September 2013

Report 16

2058

An Overview of Genetic Modification in New Zealand 1973–2013

The first forty years

Executive Summary

MCGUINNESS INSTITUTE

Project 2058: Report 16

September 2013

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The first forty years

Executive Summary

This executive summary forms part of the McGuinness Institute's report *An Overview of Genetic Modification in New Zealand 1973–2013: The First Forty Years*. The summary includes the Institute's 12 recommendations, and in order for readers to understand the basis on which they were developed, we have also included the final section of the report: 'Section 7: Observations, recommendations and reflections'.

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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)

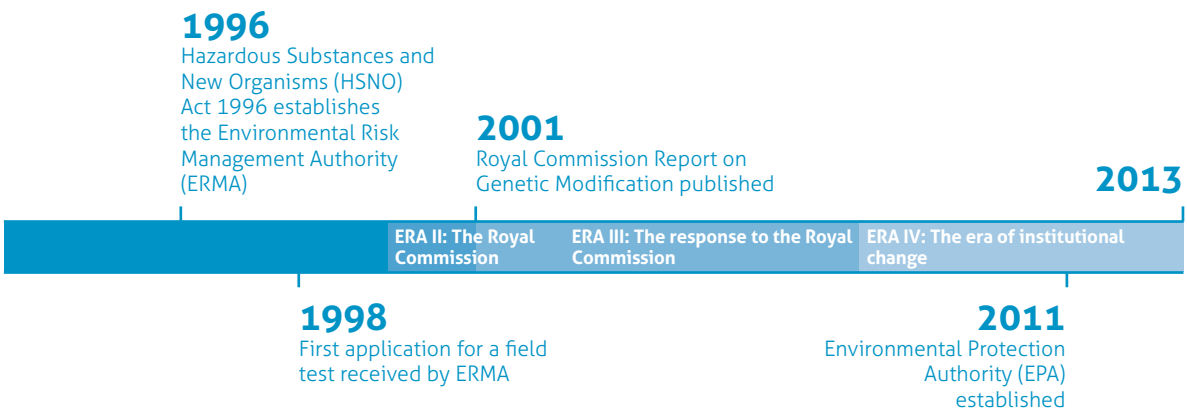
7
Trespasses or acts of vandalism on outdoor experiments

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)



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:[1]

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.

1 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

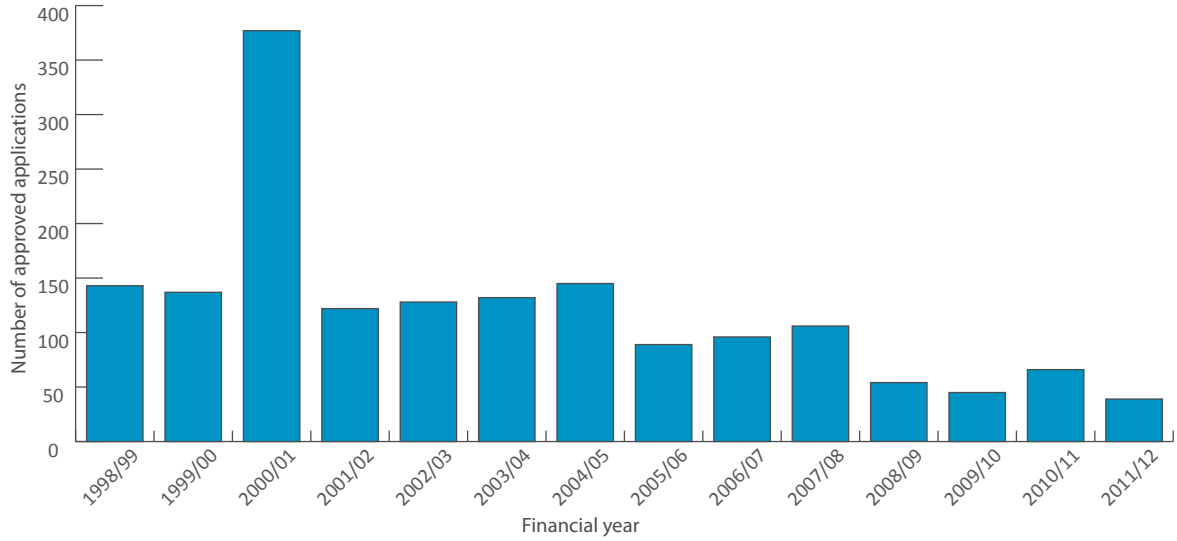
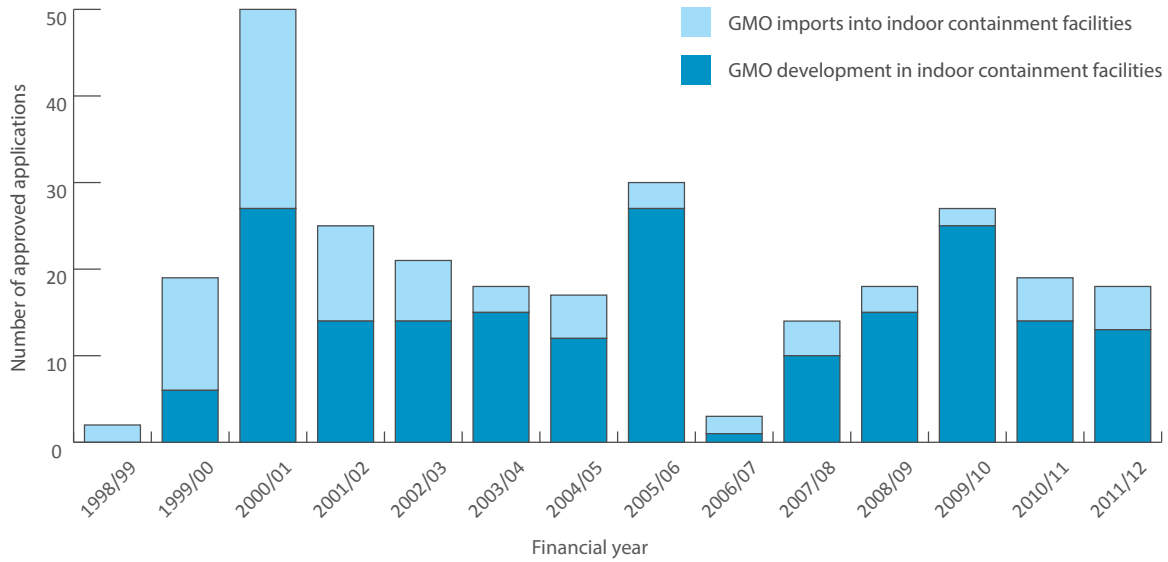


Figure 4: Indoor GMO approved applications by financial year (decisions made by ERMA/EPA) 1998/99–2011/12

Source: See Appendix 8



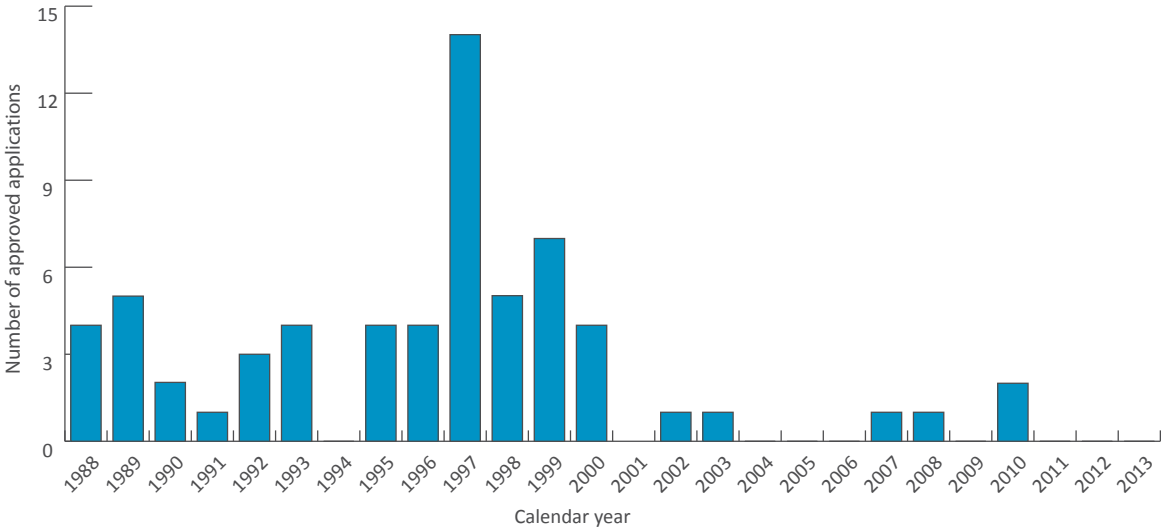
Note 1: Both Figures 3 and 4 exclude outdoor developments and all field tests.

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

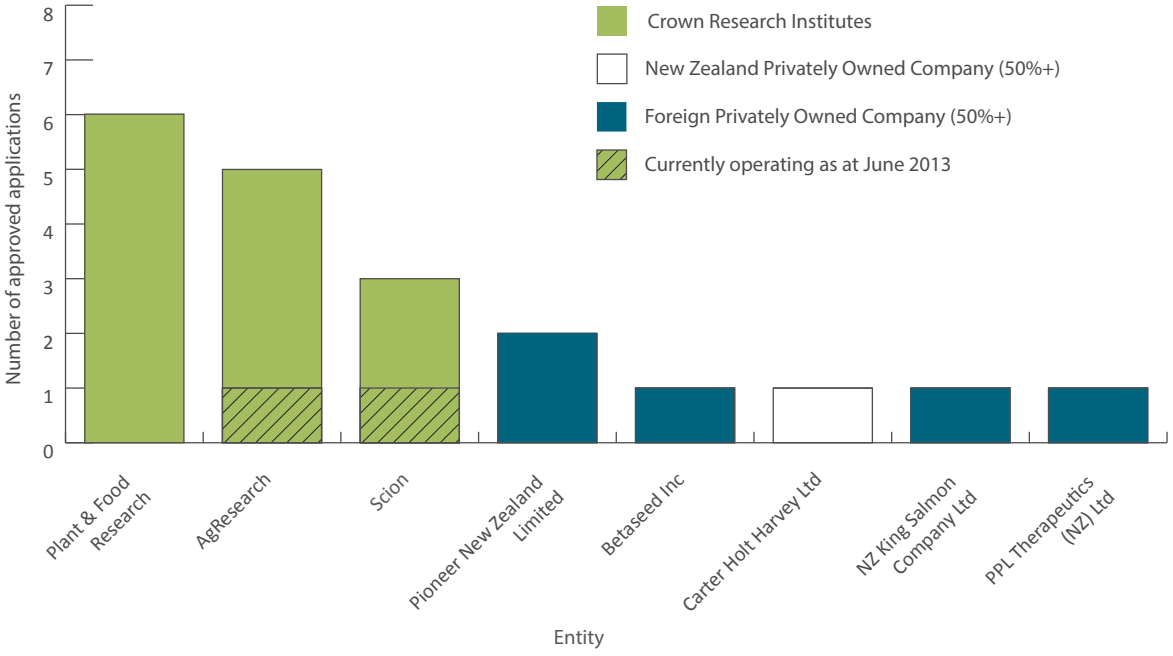
Source: See Appendix 9



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.

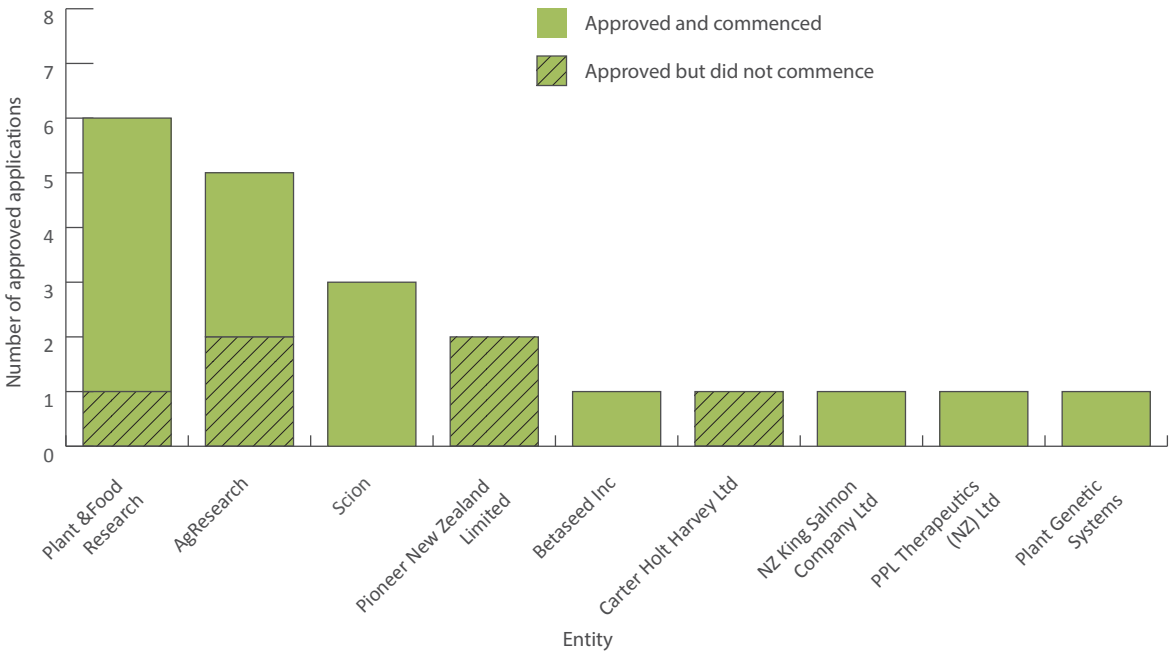
To date, the Institute is not aware of any commercial benefit from an outdoor GM experiment. However, a review focusing on the likelihood of current outdoor experiments producing commercial benefits would be a valuable policy tool. The question here is whether public investment in GMO research (through 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

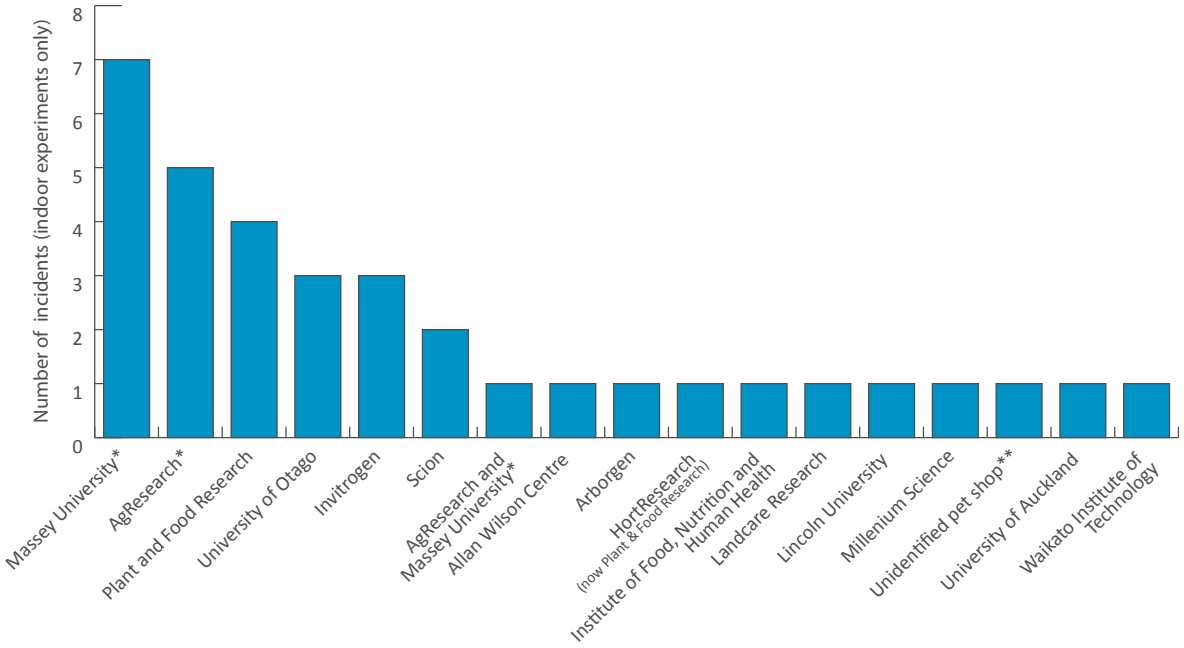
Source: See Appendix 10



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.

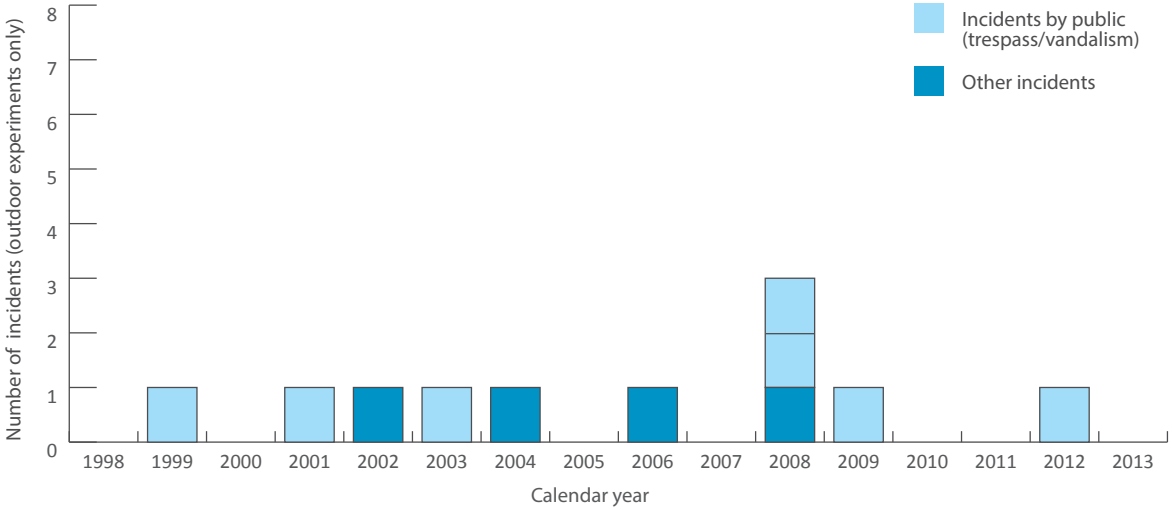
** This incident was not part of an indoor experiment but has been included as it was reported in the EPA's incident report for 2007.

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

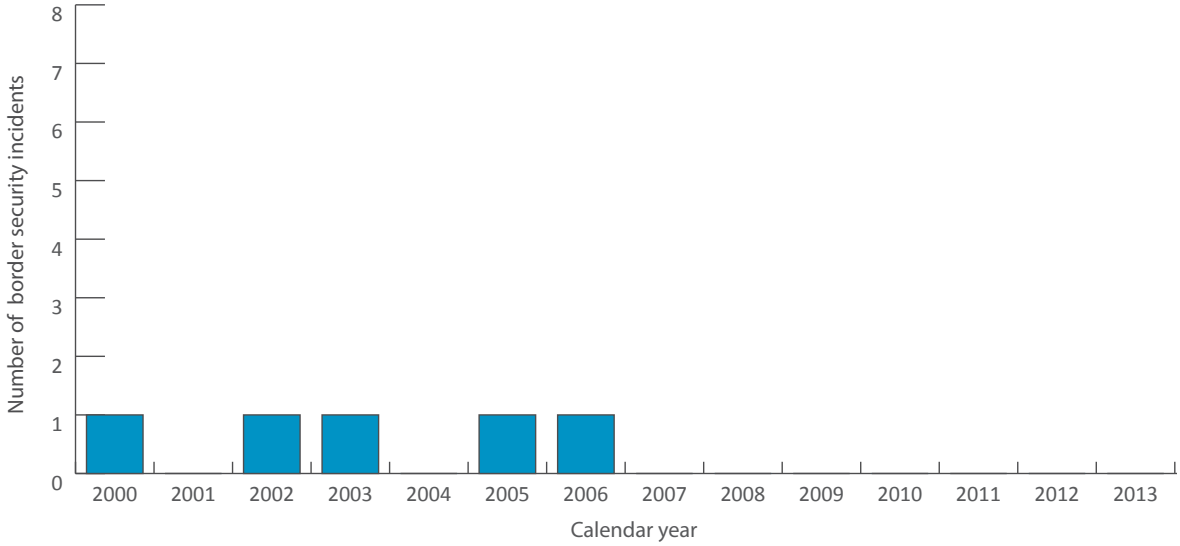
Source: See Table 17, Appendix 14



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

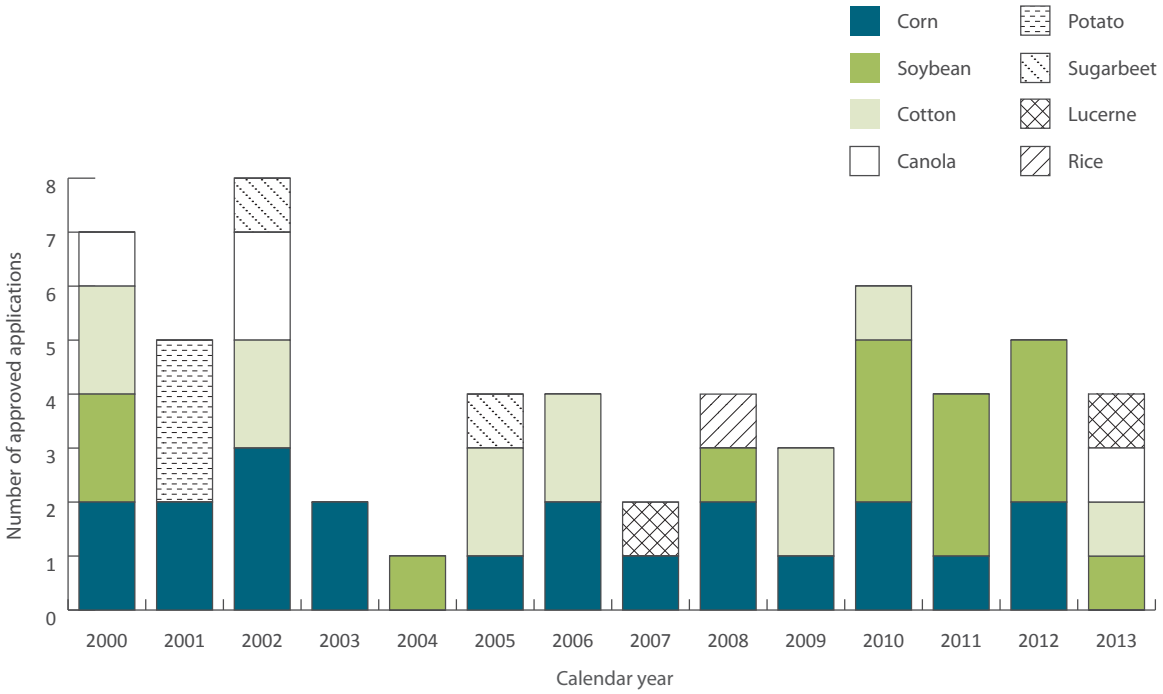


Note: This is not necessarily a comprehensive list of all instances of breaches of border security, however it does include those recorded on the MPI website.

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

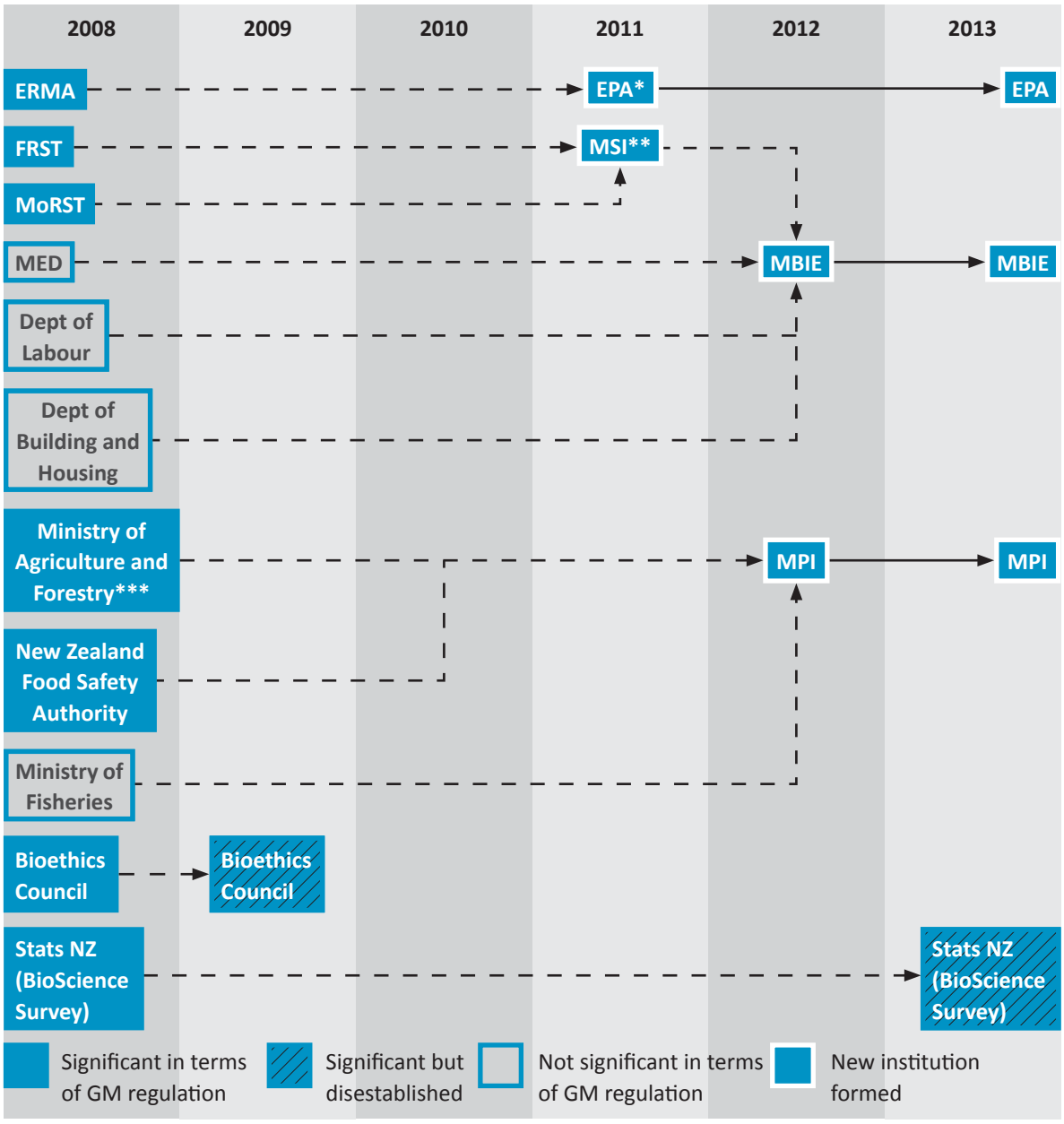


Note: Under the current system, it is difficult to know the extent of distribution within New Zealand specifically, as approvals apply to both New Zealand and Australia.

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,[2] 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.[3] 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)

2 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

3 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,[4] 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.[5] 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'.[6] 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.[7] 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 an ongoing investment of $8 million in the research programme over the next five years**. This funding will

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

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

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

7 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.

> 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).[8] 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

8 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.[9] 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

9 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.[10] 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.

10 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.[11] 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

11 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).[12] 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)[13], 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.

12 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)

13 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.[14] If the feed contains GM probiotics,[15] 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)

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

15 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).[16] 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.

16 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.[17]

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*.[18] 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

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

18 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.[19] 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.[20]

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

19 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).

20 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.[21] 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

21 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,[22] 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

22 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.[23]

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.[24] The fourth area of study was the growing of GMOs in the outdoors: 'GM crops and other field uses'.[25]

23 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]).

24 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)

25 '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.[26]

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,[27] 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.[28]

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.

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

27 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).

28 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.[29]

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:

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?

29 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)

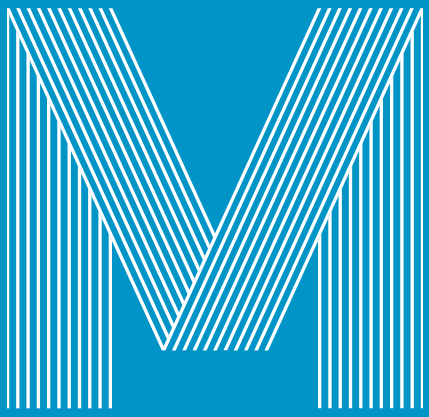
Lastly, New Zealand is currently undertaking negotiations around a Trans Pacific Partnership Agreement (TPPA), negotiations that pose a threat to New Zealand's autonomy over GM regulation, particularly around labelling. Under s 6 of the HSNO Act 1996, all persons 'exercising functions, powers, and duties 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.



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