# Designing an accountability framework for the biotechnology industry

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**Objective**: To invite readers to (1) identify risks to the industry, (2) re-consider the recommendations of the Royal Commission that were not adopted by government, (3) inform readers of the current lack of rigorous, timely and transparent in-depth qualitative and quantitative research results regarding the effects of placing genetically modified organisms outdoors in New Zealand, (4) consider the quality of ERMA's approval process and (5) support the appointment of a Parliamentary Commissioner of Biotechnology.

**Perspective**: Risk Management, Investment and Sustainability.

**Conclusion**: The manner in which scientists manage the risks and benefits of genetic modification will define New Zealand and the credibility of the scientific profession over the next few years.

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## 1. Identify risks to the industry

With the removal of the moratorium, the biotechnology industry will be given the freedom to consider the release of genetically modified organisms in the outdoors. As a consequence the industry will be vulnerable to at least five new and challenging risks.

The risks of failing:

1. to deliver on economic benefits;
2. to ensure robust standards of practice are in place and that the risks of biotechnology are well managed;
3. to be seen as independent and responsible;
4. to be transparent, and therefore failing to gain 'public trust' and lastly;
5. to be seen to be market driven.

The only way to manage risk is through leadership. This article considers the current accountability framework and examines why the industry should re-consider lobbying for the implementation of the remaining recommendations contained in the 2001 'Report of the Royal Commission on Genetic Modification' (now referred to as 'the Report'). It then discusses the opportunity for the biotechnology industry to adopt a proactive role in developing a valuable and respected industry that will generate pride in the hearts and minds of New Zealanders.

The Report contained a number of failings (McGuinness 17 September 2001 and McGuinness, October 2001), but recommended an accountability framework that would enable the biotechnology industry to both be accountable and be seen to be accountable.

Unfortunately the very recommendations necessary to strengthen the platform for developing the biotechnology industry were the very recommendations not fully adopted by Government.

**2. Re-consider the recommendations of the Royal Commission**

The Report;

1. recognised the need to create a strong research base in order to assess risks and benefits and provide timely and independent information to "allow controlled use of genetic modification" (page 331 of the Report),

2. recognised that the first conditional release or release of a GM crop was a "watershed decision" (page 338 of the Report) and recommended that the Minister should exercise the 'call-in' powers available under the legislation in order to assess the likely overall economic and environmental impacts of the first GM crop, and

3. recognised that the Environmental Risk Management Authority (ERMA) alone was insufficient, hence one of the Commissioner's three major proposals was to create a "Parliamentary Commissioner of Biotechnology" (pages 347-349 of the Report).

Many organisations, including the Science Council, recommended that the Government implement the findings of the Report, but never publicly lobbied for government to (i) delay the release until publicly funded research results were available, (ii) complete an independent assessment of the first release or (iii) appoint a Parliamentary Commissioner of Biotechnology.

**3. Qualitative and Quantitative Research**

The Government publicly funded four areas of research.

(i)Research into Soil, Ecosystems and Biodiversity

Table 1 below outlines the research approved to investigate the effects on soil, ecosystems and biodiversity. Although the research is relevant and timely, there are three underlying issues and observations.

Firstly, the due diligence is being completed after the lifting the moratorium, so decisions will be made before the research results are in. Recent research from the UK three-year study emphasises that GM crops can have significant impacts on wildlife. For example, the UK tests for GM oilseed rape "showed a five-fold decrease in flora and a 25 per cent reduction in butterflies. There were also fewer seeds for wildlife to eat" (Dominion Post, dated 18 October 2003). As a society, we need to define what level of negative effects is acceptable, how New Zealand wind, soil and biodiversity may be affected, what economic advantages or disadvantages we can expect and how we want to market New Zealand on the global stage.

Secondly, most of this research on 'impacts' is completed by Crown Research Institutes who are also funded by the Foundation for Research Science and Technology (FRST) to develop economic benefits from the use of GM technology, being 'GM products'. This means that the very entities claiming that there are benefits are also the very entities getting funding for researching the risks. Even though individual scientists researching benefits or risks may be operating independently in the same entity, they will struggle to be seen to be independent, and this may undermine the value of the research.

This issue can best be understood by considering Table 1 and Table 2. Table 1 identifies entities being funded for 'impacts' by FRST and Table 2 identifies entities approved by ERMA to explore 'benefits'. Consequently, those listed on both tables, risk being perceived as 'lacking independence'.

Lastly, Table 2 shows that no commercial organisations have researched the benefits of GMO's in the outdoors in the last few years.

**Table 1: Current Soil, Ecosystems, Biodiversity Research Funding – Impacts Research**

| Report Recommendations | FRST Funding | Research Results Due |
|---|---|---|
| 6.14 and 7.4 | AgResearch | 2004 |
| | Landcare Research | 2005 |
| | ESR | 2005 |
| | Crop and Food | 2008 |
| | Crop and Food | 2008 |
| | Hort Research | 2008 |
| | Crop and Food | 2008 |
| | Hort Research | 2008 |
| | Forest Research | 2007 |
| Approximate Funds | $17,527,000 | |

Source: Excerpt from FRST Symposium September 2003 papers.

**Table 2: Previous six applications to ERMA for outdoor GMO's – Benefits Research**

| ERMA Application Number | Applicant |
|---|---|
| GMF98009 | AgResearch - cows |
| GMF99001 | Forest Research |
| GMF99005 | Forest Research |
| GMF99004 | AgResearch - sheep |
| GMD02028 | AgResearch - cows |
| GMF03001 | Crop and Food - Onions |

Source: ERMA www.ermanz.govt.nz

(ii)Research into Social and Ethical Issues

Table 3 outlines the research approved to investigate the effects on social and ethical issues. This research also raised questions of timeliness.

The research results will not be available for ERMA to use until as late as 2008. Consequently ERMA may make decisions from 2003 to 2008 based on insufficient information. These decisions will act as a form of precedent to future decisions, making the research results somewhat academic. A classic example of this is the Bioethics Council (Bioethics Council, 30 April 2003). The Council is in the process of researching the use of human genes in other organisms, when ERMA has already approved one development for a range of GM cattle (GMD02028) and one field test (GMF98009(iii). It is another case of the cart going before the horse.

**Table 3: Current FRST funding of Social and Ethical Issues**

| Recommendations | FRST Funding | Research Results Due |
|---|---|---|
| 6.14 and 14.1 | University of Auckland | 2004 |
| | Lincoln University | 2006 |
| | AgResearch | 2004 |
| | University of Canterbury | 2008 |
| | University of Waikato | 2008 |
| | University of Otago | 2008 |
| | AgResearch | 2004 |
| Approximate Funds | $9,142,000 | |

Source: Excerpt from FRST Symposium papers (September 2003).

(iii) Research into Economic Impacts

Research into the economic impacts of GM is being funded by Government departments. A Cabinet Policy paper states "MAF and MfE [are] to report back to cabinet by 31 October 2004, on any policy implications arising from...its assessment of economic impacts within the context of the proposed co-existence mechanisms".

This timeframe raises additional issues.

Firstly, the current process means ERMA must make decisions, determine and monitor controls on field tests and conditional releases, and make decisions on commercial releases before October 2004. A more logical outcome would have been to delay the first release application until October 2004.

Secondly, I am unaware of any public information on the process, but I hope that there would be an opportunity to analyse and peer review the economic conclusions before government makes its final decision.

(iv)Research into Effective Separation Distances

Research on codes of practice for managing effective separation distances is based on recommendation 7.7 of the Report. The research is being completed by The Ministry of Agriculture and Fisheries (MAF), which is to report by 31 October 2004, "on the need for, and issues surrounding, developing a generic industry code of practice that aims to achieve effective co-existence in primary production".

In addition to the concerns raised above, I consider a code of practice is a fundamentally flawed concept, rather like the "emperors new clothes" - all image but no substance.

Besides lacking substance, this tool is very costly to instigate (creating unproductive land for buffer zones), costly to monitor and costly to clean up if a 'disaster' happens. I consider more effort should be placed at the fence at the top of the cliff (the approval process) rather than trying to place ambulances strategically at the bottom of the cliff in the hope of slowing down the negative effects. In the end, the only real protection is ERMA's approval process and, in my view, the quality of their approval process is inadequate for the task ahead. Notably, ERMA has approved **all** applications to develop or test in the outdoors.

## 4. ERMA Approval Process

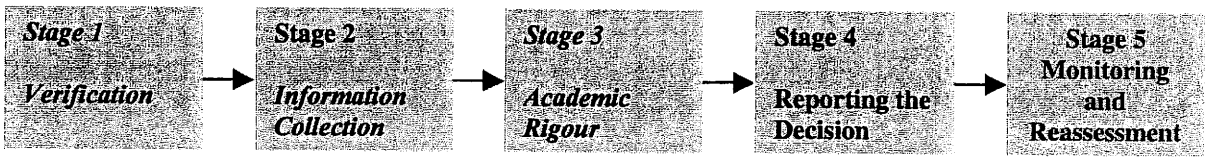
ERMA fails to apply international risk management standards or verification standards when assessing applications. Although, I can appreciate the lack of resources in the past and the difficulty of developing new frameworks, there is no excuse for a lack of benchmarking against international standards or a lack of rigour in the verification process.

The recent GM onion application by Crop and Food (known as GMF03001) is a case in point. The application contains substantial irrelevant information yet fails to provide relevant information such as the size of the trial (ERMA: McGuinness GMF03001, 20 August 2003). When asking for confirmation of the size of the trial, ERMA suggested I ask for "clarification from the applicant"(email, 20 August 2003).

The 'Verification Checksheet', used by ERMA in verifying application GMF03001 (ERMA, 9 October 2003), clearly indicates the lack of the principle-based approach commonly adopted in internationally accepted verification frameworks. The 'Science Check' which forms two of the three pages of the "Verification Checklist" lists nine questions. Question 7 states: "Does the application contain sufficient information to be verified?" The response from the application advisor has been to tick the 'Yes' box.

In order to ensure quality decisions are consistently made, ERMA must complete five consecutive stages in the decision-making process. The failure to adopt rigour in the early stages will have a multiplier effect on the lack of rigour in the final stages. The five stages outlined in Figure 1 are: verification of the application, information collection, quality decision-making, reporting the decision, and monitoring and reassessment.

Figure 1: Key stages in the ERMA decision-making process




Source: McGuinness and Associates

Table 4 below reconsiders the six applications in Table 2 in light of a principle based analysis of stages 1 and 4. This analysis indicates that the AgReserach sheep (GMF99004) was the best application and reporting of a decision to date. Even though approved, I understand that this project never proceeded.

**Table 4: Evaluation of the Previous six applications to ERMA for outdoor GMO's – Benefits Research**

| ERMA Application Number | Applicant | Quality of Verification<br><br>Stage 1[2]<br>Max Score:10 | Quality of 'Reporting the Decision'<br>Stage 4[3]<br>Max Score:10 |
|---|---|---|---|
| GMF98009 | AgResearch - cows | 3 | 4 (revisited) |
| GMF99001 | Forest Research | 3 | 3 |
| GMF99005 | Forest Research | 3 | 3 |
| GMF99004 | AgResearch - sheep | 5 | 5 |
| GMD02028 | AgResearch - cows | 3 | 4 |
| GMF03001 | Crop and Food - Onions | 2 | Not yet decided |

Source: McGuinness and Associates

[2] Stage 1: Quality of Verification:
The verification stage is where ERMA must assess the quality of the application and where necessary, require the applicant to re-write the application in order to meet the standard necessary for public release. For the purposes of scoring ERMA's verification skills, the following qualitative characteristics have been used to assess each application. Each characteristic is worth 2 points and are listed as follows;

(i) relevance (including transparency),
(ii) accuracy,
(iii) timeliness,
(iv) completeness (eg. legal) and
(v) objectiveness ( ie. lacking bias).

[3] Stage 4: Quality of Reporting the Decision
This is not about whether the decision-making is right or wrong, but whether ERMA has met its disclosure requirements. Each characteristic is worth 2 points and are listed as follows;

(i) detailed description of the GM organism (section 20 of the Hazardous Substances of New Organisms Act 1996 (HSNO)),
(ii) provide reasons for decision (section 45(3) HSNO),
(iii) be transparent by disclosing (1) where the precautionary approach has been adopted, (2) the key pieces of information relied upon, (3) what was not relied upon, (4) the extent of confidential information, (5) identify risks, (6) explain risks, (7) specify probability and magnitude (8) rank risks, (9) identify and assess benefits; (10) weigh and if approved, indicate how each risk fits with the controls. This is based on the Australian and New Zealand Risk Management Standards (AS/NZS 4360:1999),
(iv) ensure governance /accountability/ completeness frameworks are in place ie. (1) define risk appetite of ERMA (2) define risk of experiment, (3) who is responsible for what, (4) define critical risk factors (what to watch out for), (4) define disaster plan, and (5) identify worst case, and
(v) ensure the decision is useable, understandable and comparable.

**5. Why New Zealand needs a Parliamentary Commissioner of Biotechnology**

The creation of an independent body to review and audit the biotechnology industry, in particular ERMA, makes sound business and political sense. Not only would a Parliamentary Commissioner of Biotechnology audit current practice but would also actively reduce costs and improve efficiencies by operating as a complaints authority, resolving issues before they end up in court.

There are two recent public examples where a Commissioner would have been exceedingly effective. Firstly, in managing 'Corngate' and then 'Prebblegate'. Secondly, in managing concerns over legal process and public good.

Two recent court cases against ERMA - the first by Bleakley and the second, by MAdGE - occurred due to concerns over a lack of due process. In both cases AgResearch used public funds to fight for self-interest while Bleakley and MAdGE used private funds to fight for public good. As a result of the unsuccessful case brought by MAdGE, Justice Potter ordered MAdGE to pay Court costs of $24,000 to AgResearch. It is likely that MAdGE will be unable to pay the costs awarded in full (MAdGE, 22 September 2003), and AgResearch could wind MAdGE up, which in turn will prevent any additional litigation. However, such actions to prevent legal discourse tend to encourage activism rather than academic debate. I consider AgResearch is misguided if it considers that removing legal avenues will buy long-term harmony. Without an independent body such as the Parliamentary Commissioner of Biotechnology I fear the future does not bode well for the biotechnology industry.

I am reminded of the editorial (New Scientist, 19 July 2003), which stated:

> "Ten years into the GM revolution, we still have no 'killer application': no crop with unequivocal economic, environmental or health benefits for wealthy western consumers. Until that crop arrives, the public is being asked to take a risk for little return, and biotech companies and governments will continue to have a tough time convincing them to do so."

But GM crops are not the only GM product with a problem. For transgenic animals, it appears new science breakthroughs may overtake old science (Nature, 29 August 2003). In August 2003, Professor Gerngross and others have "genetically engineered yeast to produce humanised therapeutic proteins to address the manufacturing crunch currently confronting the biopharmaceutical industry" (Dartmouth College, 28 August 2003). "This technology has the potential to revolutionize the way therapeutic proteins are made - better, cheaper, faster, safer - and offer a level of control over the quality of the end product that has never existed before" (MSNBC, 28 August 2003). This technological advancement effectively turns yeast into a human protein machine without the risks of viruses and prions, effectively challenging the economic feasibility of the "fledgling industry of bioengineered animals" (MSNBC, 28 August 2003).

In addition, considering:

(i) Nine percent of "scientist's extrinsic beliefs", 'disagree' or 'strongly disagree' that the hMBP cattle project, known by its ERMA application number GMF98009 (iii), "will produce benefits that outweigh harms"(FRST symposium, Dr Bruce Small, September 2003),

(ii) PPL Therapeutics, the clone pioneer, is up for sale after "Interim losses more than doubled to £13.6m" (Guardian, 16 September 2003), and

(iii) ERMA acknowledges that GM cattle carry a significant risk of developing new diseases (ERMA, 30 September 2003);

it may be an appropriate time to reflect on how best to invest science funds for medical benefit and economic growth.

**Whatever the final outcomes, the reality is we need independent and skilled scientists.**

Recently Dr Elvira Dommisse made her concern about the threat of pollen from GM crops public. She stated: "I personally know scientists who are totally opposed to the lifting of the moratorium and others who are unhappy about GE but see it as inevitable"(Weekend Herald, 11-12 October 2003). She also added that she believes scientists within New Zealand research institutes and universities are unhappy with the emphasis that has been put on GM work at the expense of other areas of research. Dr Elvira Dommisse should be applauded, not necessarily because of her views, but because of her courage to speak out as this is the only way to judge the true health of a profession.

A Parliamentary Commissioner of Biotechnology would provide a 'middle man', an organisation to act between the industry scientists and the general public. They would be someone with a long-term view who can, where necessary, support scientists and the public alike. In addition to an audit function, the Commissioner would monitor and respond to emerging developments and develop frameworks for the long term good of New Zealand. In the same way that other dynamic industries have independent bodies such as the Securities Commission and the Stock Exchange to ensure that governance and accountability issues are paramount, so should the biotechnology industry.

**To conclude**

If the industry wishes to be a leader in research that places human genes into animals and genetically modified organisms in the outdoors, it will not only be required to report on the financial return of the investment, but also the wider impacts of that investment. Consequently, the industry must adopt a broadly based accountability framework.

The public of New Zealand are investing somewhere in the vicinity of $600,000,000 over ten years on GM crops and transgenic animals (Table 5). This is a significant financial cost even without the additional costs of the Bioethics Council, 'Corngate' and conventional laboratory research. New Zealanders have a right to hold someone

accountable for this investment and scientists have a right to expect someone to be accountable for the health of their industry.

The solution fits within the context of the recommendations contained in the Report of the Royal Commission on Genetic Modification.

The Report recommended a framework that involved the establishment of the office of a Parliamentary Commissioner on Biotechnology and an approval process based on evidence. Such an approach requires the industry to have the patience and foresight to wait for the results of critical research and the wisdom to know when to adopt the precautionary principle.

**Table 5: The estimated cost of GM crops and Transgenic Animals from 2001 to 2011.**

| Approximate Costs | **From 2001 - 2011[4]** |
|---|---|
| (a) The cost of the Report on the Royal Commission 2001, including costs to submitters. | $10,000,000 |
| (b) Crown Funding to ERMA to assess GM applications in the outdoors over 10 years. Assume: $3 million pa. | $30,000,000 |
| (c) The cost to the applicants over 10 years i.e. Crown Research Institutes and University expenses; includes ERMA application fees, indirect costs of staff time, legal counsel for hearings, and the implementation of controls. Assume: 70 applications at $250,000. | $17,500,000 |
| (d) The cost of legal actions brought by submitters, costs borne by ERMA, CRI and submitters over 10 years. Assume 4-5 actions. This includes voluntary legal costs. | $2,000,000 |
| (e) FRST Funding on Impacts of Biotechnology Research over 10 years e.g. HGT etc- Tables 1 + 2 above, indicate approximately $27 million, therefore assume $40 million until 2011. | $40,000,000 |
| (f) FRST Funding focused on developing new GM products over 10 | $490,000,000 |

[4] Note: These figures ignore the time value of money and are approximate. The intention has been to exclude the costs of low-risk GM laboratory research and any commercial applications to ERMA.
Note (b): ERMA is funded for hazardous substances and genetically modified organisms, and an assumption is made that GMO in the outdoors forms 60% of current crown funds. In addition, as low-risk GM lab experiments are assessed by safety committees and not by ERMA, the operational costs are largely due to assessing applications related to placing GMO in the outdoors.
Note (c): The applicants costs are difficult to estimate, however Dr Tony Conner estimated (The Press, 15/10/03) that the onion field test application would cost at least $250,000 and up to $1 million for larger farm scale trials. I have been conservative in selecting $250,000 for all 70 applications.
Note (c) + (f): I assume CRI and Universities will make approximately 70 applications to ERMA in order to (i) develop GMO in the outdoors and (ii) field test GMO's, and I assume, based on ERMA's current practice, that all these applications will be approved. I have assumed that CRI and Universities will not make applications for releases and nor will FRST fund them.
Note (f): I assume FRST may receive a number of applications from CRI and Universities but that they will approve about 70. The figure of $7,000,000 is a key assumption and excludes any funding by FRST for items in (c) to prevent double counting.

| | |
|---|---|
| years. Assume: 70 applications by CRI and Universities will be approved x average funding of $7m. | |
| (g) The cost of policy and monitoring work by MAF, MfE and Treasury over 10 years | $5,000,000 |
| (h) The cost to submitters submitting and attending 70 public hearings over 10 years. | $5,000,000 |
| Approximate costs to New Zealand of trying to be a leader in GMOs in the outdoors | $599,500,000 |

Source: McGuinness and Associates

**Background information about the author:** *Wendy McGuinness is a Risk Management Consultant CA, BCom, MBA and a member of the Foundation for Research, Science and Technology (FRST) Reference Group over the last three consecutive funding rounds on the risks of genetic modification. Email: wmcg@paradise.net.nz*

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