am advised that the issues raised about the methodology were not such as to prioritise its review. (Hon. Amy Adams, personal communication, 23 May 2013)

The use of section 67A of the HSNO Act 1996
This section of the Act was designed to allow minor or technical amendments to approvals:

> **s 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.

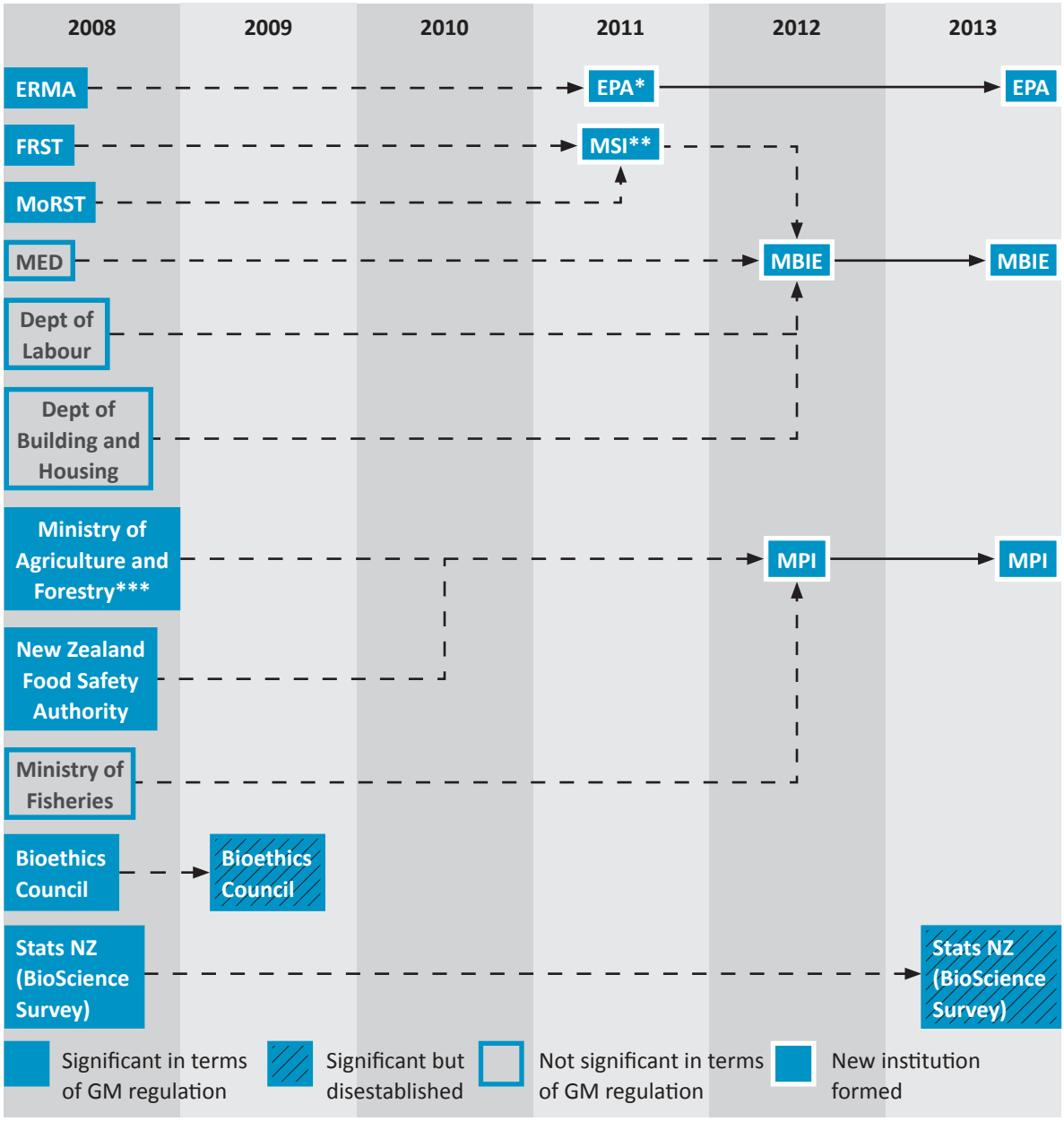
Although this clause was designed to deal with minor changes to controls, many are significant. For example, the length of time for a field test was changed from 11 to 19 years (GMF9905). While it is important to have a mechanism to introduce new controls if the need should arise, it is also important that this is not misused to subvert due process. Any legislative review should include a review of all uses of this clause and deem whether these uses have been appropriate. For a full list of amendments under s 67A to date see Appendix 11.

5.2 Central Government Institutions

There have been a number of institutional developments to the regulatory framework relating to GMOs. Figure 2 overleaf, shows the key changes, the most significant of which are discussed below. There are also a number of institutions whose roles have not changed significantly: DOC, FSANZ, Institutional Biological Safety Committees (IBSCs), Office of the Prime Minister's Science Advisory Committee (OPMSAC)[29] and the Science Media Centre. All relevant central government institutions are addressed below.

29 The Office of the Prime Minister's Science Advisory Committee is headed by Sir Peter Gluckman who has been the Chief Science Advisor to the Prime Minister since 2009. The primary role of the Chief Science Advisor is to provide strategic and operational advice on science policy issues, advise on specific aspects of science, and promote public understanding of science (OPMSAC, n.d.).

Figure 2: Institutional change over the last five years



* Some staff from MfE and MED were transferred into the newly formed EPA.

** Futurewatch reports were undertaken by MoRST to present information on the emerging areas of science and their relevance to New Zealand. The reports were not continued under MSI, see discussion in Section 5.2.10.

*** MAF published regular reports on global development surrounding GM and coexistence. However, these were discontinued in 2007. See Section 7.2.4.

5.2.1 Bioethics Council

The Bioethics Council was established in December 2002 in response to the Royal Commission's recommendations. The purpose of the Council was to:

1. Enhance New Zealand's understanding of the cultural, ethical and spiritual aspects of biotechnology.
2. Ensure that the use of biotechnology has regard for New Zealanders' values. (Bioethics Council, n.d.[a])

The Council noted, however, that this work was subject to specific boundaries:

1. Not to do the work of an existing agency.
2. Not to review, approve or offer opinion on specific proposals.
3. Not to make recommendations that are binding.
4. Not to be a quasi-judicial body. (Bioethics Council, n.d.[b])

Despite these boundaries, the Council offered policy and legislative advice on many aspects of biotechnology, and was heavily involved in decisions about research on human embryos. It issued major reports on prebirth testing, animal-to-human transplantation, and the use of human genes in other organisms (MfE, n.d.[a]).

In 2005 the Bioethics Council was independently reviewed by the State Services Commission (SSC), whose findings were published in the report *Bioethics Council Review* (SSC, 2006). The Commission found the purpose of the Council to be valid and that it had become a trustworthy vehicle for education and public discourse on emergent biotechnology issues. The report endorsed the Council's role and structure but made a number of recommendations, suggesting changes aimed at strengthening accountability and communication between the Council and key ministers and stakeholders (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, 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 previous Bioethics Council reports or any reports published since that date (see SFI, 2008a: Tables 9 and 11).

In March 2009, as documented in CAB Min (09) 8/5B, the Bioethics Council was disestablished. This decision was part of a 2008 Cabinet directive that required a review of expenditure after MfE received a $26 million funding cut (Hon. Dr Nick Smith, personal communication, 24 June 2009).

5.2.2 Department of Conservation

The Department of Conservation (DOC) is tasked with managing New Zealand's natural and historic heritage. DOC undertakes conservation research, partnering with central and local government, as well as non-governmental organisations and iwi groups (DOC, n.d.). Sections 38G, 49F and 58 of the Hazardous Substances and New Organisms Act 1996 require ERMA to consult DOC or have particular regard for the department's submissions and views; this responsibility has since passed to the EPA (see below).

5.2.3 Environmental Protection Authority

The most significant development since 2008 has been the passing of the Resource Management (Simplifying and Streamlining) Amendment Act 2009, which established a new entity, the Environmental Protection Authority (EPA). The Environmental Protection Authority Act 2011 formally established the new body in May 2011. The EPA took over the regulation of environmental functions from MfE, MED (now MBIE), ERMA, and the Ministry of Foreign Affairs and Trade (MFAT) (Smith, 2011). Information from ERMA dating from before May 2011 is still available on the EPA website or on request.

The EPA has responsibility for the regulation of new organisms (including GMOs) under the HSNO Act and is mandated to approve or decline applications before any import, development, field testing, conditional release, or manufacture of such organisms. The EPA only regulates living (viable) new organisms. The importation of food containing GM ingredients is regulated by FSANZ and MPI (see below).

5.2.4 Environmental Risk Management Authority

The Environmental Risk Management Authority (ERMA) was established in 1996 under the HSNO legislation as an independent regulatory authority, responsible for assessing the risks posed by the use of different substances and organisms. ERMA was formally disestablished in June 2011 and replaced by the EPA. From that date, the EPA has assumed all the functions that were previously the responsibility of ERMA.

A considerable number of resources, memoranda of understanding, submissions, approvals and other documents still refer to ERMA. A clear explanation of this relationship is difficult to find on the EPA or MfE websites.[30] ERMA's website no longer exists and the domain name (erma.govt.nz) does not redirect to the current EPA website. Notably s 35 of the Environmental Protection Authority Act 2011 states that all references to ERMA should be read as EPA.

5.2.5 Food Standards Australia New Zealand

Food Standards Australia New Zealand (FSANZ) was established in 1991; it is an independent statutory agency that sets joint food standards for the food industry in Australia and New Zealand (FSANZ, n.d.[a]).

5.2.6 Foundation for Research, Science and Technology

The Foundation for Research, Science and Technology (FRST) was established by the Foundation for Research, Science and Technology Act 1990. Its stated mission was: 'Investing in Innovation for New Zealand's Future' (Ministry of Justice, n.d.[b]). In 2011 FRST was merged with MoRST to form MSI (now part of MBIE; see below).

5.2.7 Institutional Biological Safety Committees

An Institutional Biological Safety Committee (IBSC) is a committee established by a research organisation, for example a university, or a group of research organisations. During the last 13 years IBSCs have significantly decreased in number from 23 to four (University of Auckland, Massey University, Lincoln University and the University of Otago). The EPA delegates the authority to assess and approve rapid assessment applications for the importation and development of low-risk GMOs to these committees (EPA, n.d.[a]). IBSCs are audited approximately every three years, to ensure applications are properly prepared and decisions are consistent with the HSNO Act and the EPA's methodology. Reports are available from the EPA via Official Information Act (OIA) requests.

30 In May 2013, the Institute emailed the EPA webmaster suggesting that a redirect on the ERMA domain name would be helpful, enabling the public to understand the continuity between ERMA and the EPA, but at the time of writing this has yet to be done.

5.2.8 Ministry of Business, Innovation and Employment

The Ministry of Business, Innovation and Employment (MBIE) was formed in 2012 with the merging of the Department of Building and Housing, the Ministry of Economic Development, the Department of Labour, and the Ministry of Science and Innovation. MBIE's purpose and role is outlined on its website:

> The purpose of the Ministry of Business, Innovation and Employment is to be a catalyst for a high performing economy to ensure New Zealand's lasting prosperity and wellbeing. MBIE develops and delivers policy, services, advice and regulation to support business growth and the prosperity and wellbeing of all New Zealanders. MBIE integrates the functions of four former agencies – the Ministry of Economic Development, the Ministry of Science and Innovation, the Department of Labour and the Department of Building and Housing. We are the lead agency for delivering Better Public Services for business – including creating a one-stop online shop for all government advice and support to businesses. We're working to reduce the effort businesses put into dealing with government, and raise performance ratings for government savings. MBIE also drives the Government's business growth agenda by:
>
> - Backing New Zealand's talent, ideas and enterprise
> - Supporting a better environment and better prospects for business
> - Helping improve the way Government works with business. (MBIE, n.d.[a])

Two boards were established in 2010 to provide strategic advice and make decisions on non-departmental funding administered by MSI. They were the Science Board and the Innovation Board. The Science Board still operates under MBIE, while the functions of the Innovation Board have been transferred to Callaghan Innovation.

The Science Board makes funding decisions to enable New Zealand research organisations to conduct high-quality research that delivers economic, social and environmental benefits for New Zealand (MBIE, n.d.[b]). Callaghan Innovation was established on 1 February 2013 as a stand-alone Crown entity. It manages a $140 million a year portfolio of government funding and grants to support business innovation and capacity building (Callaghan Innovation, n.d.).

5.2.9 Ministry for Primary Industries

On 1 July 2011, the Ministry of Agriculture and Forestry (MAF) and the Ministry of Fisheries were merged to create a single agency spanning the whole of the primary sector: the Ministry for Primary Industries (MPI) (MPI, n.d.[b]). MPI administers the Biosecurity Act 1993, enforces HSNO legislation with regard to 'new organisms' not yet in the country, and monitors containment facilities and controls on GMOs. MPI also gives advice on GM coexistence with non-GM production systems.

MPI upholds a 2003 Memorandum of Understanding with ERMA (originally held by MAF and ERMA), which relates specifically to new organisms enforcement (MPI, n.d.[c]). This was agreed following the introduction of the HSNO Amendment Act 2003, under which ERMA was responsible for ensuring the enforcement of the Act's provisions with respect to new organisms. The Memorandum established mutually agreed intentions between MAF and ERMA, to ensure successful cooperation between the two parties in the management of new organisms.

As directed in the 2003 Memorandum, MPI's (formerly MAF's) responsibilities in relation to the management of new organisms are:

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 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. MPI is also responsible for managing and responding to incursions and non-compliance situations. However, if EPA New Zealand disagrees with MPI's proposed course of action and these disagreements cannot be resolved EPA 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 EPA 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 MPI to make an application for the use of a new organism in an emergency; in this case the application must go through the normal EPA channels. (MAF, 2003: 3)

Due to the extent of recent institutional change and the large scope of MPI's mandate it seems timely to take a closer look at how some of the responsibilities relating to GM regulation have been operationalised.

> MAF Biosecurity New Zealand (MAFBNZ) (formerly the Biosecurity Authority) was incorporated into MPI in April 2012. MPI Biosecurity New Zealand is the lead agency in New Zealand's biosecurity system and has been tasked with a 'whole-of-system' leadership role, encompassing economic, environmental, social and cultural outcomes. MPI has labelled this model the Biosecurity System. It also has international trade and animal welfare responsibilities. The Biosecurity System aims to effectively manage the harm that pests or diseases can cause to New Zealand's economy and environment as well as our health. It covers activities in the following areas:
> Offshore – reducing the risks posed by other countries through activities such as developing Standards and Regulations.
> At our borders stopping biosecurity – risk pests and diseases getting into New Zealand.
> Within our borders – eradicating or managing those pests and diseases that have established. (MPI, n.d.[d])

The Biosecurity System operates at the level of central government, regional councils, industry, and community groups. The geographic model is separated into three separate but interrelated zones of activity:

> Global – rest of the world, outside New Zealand's borders, where biosecurity risks emerge and information on intelligence and surveillance is gathered and exchanged. This is where international treaties and multi-lateral agreements are negotiated and where responsibility for facilitating trade access and for New Zealand's reputation lies.
>
> Pathways and Borders – the mode in which biosecurity-risk goods and organisms arrive and enter New Zealand, the final point at which people, goods and craft are given approval to enter into or depart from New Zealand, including all the activity to manage risk prior to or at the border. This includes export trade inspection and official assurances.
>
> Within New Zealand – the management of risks and impacts of pests and diseases that have crossed the border and diseases that have already established in New Zealand. The effective national biosecurity management together with animal welfare management enables the assurance of New Zealand as an exporter that is free of biosecurity-risk goods. (MPI, n.d.[d])

To fulfil these responsibilities, MPI identifies and manages any potential biosecurity risks at the border. It also provides domestic and offshore technical inspection and clearance services.

Unlike the EPA, MPI has a role not just in the monitoring of GMOs before release, but also following EPA approval for full release without controls. In the latter case, MPI would manage any negative effects, along with DOC and the Ministry of Health if necessary.

As stated in the 2003 Memorandum of Understanding, it is MPI's responsibility to inspect and audit the containment facilities that store GMOs. MPI holds records of the number and names of all the containment facilities in New Zealand (indoor and outdoor), of which (as of May 2013) there are 94 (Kebbell, MPI, personal communication, 2013). However, MPI does not keep a record of exactly which approvals are active in each indoor containment facility at any given time, as approvals can be activated and deactivated on a regular basis. Nor does MPI have records showing which of these facilities undertake GM research or store GMOs specifically, as the standards apply to research or storage of any material that poses a biosecurity risk.

MPI/EPA containment standards for new organisms (see Appendix 6) require the annual inspection of containment facilities for plants; all other containment facilities are inspected every six months. The GM-cattle outdoor containment area is inspected every three months and the GM-plant outdoor containment area is inspected at times appropriate to stages in the life-cycle of the crop, such as planting, harvesting or when flowering structures occur (MAF, 2007). Every audit is written up as a formal report and may be accessed under the Official Information Act (OIA). Additionally, the EPA may impose further monitoring or reporting as part of the controls on an experiment under s 38D of the HSNO Act.

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

In 2010 NZFSA was incorporated into MAF; MAF, in turn, was incorporated into MPI in 2012. MPI now manages food safety in New Zealand. MPI's Food Safety Authority ensures that safe and suitable food supply is a public health priority and that foods containing genetically modified ingredients are labelled correctly (MPI, n.d.[b]).[31]

5.2.10 Ministry of Research, Science and Technology

In 2011 the Ministry of Research, Science and Technology (MoRST) merged with FRST to form the Ministry of Science and Innovation (MSI). This was followed in July 2012 by MSI's merger with three other agencies to form MBIE (Mapp, 2011; MBIE, n.d.[c]).

Before the merger MoRST had prepared a number of reports and strategies, including *Futurewatch Current Work*. An earlier research report, *Hands Across the Water* (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

31 '*Standard 1.5.2 – food prodcued using gene technology*' in the Food Standards Code, governs GM food in New Zealand.

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: 144–146).

5.2.11 Ministry of Science and Innovation

The Ministry of Science and Innovation (MSI) was formed by the merging of MoRST and FRST in 2011. It existed until 2012 when it became part of MBIE.

5.2.12 Science Media Centre

In 2007, as part of a strategy to promote science in the national media and increase public engagement with science and technology, MoRST announced a three-year pilot initiative, the New Zealand Science Media Centre. The Royal Society of New Zealand won the bid to develop and operate the Centre. After consultation with media, the scientific community and other stakeholders, the New Zealand Science Media Centre was launched on 30 June 2008. Full funding was renewed for a second three-year period in 2010 (Science Media Centre, n.d.).

The Science Media Centre has been criticised for a perceived lack of impartiality in its representation of GM issues, and accused of favouring pro-GM positions when it compiles or comments on research. University of Canterbury geneticist Professor Jack Heinemann has commented that he thought the Centre had 'failed as an objective or evidence-based provider of information for the media on the issue of GM' (Gorman, 2013).

5.2.13 Statistics New Zealand

Statistics New Zealand conducted the Bioscience Survey (formerly the Biotechnology Survey), publishing the results biennially, until the survey was discontinued in 2013 (Statistics NZ, 2013). It analysed the use, development, production, spread and size of bioscience within New Zealand industries (Statistics NZ, n.d.[a]).

5.3 Local Government Institutions

While the HSNO Act is the principal regulatory mechanism for GMOs, in some cases local authorities have been considering whether they should introduce controls on GMOs in their areas through the Resource Management Act 1991 (RMA) or the Local Government Act 2002 (MfE, n.d.[b]).

5.3.1 The Inter-Council Working Party on GMO Risk Evaluation and Management Options

The Inter-Council Working Party on GMO Risk Evaluation and Management Options (ICWP) was established in 2003 in response to community concerns in the Northland region about GMOs. The Far North, Whangarei and Kaipara District Councils, the Auckland Council and Northland Regional Council are represented on the working party. In 2009 market research company Colmar Brunton was

commissioned by the ICWP to conduct a detailed public opinion survey of attitudes to GMOs and their management in the Northland and Auckland regions (Colmer Brunton, 2012).

In February 2013, the ICWP released recommendations on risk evaluation and management options associated with the outdoor use of GMOs. The ICWP also produced draft plan change provisions, an evaluation under s 32 of the RMA and a series of reports on managing the risks associated with the outdoor use of GMOs (Whangarei District Council, 2013). While we have not surveyed councils throughout the country, the following are the current positions on this issue of councils that we are aware of.

- *Hastings District Council* – Agrees in principle to a moratorium on GMO releases to limit risk to agriculture and viticulture (Davison, 2013a). The council released a draft plan in April 2013 that proposes a prohibition on the release of GMOs and classifies outdoor field tests as discretionary activities, meaning resource consent is needed to undertake them (Hastings DC, n.d.).
- *Whangarei District Council* – Agrees to seek changes to its district plan to prohibit the release of GMOs (until more is known about risks and benefits) and make experiments a discretionary activity (Molloy, 2013).
- *Auckland Council* – Will consider putting GMO limits in its Unitary Plan in July 2013 (Davison, 2013a).
- *Bay of Plenty Regional Council* – The council released a proposed regional policy statement, including a requirement that the precautionary approach be taken when dealing with any GMOs. In 2010 Federated Farmers and Scion both appealed the clause at the Environment Court. At the time of writing this process is ongoing (Bay of Plenty Regional Council, n.d.[a]).
- *Northland Regional Council* – Decided not to include the issue of GMOs in its policy document despite over 300 submissions calling for precautions to be included. It considers the control and regulation of GMOs a matter for central government (Molloy, 2013).
- *Far North District Council* – Supports the precautionary approach to GMOs and intends to continue involvement with the ICWP (FNDC, 2013: 52).
- *Kaipara District Council* – Is involved in the ICWP and continues to support the precautionary approach toward genetic engineering (Kaipara District Council, 2012: 122).

Discussion around local councils regulating the use of GMOs themselves is still emerging. In June 2013 the Minister for the Environment, Amy Adams, announced that she will block councils from regulating GMOs in their council plans under the RMA (Davison, 2013b). This issue is discussed further in Section 7.2.6.

5.4 Crown Research Institutes

There are seven Crown Research Institutes (CRIs) in New Zealand, all established in 1992 by the Crown Research Institutes Act 1992 (MBIE, 2013). Four of these entities have conducted GM research in the past, and three of them (AgResearch, Plant & Food Research, and Scion) have played a significant role in the development of GM in New Zealand, and have conducted the majority of the outdoor experiments. See Section 6, for further discussion on AgResearch, Plant & Food Research and Scion.

5.4.1 AgResearch

AgResearch (previously known as the New Zealand Pastoral Agriculture Research Institute Limited) is charged with developing New Zealand's pastoral, agri-food and agri-technology sector (MBI, 2011a). AgResearch has been conducting GM outdoor field tests since 1996 and is running one of the two remaining outdoor GM field tests (see ERMA200223, Appendix 9, Table 11).

5.4.2 Landcare Research

While not currently conducting outdoor experiments, Landcare Research has undertaken indoor GMO experiments and research in the past.

5.4.3 Plant & Food Research

On 1 December 2008, two CRIs, HortResearch and Crop & Food Research, merged to form Plant & Food Research (Plant & Food Research, n.d.[a]). Its area of research is New Zealand's horticultural, arable, seafood, food and beverage industries (MBIE, 2011b). Plant & Food Research has undertaken no new GM field tests since the merger and their work on existing experiments ceased in 2008 following the identification of a breach of controls at their Brassica test site (see section 6.3).

5.4.4 Scion

Scion is the trading name for the New Zealand Forest Research Institute Limited. It focuses on the research and growth of forestry and wood products in New Zealand (MBIE, 2011c). Scion has been conducting outdoor GM tests since 2000, and is currently running one of the two remaining outdoor GM field tests (see ERMA200479, Table 11, Appendix 9).

5.5 Non-governmental Organisations

A number of non-governmental organisations (NGOs) and industry groups have engaged in debates and submission processes over recent years. Some of the more prominent are described briefly below.

5.5.1 Agcarm

Agcarm is an industry association representing more than thirty manufacturers of crop protection and animal health products. One of its aims is to facilitate the introduction of GM crops into New Zealand (Agcarm, n.d.).

5.5.2 Federated Farmers

Federated Farmers is a lobby group that advocates for the interests of farmers in New Zealand. Its position on GM is that farmers should have the right to decide if they want to use the technology and that a blanket ban on GM is 'unhelpful and unuseful' (Gullery, 2012). Federated Farmers recently issued a press release supporting the Minister for the Environment's proposal to block local councils from regulating GMOs through the RMA (Federated Farmers, 2013).

5.5.3 GE Free New Zealand

GE Free New Zealand is a nationwide non-profit organisation that campaigns through petitions, court actions and reporting to make New Zealand food and environment free from genetic engineering (GE Free NZ, n.d.).

5.5.4 Horticulture New Zealand

Horticulture New Zealand represents 5500 commercial fruit and vegetable growers, acting as an advocate on national, industry-wide issues. Its position on GM is that the industry should, at this stage, focus on non-GM technologies. This position recognises the considerable consumer opposition to GM food products and that the absence of commercial production of GM crops is complementary to New Zealand's 'clean green' image (Horticulture New Zealand, 2009).

5.5.5 New Zealand Biotech Association

The New Zealand Biotech Association (NZBIO) is focused on developing the bioeconomy within New Zealand, promoting the sustainable development of the biotech industry, together with economic prosperity (NZBIO, n.d.). NZBIO states that not all biotechnology involves genetic modification, and its focus is on that which is non-GM.

5.5.6 Pure Hawke's Bay

Pure Hawke's Bay is a recently established advocacy group made up of food producers who are currently lobbying their local council to formalise the region's GM-free status. The group say they are neither for nor against GM in principle, but describe themselves as 'market-led' and 'committed to building our region's reputation for safe, sustainable and high quality food' (Pure Hawke's Bay, n.d.[a]). The group hopes Hawke's Bay councils will draw on the work of the Inter-Council Working Party (see Section 5.3.1) and make field tests discretionary under the district plan (Pure Hawke's Bay, n.d.[b]).

5.5.7 Organics Aotearoa New Zealand

Organics Aotearoa New Zealand (OANZ) is a group that offers coordination, advocacy and leadership support to member organisations. It promotes the use and production of certified organic products within New Zealand (Organics Aotearoa New Zealand, n.d.). OANZ has supported court actions against GM field tests in the past, and stated that genetic modification poses a significant threat to organic farmers and growers.

5.5.8 Pastoral Genomics

Pastoral Genomics is funded by DairyNZ, Fonterra, Beef + Lamb New Zealand, DEEResearch, AgResearch and MBIE. It describes itself as an 'industry-good research consortium' (Pastoral Genomics, n.d.[a]), with the following purpose:

> Biotechnology will give the greatest stepwise and sustainable gains in forage productivity while maintaining and enhancing the sustainability and competitiveness of our country's meat, dairy and wool industries. Our strong science, industry-led strategy, and emphasis on application and development will ensure we breed the best new cultivars and place them in the hands of our farmers first, we only use ryegrass genes in ryegrass and clover genes in clover – we call this Cisgenics. (Pastoral Genomics, n.d.[b])

5.5.9 Save Animals From Experiments

Save Animals From Experiments (SAFE) is an animal rights organisation that has consistently protested against GM experiments being carried out on animals. For example, they state: 'The commercial production of transgenic livestock is likely to lead to the reduced welfare of the animals used in addition to the risks associated with breeding transgenic animals' (Kriek, n.d.).

5.5.10 Soil and Health Association

The Soil and Health Association, which publishes *Organic NZ*, is the largest-membership organisation supporting organic food and farming in New Zealand. It has been campaigning since the lifting of the moratorium in 2002 for a GE-free New Zealand (Soil and Health Association, n.d.).

5.5.11 Sustainability Council of New Zealand

The Sustainability Council is a Wellington-based research and advocacy trust that aims to assist the realisation of a sustainable New Zealand (SCNZ, n.d.). Since 2003 the Council has promoted the concept of New Zealand remaining a GM-free food producer (SCNZ, 2003a).

5.6 Review Body

In 2003 the government instigated an independent review of ERMA's management of GMOs. The review was conducted by a three-person team led by Graeme Nahkies, a former chief executive of Environment Waikato and Hutt Valley Health Ltd. It focused on ERMA's decisionmaking capacity, particularly for new organisms, under the HSNO, following the Royal Commission on Genetic Modification and the government's response (Hobbs, 2003).

This resulted in the publication of *A Review of the Capability of the Environmental Risk Management Authority (ERMA) Relating to the Risk Management of New Organisms* (ERMA, 2003a). The report, frequently referred to as 'the Nahkies report', made 49 recommendations. These included a number of clarifications, improvements and reinforcements in relation to ERMA's fitness for purpose. Recommendations were made on enhancements to:

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

The main driving factors behind the review were that: (i) the organisation had now been established and it was timely to review its resourcing and structures against current demands, expectations and operating environment; (ii) three new pieces of legislation (two on hazardous substances and one on new organisms) would require increasing ERMA's workload, and (iii) it was moving from a small to medium-sized corporate entity with 25 additional staff positions (personal communication between ERMA and the Hon. Marian Hobbs, 26 August 2003).

The key recommendations from the Institute's perspective were:

1. to ensure effective dialogue on the selection of particular controls and the frequency of monitoring (Recommendation 16);

2. to ensure that 'core registers' exist and work effectively with other key entities such as MAF, DOC and the Ministry of Fisheries (Recommendation 17);

3. to ensure that the management, communication and calculation of risk, particularly where risks and benefits are uncertain, minority views exist, and risks and benefits are not shared by the same stakeholders (Recommendations 18–28);

4. that 'there should be periodic reviews at Authority level of the satisfactory presence of specialisms and management competencies critical to the Agency's achievement of the reputation as an even-handed adviser to a wise Authority making informed judgement's' (Recommendation 43), and

5. that 'policy agency relationships should be sustained where established and reinforced where liaison is limited' and 'liaison for compliance and enforcement purposes should be examined to explore the division of responsibilities between ERMA and other agencies' (Recommendations 48, 49). (Personal communication between ERMA and the Hon. Marian Hobbs, 26 August 2003)

A November 2003 letter from ERMA to the Minister for the Environment stated 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 raising … in some cases, action in line with the review team's findings had been taken either before or during the review, and … in many instances, the changes we have made go considerably beyond the review team's recommendations. (ERMA, 2003b: 6)

5.7 Strategy Bodies

There have been two main strategy documents in this field, both published in 2003, the *New Zealand Biotechnology Strategy: A Foundation for Development with Care*, (MoRST, 2003a) published by MoRST and the *Biosecurity Strategy for New Zealand* (Biosecurity Council, 2003) published by MAF and written by the Biosecurity Council. Both documents were discussed in our 2008 report (SFI, 2008b: 40) and, to our knowledge, there have been no significant strategy documents published since 2003.

The *New Zealand Biotechnology Strategy: A Foundation for Development with Care* was released in May 2003 and the key theme was 'development with care', which 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, 2003a)

The following indicators were identified to show whether or not the strategy had been implemented successfully:

- growing public awareness of new biotechnology developments;
- public confidence in the way the sector carries out its work;
- significant movement towards sector growth targets;
- greater depth of expertise across the biotechnology sector which ensures opportunities are being seized to realise the benefits of New Zealand's world-class research;
- greater depth and breadth in biotechnology global linkages;
- public confidence that the regulatory system provides the necessary safeguards;
- confidence among researchers that the regulatory system is able to accommodate innovation;
- stronger co-ordination between key players in the biotechnology sector and relevant government agencies. (MoRST, 2003a: 34)

However, these indicators provide few measurable criteria or timeframes in which to meaningfully assess their level of implementation. MoRST has stated that progress on the taskforce's recommendations was evaluated in 2004, and it was found that good progress had been made (SFI, 2008b: 39).

The *Biosecurity Strategy for New Zealand*, was published in August 2003. Notably it does not include discussion of issues relating to genetic modification, other than to note a gap in capability that needs to be addressed:

> 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. (Biosecurity Council, 2003)

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.

5.8 International Treaties

The *Cartagena Protocol on Biosafety* (UN, 2000a) is an international agreement on trans-boundary movement of living modified organisms (and 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 that of New Zealand), it came into force on 11 September 2003. The Cartagena Protocol is a treaty designed to enhance biosecurity by providing 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 (MfE, 2013a).

> To ensure all countries have ready access to the information they need under the Protocol, an internationally centralised web-based 'Biosafety Clearing-House' mechanism has been set up. In New Zealand, the EPA is responsible for providing the Biosafety Clearing House with the necessary information on New Zealand decisions on living modified organisms (LMOs), including information relating to approved exports. (MfE, 2013a)

In February 2006, the Sustainability Council of New Zealand released *Brave New Biosecurity: Realigning New Zealand's Approach to the Cartagena Protocol*, which outlines the 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. (SCNZ, 2006)

The Council's report concludes that the New Zealand government's actions in negotiations have not supported these developments, and that New Zealand's position should be more strongly aligned with these.

New Zealand is currently negotiating an international agreement with 10 other Asian and Pacific-rim countries including the United States, called the Trans Pacific Partnership. It has the potential to have a significant impact on GM regulation and labelling requirements in New Zealand (It's Our Future, n.d.). See Section 7.2.11, Managing foresight, for further discussion.

5.9 The Situation in 2013

Many observations arise from this section, and further analytical discussion is presented in Section 7. However, the eight points below highlight our primary observations about each sector.

1. Legislative issues: legislative review of the current liability system may be required. This issue becomes especially pertinent when considering the recent developments in the relationship between local and central government. Part of the push from local government to amend GM regulation has been driven by perceived faults in the current liability system.

2. Central government: the government has implemented significant institutional changes in the last five years, none of which provide any additional assurance that the system is better positioned to manage the potential risks and benefits of GMOs. On the contrary, the changes raise concerns about the continuity of institutional knowledge within the regulatory framework. Furthermore, although the impetus for the changes has been to reduce costs, whether or not these savings have materialised is not readily apparent. Most importantly, we seem no closer to the informed governance framework that was envisaged by the Commissioners – one that would enable New Zealand to make effective decisions on GMOs in the short to medium term.

3. Local government: a recent trend has been the increase in local bodies employing the RMA framework to regulate GMOs rather than relying solely on the HSNO Act. This has created an ongoing dispute, and is likely to cause significant policy development. Currently appeals from Scion and Federated Farmers are before the Environment Court, contesting the inclusion of the precautionary principle in the proposed Regional Policy Statement for the Bay of Plenty.

4. CRIs: the only entities currently pursuing GM testing in the outdoors in New Zealand are CRIs. The benefits to CRIs do not automatically equate to benefits for New Zealand, particularly if they have entered into joint ventures with private companies. Therefore there is a need to ensure the applications of CRIs are properly scrutinised. This issue is discussed further in Section 7.2.1.

5. Non-governmental organisations: many NGOs remain heavily engaged in this debate, and 2013 has seen activity on both sides of the debate and the emergence of new groups, for example Pure Hawke's Bay (see Section 5.5.6). The most recent activity of note is the Sustainability Council's High Court action against a decision by the EPA not to classify a technique known as zinc finger nuclease (ZFN-1) as genetic modification. In addition, Federated Farmers has publicly supported potential resource management reform to prevent local councils regulating GMOs.

6. Review body: the 2003 'Nahkies report' remains the most recent instrument in this area. The recommendations made in this report are considered to have been fully implemented, however to the best of our knowledge there have been no reviews for ten years since 2003.

7. Strategy bodies: there have also been no new strategy documents produced since 2003. The absence of any recent review or strategic planning documents, combined with considerable institutional change in the last five years, raises important questions about the application of risk management policy in this area.

8. International treaties: New Zealand is still a party to the *Cartagena Protocol on Biosafety*, the international agreement on trans-boundary movement of living organisms. In addition, many have expressed concern at the potential effects of the Trans Pacific Partnership on labelling requirements and the regulation of GM food in New Zealand (It's Our Future, n.d.). See Section 7.2.11 Managing foresight, for further discussion.

6. Crown Research Institutes

Currently, only two outdoor experiments are being undertaken in New Zealand, both by Crown Research Institutes (CRIs). Since the implementation of the HSNO framework 15 years ago, CRIs have dominated GM research in the outdoors; AgResearch, Scion and Plant & Food Research (formerly Crop & Food Research) have been the major players. In this section we discuss the legislative and accountability framework around CRIs and what this means for outdoor GM research. We then look more closely at each of the three CRIs: AgResearch and Scion, which are both currently undertaking GM experiments in the outdoors, and Plant & Food, which has previously undertaken such experiments. We close this section by suggesting five principles that should be applied to the CRI system in order to deliver more effective public investment in the future.

CRIs are in the difficult position of being both inside and outside government. They are administered by MBIE under the Crown Research Institutes Act 1992, however Treasury's Crown Ownership Monitoring Unit (COMU) retains a role in monitoring the financial performance of CRIs.[32] The Act requires each CRI to operate as a going concern (i.e. a viable company), and it sets out a number of key principles that in turn create tension for CRIs undertaking GM experiments:

> Section 5 Principles of operation
> (1) Every Crown Research Institute shall, in fulfilling its purpose, operate in accordance with the following principles:
> **(a) that research undertaken by a Crown Research Institute should be undertaken for the benefit of New Zealand:**
> (b) that a Crown Research Institute should pursue excellence in all its activities:
> **(c) that in carrying out its activities a Crown Research Institute should comply with any applicable ethical standards:**
> **(d) that a Crown Research Institute should promote and facilitate the application of—**
> **(i) the results of research; and**
> **(ii) technological developments:**
> (e) that a Crown Research Institute should be a good employer as required by section 118 of the Crown Entities Act 2004:
> **(f) that a Crown Research Institute should be an organisation that exhibits a sense of social responsibility by having regard to the interests of the community in which it operates and by endeavouring to accommodate or encourage those interests when able to do so. [Bold added]**

With respect to GM research, points (a), (c), (d) and (f) are of particular relevance:

a. Whether the experiments are beneficial to New Zealand (e.g. are they in the country's best interests considering our '100% Pure' brand;

c. Whether the experiments comply with ethical standards in terms of effects on transgenic animals;

d. Whether a CRI promotes and facilitates the sharing of the results of its research (e.g. how much of the research will be made public and shared with the wider New Zealand scientific community);

32 'Until 31 January 2011, COMU was the primary monitoring department for CRIs. From 1 February 2011 until 30 June 2012, MSI was the primary monitoring department for all CRIs, with COMU having a secondary role in monitoring CRIs' financial performance. On 1 July 2012, MSI operations were transferred to MBIE, where the monitoring of CRIs continued to be carried out by the original monitoring group. Monitoring CRIs is now one of the functions of MBIE – Science, Skills and Innovation Group.' (Office of the Auditor-General, 2013b: 8).

f. Whether a CRI exhibits a sense of social responsibility in regard to the interests of the community in which it operates e.g. is an action such as Scion's appeal against the Bay of Plenty Regional Council in the best interests of the local community? (This case is currently before the Environmental Court. Scion is appealing against the proposed requirement that a precautionary approach be taken when dealing with GMOs in the draft regional plan, see Section 5.3.1).

CRIs are held to account in regard to their expenditure through a Statement of Core Purpose (SCP) negotiated between the government and each CRI. The SCP sets out the enduring purpose and focus of the CRI, and it is required to operate with regard to the principles of the Crown Research Institutes Act 1992 to deliver outcomes that resonate with its SCP. As Crown entities, CRIs are also audited by the Office of the Auditor-General. Its March 2013 report on CRIs notes:

> Crown research institutes (CRIs) are central to the Government's expectation that investing in science makes a significant contribution to New Zealand's economic and environmental prosperity … Although all CRIs had some measures for assessing outcomes, they did not always report clearly what was being measured and whether the outcome was being met. In my view, CRIs need to improve their reporting of achievements against core purpose outcomes. This is an essential part of the accountability of CRIs for the Government's investment in science. (Office of the Auditor-General, 2013a: 5)

The report notes that a key concern is the level of reporting against SCP outcomes:

> Only Landcare Research had reported against the outcome/impact measures set out in its 2011-16 SCI [Statement of Corporate Intent] for core purpose outcomes. Using the framework set out in its 2011-16 SCI, Landcare Research reported progress against its SCP [Statement of Core Purpose] outcomes in its annual report for 2011/12, using KPIs (key performance indicators) for each impact. It then discussed the highlights achieved during the year that related to each specific outcome/impact. Outcomes, impacts, and the initiatives that related to them were clearly linked, so the reader could see how Landcare Research's activities were intended to affect national outcomes and what progress had been made. Landcare Research could further improve its reporting by including measures of the outcome KPIs and providing, over time, some trend data.
>
> In comparison, most of the other CRIs had a lot of information on their main innovations, achievements, programmes, or projects and might have loosely linked these to overall outcomes. However, they did not report any results against the SCP outcome measures included in their SCI. This makes it difficult for the reader to see whether the CRI achieved what it intended to achieve. We will discuss the quality of performance reporting with the CRIs and MBIE and encourage them to make improvements …
>
> … CRIs could further improve their reporting by also disclosing the results of actual performance against outcome measures in this context. Over time, this would allow readers to see whether the achievements and core funding spent are affecting the overall outcomes.
>
> In general, CRIs need to improve how they report achievements against SCP outcomes. This is an essential part of their accountability to their sector groups and to the Government. (Office of the Auditor-General, 2013a: 27–28)

CRIs rely on public money to operate and they have a responsibility to use those funds in the public interest. The institutes currently manage a large amount of public funds and assets, and AgResearch, in particular, wields significant influence over the science industry in New Zealand (see Table 3 overleaf).

Table 3: Summary of 2011/12 CRI financial results
Source: Office of the Auditor-General, 2013a: 15

CRI	Revenue	Net profit		Planned net profit	Variance from plan	Dividend
	$ million	$ million	Percentage of revenue	$ million	$ million	$ million
AgResearch	157.6	4.2	2.7%	4.2	0.0	0
ESR	58.6	2.4	4.1%	2.9	-0.5	0
GNS	73.7	4.0	5.4%	2.2	1.8	0.6
IRL	67.8	1.2	1.7%	2.2	-1.0	0.3
Landcare Research	59.3	1.3	2.2%	1.4	-0.1	1.1
NIWA	121.3	5.5	4.6%	3.0	2.5	0
Plant & Food Research	121.4	1.3	1.1%	0.1	1.2	0
Scion	43.9	1.6	3.7%	1.3	0.3	0
Total	**703.6**	**21.5**		**17.3**		

In the following sections we review three CRIs and provide a brief analysis of some of the more controversial field tests that have been undertaken in the 17 years since the HSNO legislation came into effect.

6.1 AgResearch

> Statement of Core Purpose for AgResearch Limited – AgResearch's purpose is to enhance the value, productivity, and profitability of New Zealand's pastoral, agri-food, and agri-technology sector value chains to contribute to economic growth and beneficial environmental and social outcomes for New Zealand. (MBIE, n.d.[d])

While AgResearch works in a number of areas, with respect to its transgenic work programme the institute's overarching goal, as stated on the 'Transgenics' page of its website, is to develop and evaluate transgenic technology for livestock applications to provide potential future options for New Zealand's pastoral industries. Three main areas of work are listed:

1. 'Biopharming' or the production of proteins in the milk of transgenic dairy animals.

2. Transgenic strategies to improve food products from livestock that are safer and healthier for human consumption.

3. Improving the predictability and safety of the technology. (AgResearch, n.d.[a])

The stated purpose of its current approval is to genetically modify goats, sheep and cows to produce human therapeutic proteins, and the approval relates to the use of human DNA, *E.coli* bacteria, and mice as well as goats, sheep and cows (see ERMA200223, Appendix 9).

AgResearch is the only CRI that has undertaken research involving genetically modified animals. Its transgenic animal programme has attracted considerable controversy since the first application in 1999, which sought to produce cow's milk with proteins that could be of nutritional value or have value as a drug for the treatment of multiple sclerosis (MS) (see GMF98009 [i], [ii] and [iii], Appendix 9). A number of parties saw this aim as an example of irresponsible public relations manipulation on the part of AgResearch, believing the potential for tangible benefits to be overstated and misleading for MS suffers and the New Zealand public as a whole.

In May 2001, in response to the High Court decision of Bleakley v Environmental Risk Management Authority [2001] 3 NZLR 213 (HC), Dr Keith Steele, the CEO of AgResearch, stated:

> [T]he decision of the High Court to refer AgResearch's myelin cattle research application back to Environmental Risk Management Authority for another lengthy approval process is disappointing and will be frustrating for Multiple Sclerosis sufferers … There has been every indication that the project can assist in the treatment of Multiple Sclerosis as MBP is known to have beneficial effects for sufferers but cannot be produced in sufficient quantities to be widely available. (Steele, 2001)

At the time, few scientists were willing to speak publicly on the issue. However, Waikato University's Professor of Biological Sciences, Dick Wilkins,[33] responded to AgResearch's claims by stating that the medical benefits were 'largely a nonsense' and that 'the basic science behind the work would simply not stand up to serious review' (Court calls for rapid rethink on GM cow research, 2001; Green Party, 2001).

No international scientific evidence was ever presented to ERMA to support the claim that the protein AgResearch was trying to produce – myelin basic protein (MPB) – was required in bulk or that MPB had a significant beneficial effect for MS patients. In fact, international evidence suggested the opposite. For example, Dr Lawrence Steinman,[34] an MS specialist at the University of Stanford School of Medicine, was quoted in a Listener article in August 2001 saying that '[h]uman or cow MPB can easily be made in bacteria of microbes by fermentation. There is no need to produce it in cows at present' (Revington, 2001: 20).

Jeanette Fitzsimons, co-leader of the Green Party, noted at the time:

> AgResearch is not a medical research institution. It has absolutely no experience in multiple sclerosis, neurology or basic myelin protein. It is involved in agricultural research and the purpose of this project is to try to use cows to manufacture bulk quantities of a protein. That is where this project will stop. There is no indication who, if anyone, will then do the clinical work with that protein to see if it is useful and if so, develop a drug. (Fitzsimons, 2001)

In February 2002, AgResearch put before the Finance and Expenditure Select Committee (which was hearing submissions on the Hazardous Substances and New Organisms [Genetically Modified Organisms] Amendment Bill 2001) a statement opposing restriction on the release of GMOs. As a result, AgResearch was asked to provide quantification of the prejudice that a constraint period of two years on the release of GMOs would have on the commercialisation of research. In response, in a document dated 21 February 2002, AgResearch argued:

33 Professor Wilkins was editor of the website G&D, www.genesanddairying.com. G&D reported that '… the scientific rationale behind the trial should be re-examined and that some experts in the field had extremely strong reservations about the whole approach and its future treatment of Multiple Sclerosis and believed that serious consideration should be given to dropping the experiment, in its present form. This suggestion drew an extremely strong response from the NZ Life Science lobby group, but little information from them or any other party about the core scientific issues on which the MBP project is based.' (Genesanddairying, 2001)

34 Dr Steinman is Professor of Neurology and Neurological Sciences, Pediatrics, and Genetics at Stanford University, California. His research focuses on 'what provokes relapses and remissions in multiple sclerosis (MS), the nature of the genes that serve as a brake on brain inflammation, and the quest for a vaccine against MS' (Stanford University School of Medicine, n.d.). He is also the co-founder of Neurocrine Biosciences, Bayhill Therapeutics, Nuon Therapeutics, and Atreca (Stanford University School of Medicine, n.d.).

> Commercial prejudice is illustrated by specific reference to a project AgResearch is undertaking in alliance with PPL Therapeutics. AgResearch's negotiations for commercialisation of a transgenic cow methodology, currently under development, to produce rare proteins for unmet human therapeutic needs, are far advanced with PPL … Successful completion of the joint venture will result in the creation of a New Zealand business worth approximately $50m which can be expected to grow both domestically and internationally with time. (Atkinson, 2002)

The moratorium on releasing GM organisms continued until October 2003. Thereafter AgResearch was free to seek the commercial advantage it believed was possible, but by 2004 PPL Therapeutics (the Scottish company that had famously cloned Dolly the sheep in 1996) was facing bankruptcy (Stewart, 2004) and the $50 million promised to the New Zealand economy never materialised.

Under AgResearch's transgenic livestock programme the CRI has also grouped multiple transgenic animals together in one application. Approvals for eight animals were sought in both application GMF07001 and GMF07074, which were withdrawn in 2010. The approval for the research that is currently being undertaken (ERMA200223) relates to the use of human DNA, E. coli bacteria, cows, sheep, goats and mice. Compared to international transgenic research, this is a broad application. In a 2007 report, the US-based Council for Agricultural Science and Technology (CAST) lists North American and European groups producing bioproducts or biomedical models in transgenic livestock, showing a maximum of two animals per entity (CAST, 2007: 5).

In addition, a number of the animals in AgResearch's experiments are found in our common food chain. This was discouraged by the Royal Commission, whose Recommendation 7.5 suggested GM research be undertaken on 'non-food animals', or animals less likely to end up as food in New Zealand (RCGM, 2001a: 162).

In view of the fact that AgResearch is largely funded by the New Zealand taxpayer, we consider it has an added responsibility to provide clarity and transparency over its objectives. Arguably, a statement that now appears on AgResearch's website under the title 'Daisy Q&As' provides more accuracy than earlier statements.[35] In answer to the question 'What's the potential benefit to New Zealand of this work?' the following statement is provided:

> This work increases **the image of New Zealand in the field of science on the world stage** given the importance of the research, but it otherwise is difficult to quantify at the moment, given the discovery nature of the study and also the fact we operate within **one of the world's strictest GM regulatory environments.** [Bold added] (AgResearch, n.d.[b])

This assessment of the benefit of the research is very different from that implied in 2001 (see quote by Steele, on previous page). This statement by AgResearch directly above suggests that this work is about promoting New Zealand as a world leader in science. In addition, it suggests that, because our current regulatory system is one of the world's strictest, it acts as an obstacle to AgResearch in quantifying the benefits. This is surprising, as although our regulatory system may be strict when viewed globally, this has not prevented AgResearch from undertaking novel GM research, resulting in a 'world first'. (See also the discussion below on Scion with regard to GM trees.)

Further, stricter controls could have been applied by ERMA. The McGuinness Institute has always advocated controls such as placing transgenic cows in barns (similar to Japan's Wagyu cattle), placing the animals on one of New Zealand's outer islands (rather than in the middle of a dairy-intensive

35 Daisy, born in 2012, was the first transgenic cow to produce milk that may be hypoallergenic (AgResearch, 2012a).

region in the North Island), or even outsourcing transgenic research to a country that does not have an agriculture-based economy.

6.1.1 Pastoral Genomics

Pastoral Genomics is a research consortium funded by MBIE and a number of organisations within the pastoral agricultural industry, including AgResearch, Fonterra, Beef + Lamb New Zealand, DairyNZ and DEEResearch (Pastoral Genomics, n.d.). The consortium is currently undertaking research into GM ryegrasses, with the intention of testing the grasses in Australia before applying to the EPA for approval to begin testing in New Zealand. The consortium's chair, Mike Dunbier, has stated:

> At present, the ryegrasses are growing in containment and have come through a field trial in Florida. The next move would be to apply to the Environmental Protection Authority for approval for field trials in New Zealand, but Pastoral Genomics wants to take one more step first. Trials in South West Victoria would be in an agricultural climate closer to New Zealand's. **They would also have the benefit of Australia's experience with similar trials and the controls needed.** [Bold added] (Morgan, 2013)

Pastoral Genomics is to be commended for taking a cautious approach before bringing a GM ryegrass field test to New Zealand. However, it is interesting to note that Dunbier considers South West Victoria to be more experienced at undertaking such field tests than New Zealand, which raises questions over this country's expertise in this area. Currently there are no GM grass experiments in the New Zealand outdoors, and there have not been experiments with grasses here since the implementation of the HSNO framework (see Appendix 9). If Pastoral Genomics goes ahead with its application to the EPA, it is hard to envisage the types of control that would ensure the grass was contained adequately to protect our '100% Pure' brand, and the associated premium we get for our products internationally.

6.2 Scion

> Statement of Core Purpose for New Zealand Forest Research Institute Limited (Scion) – Scion's purpose is to drive innovation and growth from New Zealand's forestry, wood product, and wood-derived materials and other biomaterial sectors, to create economic value and contribute to beneficial environmental and social outcomes for New Zealand. (MBIE, n.d.[e])

Scion has had an ongoing work programme involving GM research on radiata pine and Norwegian spruce since 1992. It is currently running outdoor field tests with GM *Pinus radiata*, with the aim of altering plant growth/biomass acquisition, reproductive development, herbicide tolerance, biomass utilisation, wood density and wood dimensional stability (Scion, 2010: 6). In a statement of purpose in its application ERMA200479, Scion stated:

> Trees and forests are an integral part of the New Zealand landscape. Trees affect us every day from the quality of the air we breathe, the houses we live in, to the paper we write on. Scion sees a future for biotech trees to help meet New Zealand's needs for a sustainable future, alleviating climate change and producing a wide range of new environmentally cleaner bio-products and bio-fuels. We see opportunity for Maori, as major forestry owners and managers, to enhance rangatiratanga through using and controlling these biotechnologies. This is our vision, built firmly on our past. (Scion, 2010: 4)

In 2000 ERMA granted Scion approval for outdoor experiments over a 20-year period, starting in 2003. Scion has stated that its experiments to date have shown no evidence of environmental impacts of any

kind resulting from genetic modification. The results have shown 'no evidence of the modified genes having transferred to other organisms; no evidence of detrimental impact on insect diversity by the genetically modified pines; no evidence of impacts on the micro-organism populations that live in close association with the pine roots' (Scion, n.d.).

> In December 2010, ERMA approved an application from Scion to further study genetic modification of forestry species on a 4-hectare containment site in Rotorua. The research will field test radiata pine with genetic modifications for genes with traits such as tree growth and wood quality. The research will consist of experiments run over 25 years, although individual trees will be destroyed once, or before, they reach reproductive age (at approximately 8 years). (Scion, n.d.)

But the question does need to be asked: are these experiments to assess the potential effects of horizontal gene transfer (HGT) best practice, legitimate, and being carried out by independent experts?

A 2006 paper written by an MfE staff member, Fleur François, reported that ERMA 'has taken the opportunity to seek information on the potential for horizontal gene transfer (HGT) to occur in the context of a GM field test. However, this environmental monitoring information has often been encouraged by informal means rather than explicitly in the controls for an approval' (François, 2006: 79). As an example of this, François cites ERMA's decision on application GMF99005 (GM pine and spruce field test):

> The Committee considers that this field test provides an opportunity to conduct further research on the long-term effects of genetically modified trees on soil micro-organisms. The applicant provided evidence at the hearing that [it] intends to conduct research on horizontal gene transfer, either themselves or in collaboration with other research institutes. (ERMA, 2000c: 20, cited in François, 2006)

François goes on to note that 'Given the limitations of current methodologies for detecting horizontal gene transfer (HGT) events we [MfE] have found informal encouragement of environmental studies to be a more feasible option than imposing prescriptive controls on approvals' (ERMA, 2000c: 20, cited in François, 2006). From the public's perspective, it is hard to see how an informal voluntary monitoring approach is the equivalent of or better than formal controls that are regularly monitored by an independent body, or separate independent research undertaken by an expert to assess the risks of placing a specific GMO in the New Zealand environment.

In November 2010, the Institute raised concerns about staff at Scion lobbying global organisations for fewer controls on GM trees, while declaring that they had no competing financial interest. Scion's Team Leader of Future Forests and Senior Scientists of Molecular Forestry was the principal author of a letter to the editor that appeared in the July 2010 edition of Nature Biotechnology, 'The 20-year environmental safety record of GM trees' (Walter et al., 2010). In our view, the letter misled readers as it stated that the authors had no financial competing interests, when the principal author was not only an employee of Scion but led the team that put together the application to ERMA to field test GM pine trees. Interestingly, the letter recognises that New Zealand is unique in undertaking such experiments, stating that 'it is now almost impossible to undertake field trials on GM trees in most countries' (Walter et al., 2010: 656–658).

Given these insights, it is difficult to understand (i) on what basis this public investment is likely to pay dividends, (ii) why formal controls are not used comprehensively to manage risks, and (iii) why community interests are not being considered and managed, as required under law. Most importantly, New Zealand must look hard at why other countries are not allowing GM tree field tests, and whether we, as a country, are simply taking unnecessary risks and investing scarce science funds inappropriately.

6.2.1 Zinc Finger Nucleases

As mentioned in Section 5.3.1, the Environment Court is currently considering an appeal lodged by the Sustainability Council in relation to the EPA's decision not to include Zinc Finger Nucleases (or ZFN-1) in the legal definition of genetic modification. Importantly, if something is not classified as a new organism, it is not regulated at all under the HSNO framework.

In April 2013 Scion lodged an application for determination in relation to ZFNs. The stated purpose of the application is:

> To determine whether the use of custom Zinc Finger Nucleases (ZFNs) and custom Transcription Activator-Like Effectors (TALEs) results in organisms classed as genetically modified organisms, and therefore new organisms for the purposes of the HSNO Act. (EPA, 2013)

Despite EPA staff recommending that these techniques be considered similar to GM techniques, and not exempt from the regulations, a decisionmaking committee of the EPA decided that they did not fit the HSNO definition of genetic modification and are not new organisms for the purposes of the Act.

Further, this type of technology may be being considered by other CRIs. We note AgResearch may also wish to employ ZFN-1 techniques; on its website the CRI states:

> … we are evaluating the potential of novel targeting vectors and the introduction of site-specific DNA double-strand breaks by zinc-finger nucleases to increase the feasibility of targeted livestock genome modifications. (AgResearch, n.d.[b])

In order to understand this issue, we provide the definition of a new organism and of a genetically modified organism, from s 2A and s 2 of the Act respectively, below:

> A **new organism** is—
>
> a. an organism belonging to a species that was not present in New Zealand immediately before 29 July 1998:
> b. an organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation:
> c. an organism for which a containment approval has been given under this Act:
> (a) an organism for which a conditional release approval has been given:
> (b) a qualifying organism approved for release with controls:
> d. a genetically modified organism:
> e. an organism that belongs to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand.
>
> **genetically modified organism** means, unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material—
>
> a. have been modified by in vitro techniques; or
> b. are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by in vitro techniques

This decision raises a number of interesting issues, such as what happens when a new technology is not covered under the legislation, and whose responsibility it is to watch for emerging technologies that may either not include GM (but bring risks) or include GM as part of the process which may not be present in

the end organism. Further, once a new organism is released it technically becomes an old organism and is not covered under the HSNO legislation, but a GMO will always be a GMO; as such, it should continue to be assessed and reviewed for any long-term effects.

6.3 Plant & Food

> Statement of Core Purpose for New Zealand Institute for Plant and Food Research Limited – Plant and Food Research's purpose is to enhance the value and productivity of New Zealand's horticultural, arable, seafood, and food and beverage industries to contribute to economic growth and the environmental and social prosperity of New Zealand. (MBIE, n.d.[f])

In 2011, Plant & Food (formerly Crop & Food) stated that it had no plans for further field tests. However, the CRI had previously been a significant player, holding approvals for three GM outdoor experiments since 2001: two for GM Allium (onions, spring onions, garlic and leeks) (GMF03001, GMF06002), and one for GM Brassica (cabbages, cauliflower, broccoli and forage kale) (GMF06001) (see Appendix 9).

In 2003, as Crop & Food, the CRI applied to test GM herbicide-resistant onions in the outdoors at a site in Lincoln, Canterbury. This application attracted the highest number of submissions of any GM application received to date (1933 in total; see Appendix 9) and sparked a number of anti-GM rallies and marches around the country (Beston, 2003). The application was approved with controls, and completed ahead of schedule in 2008.

In May 2007 a Crop & Food application was approved to test GM Bt (pest-resistant) Brassica species in the outdoors, and in November 2008 a second Allium application was approved to continue work on GM onions.

In December 2008 Crop & Food merged with HortResearch to form a new CRI, Plant & Food Research (Plant & Food, 2011). Shortly after this merger a breach of controls was identified under approval GMF06001 after a Brassica plant (forage kale) was found to have developed a flower stem while in outdoor containment. Flowering was not permitted under HSNO controls. Following this breach all work on the experiment ceased and all Brassica material was destroyed (Plant & Food, 2011).

An ERMA inquiry found that 'the controls (if complied with) were adequate to manage risk for both the GM brassica and GM alliums field tests' (see Appendix 14). This view was not shared by anti-GM campaigners, including Soil & Health and GE Free New Zealand, who argued that the breach should see both the Brassica and Allium approvals revoked ('GE brassica trial uprooted', 2009). In early 2009, Plant & Food admitted there had been serious failures, specifically pointing to 'a serious error of judgement of the trial manager', and announced that, in addition to cancelling the Brassica test, it would be putting its Allium experiment on hold indefinitely (Booker, 2009).

In addition to Soil & Health and GE Free New Zealand, a further vocal opponent of these outdoor experiments was Dr Elvira Dommisse, a biotechnologist who had worked at Crop & Food and its predecessor, the DSIR. Dommisse had been involved in the early stages of the GM Allium experiments but left Crop & Food in 1993 citing concerns over the direction the new science was taking (Beston, 2003). Described in the media as a 'whistle-blower', Dommisse has consistently stated that the science behind GM is fundamentally flawed, specifically pointing to the instability of GM plants and the potential for toxicity:

> You take the naturally occurring DNA in bacteria (Agrobacterium) out, replace it with a mixture of DNA or RNA from viruses, bacteria, animals or plants and slam it into the recipient plant's DNA, where it inserts itself randomly, disrupting the DNA of that plant in ways that may or may not be obvious. The metabolism of the cell is often altered in such a way that new and sometimes toxic proteins are formed. The plants don't like it, and it doesn't stay where it should. It makes them unstable. (Dr Elvira Dommisse, personal communication, 2013)

Contrary to the CRI's assertion that the initial experiments were successful (Crop & Food, 2008: 6), Dommisse describes the GM onions as 'genetically inferior' and more susceptible to disease, pointing out that if they had been successful, the programme would have continued (Dommisse, personal communication, 2013). As noted earlier Plant & Food stated in 2011 that it had no plans for further field tests (Sharpe, 2011). Following the formation of Plant & Food in 2008 'the new organisation developed a new research strategy that prioritised research according to a number of factors, including our science capability and potential impact for industry' (Plant & Food, personal communication, 2013). Plant & Food has also stated that it is:

> ... unable to say how much it had spent on [GM] field trials because it had been so long since the earliest trial, many staff involved had since left, specific costs were not recorded and the accounting software that might include any data was out of use and could be restarted only at substantial cost and resources. (Sharpe, 2011a)

The Plant & Food experiments clearly demonstrate the gap between promises and reality. No commercial benefit has materialised, and long-term continuation of GM crop research appears to be commercially unviable for the CRI.

Lastly the GM Brassica experiment is a clear example of the risks associated with human error and the need for rigorous controls to mitigate these risks. It should not be the case that the actions of one staff member could lead to such a significant breach. For ERMA to conclude that the controls were adequate 'if complied with' is highly concerning and indicates the need for a more stringent framework, one that reduces the potential for non-compliance by a single individual to create such a serious issue.

6.4 Five Principles for Effective Public Investment by CRIs

In view of the above, it is important to try to draw some lessons from the last 15 years, during which CRIs have been operating under the HSNO legislation. This last section, therefore, is an opinion piece, highlighting five overarching principles that might help drive the CRI science system to meet the needs of the public in a transparent and meaningful manner.

1. Value for Money

We question what is motivating some CRIs to invest in expensive, high-risk GM experiments in the outdoors when the private sector is not interested in undertaking this research. And why the boards of the two CRIs still involved in outdoor GM research have continued to spend money on experiments that have not delivered any benefits and are not considered likely to do so in the short to medium term. On what basis are the CRI boards arguing that these experiments should be continued? The fact that there are only two outdoor experiments currently operating in New Zealand suggests that these programmes have not proven lucrative or of significant benefit to the private sector. Plant & Food's decision to discontinue its outdoor GM research was a pragmatic one – the benefits were not significant enough to warrant the research. Arguably, AgResearch and Scion are not acting pragmatically. Decisions should always be understood in terms of the benefits, costs and risks to the New Zealand public, the probability of success and the value that might materialise. See discussion on benefits in Section 7.2.1.

2. Robust Assessment, Decisionmaking and Monitoring by Regulators

Government regulators must treat all applicants equally. It is understandable that government regulators might take a softer approach to CRI applications, as there is a perception that CRIs always operate for the benefit of the public. However, regulators must not treat this perception as fact, and must ensure that sound benefits exist for New Zealand and that controls are both applied and monitored independently. This perception around CRIs possibly explains the use of informal rather than formal controls, as in the case of Scion above, where ERMA felt it could trust Scion to informally help it undertake useful research. Ultimately, regulatory and monitoring bodies must not rely on the belief that CRIs will do the right thing for New Zealand; the institutes must undergo robust assessment, decisionmaking and monitoring like everyone else.

3. Ethics should drive practice

A third observation is that CRIs have not always demonstrated their adherence to strong ethical standards. Some appear to believe it is acceptable to overstate the benefits of their research programmes, emphasising commercial, environmental or health benefits that are extremely improbable, in order to gain public support and influence funding decisions. For example, in the case of AgResearch, emotive suggestions that particular research could benefit MS patients were irresponsible.[36] The fact that so few scientists spoke out against the research, and the pressure that was put on those who did speak out, illustrates the nature of the power CRIs hold over scientists in New Zealand. Furthermore, questions have been raised over the death and deformity rate's of the animals in AgResearch's experiments (Chug, 2011).

4. Timely reporting on controversial experiments is essential

A further issue is that CRIs do not report regularly on the outcomes of such investment, especially with respect to research that has provoked high public interest. In the case of the transgenic cows, there is no way of knowing whether the cows have provided any MBP, and if they have, what is its quality and has it any value in the treatment of MS? We do not know the results of this research programme, which has been going for 12 years (starting in 2001) or the results of Scion's Pinus radiata research, which has been going for 17 years (starting in 1997) (see Appendix 9).

5. A culture of due diligence is vital across science

The absence of a culture in which due diligence is applied to investment decisions is a major concern. The way in which our current science system is set up, with multiple bodies competing for limited funds, leads to a culture of 'picking winners', with the result that 'cutting edge' new tools are more likely to attract funding. Therefore, rather than focusing on improving outcomes using older tested tools, there is a desire to create new organisms and showcase expertise using new tools.

There seems to be an expectation that New Zealanders will inherently trust CRIs because they are Crown funded and mandated to undertake research for the benefit of New Zealand. But at least two of the CRIs show symptoms of systemic risk, resulting from a lack of analysis and transparent documentation of the benefits, costs and risks of their research. Together, the transgenic animal and GM pine tree work programmes have cost New Zealanders a great deal of money, with very little reporting on benefits. The public have the right to know that: they are providing value; the risks are calculated, managed and independently monitored; medical and animal ethics are applied; research results are regularly reported and reviewed; investment decisions are market-led; the science community is able to support whistle-blowers, and scientists consistently maintain high ethical standards. These concerns were summed up well by Jeanette Fitzsimons, former co-leader of the Green Party, who in May 2001 commented in a speech to the House:

36 As a result of these suggestions, some MS patients considered camping in the paddocks to protect the transgenic cows ('I'll camp out to protect cows', 2001).

The question of why AgResearch would claim medical benefits from their work that have not been demonstrated remains unanswered, but the question we as Parliamentarians should ask is why was taxpayers' money used to fund a project like this without first answering, what is the problem we want to solve, and is this the best way to solve it?

But our commercially driven science system has instead asked, how can we use our ability to make transgenic cows to make something we can convince someone else to want? That is not science, it is marketing and AgResearch should admit it.

We as Parliamentarians should be looking closely at the accountability mechanisms that are supposed to ensure good use of taxpayers' money. If in fact this part of the bigger project was funded by AgResearch itself, rather than by FRST, what peer review process was there to check its scientific validity? (Fitzsimons, 2001)

7. Observations, Recommendations and Reflections

This section brings the report to a conclusion by reviewing the last forty years and considering what we can learn from the information that has emerged. This is the only area of the report that draws conclusions and makes suggestions on how the current system might be improved in order to create better long-term outcomes. The overall goal of this section is to assess whether the system fulfils its purpose, and if not, what the government must do to develop a better policy landscape and operational system to manage the benefits, costs and risks of genetic modification. The section opens by identifying ten observations that can be made from the last forty years. We then discuss 12 policy knots, drawing from each a recommendation to help the system flow more effectively and efficiently in the future. The section then closes with the authors' personal reflections on where we are today and how we might move forward.

7.1 Observations

Based on a review of the last forty years, a number of observations can be made about GM experiments to date:[37]

1. The number of approvals for GM indoor experiments by IBSCs is declining.

2. The number of applications for GM outdoor experiments is declining.

3. CRIs (AgResearch and Scion) are the only institutions undertaking GM outdoor experiments in New Zealand.

4. No outdoor GM application to date has been declined by the government under the HSNO Act 1996.

5. No outdoor GM experiment to date has generated any commercial benefit.

6. Applicants, including CRIs, do not always implement applications once they have been approved.

7. Incidents from GM experiments do occur.

8. Most incidents (excluding border security incidents) have occurred under applications held by CRIs and universities.

9. GM foods and fibre approved by FSANZ follow global trends; the majority are GM corn, GM soybean and GM cotton.

10. In the last five years, all institutions responsible for managing the risks of GMOs have undergone significant change.

37 It should be noted that this section focuses mainly on outdoor experiments, which include both outdoor developments and outdoor field tests. These experiments are of particular interest, as the consequences of an incident in the outdoors may be difficult to contain. Incidents that result from highly experimental GMOs in indoor containment facilities accidentally being released into the outdoors may also be significant; for this reason we also briefly discuss indoor experiments in this section.

Observation One: The number of approvals for GM indoor experiments by IBSCs is declining.

Note: Date collection and reporting has not been consistent throughout the GM regulatory scheme, for this reason the dates shown in the following figures differ depending on the availability of relevant data.

Figure 3: Indoor GMO approved applications by financial year (decisions made by IBSCs) 1998/99–2011/12

Source: See Appendix 8

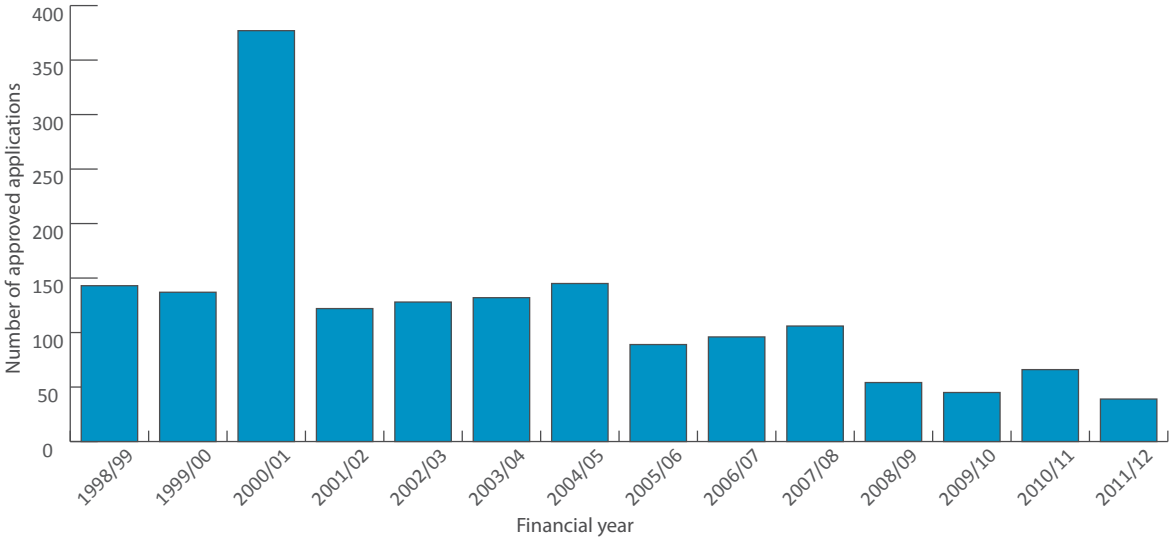
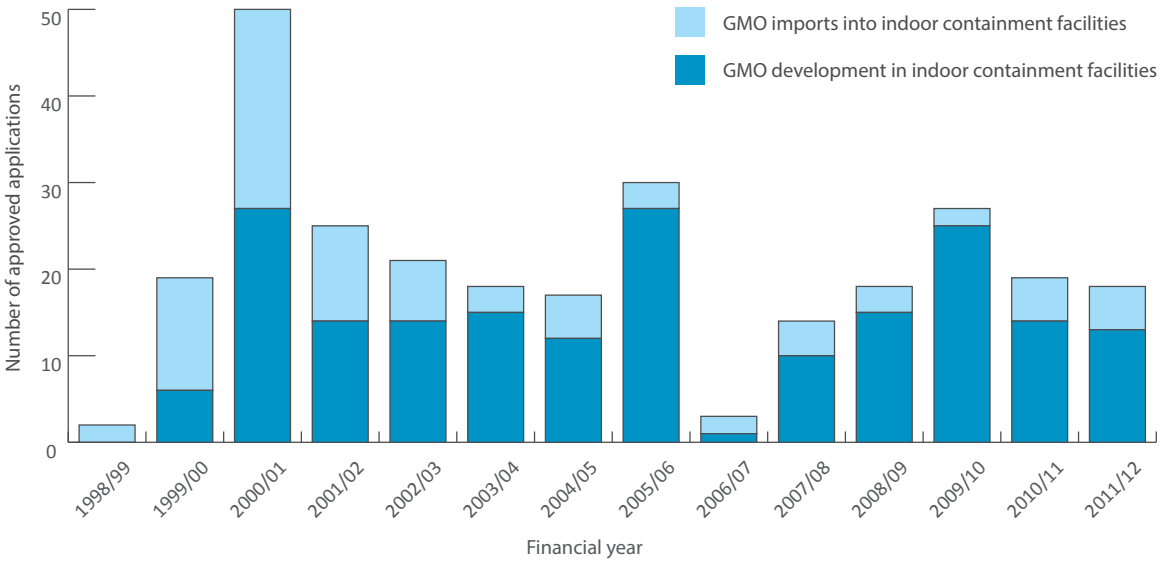


Figure 4: Indoor GMO approved applications by financial year (decisions made by ERMA/EPA) 1998/99–2011/12

Source: See Appendix 8



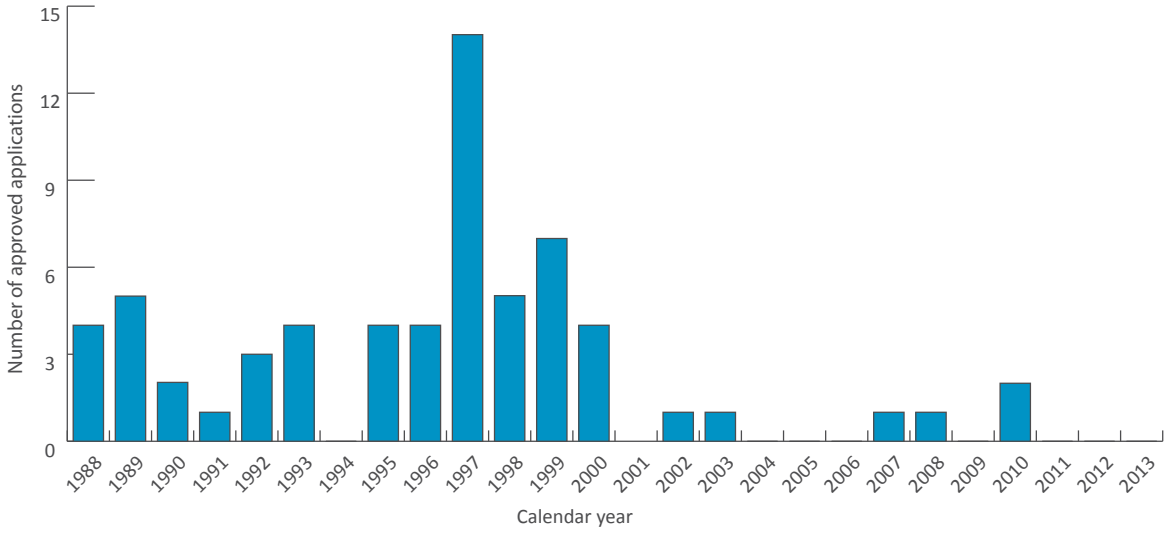
Note 1: Both Figures 3 and 4 exclude outdoor developments and all field tests.

Note 2: It is difficult to obtain a detailed picture of all indoor experiments, as one approval can relate to a number of GMOs and a number of approvals can relate to the same GMO.

Observation Two: The number of applications for GM outdoor experiments is declining.

Figure 5: Approved applications for GM outdoor experiments by calendar year 1988–2013

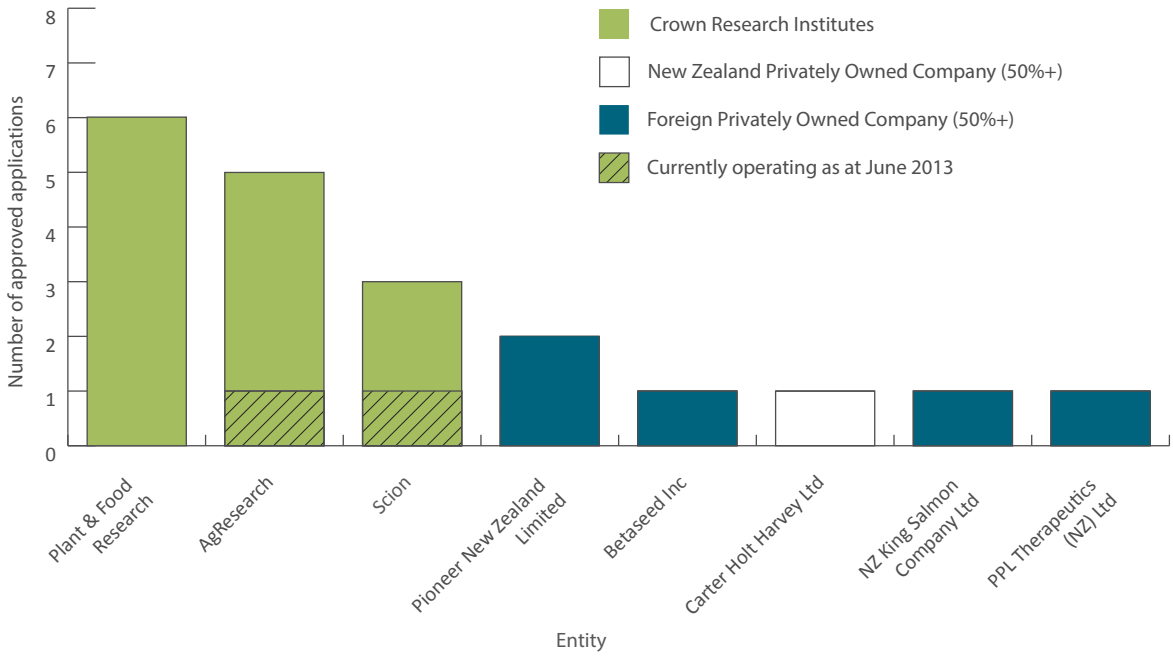
Source: See Appendix 9



Observation Three: CRIs (AgResearch and Scion) are the only institutions undertaking GM outdoor experiments in New Zealand.

Figure 6: Approved applications for GM outdoor experiments by entity since the implementation of the HSNO Act 1998–2013

Source: See Appendix 10



Observation Four: No outdoor GM application to date has been declined by the government under the HSNO Act 1996.

Practical application if the legislation has operated on the assumption that an application should go ahead unless there is adequate evidence to the contrary (Bill Falconer, former chair of ERMA, personal communication, 2000). The purpose of the Act is to protect the environment and the health and safety of people and communities. Practically, this means managing adverse effects with appropriate controls, and where this is not possible, declining the application. The protection the Act provides is largely dependent on how the EPA utilises the discretions afforded to it under the Act.

Observation Five: No outdoor GM experiment to date has generated any commercial benefit.

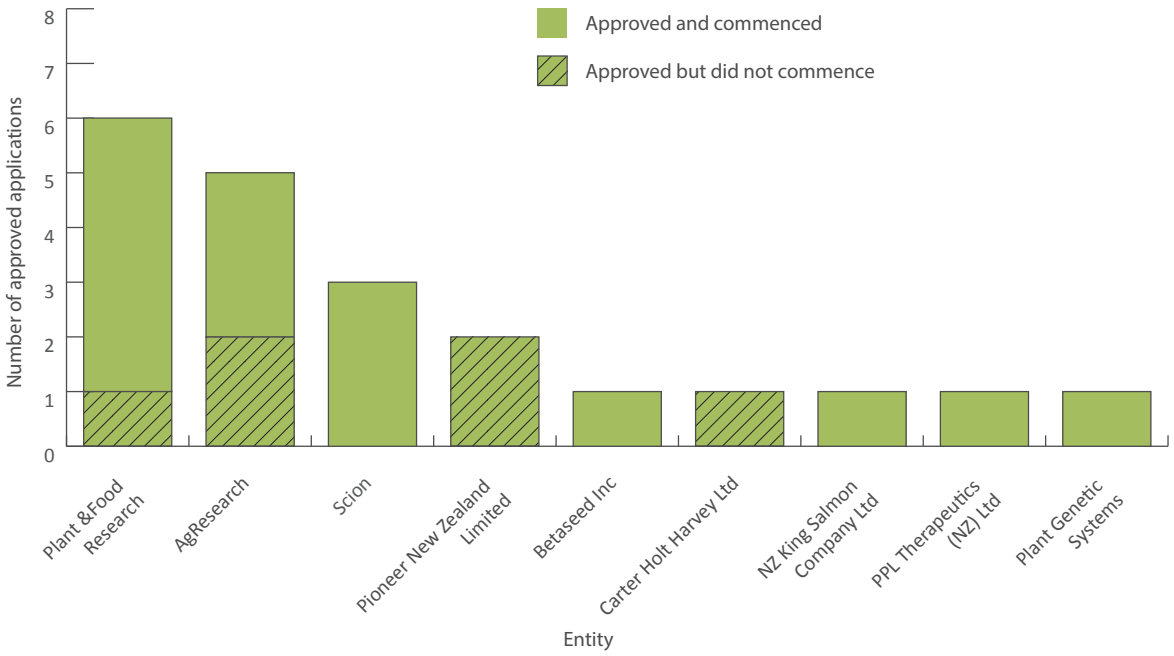
To date, the Institute is not aware of any commercial benefit from an outdoor GM experiment. However, a review focusing on the likelihood of current outdoor experiments producing commercial benefits would be a valuable policy tool. The question here is whether public investment in GMO research (through CRIs) has been beneficial to New Zealand, and if not, is it worth further investment?

Observation Six: Applicants, including CRIs, do not always implement applications once they have been approved.

After going to the considerable effort and expense of applying for approval, entities do not always implement applications once they are approved. Arguably, this issue should be included in any future review. The question here is: why were considerable amounts of public money used in gaining these approvals that were then never implemented? This could indicate a lack of a clear purpose in the initial planning stages.

Figure 7: Approved GM outdoor experiments by entity since the implementation of the HSNO Act 1998–2013

Source: See Appendix 10

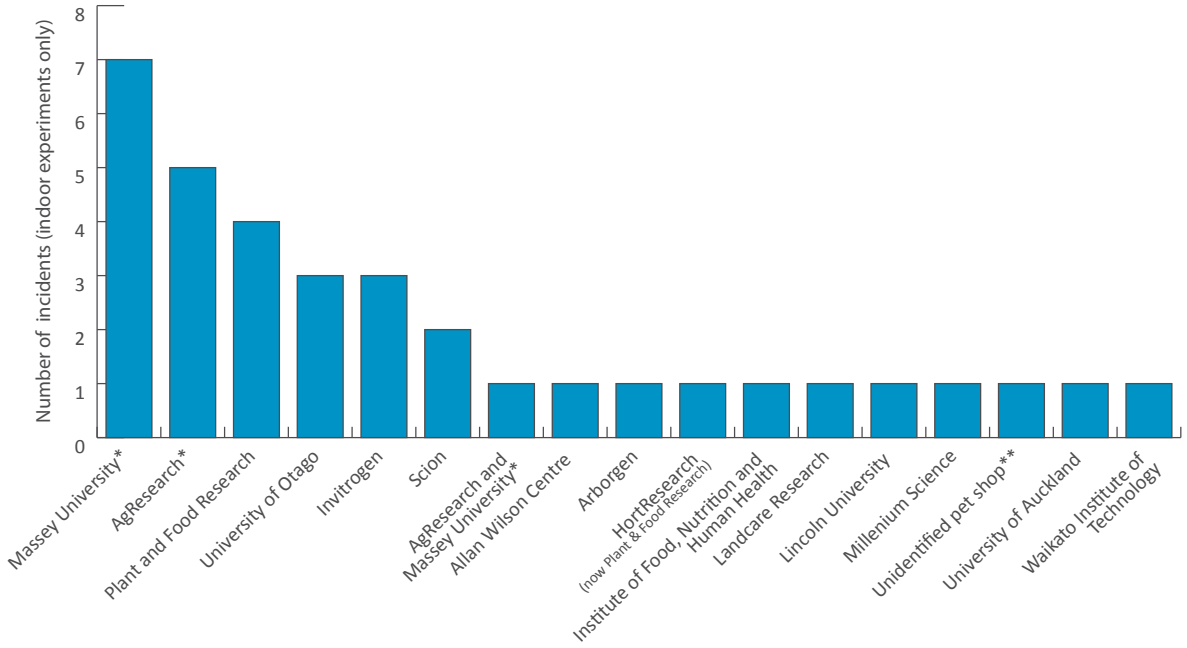


Observation Seven: Most incidents have occurred under applications held by CRIs and universities.

In 2011 the EPA changed how it categorised incidents, introducing a level 1–5 system. Previously incidents were not categorised but adverse effects were recorded. Since 2011, the highest-level breach of a GM approval was a level 3 breach in 2012 (see Appendix 14 for more detailed information about the nature of this and other incidents). The number and nature of the incidents raises questions about the ability of the entities and IBSCs to put in place and manage controls effectively. Of particular note is the closing down of one field test in 2009 after it was found that Plant & Food had breached the controls by allowing the crop to flower (application number GMF06001; see Appendices 1 and 9 for more information about this field test).

Figure 8: Incidents resulting from indoor experiments by financial year 2004–2012

Source: See Table 16, Appendix 14



* AgResearch and Massey University also hold some joint applications.

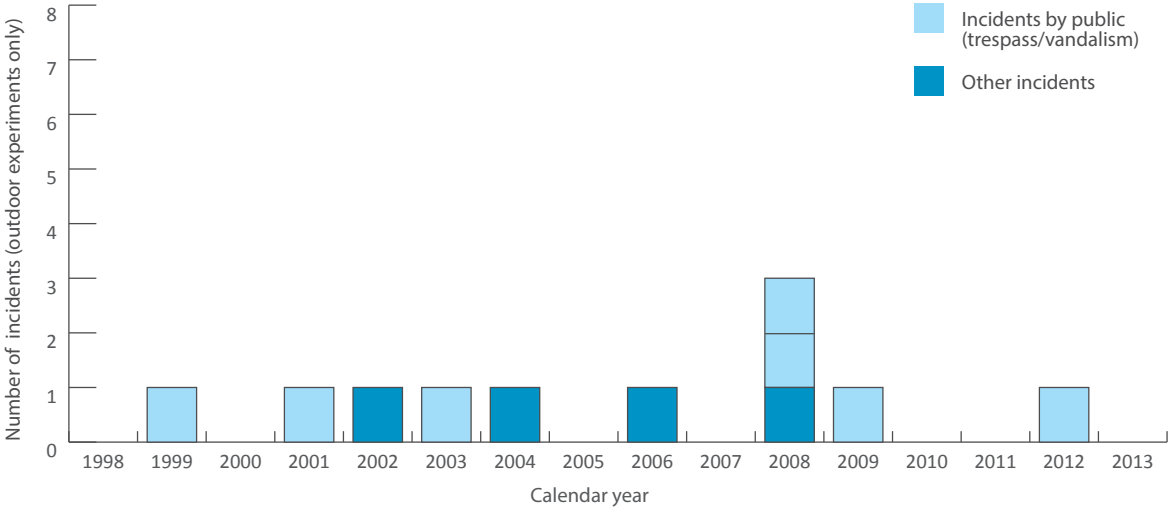
** This incident was not part of an indoor experiment but has been included as it was reported in the EPA's incident report for 2007.

Observation Eight: Outdoor incidents from GM experiments do occur.

A range of incidents, or breaches of controls, have occurred in outdoor experiments and breaches of border security at varying degrees of severity. These incidents have not been consistently reported over time and there are known gaps. For example, ERMA (and then the EPA) only have incident reports available on their website dating from 2004, however press reports indicate that there were a number of significant incidents before this date. For a more detailed explanation of incident reporting see Appendix 14.

Figure 9: Incidents resulting from outdoor experiments by application code 1998–2013

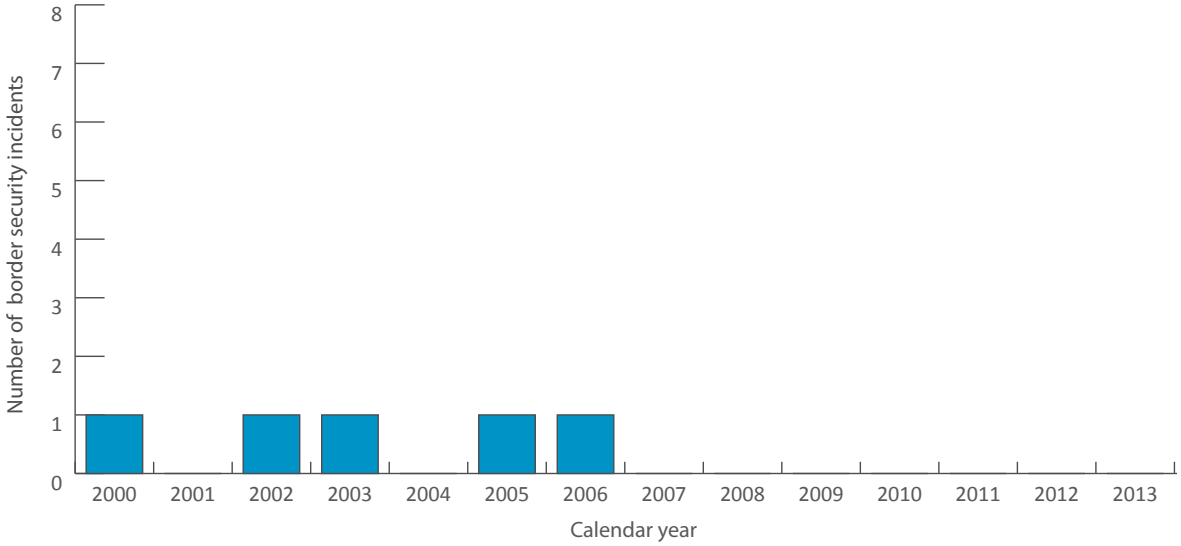
Source: See Table 17, Appendix 14



Note: These incidents occurred over five different outdoor experiments. Of the seven incidents caused by the public two have been reported as unrelated to the GM outdoor experiments; see Appendix 14.

Figure 10: Incidents resulting from a breach of border security that have been inquired into by MPI from 2000–2013

Source: See Table 18, Appendix 14

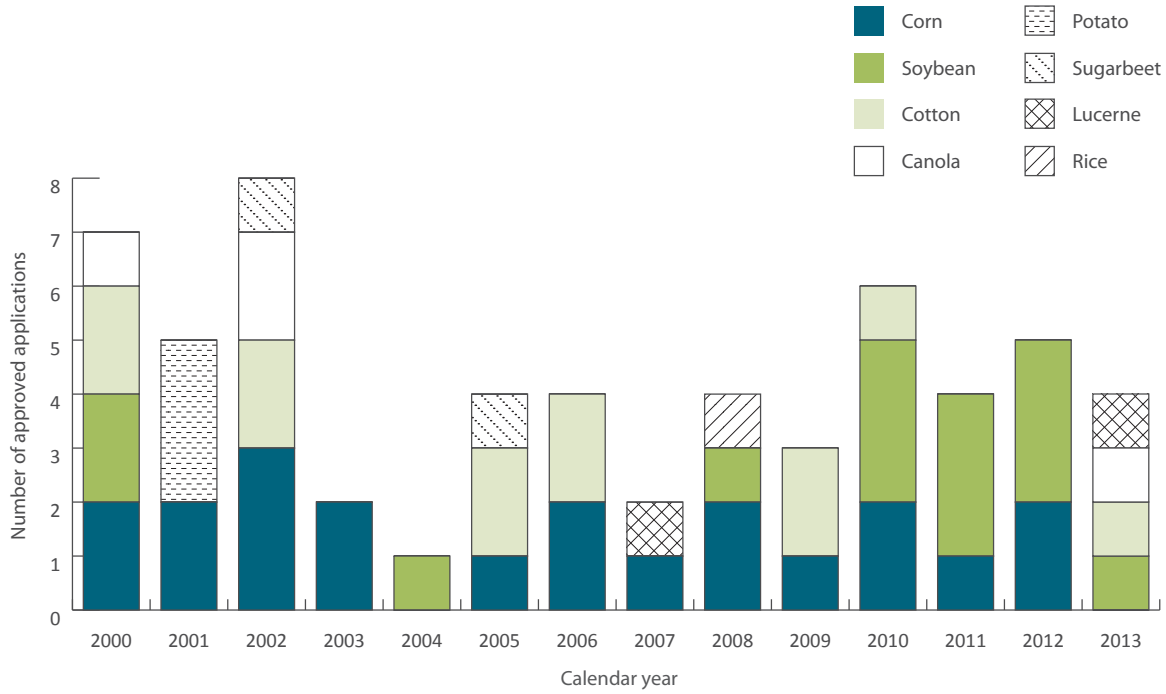


Note: This is not necessarily a comprehensive list of all instances of breaches of border security, however it does include those recorded on the MPI website.

Observation Nine: GM foods and fibre approved by FSANZ follow global trends; the majority are GM corn, GM soybean and GM cotton.

Since 2000 the majority of GM foods and fibre approved for sale in New Zealand and Australia have been corn products (35.6%), soybean products (23.7%) and cotton products (20.3%). This aligns with global production trends. Globally, four commodity crops – soy, maize (corn), canola and cotton – account for 99% of GM acreage (SCNZ, 2013a).

Figure 11: FSANZ GM food and fibre decisions by product type 2000–2013 (as at June 2013)
Source: See Appendix 15

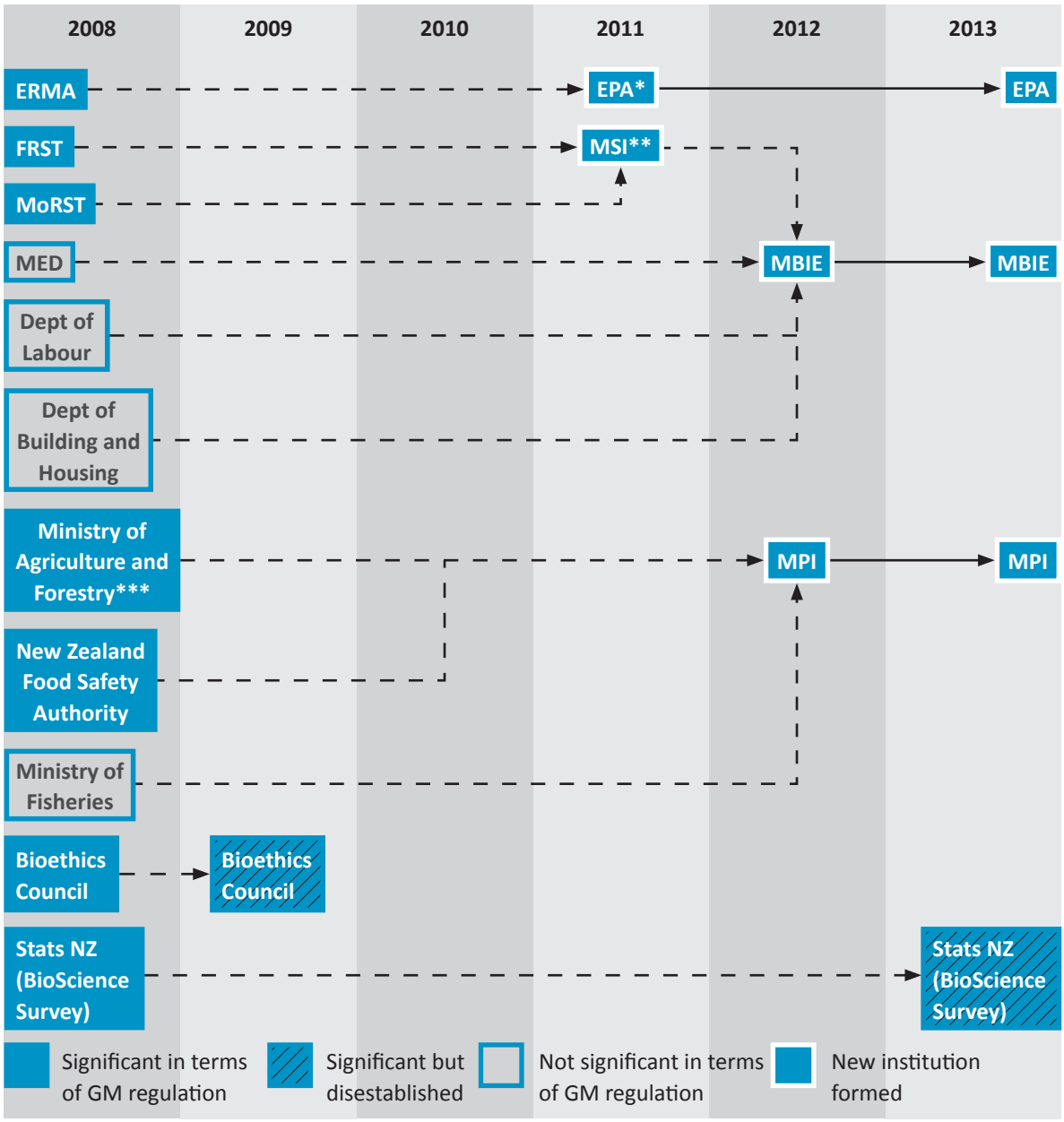


Note: Under the current system, it is difficult to know the extent of distribution within New Zealand specifically, as approvals apply to both New Zealand and Australia.

Observation Ten: In the last five years, all institutions responsible for managing the risks of GMOs have undergone significant change.

Section 5, in particular Figure 2 repeated below, summarises the significant level of institutional change in the last five years. This level of institutional change will need to be carefully managed to ensure record keeping is consistent and transparent, and that expert knowledge of risks and costs is retained. For example, we have encountered a considerable lack of continuity between institutions while researching this report. Where institutions have merged or been disestablished, often their documentation is difficult or impossible to access. Similarly, while public servants have been extremely helpful in this process, we found that in a number of cases staff did not understand the system and found it difficult to answer our questions.

Figure 2: Institutional change over the last five years



* Some staff from MfE and MED were transferred into the newly formed EPA

** Futurewatch reports were undertaken by MoRST to present information on the emerging areas of science and their relevance to New Zealand. The reports were not continued under MSI, see discussion in Section 5.2.10.

*** MAF published regular reports on global development surrounding GM and coexistence. However, these were discontinued in 2007. See Section 7.2.4.

7.2 Recommendations

In 2012, the Institute published a broader report titled *Science Embraced: Government-funded Science under the Microscope* (McGuinness Institute, 2012). The goal was to undertake a whole-systems approach to unlock the science system so as to foster significant improvements in the well-being of New Zealanders. In many respects the 2012 report took a top-down approach to the government-funded science system, while this report takes a bottom-up perspective of a particular scientific tool – genetic modification.

Our 2012 report identified five key enablers that need to be recalibrated in order for the government-science system to work effectively: the institutional framework; scientists; research infrastructure; funding, and the regulatory framework. All five enablers need to work together to deliver on the strategic intent. Past experience would indicate that decision-makers tend to focus on changes to the institutional framework, rather than considering the other four enablers. This is unfortunate as institutional change tends to be expensive and time-consuming, therefore any benefits take time to eventuate. Contrary to past practice, we consider there are real benefits to be gained from focusing and fine-tuning the other four enablers so that internal cohesion exists and synergies are gained.

With this background in mind, this subsection synthesises our findings in terms of policy knots, those areas that prevent the system of public policy working effectively. For each policy knot we put forward a recommendation aimed at unlocking the system so that optimal decisions may be made. These could relate to areas such as preventing the waste of resources, time and institutional capacity by being very selective about what New Zealand does (and does not do), and building an information system that is capable of shaping public policy in the longer term. The 12 policy knots are as follows:

1. Managing the return on the public's investment;
2. Managing risk;
3. Managing the costs of compliance;
4. Managing legal liability and the costs of coexistence;
5. Managing data;
6. Managing the relationship between central and local government;
7. Managing the assessment and monitoring of controls;
8. Managing systems through regular reviews;
9. Managing systems through memoranda of understandings;
10. Managing strategy;
11. Managing foresight, and
12. Managing the regulatory framework.

7.2.1 Managing the return on the public's investment

Understanding the consequences of the public's investment in 'GMOs in the outdoors' requires an appreciation of the way government shapes regulatory systems and utilises those same systems to undertake outdoor GM research. This section looks firstly at the decision *to invest* and then at how benefits are analysed in the decision *to approve* an application.

1. The decision to invest

Public funds are used to invest in regulatory systems and research experiments. New Zealand invests in GM through the creation and management of regulatory systems and investment in research. Trying to understand the financial investment New Zealand has undertaken to develop a GM strategy and design appropriate regulatory systems poses a significant challenge. Such an exercise would require a great deal of financial information, much of which is not available, for example:

- The cost of the Royal Commission on Genetic Modification: the Commission was provisionally estimated to cost $4.8 million (Hobbs, 2000), however the total cost amounted to over $6 million ('Commission rejects GM-free NZ', 2001).
- The cost of strategy development, such as the 2003 report on biotechnology – not available.
- The operational costs of ERMA/EPA in processing outdoor GM applications – see Appendix 12, Table 14, column (c).
- The operational fees (revenue) paid by applicants to ERMA/EPA – see Appendix 13, column (d).
- The operational costs of MAF/MPI in enforcing regulations and providing assurance – not available.
- The cost of inquiries into breaches undertaken by MAF/MPI (see Appendix 14) – not available.
- The cost of cleaning up breaches found by MAF/MPI – not available.

In addition, a considerable, yet largely indeterminable, amount of public money has been spent on outdoor GM research, in terms of developments and field tests undertaken by CRIs. CRIs not only receive 'core funding' annually from the government but are able to access research funding from MBIE for specific projects ('contestable funding'). Government funding of CRI's is allocated for broad research programmes, one aspect of which may involve GM research. Therefore initial funding is often allocated months and sometimes years before an application to develop or field test a GMO in the outdoors is considered. The impact of this is discussed in point 2 (below).

Ultimately it is the public who own CRIs, fund their investments, and absorb the risks associated with outdoor experiments. The public should therefore be able to assess the value of their investment. Such an assessment is dependent on transparency in relation to how much public money has been spent on GM experiments in the outdoors, which is currently very difficult to determine. To understand how much the New Zealand public has invested in outdoor GM research would also be difficult. Such an exercise would require a great deal of financial information, much of which is not available, for example:

- Share of CRI core funding allocated to outdoor GM research and development – not available.
- Contestable funding from FRST/MSI/MBIE/Callaghan Institute allocated to specific outdoor GM projects – not available.

- Cost of litigation to ERMA/EPA/CRIs,[38] which has been party to a number of court cases relating to GM applications – not available (see Appendix 7).

Although determining the full extent the New Zealand public have invested in GM research in the outdoors is difficult, we do know is that the Crown's investment has been significant. Since 1988, 42% of commenced outdoor research experiments have been undertaken by CRIs and 70% have received government funding.[39] Further, the only outdoor experiments being undertaken today are by two CRIs – AgResearch and Scion; currently no private firms are undertaking outdoor GM experiments.

A further complexity is the conflict that may exist where CRIs have obtained revenue from private and commercial sources. In the 2011/12 financial year, AgResearch's total revenue was $158 million, of which the government contributed $64.5 million ($38.8 million was core funding and another $25.5 million was additional funding from MSI, now MBIE, for specific projects) (AgResearch, 2012b; 2012c: 15). Determining how funding is distributed and for what purpose is complicated. For example, we know that, in 2011, $1.2 million of MSI funding was specifically allocated to AgResearch's transgenic livestock programme under contract number C10X0805 (AgResearch, 2012b) (see number 25 in Appendix 12); however, this is not necessarily an indication of the total cost of the programme. To date, a number of outdoor experiments have been undertaken by CRIs with international partners. For example, AgResearch negotiated a joint venture with Scottish company PPL Therapeutics, stating that its successful completion 'will result in the creation of a New Zealand business worth approximately $50 million' (Atkinson, 2002). In practice, this means public money is used to co-invest in science for private benefit. Co-investing with the private sector can have impacts on the extent that benefits for the public exist, and the reality may be that the benefits materialise overseas while the risks stay in New Zealand. Further, this may impact on the CRIs' ability to meet their public good obligations. The Prime Minister's Chief Science Advisor, Professor Sir Peter Gluckman, has commented on this conflict between public and private interests:

> In some cases, however, CRIs have entered into contracts with the private sector that limit their capacity to give such advice (e.g. around land use), and indeed they can find themselves being contracted to give advice contrary to the Crown's wider interest. In general, entry into such contracts is often unwise and academia has shown them to be unnecessary. Academia enters into many private sector contracts and yet essentially none limit institutional ability to publish, subject to IP protection. On the basis of the now altered expectation of the CRI's, they must now take greater care in future arrangements to avoid compromising their ability to serve the crown as important and independent advisors. (OPMSAC, 2011: 14)

38 CRI's have been party to the following cases:

AgResearch:

- Bleakley v Environmental Risk Authority [2001] 3 NZLR 213
- Mothers Against Genetic Engineering Inc v Minister for the Environment [2005] 9 NZJEL 123
- GE Free New Zealand in Food and Environment Inc v Environmental Risk Management Authority CIV-2008-485-2370
- AgResearch Ltd v GE Free New Zealand in Food and Environment Inc [2010] NZCA 89
- GE Free New Zealand in Food and Environment Inc v AgResearch Ltd [2010] NZSC 71
- GE Free New Zealand in Food and Environment Inc v Environmental Risk Management Authority [2011] NZRMA 45

Crop & Food (now Plant & Food Research):

- GE Free New Zealand in Food and Environment Inc v Environmental Risk Management Authority [2008] BCL 611

39 Of the 70 outdoor experiments applied for, only one experiment was declined by the Interim Assessment Group (IAG) in 1991 (see Appendix 9). Further, of those 69 experiments, six were withdrawn by the applicant before being decided by ERMA. Of the 63 remaining, six (although approved) were never implemented three of those were CRI approved experiments. This is how the figure of 57 approved and commenced outdoor experiments shown on page 6 was generated. In terms of CRIs, 24 of the 57 (42%), represents the percentage of outdoor research experiments implemented by CRIs in New Zealand since 1988. In addition to these 24 CRI experiments, 12 experiments were completed by the former Department of Scientific and Industrial Research (DSIR) and four by universities, meaning about 70% of approved and commenced outdoor experiments have received some form of public funding.

2. The decision to approve

Since 1988 there have been three different approving agencies for outdoor GM experiments; IAG,[40] ERMA and now the EPA. The 1996 HSNO legislation established ERMA, who would be responsible for applying the methodology. This applies both generally (the HSNO Act 1996 states its purpose in s 4 as 'preventing or managing the adverse effects of hazardous substances and new organisms') and specifically, weighing positive effects against negative effects.[41] The latter might include, for example, *containing a GMO* ('the beneficial effects of having the organism in containment outweigh the adverse effects' – see s 45 of the HSNO Act 1996), *importing or releasing a GMO without controls* ('the positive effects of the organism outweigh the adverse effects' – see s 38 of the HSNO Act 1996), and *importing or releasing a GMO with controls* ('the positive effects of the organism outweigh the adverse effects' – see s 38C of the HSNO Act 1996).

In the past, ERMA has generally considered that outdoor GM research will provide benefits in the form of scientific knowledge, and that the existence of such knowledge should be assessed as 'high'.[42] However, ERMA's decisions do not explain the basis upon which such assessments are made, and applications tend not to disclose benefits for reasons of commercial sensitivity. Further, in the case of applications by CRIs, ERMA considered that if something is publicly funded public benefits must exist.[43] Additionally, the ERMA committees established to make such decisions usually did not have the commercial skills and expertise necessary to make assessments on commercial benefit. To explain how this lack of scrutiny shows itself in previous decisions by ERMA, we revisit the AgResearch application.

In 2001, AgResearch gained approval for the use of transgenic cows to produce a protein (MBP) that could potentially help sufferers of multiple sclerosis (see discussion in section 6.1). However, the possible benefits from creating MBP were never fully assessed by ERMA. In making its 2001 decision, ERMA accepted that the principal benefit of the MBP cows experiment was the scientific knowledge to be gained, stating that the significant benefits identified for assessment and evaluation were as follows:

> Benefits of **scientific knowledge** arising from the carrying out of the research (in accordance with clause 9(b)(i); 9(c)(v).) [Bold added] (ERMA, 2001a: 10)

In 2002, ERMA assessed the benefits of a similar AgResearch application as follows:

> Benefits of **scientific knowledge** arising from the carrying out of the research including the acquisition of new skills (in accordance with clause 9(b)(i) and 9(c)(v)). … The applicant and others made reference to the specific downstream economic and health benefits to be gained from the products that might result from the commercial use or release of the genetically modified cattle. These products might especially include biopharmaceuticals. **The Committee did not consider these downstream benefits to be relevant to this application**, because it was for scientific development and not for release or commercial production. [Bold added] (ERMA, 2002a: 13–14)

In 2010, ERMA assessed the benefits of a further AgResearch application:

> 6.2.80 The Committee considered that the benefits of this research will primarily be in the form of increased **scientific knowledge** and skills enhancement. The Committee acknowledged that **FRST has made**

40 The IAG had no legislative authority (RCGM, 2001a: 105).

41 We understand this is quite novel internationally; most other regulatory authorities only assess risks, not the costs and benefits of applications.

42 See reference below to AgResearch's 2010 application, and ERMA's assessment that 'This level of benefit has been assessed as medium'.

43 Under the Crown Research Institutes Act 1992 (s 5), a CRI must operate according to the principles that all research should be undertaken 'for the benefit of New Zealand' and that 'a Crown Research Institute should be an organisation that exhibits a sense of social responsibility by having regard to the interests of the community in which it operates and by endeavouring to accommodate or encourage those interests when able to do so'. See also Section 6 for the full text of s5.

> **an ongoing investment of $8 million in the research programme over the next five years**. This funding will employ eight full time staff members, each of whom will gain knowledge and experience as a result of this work. Taking this into account the Committee considered the magnitude of this effect to be moderate.
>
> 6.2.81 The Committee also considered that this research may **enhance New Zealand's reputation in the international science community**. The Committee noted that the applicant's programme of genetic modification of animals has been operating successfully since 1998 (under previous approvals from the Authority). As this previous research has resulted in several articles in internationally recognised publications, and has attracted international commercial partners, the Committee considers the likelihood of realising this benefit from the research to be highly likely.
>
> 6.2.82 Therefore, the Committee considered that the measurable benefit of this research is the increase in scientific knowledge and the capacity for innovation in New Zealand. **This level of benefit has been assessed as medium**. [Bold added] (ERMA, 2010a: 34)

As one group of researchers noted in 2009, 'Benefits claimed for scientific research not yet carried out are necessarily speculative to some degree. However, this does not mean that these claims should not be thoroughly scrutinised' (Goven et al., 2009: 48). They went on to note that in ERMA's 2002 decision to approve AgResearch's application to biopharm cattle it was argued that, as a reputable research institution, AgResearch would be unlikely to pursue research without assurance of benefit, and that as a CRI these benefits would accrue to New Zealand. The researchers, found this argument unsound, noting that '... given the current structure of the science sector in New Zealand, it cannot be assumed that benefits to a CRI, even if these are realistically anticipated, equate to overall benefit to New Zealand' (ibid.: 49).

Every scientific experiment provides knowledge; in this context the question is the value of that knowledge, how it is gained and how it might be used. There is little value in assessing benefits so abstractly that they cannot be considered in terms of the related costs and risks. In contrast, a similarly vague assessment of risk would likely be unacceptable in the decisionmaking process. For example, in contrast the committee would not argue that this research may risk New Zealand's reputation in overseas markets, and rate that risk as medium. The level of scrutiny should be equivalent for all; potential effects, benefits, costs and risks.

Furthermore, the assumption that Crown funding is evidence of the existence of benefits for the public good is highly questionable. The Institute is of the opinion that when the EPA assesses the potential benefits of an application (as per s 45 of the HSNO Act 1996) the fact that the experiment has previously received government funding should not be used as evidence that public benefit exists. The purpose behind a decision to fund a research work programme is significantly different from the purpose of decisions made under the HSNO Act 1996.

Taken together, the points discussed above reinforce the importance of ensuring that decisions regarding the investment of public money (such as MBIE, MPI and the Callaghan Institute) and the weighing of positive and negative effects (by EPA) are sound. These decisions require separate processes; decisionmakers charged with making effective decisions to invest public funds have a very different purpose than those charged with making effective decisions to approve specific outdoor GM experiments or releases. If MBIE allocates public funding to a research programme that at some point in the future may involve GM approval under the HSNO Act 1996, they are not providing evidence that public benefits exist in regard to that GMO. That assessment can only be undertaken by the regulatory authority, the EPA; they are the body tasked with scrutinising effects, and then weighing these effects in order to make the best decision for New Zealand.

The importance of improving the quality of assessment and evaluation should not be underestimated for a country whose reputation is so tightly aligned with food quality. In 2013 Professor Sir Peter Gluckman stated that '[a] worrying feature of the New Zealand science system is that, compared to other participatory democracies, there is a relative lack of process and investment surrounding the development of objective evidence to support policy formation' (OPMSAC, 2013: 7).[44] He went on to note that:

> … the quality of policy programme assessment and evaluation is often not rigorous. Such scrutiny can be compromised or biased by agencies not wanting to embarrass the owners of a political decision. The evaluation process can be seen as unnecessary, especially where rhetoric has led to a strong political position. In general the understanding of the components of programme evaluation is weak across many agencies … Part of improving the use of government funds is also to improve the focus and commitment to programme evaluation. Ministers should expect and demand that more programmes are subject to efficacy evaluation, that funds are allocated for that purpose, and that reviews consider not only new programmes as they are rolled out, but where possible current programmes. There should be no political embarrassment in acknowledging that the impact of a new programme is not known and must be evaluated. (ibid.: 7, 9)

The above discussion raises a number of questions for further consideration:

- What is the true cost to the public of maintaining a strategy of GMOs in the outdoors?
- What is the return on the public's investment of CRIs undertaking outdoor GMO research?
- To what extent should benefits be scrutinised; both in terms of the potential scientific knowledge gained and justice – who benefits from this knowledge as compared with who bares the harm if risks occur?
- If outdoor GM experiments are carried out by CRIs in joint ventures with private companies, who owns the resulting intellectual property? If the private company is overseas based and has control over those benefits, should not the overseas company's share be removed from the assessment by the EPA?
- To what extent should highly improbable future benefits be taken into account when balancing benefits with risks and costs? Importantly, the purpose of scientific research should not always be commercial, but if applicants argue that commercial benefits exist, they nevertheless should be scrutinised in terms of probability and magnitude.
- Is it acceptable for the EPA to argue that public good benefits exist because a government institution funding science research, such as MPI, MBIE or the Callaghan Institute, have agreed to fund a research programme?
- How can we evaluate and ideally improve the quality of assessment and evaluation in regard to investment decisions by MPI, MBIE and the Callaghan Institute?
- How can we evaluate and ideally improve the quality of assessment and evaluation in regard to approval decisions by the EPA?

Recommendation 1: Investment programmes should be evaluated as a matter of good practice

Investment programmes developed by the government (including CRIs) that are particularly risky, contentious, involve joint ventures and/or represent a significant investment of public funds, must be regularly assessed. The Institute would like to see significant improvements in procedural transparency. Integrated reports must be published regularly, identifying the aim of the project, primary goals, key stakeholders (including relationships such as joint ventures/partnerships), recognised and perceived benefits (in particular, clarity over who owns the benefits of the investment programme), costs (in

44 It should be noted that in his role as Chief Science Advisor Professor Gluckman has never stated explicitly whether he supports or opposes GM research and development in food production; rather, he emphasises governance issues such as the need for effective communication between the public, scientists and government, risk management and evidence-based decisionmaking (OPMSAC, 2012).

particular, the size of the public's investment) and a full assessment of all known and potential risks (including investment, financial, legal liability and environmental risks). Any review of the HSNO legislation should consider whether the current arrangement allows a true analysis of benefits (see also the discussion in Section 7.2.12). If government is going to continue to invest significant amounts of money in a framework for CRIs to undertake outdoor GM experiments, it must provide assurance that the benefits are adequately scrutinised in terms of the benefits that will accrue to New Zealand, that costs are borne by the applicant (not the public) and that risks are well-managed. Further, we believe a register of all government funds, including grants and capital, should be made transparent to the public to ensure companies are not double dipping and to ensure the focus remains on the public's return from investment.

7.2.2 Managing risk

Risk management is a fundamental part of managing any new scientific tool. With any tool it is about best practice: when to use the tool, when not to use it, and how to know the difference. Genetic modification is a great example of a tool that demands answers to these questions, a point not lost on Sir Peter Gluckman, who said the following in a 2012 blog post titled *Dialogue or direct action?*

> But at the heart of that dialogue is a complex interaction that can be summed up in three words: 'understanding of risk'. Risk means different things to different people – scientists may talk in mathematical probabilities; politicians think of risk in an electoral sense; the public generally sees risk through a lens that can be instinctive. This can lead to some misunderstandings – for example the precautionary principle is not a way to avoid action, rather it is a tool for managing risk in an active way that should be revised as the risks become better understood. Unless we get better at talking about risk and its management, the dialogue between science and technology and the public will fail. (OPMSAC, 2012).

In recent years the government has used three mechanisms to allow a place and a space for dialogue: moratoria, the 2001 Royal Commission, and legislation. Further, the legislation was designed in the mid-1990s using the latest risk-management best practice – its original shape and design were simple and logical, although more recent amendments have, to some extent, pulled it out of shape.[45] Given all these opportunities to buy time and engage the public, the question arises as to why today this scientific tool still remains a matter of debate and indecision. There is possibly a range of reasons for this, a few of which we explore below.

One view is that the science is not clear, and that scientists as yet do not have clear consensus, especially in regard to GMOs in the outdoors. An insight can be gained from Professor Jack Sommer's 2008 survey of New Zealand scientists and technologists (Sommer, 2010). The survey showed that there was a range of differing positions on GM within the science community. Question 25 asked respondents to provide their level of agreement with the following statement.

> My understanding of the science of genetic modification of organisms leads me to believe they pose sufficient threat to the ecosystem to warrant suspension of research endeavours. (Sommer, 2010: 25)

Analysis of the survey results found that 1.9% of respondents agreed emphatically with this statement, 10.8% agreed in substance, 21.9% neither agreed nor disagreed, 39.9% disagreed in substance, and 20.2% disagreed emphatically. Overall, 12.7% agreed with the statement, while 60.1% disagreed to some extent. Earth and environmental scientists, and mathematics and computer scientists, agreed the most (20.0% and 26.9% respectively), while agricultural and soil scientists (3.2%), medical and health scientists (8.6%), and

45 For example, the introduction of conditional release, the creation of project-based applications and changes that allow GMO developments now being used for outdoor experiments.

biologists (9.1%) agreed the least (Sommer, 2010: 25). It is interesting to consider the questions that arise from the differing opinions of this diverse range of scientists. Some take a more whole-system approach to risk and therefore rate low-probability high-magnitude events more highly than scientists who deal with specific areas like agriculture and medicine. This would be a very interesting area to explore in more detail but is beyond the scope of this report.

Another view is that New Zealanders are particularly risk averse where risks may be considered irreversible and their magnitude significant (as indicated by the response to nuclear power, 1080 and GM). This may be due to our values, including our deep connection to the land, our considerable reliance on agriculture, and past disasters. New Zealand is an island nation with a delicate ecosystem; therefore we must be prudent in regard to ecological risks. Past lessons include the introduction of gorse, rabbits and possums, and more recently didymo and the varroa bee mite, which have all demonstrated how fragile our ecosystem can be (MfE, 2013c). The risks of contamination brought about by the genetic modification of plants, trees and animals in the outdoors, therefore, may legitimately be seen by many as not worth taking.

Related to this view are risks to our food. A particular concern noted by the Royal Commission was the possibility of GM animals entering the food chain. As a result the Commissioners recommended that non-food animals be used as bioreactors, rather than animals that are a common source of food. They suggested that goats be used instead of sheep, as less goat meat is eaten in New Zealand (RCGM, 2001a: 161–162).

Perhaps even more pressing is the idea that we could lose sovereignty over our food. Another important element of the GM debate is the risk to food security and control of intellectual property (IP). As GMOs are technically invented, they can be patented. This use of patents is very controversial and has attracted significant attention in the US, where agricultural biotechnology giant Monsanto has sued 410 farmers and 56 small businesses to prevent them replanting crops they have produced from genetically modified Monsanto seeds (Harris, 2013). This control of IP could, it is argued, have a significant impact on food security.

This argument has fed into the current debate in the UK which has pitted the Environment Secretary, Owen Paterson, against the European Commission, policymakers, and anti-GM groups (see Section 7.2.11). Paterson has stated that GMO crops are necessary to alleviate hunger in the developing world (Paterson, 2012). While many support this view, there are those who are concerned about the implications patents could have for farmers. According to advocates for African food sovereignty and biodiversity, Paterson does not understand the complex realities and challenges for Africa where 'about 80% of small-scale farmers save their seed. How are they supposed to protect the varieties they have developed, crossed and shared over generations from GM contamination? This will be a disaster for them' (Belay & Nyambura, 2013). The idea that small-scale subsistence farmers in the developing world could find themselves liable to multinational corporates is therefore a significant concern.

There would be nothing to stop these kinds of issues with patents manifesting in New Zealand. As a country with an agricultural economy it would be foolish to open ourselves up to a situation where corporations could have monopolies over food production.

Another potential threat to food security is the development of sterile GMOs (often known as the terminator gene), which was touted initially as a solution to cross-contamination. There already exist a number of patents for sterility technology (RCGM, 2001a: 178). However, critics point out that the reality of such technology is that farmers and food producers need to purchase new seeds every season, making them dependent on corporations for their yearly yield.

Ethics and values often lie under the surface of many discussions. The risks associated with using new organisms would have been one of the areas considered by the former Bioethics Council or by the Office of the Parliamentary Commissioner on Biotechnology. However, the Bioethics Council was abolished in 2009, and the recommendation of the 2001 Royal Commission on Genetic Modification to establish the Office of the Parliamentary Commissioner on Biotechnology was never implemented.

Financial risks, such as impacts on a national brand, and understanding the economic impacts of consumer resistance to GM food, are also key. While some consider the benefits of GM have not been communicated, more importantly, the evidence supporting these perceived benefits is not apparent. Decisionmakers need to weigh the benefits, costs and risks together, in an integrated manner. There are a number of examples where government has simply tried to push forward without taking an integrated and balanced approach. In November 2011 the Ministry for the Environment called for proposals to 'determine the factors influencing New Zealand businesses' decisions to innovate using new organisms'. This was intended to inform the government's decision over whether regulatory changes with respect to new organisms were required. An extract from Appendix 1 of the *Request for Proposals* states:

> The Treasury and some research and industry stakeholders have raised concerns that the current regulatory environment associated with the deliberate introduction of new organisms impedes the introduction and uptake of biotechnological innovation. These stakeholders believe that New Zealand's economic performance may be increasingly affected over time, and our competitive position in relation to more permissive economies will be eroded. Others challenge this view with concerns over potential risks arising from the introduction of new organisms. (MfE, 2011: 8)

If the evaluation focuses on the extent to which government regulation impedes innovation, at the expense of other factors that might also influence business decisions, it may fail to account for further risks that might arise from reducing controls on new organisms. This issue was raised in the press, showing how sensitive this proposal was when aired in the public arena (Fisher, 2011). Benefits, risks and costs should not be assessed in isolation.

What is clear is that there is very little consensus over the potential risks, costs and benefits of GM in the outdoors and very few mechanisms that are likely to create a space for a discussion between science, technology and the public, as Sir Peter Gluckman notes in his 2012 blog post *Dialogue or direct action?* (quoted at the beginning of this Section).

Recommendation 2: Risk management requires a whole-of-government approach

This might take the form of an integrated standard developed by the SSC, to be applied across the entire public sector, that aims to emphasise transparency and build linkages between regulatory institutions and departmental science advisors.[46] There is currently a risk that science advisors are seen as risk management experts. Risk management is far more than identifying and weighing scientific risk; it is critical that an integrated and transparent approach to decisionmaking must drive public policy.

46 For example, the recently released HM Treasury's *Managing public money* sets out the main principles for dealing with resources in UK public sector. The key themes are 'the fiduciary duties of those handling public resources to work to high standards of probity; and the need for the public sector to work in harmony with parliament' (HM Treasury [UK], 2013). This works alongside HM Treasury's *Corporate governance in central government departments: Code of good practice 2011* that covers protocols on areas like risk management and arms-length bodies (HM Treasury [UK], 2011).

7.2.3 Managing the costs of compliance

An on-going issue, and one recognised by the Commissioners (RCGM, 2001a: 131), is who should pay the decisionmaking and compliance costs of ERMA's (now the EPA's) decisions. In 2008 the Institute sought from ERMA a breakdown of actual expenditure on outdoor GMO applications, but this information was not easily available and could not be provided without significant cost under the OIA. More recently we have sought information from the EPA, MPI and CRIs; the information that was freely available is contained in Appendix 13, Table 15. This indicates that the additional costs of processing outdoor applications – including the notification, the public hearing process and the decisionmaking process – are significant. However, without the expenditure on new GMOs being broken down by type of outdoor experiment, we believe the true risk, costs and benefits of this technology cannot easily be assessed.

A notable feature of this data is the discrepancy between the true cost of new organism expenditure (Table 15, column c) and the application fee received (column d). Although the figures are not directly comparable, it is clear that outdoor experiments are likely to cost a great deal more than the amount applicants are currently being charged.[47] This is surprising when considering that the EPA's 2010 pricing principles aim to achieve an optimal balance between reflecting actual costs (principle 1 below) and other values (principles 2 and 6 below, arguably principles 2 and 6 have the same intent):

1. reflect actual costs;
2. [do] not discourage applications;
3. ensure predictability [for applicants];
4. recognise public benefits;
5. enable EPA to anticipate planned legislative change, and
6. [are] not a barrier to growth and innovation. (EPA, n.d.[b])

This apparent tension raises issues about the extent to which application fees should reflect actual costs, and the types of incentive that may exist and support applicants to pursue the commercial use of GM in the outdoors.

Recommendation 3: Compliance costs should be fully recovered from applicants

There should be a reassessment of the EPA's pricing principles, placing the responsibility for the full costs of processing an application on the applicant. Further, applications that are viewed as beneficial to New Zealand should be able to apply for funding by a government institution that has the mandate to make such a judgement – such as MBIE – rather than the EPA, separating the government investment decisions from the EPA approved decisions. In addition, more effective reporting in this area is likely to create better decisions regarding application fees and strategic options.

7.2.4 Managing legal liability and the costs of coexistence

1. Defining legal liability

The HSNO legislation prescribes liability for any person failing to comply with controls, or for any action or omission in breach of the Act that results in loss or damage. However, things become less defined if damage occurs without any breach of the controls imposed by the EPA; for example, if an applicant for a conditional release complies with all the protections the EPA specifies, but GMOs still cause damage to neighbouring crops. While there are actions available under common law, a number of factors may limit

47 It is not possible to compare columns directly in Table 15; for example, columns (c) and (d) cannot be compared as (c) pertains to decisionmaking for all new organisms, while (d) contains only outdoor GM experiments.

the tangible relief that can be attained, for example, if the defendant is insolvent or is a shell company. This point was raised by the Royal Commission in its 2001 report, but the Commissioners decided no changes were required to the liability system at this point in time (RCGM, 2001a: 319). However, in a 2004 opinion provided by Crown Law, it was noted that GM contamination of plants that are not commercially farmed may not constitute 'environmental damage' under common law. Meaning that an essential element ('financial loss') of a claim under negligence or nuisance would not be present and common law remedies may not provide relief unless the damage caused was to commercially farmed plants.

> If that cross pollination was with a native plant which was not commercially farmed then there would be no damage as far as the common law is concerned even though there may be 'environmental damage' in that the genetic make-up of a particular species is altered. (Arthur, 2004: 4)

Furthermore, the current liability scheme makes no requirement for an applicant to provide proof of financial fitness. Section 38D(d) of the HSNO Act 1996 allows for this, but to date neither ERMA nor the EPA has ever required it. This means there is no requirement on an entity applying for approval to develop, test or release a GMO to provide an assurance that they can afford to mitigate any damage caused in the event of an environmental disaster. Such issues have raised concerns that landowners will be left with few options in the event of contamination and that local councils could face responsibility for clean-up costs, instead of the entities responsible for causing the damage. This has been cited as a motivating factor in the decision made by some regional and district councils to regulate the use of GM in their plans under the RMA. See Section 7.2.6 for further discussion on the issue.

These issues mean the quality of controls is extremely important. As outdoor experiments are currently in operation, it seems appropriate that regular control reviews take place to account for both emerging scientific knowledge and knowledge gained from incidents. However, potential controls for any future conditional releases pose more difficult questions; for example, the effectiveness of 'buffer zones' and the probability of achieving actual coexistence.

2. Defining coexistence

The issue of what is meant by 'actual coexistence' continues to pose a dilemma. Farmers have always had issues over coexistence; for example, the neighbour who does not manage gorse so that the flower travels by wind and replants on another's property, the neighbour who does not fix the hole in the fence, or fails to control his rabbits – these are all issues of coexistence. In the context of GM, coexistence has also been discussed in terms of the ability of different production systems to exist compatibly. This aligns with the definition used by MPI today:

> 'Coexistence' is where different primary production systems are each contributing to the overall benefit of New Zealand while ensuring that their operations are managed so that they affect each other as little as possible. This can include non-GM systems such as organic production and conventional agriculture, and GM systems. In practice, the aim is for different production systems each to 'do their own thing' and not get in each other's way. (MPI, n.d.[e])

During the Royal Commission, MAF stated:

> … if organics standards allow the possibility of accidental contamination, then coexistence is possible. If standards demand zero tolerance for accidental GM contamination, then coexistence may not be possible. (RCGM, 2001a: 171)

As a result, the Commissioners discussed issues over coexistence, recommending 'an element of government regulation to develop and maintain coexistence' (RCGM, 2001a: 174).[48] We understand this recommendation has not been implemented, and that the Commissioners themselves reached no specific conclusions on this issue.

By 2002, it was generally accepted that zero contamination was 'virtually impossible' (EC, 2002: vi). At this point the debate moved from zero contamination to whether a limited 'level of contamination' would be acceptable. For example, in 2006 the Commission of European Communities reported that:

> Agriculture is an open process, which means that perfect segregation of the different agricultural production types is not possible in practice. Coexistence of these production types which will not lead to a systematic exclusion of one or more of them can only be ensured if the segregation measures are designed in a way that takes these *limitations* into account. [Italics added] (Commission of European Communities, 2006: 2)

In Europe, these limitations are described in relation to the regulations that establish a threshold for the 'adventitious or technically unavoidable presence' of GM material below which food and feed do not require labelling – this threshold currently sits at 0.9% (Commission of European Communities, 2006: 2). Our concern is that once this instrument is used, the threshold could simply be raised over time in response to increased levels of contamination.

In 2004 a report of the Western Australian Parliamentary Standing Committee found 'that contamination of non-GM crops by GM crops is inevitable, [and] segregation is not practical' (Western Australia Legislative Council, 2004: 9). The European Commission's Scientific Committee on Plants stated in 2001 'that it did not believe a zero level of unauthorised GM seed was obtainable in practice' (EC, 2001: 4). The European Commission Joint Research Centre held 'that coexistence with thresholds in the region of 0.1% is virtually impossible in any of the scenarios considered' (EC, 2002: vi). A 1% level might technically be possible, but it would be economically difficult (EC, 2002: vi). Interestingly, in response to the importation of GM produce and the risk of spillage, a statutory advisory body in the UK, the Advisory Committee on Releases to the Environment (ACRE)[49], holds the view 'that horizontal gene transfer (HGT) between plants and soil bacteria (under field conditions) is a very rare phenomenon, if it happens at all. However, our approach is to assume that HGT of transgenes may occur and to consider the consequences' (ACRE, 2012: 2).

MAF (now part of MPI) used to produce regular updates on international developments in GM policy, with a particular focus on coexistence (MPI, n.d.[f]). However, the Ministry stopped producing these reports in 2007 as it considered effective coexistence practices to be well understood and the exercise was no longer thought to be valuable (MPI, personal communication, 30 July 2013).

In practise, the introduction of GM agriculture created a completely new issue – what we refer to as the technical coexistence issue – the compatibility of GM food production with non-GM food production.

48 Recommendation 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. (RCGM, 2001a: 177)

49 ACRE is a statutory advisory committee appointed under section 124 of the UK Environmental Protection Act 1990 (the UK equivalent to New Zealand's EPA) to provide advice to government regarding the release and marketing of genetically modified organisms (DEFRA, 2012).

This issue calls into question the rights and responsibilities of farmers to coexist. This is particularly significant in terms of limited liability, as the potential harm to farmers is both significant and one way: for example, where a GMO farmer damages the marketability and therefore the profitability of another, GMO-free, farmer (since traditional and particularly organic farmers tend to obtain higher premiums), or where a GMO farmer could lead to a GM-free farmer being sued by the GMO manufacturing company as a result of GM seeds blowing onto his farm without his knowledge.

Today, it is on the second layer that the issue of coexistence rests: (i) what does successful coexistence look like, and how could we measure successful coexistence; (ii) who will develop, manage and police an industry code on GM coexistence to manage the agreed-upon threshold, and (iii) how will the liability system ensure farmers act responsibly and that their rights are protected when the system delivers adventitious events. Our understanding is that, as of 2013, none of these three questions have been dealt with consistently and completely throughout central government.

3. Defining GMO's

Another area of potential legal uncertainty is the current definition of a GMO and its ability to encapsulate emerging techniques. This issue was recently explored by the ACRE in its report *New Techniques Used in Plant Breeding*, with respect to the EU's definition of GMOs and new or emerging techniques (ACRE, 2013). The ACRE report pointed out that, 'with the advance of biotechnology, it is becoming increasingly difficult to distinguish between GM and other plant biotechnological techniques' (ACRE, 2013: 34). This is an emerging issue in New Zealand. Currently a High Court action is being pursued by the Sustainability Council New Zealand against the EPA decision not to classify a technique known as ZFN-1 as genetic modification.

The definition of a GMO in s 2 of the HSNO is:

> Genetically modified organism means, unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material –
>
> a) have been modified by in vitro techniques; or
>
> b) are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by in vitro techniques.

However, since New Zealand is a signatory to the *Cartagena Protocol on Biodiversity* (see Section 5.8), it is worth noting that the definition in the protocol is somewhat broader, and does not refer to GMOs but to LMOs:

> 'Living modified organism' means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. (UN, 2000b: Article 3)

When it looked at a number of techniques that pose particular challenges to the EU legislative definition of GM, the ACRE found that the flexibility of the EU definition presents regulatory problems. It advised that a more transparent, scientifically robust interpretation be adopted if the EU continued to employ the current definition. It also discussed the option of a 'product-based approach' to GM regulation rather than the current process-based approach (ACRE, 2013: 34). The techniques identified by an EU Commission working group as posing particular challenges were cisgenesis/intragenesis, reverse breeding, agroinfiltration, grafting (non-GM scion/GM rootstock), RNA-dependent DNA methylation, oligo-directed mutagenesis and zinc finger nucleases (mutagenesis) (ACRE, 2013: 2).

To the best of our knowledge such analysis is yet to be carried out in New Zealand, which leaves our country vulnerable to these new technologies, which may not be caught under the HSNO regulatory

regime. Like the UK, it is timely for New Zealand to explore our current definitions and see how they line up against new and emerging technologies.

Recommendation 4: Legal liability should be reviewed as coexistence with zero contamination is not possible and definitions of new organisms have become increasingly unclear

Given the concerns of stakeholders in New Zealand and the limitations of coexistence, New Zealand should undertake a full review of current legal liability, with particular focus on the potential for incorporation of financial fitness, ensuring companies undertaking GMO releases are capable of paying the costs resulting from any contamination. Since a GMO release would inevitability deliver contamination of some level to both traditional and, in particular, organic food producers (a point that the science was unclear on during the Royal Commission hearings), it is timely to consider firstly whether GMOs should ever be released into the outdoors in New Zealand, and secondly whether the liability system in New Zealand is able to deal with contamination from emerging technologies.

7.2.5 Managing data

Managing the risks of GMOs requires robust data management; quality data provides the strategic knowledge necessary to inform effective public policy. Without such a methodology, our ability to identify and manage both the positive and the negative effects of the technology is severely hampered. In a speech given in February 2013, the Prime Minister's Chief Science Advisor, Professor Sir Peter Gluckman, discussed the 'importance of ensuring effective incorporation of objective evidence, science and data into the policy process' (OPMSAC, 2013: 1).

In order to deliver effective outcomes, data must answer key questions in an integrated, transparent and timely manner. Questions such as: What is the organism? Who owns the technology? Who approved it? Where was it located? Did taxpayers fund or invest in the GMO? What were the controls? Were the controls breached? And who is responsible for any unwelcome consequences? Data management systems must be accessible, and the data itself must be accurate, verifiable and traceable. We have observed that the institutional changes that have occurred over the last five years have led to increasing challenges in the ability to maintain a comprehensive and coherent reporting system. This can be best understood in terms of the following examples:

1. *Information on field tests pre-1998 – finding comprehensive information about past experiments*

The EPA does not provide online access to approval documents for experiments processed under the Interim Assessment Group (IAG) system that existed between 1988 and 1998. *The New Zealand Gazette* contains information on experiments that were transferred to come under the HSNO Act in 1998, but information about those that were not transferred is difficult to find. Further, as indicated in the list of applications for outdoor experiments between 1988 and 2013 (contained in Appendix 9), the term 'not known' is used to indicate that the EPA does not appear to have information on old IAG approvals (EPA, personal communication, 7 May 2013). This information is important in terms of revisiting past sites, assessing impacts, cleaning up, and/or compensating landowners if unwelcome consequences occur.

2. *GM research – searching approvals in terms of entities*

There is no publicly accessible integrated list of all entities undertaking research on GMOs. IBSCs approve the majority of indoor experiments through delegated authority of the EPA. The EPA is the regulatory body that collects information on IBSCs and outdoor approvals. In contrast, the MPI is the compliance and enforcement body, which collects information on monitoring and incidents. However, this information is not collated in a comprehensive manner and made available to the public. Entity reporting is important as it ensures that organisations legally undertaking such experiments are known and, if controls are breached

or unwelcome events occur, liability can be traced. Further, it provides useful information in terms of public policy, knowledge of who is undertaking such experiments, whether the number of entities doing so is increasing, and who has undertaken compliance audits and when. As a result, regulatory frameworks can be assessed from the perspective not only of those who use the system, but also the public, who have a vested interest in the system, thus delivering optimal outcomes in the long term.

3. Outdoor experiments and funding – assessing public investments in terms of risk and return

The EPA, MBIE and MPI each use different record-keeping systems to track applications, making it very difficult to track the progress of experiments. For example, an approval for a field test is allocated a number by the EPA, however, if that same project has received funding from MBIE, it also has an MBIE contract number. These numbers do not correspond, and neither the EPA nor MBIE has records of the other department's identifying numbers. Furthermore, funding from MBIE is usually allocated for large projects, which may include multiple indoor and outdoor experiments. These tests all have their own EPA approval numbers, making it difficult to track how the funding was distributed once it was allocated. This is important because some applicants have previously argued that their proposal was approved for government funding, therefore proving public benefits exist (see Section 7.2.1). Hence, when ERMA weighed benefits against costs and risks, it was argued that the benefit had already been proven to be significant because the experiment received public funds. Understanding this link between public investment and public risk is important. Any public investment, and in particular investments that are generally considered risky by the public, should attract higher levels of transparency, traceability and accessibility as a matter of principle. This may be compared with the way in which companies should, as a matter of good business practice, require regular, in-depth reporting on all their high-risk investments.

4. Incidents – tracking breaches in terms of entities undertaking experiments or importing GMOs

Incident reports published by the EPA on its website do not include the EPA approval number of the experiment in which the incident took place, nor the specific control (the number) that was breached. This makes it difficult to identify and trace breaches of controls per GMO experiment, review the quality of controls used, and gain an understanding of the quality of controls or the quality of the containment facility. Where import breaches are recorded, in some cases the entity concerned is not identified (see Appendix 14, Table 18). We also encountered difficulty regarding the continuity of information relating to historical events. For example, in the Institute's 2008 report on the history of GM in New Zealand, we noted that 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 there were 196 examples of research that had not been notified to the Ministry for the Environment when it prepared the Order in Council to gazette existing approvals in July 1998, and 113 instances of unauthorised GM work with no proper approval (ERMA, 2000a: 1–2). However, these records are no longer available online, and they are not included in the EPA's current reports, which do not go back prior to 2004.

Furthermore, the incident rating system (which currently consists of five levels, from minor to major) could be better described in terms of probability and magnitude, factoring in how preventable the incident was and its causes. How the EPA assesses the tangible effects of a breach is also important. And, in regard to monitoring, it is important to consider who is responsible for verifying that the applicant is meeting the controls. Hence the process requires linkages between the data collection component (e.g. the EPA's decision to accept the application), the judgement component (e.g. the EPA's decision to approve the application) and the public reporting component (e.g. the EPA's responsibility to report on the implementation of the application).

5. GM foods in New Zealand – linking imports to food consumed

FSANZ provides records on its website of which GM foods have been approved for sale in New Zealand and Australia, but not which foods are currently sold in either country. FSANZ is the regulatory body

responsible for developing food standards, but not for enforcing them; in New Zealand this is the responsibility of MPI. However, the absence of a publicly accessible list stating which foods currently for sale in New Zealand contain GM material is concerning. This may become a problem in terms of tracing and removing products from the market if risks become apparent, after the food has been approved for sale.

6. GM feed in New Zealand – linking imports to feed consumed

Unlike human food, the level of GM ingredients in imported animal foods is not regulated in New Zealand. The current import health standards do not restrict the importation of feed if it contains non-viable animal material originating from a genetically modified animal.[50] If the feed contains GM probiotics,[51] it may be subject to restriction at the discretion of the EPA. MPI has an import health standard in place for various highly processed plant-based feeds, which may include processed seed meals or pelleted products (e.g. byproducts of the extraction of oils – such as canola meal, cotton seed meal and soybean meal) which may have been grown and manufactured overseas using GM crops. (MPI, personal communication, 20 May 2013; 24 May 2013)

7. Documentation – lack of dates, author information and references

During this research we have come across a considerable number of documents that are undated, lack the author's name, are unreferenced or are referenced incorrectly. For example, the *Questions and answers on coexistence* document on the MPI website, which based on its contents appears to have been written in 2003, is listed under publications on the website as May 2005. The document itself is not dated and the author is not named (MPI, n.d.[f]).

Recommendation 5: Data management requires urgent attention

A review must be undertaken of the way information relating to GMO experiments is handled to ensure continuity across the GMO governance system so that data is timely, comprehensive and useful. We have provided seven examples of where the system is not working effectively, but we suspect there would be many further opportunities to improve the process and develop a system that draws all key institutional parties together. We suspect this review would best be led by MfE, with assistance from the EPA, MBIE and MPI (see Figure 2, repeated in Section 7.1).

7.2.6 Managing the relationship between central and local government

Chapter 13 of the report of the Royal Commission on Genetic Modification discusses the compatibility between GM and non-GM land uses, noting that one possibility would be to establish regional GM-free zones under the Resource Management Act 1991. While the Commissioners noted they were unable to reach a decision on this, and that in practice it would be difficult to implement, they did suggest that regional or district plans that make provision for specific land use under the RMA could be one mechanism to achieve this:

> Genetically modified and non-genetically modified crops might be permitted or prohibited on a crop-by-crop and region-by-region basis. This would require a genetically modified crop to be designated as a different use from a non-genetically modified crop of the same species. It may also be that over a period of time an aggregation of genetic modification or non-genetic modification uses became characteristic of particular regions and that identifiable regional differences emerged. These distinctions in land use might be written into regional or district plans, just as industrial use is separated from residential use. (RCGM, 2001a: 337–338)

50 Non-viable animal material is that which is not capable of living, reproducing or developing, as in a non-viable cell.

51 Probiotics are microorganisms that may confer a health benefit on the host.

The option of using the RMA to formalise regional GM-free status is currently being explored in Northland and Auckland by the Inter-Council Working Party (see Section 5.3.1) and by the advocacy group Pure Hawke's Bay (Section 5.5.6).

However, the Minister for the Environment, Amy Adams, has recently indicated that the decision to further regulate GMOs is not one to be made by local government. Adams has announced that she will block councils from regulating GMOs under the RMA (Davison, 2013b). Nick Smith, the former Minister for the Environment, responded similarly on 16 August 2013, reacting to a letter to the editor in the *Nelson Mail* on the question of the RMA being used to regulate GMOs:

> There is no use in having councils regulating new organisms because we do not have biosecurity controls between our 67 district and city councils. **If a new plant, animal or GMO is released in one area, there are no practical means to stop it spreading to others.** Nor do councils have the specialised scientific expertise needed to deal with the complex issues of safely regulating these technologies. I support these changes to the RMA that makes plain that councils should not second guess decisions of the Environmental Protection Authority. Effective governance requires that we are plain about what our elected councils do and what are the roles of central government. [Bold added] (Smith, 2013)

However, this position is at variance with a comment previously made by Nick Smith, in a letter written in 2010, which confirmed the ability of local authorities to regulate GMO use in their plans, provided they meet the relevant requirements of the RMA:

> Decisions on whether to approve a GMO are best undertaken by the independent, quasi-judicial body, the Environmental Risk Management Authority (ERMA). However, this does not preclude a council from restricting or preventing the use of GMOs in their region, provided that this action meets the relevant requirements of the Resource Management Act 1991. (Smith, 2010)

The lack of consensus on this issue is not resolved by the statement of the current Minister, which seems to reflect a change of direction by the Ministry. When pressed on this issue in Parliament by the Green Party's Steffan Browning, Adams referred to the 2003 and 2004 advice given by Crown Law, which stated that local government is unlikely to be exposed to liability in the event of GM contamination (Arthur, 2003; 2004). However, as noted in *Community Management of GMOs II*, legal liability is not the sole concern of local governments, and the more pertinent issue is financial liability or the ability to obtain compensation from those causing damage (Simon Terry Associates and Mitchell Partnerships, 2005: 34). Considerations of environmental damage, effects on biodiversity and potential effects on human health were also not assessed by Crown Law. Furthermore, in the event of damage or contamination, local councils could be tasked with ongoing monitoring responsibilities. These issues have not been acknowledged by the Minister in recent media statements.

The Minister's concern is with local government trying to rewrite nationally set frameworks, and she has stated that the HSNO Act currently provides adequate protections. In response to questions on the matter in the House, Adams stated that councils 'should raise these issues with the EPA and attempt to address the regulation on a national basis' (Adams, 2013).

The *Resource Management Summary of Reform Proposals 2013* released in August this year states:

> The explicit function for councils to control hazardous substances and the ability to control new organisms (GMOs) through the RMA will be removed. This is considered to be best managed under the Hazardous Substances and New Organisms Act 1996 and by the Environmental Protection Authority. (MfE, 2013b)

Transparency and participation are crucial to open government. Local government acts as a useful mechanism to not only facilitate two way conversations on complex issues, but to source public opinion on emerging issues where public policy is not adequate for resolving the practical issues facing communities. Therefore, if a centrally managed regulatory scheme is desired by central government, there must be a mechanism for communities to collect public opinion on emerging issues and report on those opinions to central government. The local plan is the best instrument for this. Without the ability to do this, central government is expecting local government to submit against every application that may adversely affect their community. This onus should be reversed; local government should not have to prove that applications are damaging to the specific characteristics of their communities, rather applicants should have to prove they are not.

Further, as the legislation stands, there is no certainty over how local communities' wishes will be pursued and integrated into controls by the EPA. The HSNO Act 2003 states that the EPA *may* decide to impose controls on a conditional release, see s 38D(1)(g) of the HSNO Amendment Act 2003 below:

> *38D Controls*
>
> (1) The controls that the Authority *may* impose on a **conditional release** approval include –
>
> (g) limiting the proximity of the organism to other organisms, including those that could be at risk from the conditionally released organism [italics added] [Bold added]

Further, this mechanism in law is not available for developments or field tests. As previously discussed the majority of outdoor GM research is undertaken by CRIs, which are required by s 5(1)(f) of the Crown Research Institute Act 1992 to exhibit a sense of social responsibility and have regard to the interests of the community in which they operate.

Effectively central government is refusing to address local authority concerns, while simultaneously proposing to prevent local governments from responding to their communities concerns with the only mechanisms they have, through the RMA.

Recommendation 6: Allow local authorities to regulate GMOs or amend the HSNO framework accordingly

The government should not prevent local bodies from using the RMA to regulate GMOs. If it does so, it indicates a bias toward GM producers at the expense of non-GMO food producers; communities should have both the right and the responsibility to make decisions over land use. Further, the fact that some of these authorities deem a plan change to be necessary indicates that the current approach should be revisited; policy analysts should not be focusing on trying to entrench past ideologies but look at why regions might wish to brand themselves as GM-free food producers – what are the benefits that are driving their behaviour, and might this be a useful perspective for the country to consider?

One option would be to amend the HSNO regulatory framework to prohibit field tests and outdoor developments of GMOs, with defined exemptions. This would mean that applications under HSNO would be considered on the assumption that the application will be declined unless the applicant can prove that the benefits will justify the exemption.

In practice, prohibiting only GM outdoor experiments and field tests and outdoor developments, rather than an outright ban on GM research would add a crucial extra step in the approval process. It would also serve as an opportunity for both local and central government to clarify exactly what they believe to be the purpose of allowing GMO outdoor developments and field tests in a considered and transparent manner. This would not be a fundamental change, but a change that more closely aligns with the

Royal Commission's recommendation that the government take a precautionary approach to genetic modification while preserving optionality.

7.2.7 Managing the assessment and monitoring of controls

New Zealand is dependent, to a large extent, on the results of research undertaken by other countries on GMOs in the outdoors. As noted in a paper by Fleur François (see Section 6.2) New Zealand's regulatory system 'recognises that post-release monitoring of GM crops is not a substitute for the adequate pre-release risk assessment of novel organisms' (François, 2006: 80). Further, François noted that as a consequence of New Zealand being a very small nation, 'environmental research cannot always be carried out independently of the approval holder, and funding sources are limited for comprehensive long-term monitoring studies' (François, 2006: 75). In her paper François identifies a number of specific constraints on environmental monitoring programmes for GM crops in New Zealand, specifically:

- Monitoring cannot be carried out independently of the institution performing the research because of the lack of available expertise and research funds in a small local scientific community;
- The need for long-term control of land management of a site where GM crops have been cultivated in order to obtain long-term data beyond the end of the test, and
- The actual cost of the work is an issue because in New Zealand there are limited funding sources available to scientists for long-term environmental monitoring research. This is particularly significant considering that the majority of GM crop research and field testing is being performed by CRIs or public universities whose predominant source of funding is the government. (François, 2006: 79–80)

As evidenced by the effects of previously introduced species, New Zealand has particularly sensitive natural ecosystems (MfE, 2013c). It is therefore extremely important that New Zealand undertakes field tests before introducing new species into our unique environment. At the moment, there is no prerequisite requiring a field test to be undertaken before an application to release (or conditionally release) a new organism. In fact, the Hazardous Substances and New Organisms (Genetically Modified Organisms—Information Requirements for Segregation and Tracing) Regulations 2008 allow for any applications to be received provided such an application contains information to allow for segregation and tracing, as stated in s 4:

> *Section 4: Information on segregation and tracing required with application for **conditional release***
> (1) An application for a conditional release approval for a genetically modified organism under section 38A of the Act must include information about –
> (a) specific measures, if any, the applicant intends to take to –
> **(i) keep the genetically modified organism separate from other organisms, whether the other organisms are genetically modified or not; and**
> **(ii) enable the genetically modified organism to be traced after it is released with controls; and**
> (b) the level of effectiveness the applicant expects the measures to achieve.
> (2) The information required by subclause (1) includes information about any code of practice or standard relating to the segregation or tracing of organisms, including genetically modified organisms, that applies to the applicant's intended use of the genetically modified organism.
> (3) If the applicant does not intend to take measures referred to in subclause (1), the application must set out the applicant's reasons for not taking the measures. [Bold added]

The explanatory note to the regulations states:

> [If] the applicant does not intend to take such measures, the application must include his or her reasons for not doing so [and if] the Authority imposes such controls, they may help the producers of non-genetically modified organisms to satisfy their markets of the non-genetically modified status of their products.

Therefore the legislation accepts that producers of non-GM crops have an interest in protecting their crops, but in our view it does not stipulate the need to place measures (as in tight controls) and monitoring on any potential conditional releases. As yet this legislation has not been tested as New Zealand has had no applications for conditional release, but it is timely to consider whether the current legislation is adequate to manage such an application.

Recommendation 7: Before the conditional release of any GMO, a field test should first be undertaken

A field test enables a much higher level of scientific rigour and due diligence to be applied both within and on the border of the contained area, rather than the more ad hoc approach advocated under the 2008 segregation and tracing regulations that relate only to conditional release. This is an important consideration as New Zealand has (i) little experience with field tests of GM crops (other than Scion's trees) and (ii) we do not have a large number of independent scientists to undertake peer review of controls and assess long-term impacts. Hence New Zealand is not well placed to undertake the necessary assessment and measurement of the effects of GM crops, in particular grasses, as we have no expertise in this area (see discussion on GM ryegrass in Section 6.1.1).

7.2.8 Managing systems through regular reviews

With so many institutional changes occurring within a relatively short time, the Institute considers it timely to review the whole system, including auditing MPI's controls in outdoor GMO experiments, the role of MPI with regard to border security (see Figure 8 and Appendix 14), the role of IBSCs in managing and auditing physical containment structures, and the role of the EPA.

By way of example, in February 2013 Lyn Provost, New Zealand's Controller and Auditor-General, noted in the preface to a performance audit of the Ministry for Primary Industries:

> … it is my view that MPI is under-prepared for potential incursions from some high-risk organisms. Responding to incursions has taken precedence over preparing for the potential arrival of other pests and diseases. Not enough priority has been given to planning. Many response partners who have worked with MPI and its predecessors believe that stronger response capability is also needed. (Office of the Auditor-General, 2013b: 5)

This 'under-preparedness' is of significant concern in the context of GM, particularly if New Zealand decided to adopt the status of a GM food producer. Crucially, performance audits are only the first step. An integrated review with a clear strategy for the way forward is required.

Considering both the number of breaches and the number of institutional changes that have occurred, we expect there will be areas where the systems have lost their integrity or been compromised. Furthermore, it would be wise to review the bodies of scientific knowledge on GMOs regularly to ensure New Zealand has in place best practice regarding import controls, containment controls, and the management and clean-up of adverse effects. Both the legislation and the regulatory bodies must be able to keep up with

scientific developments. Regular reviews would prevent biotechnology developments operating out of regulatory scope, or in a manner that goes against the intentions of public policy. Similarly, concerns have been raised in New Zealand about the detectability of new types of GM known as cisgenics (SCNZ, 2011a), and the EPA's recent decision that a new technology called ZFN-1 challenges understandings about the legal definition of GM (Fisher, 2013).[52] See Section 6.2.1 for further discussion on ZFN-1.

Recommendation 8: Reviews should be tactical and regular

Tactical reviews are critical to the underlying operation of a system and must be undertaken on an adhoc basis. In this system, the most urgent is a review of controls on outdoor experiments and any breaches of those controls – a breach of a control could mean that there is nothing between an experimental GMO and the natural environment. These reviews should be undertaken by a group of scientific experts. Secondly, regular assessments of those monitoring and reporting on the controls must also be undertaken. Do those undertaking assurance understand the controls, and are they completing reviews to the standard the public expect? We have seen no evidence that these reviews are happening, and in view of the number of outdoor breaches that have occurred we suggest more work is needed to provide a high level of assurance to policy analysts and the public alike. Regular assessments should be undertaken to ensure the system works effectively, particularly considering the level of institutional change that has occurred in recent years (see Figure 2) and concerns over the reporting of data and information noted in Section 7.2.5.

7.2.9 Managing systems through memoranda of understandings

Between 1998 and 2010 a number of Memoranda of Understanding were signed between ERMA (now transferred to EPA) and various government entities in New Zealand and Australia (see Appendix 16). These entities included MAF, the Forestry Regulatory Authority, the Forestry Biosecurity Authority, FSANZ, the Department of Labour, the Ministry of Health, NZFSA, and the Australian Department of Health and Ageing. It seems appropriate, particularly in consideration of the extensive institutional changes over the last five years, that these relationships be reviewed and assessed in terms of whether they are supporting the overall goal of the broader risk management system. It seems appropriate, particularly in consideration of the extensive institutional change in the last five years, that these relationships be reviewed and assessed in terms of whether they are supporting the overall goal of the broader risk management system (see Figure 2, repeated in Section 7.1).

Recommendation 9: Memoranda of Understanding should be urgently reviewed and updated

Nineteen Memoranda of Understanding (MOUs) exist between the EPA and third parties, the oldest dating from 1998. Of these 19 types of MOUs, nine are more than five years old (see Appendix 16 for more detail). All MOUs should be reassessed to ensure they have been actioned appropriately and stand as complete, accurate and relevant records of the understanding between the two parties. We recommend that all MOUs regarding the operation of the regulatory system between significant parties also be re-signed as of 2013, and are easily accessible on the EPA website.

52 ZFN-1, also known as zinc finger nuclease, can be used to create specific mutations in genes (Fisher, 2013).

7.2.10 Managing strategy

There are in effect four types of strategy for discussion. The first is a national strategy for New Zealand, something for which the Institute has been proposing for many years.[53]

Next there is the biotechnology strategy. The New Zealand Biotechnology Taskforce was set up to prepare a biotechnology strategy, and in 2003 it published the *New Zealand Biotechnology Strategy: A Foundation for Development with Care*.[54] To our knowledge only one evaluation of the strategy has taken place since that time, and that was in 2004. If the government wishes to pursue biotechnology, 2013 seems an appropriate year for a comprehensive reassessment of the 2003 strategy and possibly to develop a new strategy. Of course, not all biotechnology is GM; rather, GM is only a very small part of biotechnology.

Then there is the GM strategy. The Royal Commissioners considered GM in terms of a spectrum, with a New Zealand free of all GM material at one end, and the unrestricted use of GM at the other (RCGM, 2001a: 332–333). Their conclusion was that New Zealand should preserve opportunities, believing: '... either of the extreme options would significantly restrict New Zealand's future choices and has the potential to impose considerable costs. All sectors of our economy should remain viable and be able to expand to their full potential within the constraints of a competitive environment' (RCGM, 2001a: 333). A broader discussion of the Commission's four key findings can be found in Section 3.4; we discuss the way forward in Section 7.3, 'Reflections'.

Lastly, there are specific aspects within the GM strategy. This is the lowest level of strategy, which would, for example consider how to optimise the use of this scientific tool in the outdoors. Although we could not find any information to suggest that such a strategy exists, with two CRIs pursuing such experiments it would seem the government does have such a strategy in practice. Considering the topicality of this issue, we believe a strategy should be published and in place so that it can be evaluated and reviewed in light of the broader strategy.

Underlying all of the above is the need for any strategy to be robust and evidence based. Strategy is as much about action not taken as it is about action taken. All related strategies should align – internally, horizontally (with similar strategies) and vertically (with the primary strategy for a country). However, strategy is only as good as the person or organisation made responsible for its implementation (the owner). The fact that the 2013 biotechnology strategy remains dormant is an example of what happens when a strategy fails to make clear who owns it and who is going to review it, both during and at the end of its timeframe. The Institute considers this to be a weakness in the strategy-development process across central government, and that this simple practice of ownership (signing-off strategies) could significantly improve outcomes. (See the Institute's *Report 2: New Zealand central government strategies: Reviewing the landscape 1990 –2007*).

Good business practice demands frequent and ongoing consideration of all strategic options, but changing from one strategic option to another takes courage and leadership. During this review of GM in New Zealand it has been interesting to trace the highly reactive policymaking process over the last forty years, with lobbying from all sides forming a very large part of the process.

Ideally, policy analysts should have taken a stronger and more prominent stance, representing the public interest by providing better data and more useful information. Further, a reactive policymaking process

53 Project 2058 is this Institute's flagship project, working towards a National Sustainable Development Strategy for New Zealand.

54 The chair of the New Zealand Biotechnology Taskforce was Bill Falconer, a former chair of ERMA.

does not necessarily lend itself to good strategic decisionmaking.[55] To this end, one of the purposes of this report is to provide a history so that analysts who are new to this area have a deeper understanding of the past, so they can develop a more informed way forward.

Recommendation 10: Strategy should be revisited

The Institute considers all four levels of strategy should be revisited. Although we would like to see a national strategy, we also support seeing the biotechnology strategy, GM strategy and outdoor GMOs strategy being revisited and published. This last point, relating to outdoor GMOs, is discussed further in Section 7.3, 'Reflections'. Reassessing the 2003 New Zealand Biotechnology Strategy might prove insightful, possibly with a view to preparing a strategy with an action plan for 2013–2023.

7.2.11 Managing foresight

Foresight is not so much about forecasting, but exploring the landscape, identifying weak signals (new and emerging issues) and key drivers of change. For an agriculture-based economy such as New Zealand's, it is not only necessary to invest in effective regulation but also to ensure the benefits of research exceed the risks. This is not easy; it calls for a deep understanding of the landscape. To gain such an understanding many questions need to be asked: firstly, who are the key players, what risks exist and who wears the risks, what opportunities and challenges can we expect, and can emerging GM technologies be managed within the current regulatory framework? Further consideration is required to ascertain what our current and future trade partners think, and what effect outdoor GM research will have on our national brand – does it have the potential to strengthen or cannibalise value? All these questions must be considered by those in central government.

Perhaps the most important question is, who is looking ahead? If the Commissioners' recommendations had been implemented, New Zealand would now have a Parliamentary Commissioner on Biotechnology to undertake this role. But even without such an institution, it would still be possible to position this role within some other independent institution, such as the Treasury, DPMC, or MfE. There are other, bolder ideas, for example the establishment of an entity in the form of a Futures Commission or a Sustainable Development Council.[56]

The global public policy debate remains unsettled; trade implications and the health effects of GM foods are still being debated in the media. Although not an extensive list, the following are some recent examples of global development of science and public policy.

Australia: A recent study conducted in South Australia on GM feed for farm animals found that pigs fed on a diet of GM grain showed higher stomach inflammation than those fed on conventional feed (Duxfield, 2013). The dairy industry in Australia made a definite decision to discontinue investment in transgenics, and we understand that there is currently no active research on GM cows in Australia (Salleh, 2011). Victoria, New South Wales and Western Australia allow the planting of commercial GM canola crops but South Australia is currently GM free. State Agricultural Minister Gail Gago has stated that South Australia is committed to the ban until September 2019 (Hemphill, 2012). Tasmania

55 An example of this was the 'anti-regulation' attitude adopted by some scientists as a reaction to initial over regulation surrounding 'low-risk' GM applications. Prior to 2003, each experiment required a new application to the local IBSC creating a great deal of unnecessary paperwork in research laboratories, universities and CRIs (Wilkins, personal communication, 31 August, 2013). This over-regulation of indoor low-risk experiments from 1998, may have led to the pro-GM positioning of many GM scientists, and the support of Life Sciences Network in 2000 (see Section 4.3).

56 The Institute is currently involved in discussions with Bryce Johnson from Fish & Game and Shaun Hendy from the New Zealand Association of Scientists, and members from Generation Zero, to prepare a discussion paper on the need for mandated foresight in the public sector. This paper will discuss institutional options; the working title is *An Argument for Mandating Foresight*.

has had a moratorium on GM crops in place since 2000, but despite there having been no GM outdoor experiments in the last 15 years and the state government spending on average $250,000 a year since 2001 on eradication, rogue GM canola plants, a product of GM testing in the 90's, have continued to sprout (Bevilacqua, 2013). The current moratorium on GMOs in Tasmania is due to expire in 2014 and the state government is currently conducting a review. The Department of Primary Industries, Parks, Water and the Environment will release a report by the end of 2013 (Department of Primary Industries, Parks, Water and Environment, 2013).

China: The world's biggest grain producer maintains a standing policy that forbids growing GM grain. However, China does allow imports of certain GM products. In 2012, China imported over 58 million tonnes of soybeans, mostly genetically modified – a practice that has been going on for years. 'Public opinion on GM crops in China is polarised, with many people being suspicious of GM products' (Zichen, 2013).

Europe Union: In mid-2010 new rules were proposed for the authorisation of GMOs. If adopted, EU countries will be able to restrict or ban GMO cultivation on their territory. 'They will be able to use any acceptable reason under the Treaty without undermining the EU risk assessment which remains unchanged' (EC, n.d.[a]). Currently the EU also has in place a very sophisticated system of labelling, reporting and regulating GMOs.[57] Consumer resistance to GM foods in Europe is high, with the EU estimating that opponents outnumber supporters three to one (EC, 2010: 7). In the last two years, France and Germany have introduced GM-free labelling schemes for animal products, and major supermarket chains in Italy, Switzerland and the UK either prohibit the use of GM animal feed in their own brands or provide clear choice (SCNZ, 2013a). Recently Monsanto has withdrawn eight of its nine pending applications to grow GM crops in Europe, citing political obstructionism as the reason behind this decision (Lopez, 2013).

India: In October 2012, a court-appointed science panel recommended a 10-year ban on GM foods. The panel recommended a decade as it 'is a reasonable length of time' to strengthen India's regulatory regime and develop 'a cadre of experts in areas of relevance to food safety evaluation, environmental impact assessment etc.' The call for a ban was at odds with a report just a week earlier from Indian Prime Minister Manmohan Singh's scientific advisory council, which hailed genetic modification as a transformational technology that has paid dividends for agriculture and health (Bagla, 2012).

Peru: Peru has become the first South American country to ban GM foods (Murphy, 2013). A law establishing a 10-year ban on GM food was introduced in 2011 and came into effect at the end of 2012. The law prohibits the importation, production and use of GMO foods and is aimed at preserving Peru's biodiversity and supporting local farmers. The ban protects Peru's exceptionally varied native plant species – the importation and use of GM seeds for corn, for example, would eventually destroy the different and multicoloured species grown in the Andean region ('Ten year ban on genetically modified seeds and foods takes force Thursday', 2012).

United Kingdom: The UK only has one GMO approved for release. In 2013 the issue of GM foods received renewed attention in the UK, following a speech from Environment Secretary Owen Paterson in which he asked the European Union to relax its legislation around GM. Paterson was reported as saying 'he wants Brussels to lift restrictions in EU legislation that currently allow only one type of GM maize to be grown in the UK. He called on industry and science to join forces with the government to win round public opinion (Watson, 2013). While the government reportedly says that current restrictions mean Britain and the rest of the EU are trailing behind the US in a technology that could help alleviate hunger

57 There exists a comprehensive register of authorised GMOs by type of food or feed (EC, n.d.[b]).

for millions, a poll taken in May 2013 showed that 35 percent of people were opposed to GM foods, with 21 percent in favour; 43 percent said the government should not be promoting GM food, while 22 percent believed that it should (Watson, 2013).

United States: A recent study by a team of scientists led by Professor Jack Heinemann at the University of Canterbury shows that GM crops have not demonstrated exceptional yields, or significant reductions in environmental impact in the US when compared with non-GM production in Western Europe:

> Despite the claims that GM might be needed to feed the world, we found no yield benefit when the United States was compared to W. Europe, other economically developed countries of the same latitude which do not grow GM crops. We found no benefit from the traits either. (Heinemann et al., 2013: 13)

Consumer resistance is also present in the US. Although the FDA appears close to approving GM salmon, there remains on-going resistance. A recent Nature article notes:

> Yet even with regulatory approval, the battle over AquaBounty's salmon will be far from over. In March, several speciality grocery stores, including Whole Foods, an international chain based in Austin, Texas, said that they would not sell AquAdvantage fish. Lawmakers in Alaska and Oregon, which both export wild salmon, have repeatedly tried to block the GM fish because they fear contamination of the wild stock and worry that it could drive down the price of farmed salmon. (Ledford, 2013)

In New Zealand there is also concern that the potential for GM labelling requirements might be threatened by the proposed Trans-Pacific Partnership Agreement. The annual US report on New Zealand's 'trade barriers' confirmed that it will 'continue to raise trade-related concerns with mandatory biotechnology labelling regimes' (It's Our Future, n.d.). It's Our Future, a New Zealand group that is running a public campaign on the agreement, notes that the Biotech Industry Organisation,[58] which represents the world's giant GMO companies like Monsanto and Cargill, has also stated that it wants GM labelling restricted under the TPPA (It's Our Future, n.d.).

In an article in the *Dominion Post* Simon Terry from the Sustainability Council New Zealand noted:

> Washington's tool of choice is 'harmonisation' and the delivery vehicle is free trade agreements. … For the US, the imperative is to normalise GM foods by getting everyone else to 'harmonise' to permissive US standards. It has first been rounding up friends in the Americas and proposed arrangements with Canada describe precisely what the US is seeking:
>
> - 'Mutual Recognition Agreement for biotechnology products' – meaning any GM product the US approves is legal in the other country.
> - 'Harmonised risk assessments' – meaning the assessment processes for GMOs in the US and the other country will need to come to the same conclusions. (Terry, 2013)

Parties engaged in negotiations currently include New Zealand and 10 other Asia Pacific countries: Australia, Brunei Darussalam, Chile, Malaysia, Peru, Singapore, the United States, Vietnam, Mexico and Canada (MFAT, 2013). Peru, Canada and Mexico are the only other negotiating partners with which New Zealand does not already have an Free Trade Agreement (MFAT, 2013).

International trade agreements, such as the TPPA, cannot be overlooked as they are an enormously significant factor in determining the future of GMO regulation in New Zealand. One significant historic

58 The Biotech Industry Organisation (BIO) is the world's largest biotechnology trade association, based in Washington, D.C.

example of this was the dispute between the US and the EU in the 2000s. In 2003 the US – with support from Canada and Argentina – asserted that the European 'de facto' moratorium on the approval of biotech products was a trade barrier that impeded sales of US GM crops (Palmer, 2010; WTO, 2006). The dispute was heard by the WTO, which in 2006 ruled in favour of the US (WTO, 2006). Trade issues are inevitable when countries have different regulations and priorities. The TPPA negotiations are an important opportunity for New Zealand to ensure that our sovereignty on this issue is maintained.

In New Zealand, MoRST established the Futurewatch programme in response to a recommendation from the Royal Commission on Genetic Modification that the government develop a capability for 'biotechnology futurewatch' (RCGM, 2001a: 360). This technology-scanning activity was not continued under MSI (personal communication, MBIE, 26 August, 2013), leading to a lack of on-going foresight activities among government agencies. We are unaware of any similar publications continuing under MSI or MBIE. Embedding foresight activities within government agencies would not necessarily entail greater financial investment, but it would require a commitment to build capacity to identify and engage with emerging policy issues.

Recommendation 11: A high-level foresight unit should be established

A foresight unit should be established to identify new and emerging issues on the horizon before they become significant and difficult to manage. Importantly, the foresight unit should operate separately from the management function of these new and emerging issues. This will ensure that the foresight team remain open to new opportunities and the policy team does not fall into the common trap of seeking out information to support a particular hypothesis or ideology. The Institute, in collaboration with others (see footnote 56) is in the process of preparing a discussion paper on where this foresight unit might best fit within central government.

7.2.12 Managing the regulatory framework

The last two policy knots – managing strategy and managing foresight – are crucial considerations when dealing with new organisms. This raises an issue the Institute considered in early 2001, that hazardous substances and new organisms have very different risk profiles and do not sit comfortably within the same legislation. When issues around how to manage GM were first raised, the solution was to try to find a similar policy framework and institutional body to manage the legislation.

In 1996, it seemed logical to regulate new organisms alongside hazardous substances; hence the HSNO legislation was passed. At the time it was not apparent that debate around GM would continue and lead to the establishment of a Royal Commission five years later. The Royal Commission's suggestion to use the 'call-in' powers to make a strategic decision on GM crops was well in the future. Further, no one expected that almost twenty years later debate would rage internationally, to such an extent that Monsanto has largely removed GM trials from European Union countries. In contrast to the regulation of GM, hazardous substances does not require testing in New Zealand, as they are well-tested internationally; their risks, costs and benefits are well-known and acknowledged, and there are well-recognised controls for managing the risks of using such substances.

Recommendation 12: Decouple hazardous substances from new organisms, creating separate legislation for both

New Zealand needs to make strategic decisions around GM technology, developing strategy based on calculated risks, optionality and strategic foresight. We consider the regulation of new organisms alongside hazardous substances to be increasingly challenging, and that they would be better decoupled.[59]

Further, we consider the assessment of benefits in the HSNO legislation problematic, as only a narrow view of benefits is required by the HSNO legislation; the benefit of the application is only considered in terms of what the experiment will produce once it has been completed (in contrast to the risks that exist beyond the length of the application). This has led to previous ERMA decisions noting that significant scientific knowledge will be created without any classification of the probability or magnitude of those benefits in terms of the public good; nor any clarity over who will gain those benefits as distinct of those that will bare the risks. See discussion in Section 7.2.1.

7.3 Reflections

While Section 7.2 identifies a number of policy knots in which operational improvements must be made, the focus of this final section is strategic. Its purpose is to pause and reflect on forty years of public policy.

Given the earlier discussion, it would seem that New Zealand is no further ahead strategically on public policy regarding outdoor GMOs than it was when the Commissioners reported their findings in 2001. The Commissioners put forward 49 recommendations based on public consultation, many of which were focused on gaining foresight and developing an infrastructure of institutional structures which develop strategic information systems and encourage foresight. As these were not put in place, we consider New Zealand is less equipped to make a strategic decision to release GMO in the outdoors in 2013 than we were in 2001. Although operational changes have been made, the main thrust of the current legislation remains unchanged – that outdoor GMOs are acceptable under prudent management.

Background

The major theme of the Commissioners report was 'preserving opportunities', and their overall conclusion was that New Zealand should keep its options open and 'proceed carefully, minimising and managing risks' (RCGM, 2001a: 2). To summarise, the Commissioners' report defined four areas of study. The first three – research, medicine and food – required only operational improvements. Many of the recommendations in these areas have now been fully implemented, with only those over labelling remaining outstanding.[60] The fourth area of study was the growing of GMOs in the outdoors: 'GM crops and other field uses'.[61]

59 MBIE provides a useful code of good regulatory practice. This code can be used to develop effective regulations in the following areas: efficiency, effectiveness, transparency, clarity and equity (MBIE, n.d.[e]).

60 Although New Zealand legislation generally requires the labelling of food products that have more than 1% GM content (SCNZ, 2011b), how this operates in practice remains unclear. In our 2008 report *Review of the Forty-nine Recommendations of the Royal Commission on Genetic Modification*, we concluded that Recommendations 7.2 and 8.2 had not been implemented and that Recommendation 8.3 had been only partially implemented. These are:

> 7.2 That the appropriate agencies develop a labelling regime to identify genetically modified seed, nursery stock and propagative material at point of sale.
>
> 8.2 That Government facilitate the development of a voluntary label indicating a food has not been genetically modified, contains no genetically modified ingredients and has not been manufactured using a process involving genetic modification.
>
> 8.3 That, as a matter of priority, the Food Administration Authority disseminates information on the labelling regime for genetically modified foods and consumer rights in relation to foods made available for consumption at restaurants and takeaway bars. (RCGM, 2001a: 354, 356)

61 'GM crops and other field uses' includes any GMO placed in the outdoors, such as fruits and vegetables, ornamental and nursery plants, bees, forestry, bioremediation, bioreactors (plant, cell and animal), pest control, biofuels, and bioprospecting.

The Commissioners believed the best approach for this forth category was to postpone a decision on the release of GMOs until more information had been obtained. Regarding release, the Commissioners' view was clearly not a green light, but an amber one. They acknowledged that the first GM release would be a game changer, describing it as a 'watershed' decision that would require a considered and careful approach. To this end they made nine recommendations (see the discussion in Chapter 13 of the Commissioners' report, and the summary in Table 1 of this report), most of which have not been fully implemented.

Most importantly, the Commissioners called for the creation of two independent institutions that did not have a financial vested interest in GM: a Parliamentary Commissioner on Biotechnology and a Bioethics Council. The idea was that such institutions would be able to provide accurate and up-to-date information on international markets and scientific research. They would also maintain a barometer of public opinion and an understanding of the values driving that opinion. Under this approach decisionmakers would be informed and knowledgeable, and future policy decisions would be based on relevant, complete and timely information (see the discussion in Chapter 14 of the Commissioners' report).

However, neither of these institutions exists today, nor to our knowledge is there a government institution undertaking either of these functions, which the Commissioners regarded as so critical. These institutional recommendations formed two of their three major proposals for the biotechnology century.[62]

The third was a biotechnology strategy; the aim of this recommendation was 'to ensure that New Zealand kept abreast of developments in biotechnology, and that these were used to national advantage while preserving essential social, cultural and environmental values' (RCGM, 2001a: 349). As discussed in Section 7.2.10, a biotechnology strategy was published in 2003, however it expires in 2013; indeed, it appears to be continuing down the same path as previous government strategies, which the Institute has described in a think piece as 'lost in space' (SFI, 2009). Notably, the 2003 strategy was not a practical document; it was light on detail and lacked measurable milestones.

Based on the implementation of their 49 recommendations, and keeping in mind that at the time it was thought that coexistence was technically possible,[63] the Commissioners believed that the final decision on GM crops could legitimately be postponed until it was triggered by the first application to release a GMO; in other words, they relied on the recommendations discussed above to deliver the knowledge needed to make the first release decision. It is therefore timely in 2013 to revisit New Zealand's GM strategy. GM continues to generate consumer resistance globally, and production benefits remain inconclusive (see Section 7.2.10). Coexistence with zero contamination is no longer a real option, and GM has not proven to be the silver bullet for global hunger, as has been suggested by some pro-GM groups.[64]

Overarching conclusion – outdoor GM experiments/research

Currently, only two outdoor GM experiments are being undertaken – by AgResearch and Scion (see discussion in Section 6) – and no releases have been made. Since the 1980s and 1990s the number of applications has declined significantly. The low uptake of outdoor experiments by private companies and the fact that no applications for release have been received means that New Zealand has the perfect opportunity to cease experiments and brand itself as GM-free in the outdoors, food and fibre.

62 Tables 1 and 2 divide outstanding recommendations into 'not implemented' and 'partially implemented' as at 2008.

63 At the time of the Royal Commission there was little scientific evidence that horizontal gene transfer (HGT) could occur. The debate was based around the assumption that if HGT was possible, it might be able to be managed through buffer zones, sterility technology, or regional GM-free zones (see RCGM, 2001a: 171, 176–178). The discussion was also about preserving opportunities and trying to answer the question of whether compatibility was possible (see RCGM, 2001a: 336–338).

64 The UN World Food Programme has stated that world hunger is caused by logistical and environmental issues (systems), rather than a lack of production (quantity). There is enough food to feed the entire global population; it is just not distributed well (World food programme, n.d.).

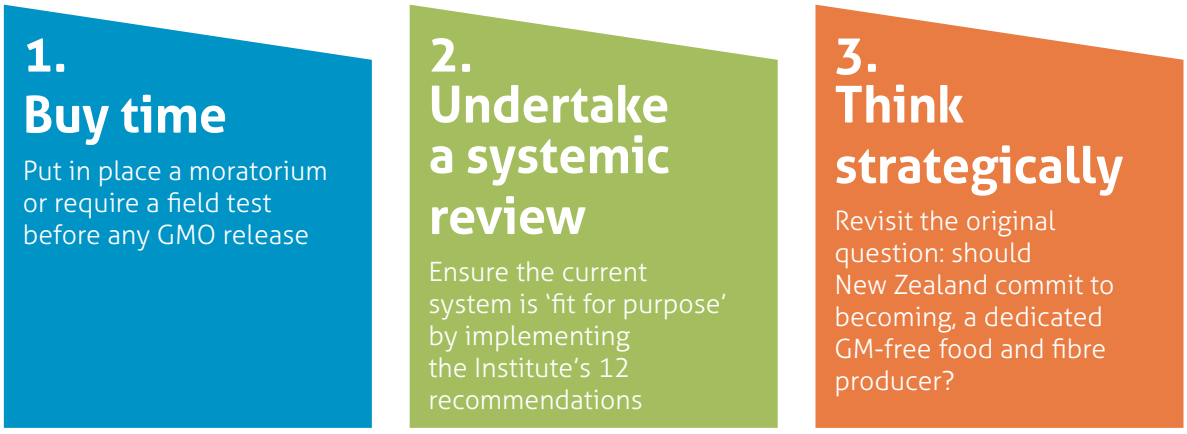
It is likely that AgResearch and Scion would argue that the removal of outdoor experiments would serve as a commercial disincentive to CRIs and private companies to develop new technologies and techniques. However, this argument should be seen in light of the information that after more than twenty years of field tests there is a clear absence of any commercial or other benefit to the New Zealand public. In addition to the real public risk to our 'clean, green' brand and the potential risk to our agriculture-based economy, we are not seeing any public benefit. What has this investment delivered New Zealand? We estimate that CRIs have spent a considerable amount of public money on GM research in the outdoors, although it is difficult to arrive at a precise figure. So not only does the public not know what their investment has delivered, they do not know the exact size of the investment, or the risks it might deliver.

Overarching conclusion – outdoor GM crops and other uses

Until the intent of the Commissioners' strategic recommendations is implemented, we believe New Zealand is not equipped to make a decision on the release of a GMO in the outdoors; however, we do consider there is sufficient evidence to make a decision on New Zealand becoming a dedicated GM-free food and fiber producer in the short to medium term.

Further, there exists a mismatch between our legislative framework and our public policy framework in regard to the release of GMOs. Under the current legislation applications for release are invited, while the public policy framework implies the Minister for the Environment will utilise her or his 'call-in' powers for the first application to release (as recommended by the Commissioners in 2001). There is thus considerable uncertainty in the system.[65]

In short, politicians and public policy analysts are faced with an uneven and incomplete policy landscape, leaving them ill-equipped to make sound decisions on New Zealand's position regarding the release of a GMO. Both politicians and policy analysts need to reconsider what decisions they are prepared to take, and what information is needed. Our approach to GM crops in the outdoors would be threefold:



65 The current framework requires the EPA to publicly notify its decision on any HSNO application no later than 30 working days after completion of the submission or hearing process (s 59 HSNO Act 1996). Alternatively, the Minister can choose to 'call-in' an application that is deemed to have significant cultural, economic, environmental, ethical, health, international, or spiritual effects (s 68 HSNO Act 1996). In this case the EPA conducts an inquiry and reports its recommendations, tot he Minister after which the Minister has 20 days to make a decision (s 73 HSNO Act 1996).

Why urgency is necessary

In addition to the difficulties inherent in the regulatory system, there are currently five emerging issues that create a strong impetus for strategic decisionmaking. There is a risk that one or more of these issues will lead to reactive rather than proactive decisionmaking by central government.

The first issue is the recent move by a number of local authorities to update their regional or district plans to make the release of GMOs, field tests and outdoor developments a prohibited or discretionary activity under the RMA. This appears to be a response to the market benefits of remaining GM-free and concerns about who pays the costs if contamination occurs. There is always a risk that central government will take on too much control of the regions; the advantage of the government not dictating GM practices in regions is that it enables it to be strategic, dealing with checks and balances, rather than being too involved in operational matters. This is clearly an area of contention that requires more independent analysis and strategic decisionmaking. (see Section 5.3 and the discussion in Section 7.2.6).

The second issue is that under the current regulatory process the EPA is required to make decisions in an effective and efficient manner, often within a relatively short timeframe. This is quite understandable where the EPA is required to make relatively standard decisions where the risks are known and controls can be replicated, for example, as in the case of hazardous substances or low risk GMOs in indoor containment facilities. Given this context, an application to release a GMO that has already been approved overseas and/or is already approved for food consumption in New Zealand might not trigger some parts of s 68 (such as health effects). Since FSANZ continues to approve a range of GM food (see Appendix 15), the first application might be relatively easy for the EPA to approve, without the perceived need for the Minister to call it in. The government must therefore work hard to provide a reliable and consistent regulatory environment for all stakeholders, one that provides certainty for applicants and members of the public alike. Currently, there is very little information on what would trigger a 'call-in', and what subsequent decisionmaking processes the Minister might put in place. (See Section 7.2.12)

The third issue is the potential application for a conditional release or full release of a novel GMO. For example Pastoral Genomics is hoping to release GM ryegrass in the near future. This first application is likely to trigger a great deal of public debate at a time when the public policy framework, and in particular institutional knowledge and expertise in managing controls of crops, is at an all-time low. (see discussion in Section 6.1.1).

It is time to reconsider the definition of genetic modification, and the definition of 'new organism', to better incorporate emerging technologies. Similarly, a review of the HSNO legislative framework, specifically whether new organisms should continue to be regulated under the same framework as hazardous substances, may be useful. The two groups have significantly different risk characteristics, and there is much more certainty around the safety and long-term effects of hazardous substances than of new organisms. These may be relevant starting points from which to spark a broader conversation around the adequacy of the current framework's ability to regulate new organisms. Such conversations are crucial to ensure the development of durable public policy. (See Section 7.2.12)

Lastly, New Zealand is currently undertaking negotiations around a Trans Pacific Partnership Agreement (TPPA), negotiations that pose a threat to New Zealand's autonomy over GM regulation, particularly around labelling. Under s 6 of the HSNO Act 1996, all persons 'exercising functions, powers, and duties under this Act' must take into account New Zealand's international obligations. The current negotiations are not being conducted in the public sphere, meaning it is possible for US biotechnology lobby groups to influence New Zealand's GM labelling laws (Terry, 2013). (See Section 7.2.11).

Looking back over the last 12 years, GM has not been the silver bullet many thought it would be. Thinking strategically, we must look deeper and create the best legislative and public policy frameworks that we can. We need to think critically, research meaningfully, and take time to pause and reflect on what would be the best outcome for New Zealand. In our view the most dangerous position for New Zealand's national brand is having one foot in and one foot out of GM, and putting too much faith in the belief that New Zealand has one of the most rigorous system in the world. We do not have the resources and expertise to operate and independently monitor a GM agricultural based economy, and our current regulatory system is showing signs of fatigue.

This recent example highlights the vulnerability of our agricultural-based economy and demonstrates the importance of timely and effective testing. In August 2013, testing showed the presence of *Clostridium botulinum* in Fonterra's whey protein, causing a contamination scare that was damaging to the reputation of both Fonterra and New Zealand.Fonterra Chief Executive Theo Spierings said at the time that, 'food safety and quality must always remain our top priority.' Fonterra commissioned independent testing from AgResearch, as it was only one of two research facilities in New Zealand capable of carrying out testing for the bacteria. Following extensive domestic and international media coverage of this 'botulism crisis', it was later determined that the bacteria had never been present. Spierings commented on 28 August, 'On the basis of the results we received from the AgResearch tests, we had no choice but to alert regulators, and announce a global precautionary recall with our customers. However additional independent testing carried out late August definitively established that there was no presence of these bacteria in the whey protein (Fonterra, 2013).

The effects of GMOs placed in the outdoors remains uncertain. While the risk characteristics are low in terms of probability, considering New Zealand's agricultural-based economy, the magnitude remains high. The Fonterra example demonstrates how easily our reputation can be eroded, highlighting the importance of robust risk management systems in relation to the testing, traceability (recall) and communication of risk. If we fail to independently review the quality of our risk management systems regularly by independent parties, the quality of our international reputation is put at risk. New Zealand must not only learn to question myths, but embrace uncertainty and seek out optionality. Strategically it is always important to keep one's options open, and develop the ability to benefit from uncertainty, what economist Nassim Nicholas Taleb describes as being 'antifragile', or moving beyond resilience to embracing change, so that when change happens one benefits from it. Using his terminology, New Zealand has too much 'skin in the game' to place GMOs in the outdoors; the benefits do not exceed the costs and the risks to New Zealand. Most importantly, we should beware of those who have no 'skin in the game'; those that retain the benefts but transfer the costs and risks to others.

We hope this report, and in particular our proposals, will prove useful to policymakers in this controversial area of public policy. As noted earlier, it is not often that something presents itself as a brand new policy challenge; it is rare to be able to trace the way in which public policy has responded to a new technological tool. While it has been interesting to survey developments over the last forty years, the real learning is that decisionmakers and policy analysts need to be proactive. Genetic modification is no longer new. We need to build on the findings of the Royal Commission, and in particular we must collect the data, synthesise it into relevant information, and build the strategic knowledge to ensure strategic decisions are evidence-based, rather than pursuing a reactive approach to public policy.

Abbreviations

ACNGT	Advisory Committee on Novel Genetic Techniques
ACRE	Advisory Committee on Releases to the Environment
AERU	Agribusiness and Economics Research Unit
AVCM	Agricultural Compounds and Veterinary Medicines Act 1997
BERL	Business and Economic Research Ltd
BST	Biotechnology Sector Taskforce
CAR	Corrective Action Requests
CBD	Convention on Biological Diversity
CRI	Crown Research Institute
DEFRA	Department for Environment, Food and Rural Affairs
DOC	Department of Conservation
EPA	Environmental Protection Authority
ERMA	Environmental Risk Management Authority
FRST	Foundation for Research, Science and Technology
FSANZ	Food Standards Australia New Zealand
HSNO	Hazardous Substances and New Organisms Act 1996
GE	Genetically Engineered
GIF	Growth and Innovation Framework
GM	Genetic Modification
GMD	Genetic Modification Development
GMF	Genetic Modification Field (Test)
GMO	Genetically Modified Organism
IAG	Interim Assessment Group
IBAC	Independent Biotechnology Advisory Committee
IBSC	Institutional Biological Safety Committee
ICWP	Inter Council Working Party
LGA	Local Government Act 2002
LMO	Living Modified Organisms
LSN	Life Sciences Network
MAdGE	Mothers Against Genetic Engineering
MAF	Ministry of Agriculture and Forestry
MAFBNZ	MAF Biosecurity New Zealand
MBIE	Ministry of Business, Innovation and Employment
MFAT	Ministry of Foreign Affairs and Trade
MfE	Ministry for the Environment

MoRST	Ministry of Research, Science and Technology
MPI	Ministry of Primary Industries
MSI	Ministry of Science and Innovation
NFO	Now TNS, formerly known as NFO NZ (a market research company)
NGO	Non-governmental Organisation
NOCR	New Organism Conditional Release
NOR	New Organism Release
NZBIO	New Zealand Biotech Association
NZFSA	New Zealand Food Safety Authority
OANZ	Organics Aotearoa New Zealand
OIA	Official Information Act
OPMSAC	Office of the Prime Minister's Science Advisory Committee
PC	Physical Containment
QMS	Quality Management System
RCGM	Royal Commission on Genetic Modification
RMA	Resource Management Act 1991
SAFE	Save Animals From Experiments
SCP	Statement of Core Purpose (for CRIs)
SSC	State Services Commission
SCNZ	Sustainability Council New Zealand
SFI	Sustainable Future Institute
TPPA	Trans Pacific Partnership Agreement

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).

Coexistence
'Coexistence' is where different primary production systems are each contributing to the overall benefit of New Zealand while ensuring that their operations are managed so that they affect each other as little as possible. This can include non-GM systems such as organic production and conventional agriculture, and GM systems. In practice, the aim is for different production systems each to 'do their own thing' and not get in each other's way (MPI, n.d.[e]).

Conditional release
Conditional release is an intermediate stage between new organisms being in fully contained conditions and these organisms being released without any conditions. This category was added via amendment to the HSNO Act in 2003 to give the EPA the ability to attach controls to the approvals to release new organisms (MfE, n.d.[c]).

Conditionally released new organism
A new organism subject to a conditional release approval (MfE, n.d.[c]). (See 'New organism'.)

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, 2001a: 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, 2001a: 94).

Compliance costs
These are 'the administrative and paperwork costs that businesses incur when meeting an obligation imposed by regulation' (Ministerial Panel of Business Compliance Costs, 2001: 31). These costs are related to the additional costs of meeting an obligation but not the actual cost of the obligation itself.

Corrective Action Requests (CARs)
A request for a corrective action to remedy a non-compliance (MAF, 2007: s4).

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, 2007: s 8.12.2)

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

Field test
'Field test means, in relation to an organism, carrying out tests 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 tests. It includes large-scale fermentation of micro-organisms' (MfE, 2001a: 96).

Field trial
Field release is a combination of the term field test and release. The phrase was often used early on in policy discussions. 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 report, unless quoting another source, we use the term 'field test' as this term is used in the HSNO legislation.

Genetic engineering or genetic modification
Genetic modification, GM, is a technology for altering the genetic make-up of living organisms so they are able to make new substances or perform new or different functions. Genetic modification is sometimes referred to as genetic engineering, or GE (MfE, 2004: 1).

Genetically modified organisms (GMOs)
A genetically modified organism is defined in s 2 of the Hazardous Substances and New Organisms Act 1996 as, unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material:

a. have been modified by in vitro techniques; or
b. are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by in vitro techniques.

GM-free food producer
A country where there is no commercial production of GM food (SCNZ, 2003a).

Horizontal gene transfer (HGT)
Horizontal gene transfer (HGT) is defined as the transfer of genetic material from one organism to another outside the context of parent to offspring (i.e. vertical) reproduction (Heinemann, 2003: 18–20).

Importing GMOs into containment
Importing into containment is when GMOs are imported into New Zealand from another country and kept inside approved indoor or outdoor containment facilities (EPA, n.d.[c]).

Institutional Biological Safety Committees (IBSCs)
Groups of people from organisations (usually universities or CRIs) that have been delegated by the EPA decision-making committee to make decisions on applications to import or develop low-risk GMOs in indoor approved containment facilities (EPA, n.d.[a]).

Low-risk GMOs
Low-risk GMOs are those that are seen as presenting minimal risks to both people and the environment. The HSNO (Low Risk Genetic Modification) regulations specify the circumstances in which the genetic modification of an organism is considered low risk (EPA, 2011b: 37).

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, 2007: s 8.12.3).

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:

- Quality Management System (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, 2007: s 8.12.4).

New organism (NO)
Any organism that:

- arrived in New Zealand after 29 July, 1998
- became extinct before 29 July, 1998
- with approval to be in containment
- with approval to be released with controls
- is genetically modified
- was deliberately eradicated from New Zealand (as the result of a specified eradication programme with a stated goal or purpose of eliminating the organism from New Zealand)
- was present in New Zealand before 29 July, 1998 in a contravention of the Animal Act 1967 or the Plants Act 1970
- is a risk species (EPA, n.d.[d]).

New organism release (NOR)
Release of a new organism (see 'Release' below).

Notified decision
If an application is for a field test or release then it must be publicly notified. If the application is for a development the EPA 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 (EPA, n.d.[e]).

Outdoor experiments
Outdoor experiments include both outdoor developments (which have GMD application codes) and field tests (which have GMF application codes). 'Development' describes using in vitro techniques to modify the genes or genetic material of an organism. These organisms are held in approved indoor or outdoor containment facilities (EPA, n.d.[f]). A 'field test' is an outdoor trial. GMOs and their heritable material must be restricted to the field test site (an approved outdoor containment facility) and are considered to be held in outdoor containment (EPA, n.d.[g]).

PC1, PC2, PC3, PC4
Indoor containment facilities such as laboratories, glasshouses and animal facilities are approved to specific Physical Containment (PC) levels referred to as PC1, PC2, PC3 or PC4. These levels are arranged in order of increasing stringency of operational and structural requirements. The requirements are described in the Australian and New Zealand Standard 2243.3 (with any exemptions listed in the MAF/ERMA New Zealand Standards). PC1 is the least stringent level, with PC4 being the most stringent (EPA, n.d.[h]).

There are currently no PC4 containment facilities in New Zealand (Chris Kebbell, personal communication, 27 May 2013).

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 EPA 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 (HSNO, 1996: s 42).

Release
To allow an 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 (HSNO, 1996: s 2[1]).

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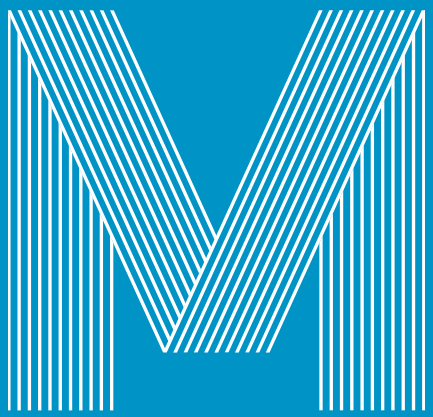

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