The Economic Analysis of GM Crops

Paper prepared by Wendy McGuinness of McGuinness & Associates for the New Zealand Society for Risk Management Conference, November 2004.

This paper considers the involvement of government and the resulting use of analytical tools to date in both 'national' and 'case by case'[1] decisions (the latter being specific applications considered by the Environmental Risk Management Authority (ERMA)). The paper concludes that the quality of economic analysis in New Zealand on Genetically Modified crops must be improved. In this paper, twelve recommendations are made aimed at improving decisions, and consequently improving public governance and public trust in the decision making process.

The paper concludes that there are substantial problems, including the lack of accurate and complete information to input into the identification process, the lack of guidance on valuing non-market risks and benefits to input into the analysis process and the failure to define minimum standards to input into the evaluation process. It outlines the necessary actions to achieve the desired objective of quality, transparent and cost-effective decision-making. Recommendations are summarized in Appendix 1.

Background

New Zealand has not approved the release or conditional release of any GMO, either in primary production or in any other industry. Only one release application has got so far as to be given an application number by ERMA, being GMR98001[2], although it never proceeded to a fully-considered application. The application was for 'an import for release' of GM canola with resistance to round-up herbicide and was received by ERMA in 1998. Appendix 2 provides the status of all outdoor GM applications processed by ERMA as at 1 March 2004.

Market Failure

The development of biotechnology raises a number of issues that impact on environmental economics and natural resources, in particular allocative efficiency and market failure. Well defined and enforceable property rights are a key platform upon which the market can operate. With the development of biotechnology, in particular genetically modified organisms (GMO), two key things happened. Firstly, private sector interests lobbied for property rights over GMO's followed by scientists and environmentalists who lobbied for further research into the effects and monitoring of this new technology. Some individuals (including scientists) and organisations went further lobbying for moratorium. This debate is still ongoing and although the first, being the property rights are largely defined in legislation, there are no price signals to reflect the true social costs and benefits of this technology (e.g. the value of externalities) or the subsequent impacts in the form of a public bad or public good, hence a prima facie case exists for government policy intervention to ensure gains in efficiency are achieved.

New Zealand, like many countries, accepted the market would fail to value the social costs and benefits of this technology due to the high degree of uncertainty over effects and the range of impacts that may result (e.g. ethical, cultural, contamination etc over different sectors/individuals and over different timeframes), consequently a quasi-government organisation (ERMA), was set up under the Hazardous Substances and New Organisms (HSNO) legislation to value and weigh the all (including economic,

[1] The term 'case by case' is used to describe specific applications received and considered by the Environmental Risk Management Authority (ERMA) under the Hazardous Substances and New Organisms Act 1996

[2] GMR means Genetic Modification Release

environmental, social and cultural) costs and benefits of placing GMO's in containment (which includes field tests) or in the outdoors (which includes weighing and applying a minimum standard of protection).

In order to produce a conclusive statement on the economics of GM crops, either on a national or case by case basis, complete and accurate information must be available. This paper does not intend to assess the range and variety of risks of GM crops, although readers need to be aware of the current debate about the uncertainty over identifying, valuing and monitoring risks. Two recent papers by 'Heinemann & Traavik (2004)' and 'Heinemann, Sparrow and Traavik (2004)' discuss concerns about 'existing approved transgenic crops that contain antibiotic resistance genes (which nearly all do)'[3] and the 'need for increased monitoring'[4].

In addition, the 'Inquiry into the alleged accidental release of genetically engineered sweet corn plants in 2000 and the subsequent actions taken (2004)'[5] raised concerns about process. It also raised issues about risk, probability, magnitude, transparency, tolerance, and the probability of having to increase degrees of tolerance in the long term due to increased contamination.

Background – The Public Policy Landscape

Accepting market failure can occur, does not necessarily imply government will necessarily design or implement the optimal solution for the most effective allocation of resources; consequently we should continually question whether the current system will lead to the optimal outcome. Government has delegated this role to the Ministry for Research Science and Technology, who are required to consider the barriers as well as the benefits of assurance.

To date, public policy objectives have focused on the need for 'achieving a balance between assurance and innovation'[6]. However, in practice, there is no framework that considers the relationship between innovation and assurance and no public sector entity focussing solely on monitoring assurance as a strategic level, as per recommendation 14.3 of the Report of the Royal Commission on Genetic Modification.

If economic analysis is going to assist decision makers in making effective 'national' and 'case by case' decisions, the relationship between assurance and innovation must be clear and complete. Appendix 3 outlines the background and a possible framework for discussion.

The National Decision to allow the Release of GM Crops

The Report of the Royal Commission on Genetic Modification reported to Government in 2001. In reviewing the report, the author of this paper wrote to Members of Parliament on 17 September 2001[7] highlighting seven critical weaknesses, one of which noted that the report failed to complete any economic analysis. This was a lost opportunity.

[3] Heinemann Jack A & Traavik Terje; Nature Biotechnology, Vol 22, Number 9, Problems in monitoring horizontal gene transfer in field trials of transgenic plants, September 2004

[4] Heinemann Jack A, Sparrow Ashley D. and Traavik Terje; Is confidence in the monitoring of GE foods justified?, TRENDS in Biotechnology, Vol 22, No7, July 2004

[5] Report of the Local Government and Environment Committee, Forty-seventh Parliament (Jeanette Fitzsimons, Chairperson), October 2004

[6] Biotechnology Strategy 2003, page 27

[7] McGuinness, W., Letter to Ministers reviewing the Report of the Royal Commission on Genetic Modification, dated 17 September 2001. (A copy is available from the writer.)

This gap in analysis was evident and Cabinet, as part of its November 2001 response to the report of the Royal Commission on Genetic Modification, directed officials to report back on an economic analysis of the risks and opportunities that may arise from GM and non-GM technologies[8]

The second opportunity was in early 2003, when economic consultants BERL and AERU (BERL) prepared a report, titled; 'Economic Risks and Opportunities from the Release of Genetically Modified Organisms in New Zealand', published April 2003. The purpose of the report was to investigate economic impacts in order to identify and, where possible, measure the effect on New Zealand's CRI [Clean Green Image] of releasing GMOs and the economic risks and opportunities from the release of GMOs. BERL developed four scenarios (refer Table 1) and reported the results of their modelling to Treasury and the Ministry of the Environment in advance of publication. Sensitivity analysis was applied to each scenario to reflect and understand the impact of changes in assumptions that underline the model.

Only one scenario could be considered a GM crop, being a rye grass, which implies no human food, grain, fibre or forestry crops were analysed. This is surprising when ERMA has not received any applications for developing or field testing pastoral grasses in the outdoors; whereas in contrast, ERMA has received a number for GM food crops (refer Appendix 2). Notably, GM food crops are more likely to incur a higher degree of consumer resistance/intolerance and therefore are more likely to have a negative impact on GDP.

On 28 March 2003, Treasury prepared their own report, titled 'Treasury Report: Briefing on Genetic Modification Economic Analysis Cabinet Paper'[9] (Treasury Report) on the same scenarios, indicating they disagreed with the findings of the initial modelling results. A comparison is discussed between the initial modelling results (which I have assumed were from BERL) and Treasury's adjusted results, which are outlined in Table 1. Key assumptions made by Treasury include;

- 'The 'survey overstates the likely negative impacts, and overseas evidence shows no indication of economy-wide negative price impacts in countries that have released GMO's'[10].
- 'The survey suggests that that any widespread negative price impact would likely be only one-off when the first release of GM occurs.[11] [emphasis added]

The first assumption raises issues on the (i) quality of the survey and the (ii) negative price impacts on countries that export GMO's to non GMO producing countries and the latter assumption raises issues on the (iii) impact of approving the first application. For example, the latter assumption is surprising considering risk intolerance has increased substantially in regard to outdoor experiments in New Zealand. For example, one of the first GM food applications approved for GM potatoes - received 17 submissions (1988) whereas the most recent GM food application approved for GM onions – received 1933 submissions (2003).

[8] CAB Min (01) 33/22. http://www.treasury.govt.nz/gmeconomic/
[9] http://www.treasury.govt.nz/gmeconomic/
[10] http://www.treasury.govt.nz/gmeconomic/ - Treasury Report, Briefing on Genetic M Economic Analysis Economic paper, Para 29
[11] http://www.treasury.govt.nz/gmeconomic/ - Treasury Report, Briefing on Genetic M Economic Analysis Economic paper, Para 42

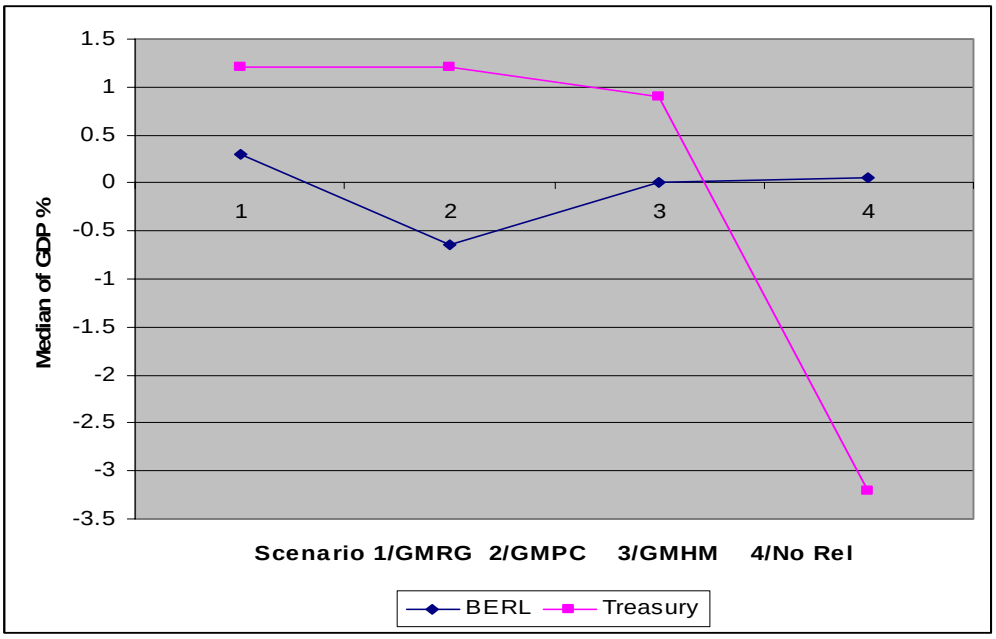
Table 1: Scenario Analysis Results (Source: Treasury Report: Briefing on Genetic Modification Economic Analysis Cabinet Paper – 28 March 2003 – Annex Two)[12]

	Initial modelling (Assume BERL) - Wider Range	Median[13] GDP	Treasury Officials View -Wider Range	Treasury Median GDP
Scenario 1: Release of GM Rye-grass	3% to -2.4%	0.3%	2.5% to -0.1%	1.2%
Scenario 2: Release of GM Pest Control	1.2% to -2.5%	-0.65%	1.2% to 1.2%	1.2%
Scenario 3: Release of GM human medicine	1.4% to -1.4%	0%	1.4% to 0.4%	0.9%
Scenario 4: No Release of GMO's	11.3% to -11.2%	0.05%	0% to -6.4%	-3.2%

The differences between the results in Table 1 are significant, and are reflected in Figure 1 below. Notably the Treasury Report significantly increased the median of all three GM scenarios and significantly decreased the median of the GM Free scenario.

While the cumulative conclusions of the initial findings (BERL) may have led decision-makers to delay GM releases, the effect of Treasury's Report adjustments to assumptions may have led decision makers to proceed with GM release (see paragraphs 42 and 43 of Treasury's Report). Hence the adjustments to assumptions by Treasury were significant.

Fig. 1: GDP Median % Change in GDP by the Two Different Groups of Economists



The conclusions of officials were recorded in a Cabinet Policy Committee Minute: 'Government Response to the Royal Commission on Genetic Modification: Economic Analysis Results and HSNO Act Implications' dated 9 April 2003.[14]' A copy is contained in Appendix 4 and is recommended reading. Notes 3-5 are contained below as they are discussed further in this paper.

[12] http://www.treasury.govt.nz/gmeconomic/
[13] Median – the number in the middle of the set of given numbers, Excel
[14] http://www.treasury.govt.nz/gmeconomic/

3 **noted** that the economic modelling undertaken with New Zealand-specific GM organism release applications indicates a range of possible positive and negative impacts on Gross Domestic Product (GDP), depending on the productivity improvements, price impacts and types of technology modelled;

4 **noted** that officials' analysis of the modelling results suggests that foregoing the release of GM organisms is likely to have a more significant negative impact on GDP than any of the GM organism release scenarios;

5 **noted** that the analysis suggests that the two major determinants of whether the economic impact of releasing GM organisms is positive or negative in New Zealand are:

5.1. the effect of a release of a GM organism on the international price of New Zealand produce; and

5.2. the size of the productivity gain that can be achieved through the release of a GM organism.

Consequently it is the author of this paper's opinion that the national decision to allow GM release should be re-considered on the grounds of the high degree of uncertainty, indicated by the significant variation between the two expert reports in regard to assumptions, determinants and conclusions, and the worst case scenarios.

Importantly, sensitivity analysis[15] does not produce a unique decision, as supported by Perman et al when discussing how to incorporate into project appraisal the fact that we are dealing with imperfect knowledge about the future: [16]

> A flexible way of informally considering the impact of risk would be to compute the NPV[17] for different assumptions about future expenditures and receipts, to examine the sensitivity of the decision to assumptions built into the net cash flow projections. This kind of sensitivity analysis does not produce a unique decision, but it can illuminate key areas of the underlying project analysis [emphasis added]

Notably, scenario analysis has also been used in the July 2003 UK report: 'Field Work: Weighing Up the Costs and Benefits of GM Crops.' Like BERL, the UK writers also used scenario analysis to identify critical elements/determinants and next steps, but also like the writers of the BERL Report, they did not use sensitivity analysis to provide a conclusive statement as to economic outcomes from release.

Sensitivity analysis has a number of strengths and weaknesses, and users of this approach need to understand the dynamics of the tool, in particular that is does not consider the impacts on who bears the risks and benefits, and is dependent on the range (completeness) and values of inputs. For example, in the analysis above, the extent all risks were considered or were not considered (e.g. contamination / weedy grasses) must be transparent. Sensitivity analysis requires setting scenarios, determining appropriate assumptions and determining values in a transparent and accurate manner. The BERL and Treasury Reports would have both benefited from being more transparent about what risks were not taken into account when developing their scenarios (e.g. HGT/antibiotic resistance).

What the BERL Report promised to deliver from the sensitivity analysis it did deliver, as outlined in the last section 'Critical Factors Determining Economic Outcomes', being: [18]

(1) The magnitude of the change in demand for New Zealand goods and services.
(2) The responses of foreign consumer demand to price changes.
(3) The access of New Zealand goods to global markets.
(4) The opportunities for productivity enhancements.

[15] Sensitivity Analysis – the analysis of the effect of changes in the estimated values used in a forecast on the final result of the forecast. Collin P H, Dictionary of Economics, Bloomsbury, 2003, Page 183

[16] Perman Roger, Yue Ma, James McGilvray and Michael Common, Natural Resource and Environmental Economics, 3rd Edn, Pearson, 2003, page 367

[17] NPV - Net Present Value - the value of future cash inflows less future cash outflows discounted at a certain discount rate, usually the company's cost of capital. Collin P H, Dictionary of Economics, Bloomsbury, 2003, Page 139

[18] BERL and AERU, Report of the Ministry for Environment and the Treasury, Economic Risks and Opportunities from the Release of Genetically modified Organisms in New Zealand, April 2003, page 59-62

Importantly, the last sentence of the BERL Report, 'Conclusions on Economic Outcomes', states:

> As such, reducing the degree of uncertainty surrounding these elements is a prerequisite to reaching a conclusive statement on the economic outcome of either a GMO release or a policy foregoing GMO release.

Notably, BERL provides no 'conclusive statement' on the 'impact on GDP'. BERL only went as far as to state:

> The range of experiments performed using the two economic models signal a range of outcomes in terms of economic impact. In particular, given the range of productivity and demand preference shifts modelled, the impact of releasing a crop or bio control-based GMO in New Zealand can result in both negative or positive overall economic outcomes.[19]

It is therefore surprising that officials went further than the writers of the BERL Report and concluded that;

> 'the modelling results suggest that foregoing the release of GM organisms is likely to have a more significant negative impact on GDP than any of the GM organism release scenarios'. [Refer Note 4 of the Cabinet Policy Committee Minute, paragraph 17 above.]

This analysis highlights the potential failure by government, in light of concerns over assumptions and the method of combining results to develop conclusions.

The third (and final) opportunity to assess the economics of GM crops will be when ERMA receives the first application for a release or conditional release. It is expected that such an application will be 'called in'[20] by the Minister due to the potential for 'significant economic effects', as reflected by the range of various assumptions and variety of results for a GM grass crop, noted in Table 1 above.

Case by Case Analysis – The Use of Public Funds

Concern has been raised about the quality of past public funding decisions in relation to GM crops, and this was actually noted in an ERMA decision on the field test for GM onions, GMF 03001. This application was approved by ERMA even though the Committee, in writing its decision, acknowledged that the long term environmental benefits of herbicide-tolerance technology was 'not a soundly based use of research funding', notably: [21]

> The uncertainty about the long term environmental benefits of herbicide-tolerance technology invites the conclusion that this is not a soundly based use of research funding. This decision under the HSNO Act should not be seen as an endorsement of the decision to fund this research.

The Risk Management Guideline also supports the need for benefits to be proven, when it states: [22]

> Thus individuals are prepared to 'tolerate' some risks under certain circumstances in return for specified benefits.

If government continues to invest through fee subsidies, providing cheap investment funds, funding research projects and/or approving applications (through ERMA), not only should decision-makers put in place a rigorous and transparent decision making process, but they should ensure that (i) benefits exist, (ii) benefits are relevant to 'public good' objectives, and (iii) benefits are largely able to be retained in New Zealand.

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[19] BERL and AERU, Report of the Ministry for Environment and the Treasury, Economic Risks and Opportunities from the Release of Genetically modified Organisms in New Zealand, April 2003, page 58
[20] Minister's Call in – HSNO Act 1996, Section 68
[21] GMF03001 Decision (GM Onions), Para 2.6.5.16
[22] Risk Management Guideline, Companion to AS/NZS 4360:2004, page 65

Case by Case Analysis – The Legal Framework

The methodology for economic analysis is contained in the Hazardous Substances and New Organisms Act 1996 and the regulations made under that Act. The statutory and regulatory scheme contains two key tests for ERMA in regard to the assessment of GM crops and these are attached in Appendix 5 with definitions.

It is important to note that the HSNO (Methodology) Order 1998, being the risk management process for considering applications, has been under review since 2002, and although a proposed methodology (in my view a weaker form than the 1998 version) has been in the public domain since 2003 (and a confidential proposed Order has been with the Hon. Marion Hobbs since December 2003), no new HSNO (Methodology) Order has been approved to date. Consequently there is considerable uncertainty for ERMA and stakeholders.

Since 2000, there have been five key amendments to the HSNO Act, two of which are significant in terms of the purpose of this paper. These are identified in Appendix 5.

In May 2004, ERMA issued a 'Draft Technical Guide for Discussion on the Assessment of Economic Risks, Costs and Benefits (Draft Guide)'. To date, this has not been published on their web site.

To conclude, the legal framework for release does require economic analysis in the weighing of beneficial effects against adverse effects. It does not specify the requirement to apply 'the time value of net benefits' nor the application of NPV[23] or IRR[24], but it does require the Authority to take into account:

- 'risks that persist over time' (HSNO (Methodology) Order 1998, clause 33(b)),
- 'the distributional effects of the costs and benefits over time, space and groups in the community' (HSNO (Methodology) Order clause 13(c)), and
- when evaluating … 'combine groups of risks, costs and benefits using common units of measurement, including where applicable, monetary valuations' (HSNO (Methodology) Order clause (34)).

In order to provide clarity, ideally ERMA should re-write the HSNO (Methodology) Order 1998 in light of the new Risk Management Standard AS/NZS 4360:2004, invite public comment, review and then make law (as intended by section 9 of the HSNO Act). Only then should ERMA finalise the 'Draft Guide', ensuring the focus is in line with the purpose of the Act, namely, to 'protect'.

Case by Case Analysis - Risk Management

Risk assessment involves three stages, the identification of risks, the analysis of risks and the evaluation of risks[25]. It is important to appreciate it is not always necessary to complete the whole process. For example, the mere fact that the risks are identified may meet the appropriate level of rigour, or simply identifying a risk that is unacceptable may result in the project being rejected outright.

Critical to the definition of risk in terms of GM crops is the application of the Australian / New Zealand Risk Management Standard 4360:2004 (AS/NZS 4360:2004). Key definitions used below are set out in Appendix 6.

[23] NPV - Net Present Value - the value of future cash inflows less future cash outflows discounted at a certain discount rate, usually the company's cost of capital. Collin P H, Dictionary of Economics, Bloomsbury, 2003, Page 139
[24] IRR - Internal Rate of Return - the discount rate at which the cost of an investment and its future cash inflows are exactly equal. Collin P H, Dictionary of Economics, Bloomsbury, 2003, Page 104
[25] Risk Management Standard AS/NZS 4360:2004 Page 4

The approach outlined in the Risk Management Standards 4360:2004, divides risks into three bands, using the ALARP principle, which is described in Figure 2 below.

> For risks with significant potential health, safety or environmental consequences, this is expressed as the 'As Low As Reasonably Practicable' or ALARP concept illustrated in Figure 7.1 [being Figure 2 below], but the concept is also applicable for other risks. The width of the cone indicates the size of risk and the cone is divided into bands as discussed above. When risk is close to the intolerable level the expectation is that risk will be reduced unless the cost of reducing the risk is grossly disproportionate to the benefits gained. Where risks are close to the negligible level then action may only be taken to reduce risk where benefits exceed the costs of reduction.[26]

Fig. 2: Excerpt from Risk Management Standard 4360:2004

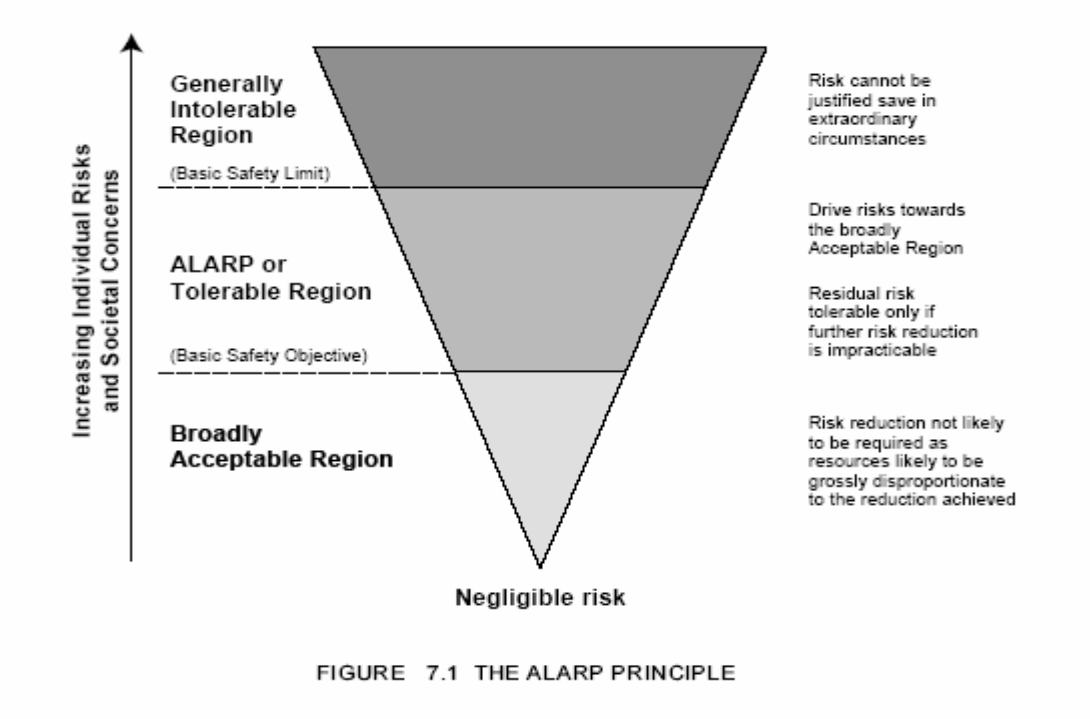

FIGURE 7.1 THE ALARP PRINCIPLE

The ALARP principle will be a useful tool for ERMA in assessing and treating risk. Importantly it identifies the need for a basic safety limit, notably, the need for a basic safety limit is equivalent to the 'minimum standard' for release set in HSNO Amendment Act 2003, which states:

> Section 38C(1): The Authority may … grant a conditional release approval with controls, but only if the Authority determines that, -
> (a) after taking into account the matters in subsection (3), the new organism is likely to meet the minimum standards set out in section 36;

This aligns with the 'sustainability constraint' advocated by Pearce and Warford[27]. This approach would largely negate the problem of choosing a discount rate to reflect/take into account the rights of future generations.

Both the 'basic safety objective' and the 'basic safety limit' (sustainability constraint) should be determined when establishing the context, which is set after the 'communicate and consult' steps in the risk management process. Refer AS/NZS 4360, Figure 2.1 Risk Management Process Overview.

[26] Risk Management Guideline, Companion to AS/NZS 4360:2004, page 75
[27] Pearce, D., W., & Warford, J.J. World without End. Economics, Environment and Sustainable development. World bank, Chapter 3, Fairness and Time 1993

Importantly, if applications are considered to fit in the ALARP region, the combined benefits would need to exceed significant risks in order to approve an application.

A practical example where this principle could have been applied (but was not), was the GM onion decision. This was a field test application and was referred to earlier. Interestingly, there is no 'minimum standard' (read 'basic safety limit') for field tests, which has been voiced as a serious failing by some stakeholders.

The GM onion decision identified and assessed three significant risks and five significant benefits, from the 10 originally identified in the application as negligible (refer Appendix 7). What ERMA was suggesting was that after treating risks, three risks remained above the 'basic safety objective line' and that the benefits, when combined and weighed against the significant risks, had a net benefit to New Zealand.

Tables 2 and 3 below also record the Authority's approach to risks and benefits insofar as they can be identified in the GM Onions decision.

Table 2: Significant Risks

Characteristics of Risk	**1. Potential pollen contamination of other produce**	**2. Anticipated effects due to the incomplete characterization of the genetically modified onions**	**3. Opportunity cost of not funding more beneficial research**
Probability	Not specified	Not specified	Not specified
Magnitude	Not specified	Not specified	Not specified
Who Bears the Risk	Not specified	Not specified	Not specified
Ability to Reverse Effects	Not specified	Not specified	Not specified
Level of Uncertainty	Not specified	**Significant**[28]	Not specified
Weight	**Very Low**[29]	**Very Low**[30]	**Low**[31]

[28] GMF03001 Decision (GM Onions) – Para 2.6.7.5
[29] GMF03001 Decision (GM Onions) – Para 2.6.5.5
[30] GMF03001 Decision (GM Onions) – Para 2.6.7.5
[31] GMF03001 Decision (GM Onions) – Para 2.6.5.17

Table 3: Significant Benefits

Characteristics of Benefits	1. Scientific and other knowledge generated by the field trial	2. A platform for research into environ-mental effects	3. The development of lines of GM onions which are patented by Crop and Food Research Limited	4. Continued funding for C+F from NZ and overseas	5. The retention of scientific expertise in New Zealand
Probability	Not specified	Not specified	Not specified	Not specified	Not specified
Magnitude	Not specified	Not specified	Not specified	Not specified	Not specified
Who Receives the Benefit	Primarily Crop and Food[32]	Primarily researchers then the Public once published[33]	Not specified	Not specified	Not specified
Level of Uncertainty	Considerable[34]	Not specified	Not specified	Not specified	Not specified
Weight	At least moderate[35]	Low to moderate[36]	Low[37]	Low to moderate[38]	Low[39]

Tables 2 and 3 indicate a number of concerns about the process of weighing risks and benefits, namely;

- The acceptance of risk 3, calls into question the validity of all benefits 1-5.
- Benefits 1 and 3 are reliant on the applicant producing published papers, yet there is no description to support the value of these benefits, nor are the content of these possible published papers stated in the controls. Consequently, the applicant could fail to publish anything of merit.
- Risks 1 and 2 should clearly have the precautionary approach[40] applied to the weights given, yet that has not been recognised in the written decision. In fact, neither section 7 of the 1996 Act nor the precautionary approach is mentioned in the GM onions decision.
- Risks 1 and 2 are considered significant (i.e. not negligible) and appear to be within the meaning of section 36(d) of the Act set for releases. Therefore arguably the implication remains that the minimum standard for a 'release' has been crossed, yet because this is a 'field test', ERMA can and has been able to approve this application.
- There are a number of phrases written in the decision that raise additional questions. For example:
    1. Benefit 1: "On balance the committee considers the benefit (beneficial effect) and its value in this area to be at least moderate, but subject to considerable uncertainty"[41]. Q: What would the weight/value be if they took into account the uncertainty when actually assessing the value?

    2. Risks: "The duration of the approval is limited and none of the significant risks identified are considered to persist over time".[42] Q: This is surprising considering that risk 1 is about the possibility of pollen contaminating other produce.

[32] GMF03001 Decision (GM Onions) – Para 2.7.2.5
[33] GMF03001 Decision (GM Onions) – Para 2.7.3.8
[34] GMF03001 Decision (GM Onions) – Para 2.7.2.6
[35] GMF03001 Decision (GM Onions) – Para 2.7.2.6
[36] GMF03001 Decision (GM Onions) – Para 2.7.3.8
[37] GMF03001 Decision (GM Onions) – Para 2.7.4.8
[38] GMF03001 Decision (GM Onions) – Para 2.7.6.2
[39] GMF03001 Decision (GM Onions) – Para 2.7.5.3
[40] Precautionary Approach – HSNO Act 1996, section 7 and www.biodiv.org/biosafety/ratification.asp
[41] GMF03001 Decision (GM Onions) – Para 2.7.2.6

- The list of benefits indicates the failure of section 44A(2)(b) – the new section requiring consideration of alternative options – to have its intended effect. For example, the Authority did not consider which option would best reduce herbicide use in onion production, but whether another GM onion field trial would produce fewer risks; and
- The lack of information gaps in Tables 2 and 3 about the Authority's assessment of risk, in particular the lack of information supplied about probability and magnitude, are a concern in regard to transparency and accountability.

Currently, there is no detailed public paper indicating how ERMA will interpret the minimum standard in the legislation. Interestingly, if a minimum standard had been applied to the GM onion application, at least two of the significant risks identified, are likely to fall above the minimum standard, indicating the application may have been declined.

The legislation is vague (Refer Appendix 5 / Paragraph 2). For example, what does 'likely' or 'significant' mean? Consequently, without a transparent and agreed framework, ERMA will be making decisions on the acceptability of risk without any agreed limits for safety.

Case by Case Analysis - Cost Benefit Analysis

When the risks fit in the ALARP band, the application of risk management, being 'the culture, processes and structures that are directed towards realizing potential opportunities whilst managing adverse effects'[43] often results in the application of a tool called 'Cost Benefit Analysis' (also called CBA or Benefit Cost Analysis).

CBA is based on the principle that 'an individual (or a firm, or a society) should take an action if, and only if, the extra benefits from taking that action are at least as great as the extra costs'[44.] This demands that sunk costs (being costs already committed) are ignored and any comparison with alternative options (e.g. the status quo option) must include the opportunity cost (opportunities forgone) of using those funds in another way to meet end objectives. In relation to GM crops, this means ERMA should take into account (when considering the status quo) the 'value of the next best alternative that must be forgone in order to engage in that activity'[45].

In relation to the GM onion field test, the CBA would require consideration of the effects of the funds being utilised in sound research.

Perman et al state that 'the commercial viability of a project can be assessed in two equivalent ways – the net present value test and the internal rate of return test'[46]. They highlight the challenge of uncertainty:[47]

> 'The net cash flow figures that are input to NPV or IRR calculations are derived from projections, or estimates, of future receipts and expenditures, and the important question is: how do we incorporate into project appraisal the fact that it is dealing with imperfect knowledge of the future?'

One solution to uncertainty is 'sensitivity analysis', being the concept used by BERL and Treasury to test a variety of assumptions. Sensitivity analysis analyses 'the effect of changes in the estimated values

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[42] GMF03001 Decision (GM Onions) – Para 2.9.1.3
[43] Risk Management Standard AS/NZS 4360:2004, Page 4
[44] Robert H Frank, Ben S Bernanke, Principles of MacroEconomics, 2nd Edn, McGraw Hill 2004, Page 4
[45] Robert H Frank, Ben S Bernanke, Principles of MacroEconomics, 2nd Edn, McGraw Hill 2004, Page 9
[46] Roger Perman, Yue Ma, James McGilvray and Michael Common, Natural Resource and Environmental Economics, 3rd Edn, Pearson, 2003, page 364
[47] Roger Perman, Yue Ma, James McGilvray and Michael Common, Natural Resource and Environmental Economics, 3rd Edn, Pearson, 2003, page 367

used in a forecast on the final result of a forecast'[48]. It identifies key determinants rather than indicating the best project/decision as discussed earlier. This approach is very good for economists, as it identifies areas of focus for further research and helps decision makers to concentrate on the risks to treat.

Sensitivity analysis may help with understanding the impacts if a risk occurs, however, there must also be clarity as to what risks are to be included (and at what values) or excluded but made transparent, and if the latter, the nature of the qualitative identification, analysis and subsequent evaluation.

The AS/NZS Risk Management Guidelines (2004) clarify the potential breadth of analysis, when it states: [49]

> Decisions should take account of the need to consider carefully rare but severe risks that may warrant risk treatment actions that are not justifiable on strictly economic grounds. Legal and social responsibility requirements may override simple financial cost benefit analysis. Risk treatment options should consider the values and perceptions of stakeholders and the most appropriate ways to communicate with them.

ERMA must consider all of the above when considering the 'with or without situation'. This concept is discussed in the 'Draft Technical Guide for Discussion on the Assessment of Economic Risks, Costs and Benefits', which states: [50]

> The economic principles require that at least two scenarios are evaluated. The first considers the economic substance with the substance or organism while the second evaluates economic costs and benefits without the substance or organism.

The range of effects that must be taken into account is extensive and sometimes this leads to a distinction between the ranges of CBA. Notably, Perman et al[51] refers to Environmental Cost Benefit Analysis (ECBA) being a CBA where a project involves environmental impacts that are not valued in markets. It is the fact that values are required for non-traded products and services (like fresh air) which often leads to criticism of ECBA.

Perman et al also notes criticisms around ethics, namely, that individual preferences are a poor guide to individual human interests and that impacts should not just be identified and valued through the human lens. Perman states this argument:

> A second class of argument is that the scope of ethical concern should not be restricted to humans, that animal and plants (and in some versions non-living entities) should have moral standing.[52]

Consequently, in applying economic analysis to possible effects of GM crops, applicants, ERMA and submitters must consider the appropriateness of NPV and make firm decisions on what effects should be given monetary values and whether these monetary values should be discounted, for example using NPV[53] or IRR.

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[48] Collin P H, Dictionary of Economics, Bloomsbury, 2003, Page 183

[49] Perman Roger, Yue Ma, James McGilvray and Michael Common, Natural Resource and Environmental Economics, 3rd Edn, Pearson, 2003, Section 11.3

[50] ERMA, 'Draft Technical Guide for Discussion on the Assessment of Economic Risks, Costs and Benefits', May 2004: Scenario Analysis Page 13

[51] Perman Roger, Yue Ma, James McGilvray and Michael Common, Natural Resource and Environmental Economics, 3rd Edn, Pearson, 2003, page 373

[52] Perman Roger, Yue Ma, James McGilvray and Michael Common, Natural Resource and Environmental Economics, 3rd Edn, Pearson, 2003, page 379

[53] Risk Management Guidelines Companion to AS/NZS 4360:2004, page 86 [Net Present Value (NPV) is the most often used measure for Discounted CBA. Discounted CBA and NPV calculation is appropriate where -

- there is significant uncertainty that the full value of the benefit will be gained or that the cost will be as predicted; and
- most of the costs and benefits will not be incurred within the first year or so.]

Before applying NPV to GM crops, the effects of applying discount rates on cash flows should be fully understood. For example, the lower the discount rate, the more weight is given to long term costs. In contrast, the higher the discount rate, the more weight is given to short term benefits (Perman et al, 2003). Hence, normally, private sector interests would lobby for high discount rates, as their financial benefits tend to be in the short term.

In addition, because environmental costs are usually incurred in the long term, many environmentalists do not like to apply discount rates at all, as sustainability is about giving rights, utility and values to future generations and a conventional NPV fails to recognise those rights. In addition, as private sector benefits are usually short term in nature, private sector interests may strongly influence the resulting net value.

Interestingly, with field tests the costs are high in the short term and the benefits, if identifiable, are long term and uncertain. Consequently, in order to maximise the positive results of NPV, applicants may wish to apply low discount rates and value benefits but argue that risks are highly improbable or too difficult to value and therefore should not be valued.

There are a number of solutions available, including the use of different discount rates to reflect uncertainty. For example, if a risk could be that land is rendered contaminated, but it may be a remote risk at a massive cost, then it may be appropriate to recognise this potential cost by using a high discount rate to reflect low probability. Naturally, this also works in reverse.

To conclude, regardless of what solution is used, all assumptions, risks and benefits must be transparent, including those not valued or used in the NPV. Without a complete picture, decision-makers will have incomplete information that in turn, may deliver poor quality decisions.

ERMA must demand relevant, accurate and complete information from applicants and ensure all risks and benefits are identified and rigorously assessed to determine values. The key points from the above discussion is the need for all stakeholders, in particular ERMA, to understand the strengths and weaknesses of all tools used to weigh the effects of GM crops and to be transparent about the assumptions made, the tools used and the strengths and weaknesses of those tools. Particular guidance should be provided in advance to applicants and submitters on;

- How the precautionary approach will be applied to economic analysis
- The way non-market goods and services (e.g. externalities) should be valued in quantitative terms or not valued but clearly stated in qualitative terms
- Whether ERMA should require a NPV from applicants, and if yes, at what discount rate
- Whether ERMA staff should be required to provide an NPV in the Evaluation and Review Report[54], and if yes, at what discount rate,
- Assuming ERMA (the Committee hearing the decision) uses NPV, the extent ERMA should disclose the NPV model, the discount rate applied in making the decision, the methodology underlying values used (including externalities), the way the precautionary approach[55] has been applied and the nature of risks and benefits have been excluded in the NPV and how these have been identified, assessed and evaluated in the decision making process.

Conclusion

[54] Evaluation and Review Report, being a report prepared by ERMA staff and made public in advance of public hearings on the development, test or release of a GMO or on a project, containing a group of GMOs'.
[55] Precautionary Approach – HSNO Act 1996, section 7 and www.biodiv.org/biosafety/ratification.asp

Recognising a market failure is not enough. Government has a responsibility to not only design the optimal solution, but to ensure that the proposed solution operates in such a way to achieve the effective allocation of resources or in this case prevent the release of an unsuitable crop. In this project, what is apparent is that generally (i) the legislative design is appropriate, (ii) operationally ERMA does appear to have adequate funds, skills, time and information to complete the task and (iii) the scope of the task set within the legislation is appropriate to the task. Where the system fails is a culture of transparency, discovery and a focus on public good. In addition the theoretical risk management process, which should be outlined in the Methodology Order 1998, Guidance on Minimum Standards, and Guidance on Economic Analysis is either not available or outdated.

Failures by Government, in particular ERMA, mean that the current risk management process cannot be consistently applied or effectively managed and mistakes are occurring. For example, that the GM onion application was approved.

In addition, this discussion questions the ability of ERMA and Government to assess the first application to ERMA for release or conditional release of a GM crop. This paper acknowledges we have missed the opportunity twice, the Royal Commission (2001) and the BERL/Treasury Reports (2004), and suggests we must assess GM crops (other than rye grass), improve our methodology (processes), increase the quality of relevant information (input) and provide decision makers with all relevant information on risks and benefits (completeness), so that we get it right the third time round.

This paper outlines eleven recommendations (refer Appendix 1), that are designed to install rigour into the process; however, none of the recommendations will fill the current futurewatch and assurance gap identified in this paper. Consequently, a twelfth recommendation is added.

Government must implement the second of the three major proposals recommended by the Report of the Royal Commission on Genetic Modification 2001, being Recommendation 14.3:[56]

> That Government establish the office of the Parliamentary Commissioner on Biotechnology to undertake future watch, audit and educational functions with regard to the development and use of biotechnology in New Zealand.

[56] Report of the Royal Commission on Genetic Modification, 2001, pages 347-349

Appendix 1: **List of Recommendations**

2. **Recommendation 1**: Complete a review of GM risk and monitoring programs/projects to ensure they are relevant to, and in line with, international findings.

3. **Recommendation 2**: Provide a framework for the relationship between assurance and innovation.

4. **Recommendation 3**: Provide indicators in order to be able to assess the success or failure of decisions and regulatory processes.

5. **Recommendation 4:** BERL and Treasury should clarify what risks were excluded from the scenarios, e.g.: antibiotic resistance and herbicide tolerant weeds.

6. **Recommendation 5:** Officials should develop a plan of action in order to meet the objective of providing additional information to economists on the four critical elements/determinants identified by the BERL and on any other areas they consider significant – e.g. risks ignored in the scenarios – in order for Cabinet to be provided with more certainty on long term outcomes in the future.

7. **Recommendation 6:** That the national decision to allow release should be re-considered on the high degree of uncertainty, indicated by the significant variation between the two expert reports and the worst case scenarios. In order to make the best decision for all New Zealanders, considerable work must be completed on economic analysis and any potential decision on release or conditional release of GM crops should involve a full public hearing process.

8. **Recommendation 7**: If government is investing through fee subsidies, providing cheap investment funds, funding research projects and/or approving applications (through ERMA), not only should decision-makers put in place a rigorous and transparent decision making process, but they should ensure that (i) benefits exist, (ii) benefits are relevant to 'public good' objectives, and (iii) benefits are largely able to be retained in New Zealand.

9. **Recommendation 8**: Re-write the HSNO (Methodology) Order 1998 in light of the new Risk Management Standard AS/NZS 4360:2004, invite public comment, review and then make law (as intended by section 9 of the HSNO Act).

10. **Recommendation 9**: Following implementation of Recommendation 8, ERMA should finalise the 'Draft Technical Guide for Discussion on the Assessment of Economic Risks, Costs and Benefits', ensuring the focus is in line with the purpose of the Act, namely, to 'protect'.

11. **Recommendation 10**: ERMA should describe in detail what they consider is the basic safety limit (namely the minimum standard – section 36, HSNO Amendment Act 2003) and invite public comment in order that all stakeholders are provided with an opportunity for debate and discussion about the level of tolerable risk. Without a transparent and agreed framework, ERMA will be making decisions on the acceptability of risk without any agreed limits for safety.

12. **Recommendation 11**: ERMA must demand relevant, accurate and complete information from applicants and ensure all risks and benefits are identified and rigorously assessed to determine values. The key points from the above discussion is the need for all stakeholders, in particular ERMA, to understand the strengths and weaknesses of all tools used to weigh the effects of GM crops and to be transparent about the assumptions made, the tools used and the strengths and

weaknesses of those tools. Particular guidance should be provided in advance to applicants and submitters on;

a. How the precautionary approach[57] will be applied to economic analysis
b. The way non-market goods and services (e.g. externalities) should be valued in quantitative terms or not valued but clearly stated in qualitative terms
c. Whether ERMA should require a NPV from applicants, and if yes, at what discount rate
d. Whether ERMA staff should be required to provide an NPV in the Evaluation and Review Report[58], and if yes, at what discount rate,
e. Assuming ERMA (the Committee hearing the decision) uses NPV, the extent ERMA should disclose the NPV model, the discount rate applied in making the decision, the methodology underlying values used (including externalities), the way the precautionary approach[59] has been applied and the nature of risks and benefits have been excluded in the NPV and how these have been identified, assessed and evaluated in the decision making process.

13. **Recommendation 12:** Government must implement the second of the three major proposals recommended by the Report of the Royal Commission on Genetic Modification 2001, being Recommendation 14.3**:**[60]

That Government establish the office of the Parliamentary Commissioner on Biotechnology to undertake future watch, audit and educational functions with regard to the development and use of biotechnology in New Zealand.

[57] Precautionary Approach – HSNO Act 1996, section 7 and www.biodiv.org/biosafety/ratification.asp
[58] Evaluation and Review Report, being a report prepared by ERMA staff and made public in advance of public hearings on the development, test or release of a GMO or on a project, containing a group of GMOs'.
[59] Precautionary Approach – HSNO Act 1996, section 7 and www.biodiv.org/biosafety/ratification.asp
[60] Report of the Royal Commission on Genetic Modification, 2001, pages 347-349

Appendix 2: Status of Outdoor Applications processed by ERMA NZ as at 1 March 2004 [Shaded area represents current outdoor experiments]

Organisation **Being Crown Research Institutes**	**Application code**	**The Entity** – As referred to in the Act, under "organism"	**Date** of decision	**Date** approval expires	**Number** of public submissions received	**Status** Being assessed	**Status** Withdrawn	**Status** Declined	**Status** Approved and in operation	**Status** Research stopped or on hold - but ongoing controls still apply.	**Status** Research stopped with no ongoing controls	**Status** Organisation decides not to proceed at all
AgResearch	**GMF98009 (I) and (ii)**	**Cattle**	**Nov 1999**	**Nov 2004**	**30**				#			
AgResearch	**GMF98009 (iii)**	**Cattle**	**May 2001**	**May 2006**	**30**				#			
AgResearch	GMF98010	Bacteria/hydatids vaccine	June 1999	Not specified	2							#
AgResearch	GMF99004	Sheep	Oct 2000	Oct 2005	80							#
AgResearch	GMD01194	Cattle	Withdrawn	N/A	383		#					
AgResearch	**GMD02028**	**Cattle**	**Sept 2002**	**March 2010**	**863**				#			
Crop & Food	GMF98002	Petunia	March 1999	Feb 2000	8						#	
Crop & Food	GMF98007	Potatoes	Dec 1988	June 2003	17					#		
Crop & Food	GMF98008	Potatoes	Dec 1998	June 2003	17					#		
Crop & Food	**GMF03001**	**Onions**	**Dec 2003**	**Dec 2013**	**1933**				#			
Forest R Inst	**GMF99001**	**Pinus Radiata**	**Dec 2000**	**Dec 2022**	**735**				#			
Forest R Inst	**GMF99005**	**Pinus Radiata and Norway Spruce**	**Dec 2000**	**Dec 2011**	**735**				#			
Forest R Inst	IAG 45*	Pinus Radiata	Jan 1998	Jan 2003	Not requested	-	-	-			#	
Hort Research	IAG 51*	Tamarillo	Jan 1988	Jan 2001	Not requested						#	

Being NZ owned Companies (75+%)	-	-	-	-	-	-	-	-				
Organisation	**Application code**	**The Entity** – As referred to in the Act, under "organism"	**Date** of decision	**Date** approval expires	**Number** of public submissions received	**Status** Being assessed	**Status** Withdrawn	**Status** Declined	**Status** Approved and in operation	**Status** Research stopped or on hold - but ongoing controls still apply.	**Status** Research stopped with no ongoing controls	**Status** Organisation decides not to proceed at all
The N Z King Salmon Company Limited	GMD 99003	Chinook salmon	Feb 2000		Public not invited to make submissions	-	-	-		# Trial stopped but frozen semen remain		
Wrightson Seeds (Kimihia Research Company)	GMF98004	Sugar beet	Nov 1998	Dec 2000	9						#	
Carter Holt H Ltd (Forests)	GMF98011	Pine trees	Dec 1999	June 2003	13							# but shadehouse component continued

Being International Companies (less than 25% owned by NZ interests)												
Organisation	**Application code**	**The Entity** – As referred to in the Act, under "organism"	**Date** of decision	**Date** approval expires	**Number** of public submissions received	**Status** Being assessed	**Status** Withdrawn	**Status** Declined	**Status** Approved and in operation	**Status** Research stopped or on hold - but ongoing controls still apply.	**Status** Research stopped with no ongoing controls	**Status** Organisation decides not to proceed at all
PPL Therapeutics NZ Ltd	GMF98001	Sheep - insertion of an artificial gene based on a gene of human origin.	March 1999	Not specified in controls	30					#		
Not known - refer note below.	GMR98001	Canola - import for release ** GM for resistance to roundup herbicide	Withdrawn	N/A	Although an application number was given, a formal application was never received by ERMA.		#					
Monsanto	GMF99003	Roundup Ready Wheat	Withdrawn	N/A	1411		#					
Monsanto (CropMark)	IAG 60*	Roundup Ready Canola	Nov 1997	Nov 1998	Not requested					#		

Monsanto (CropMark)	IAG 42*	Roundup Ready Canola	Nov 1997	Nov 1997	Not requested					#		
Aventis (Plant Genetic Systems (PGS), Belgium	IAG43*	Canola	Nov 1997	Nov 1997	Not requested					#		
Pioneer NZ Ltd	GMF98005	Maize	Oct 1999	Not specified in controls	10							#
Pioneer NZ Ltd	GMF98006	Maize	Oct 1999	Not specified in controls	9							#
Notes:												

GMR98001 :- (for the purpose of seed multiplication, export of grain and to allow breeding of specific brassica crops for animal forage in New Zealand)
IAG - stands for Interim Assessment Group, being the group that assessed applications before ERMA

Source: McGuinness and Associates

Appendix 3: Public Policy Update

1. In 2001, the government released the report of the Royal Commission on Genetic Modification. Two relevant recommendations were:

> Recommendation 14.4
> That the Ministry of Research, Science and Technology develop on a consultative basis a medium- and long-term biotechnology strategy for New Zealand[61].
>
> Recommendation 14.3
> That government establish the office of the Parliamentary Commissioner of Biotechnology to undertake Futurewatch, audit and education functions with regard to the development and use of biotechnology in New Zealand'.[62]

2. Notably, recommendation 14.3 has never been implemented; however there has been substantive work on recommendation 14.4.

3. In early 2002, the Government released its Growth and Innovation Framework. The goal of this framework was to return New Zealand to the top half of the OECD in GDP per capita rankings. One of the initiatives outlined in the Framework was to select areas of potential that were worthy of special attention and direct government attention. The three areas that were identified were 'Information and Communications Technology', 'Creative Industries' and 'Biotechnology'. Government established sector-led taskforces in all three areas. Their aim was to agree priorities and develop action plans to stimulate growth and develop international competitiveness for each sector[63].

4. In May 2003, the Biotechnology Taskforce presented a report titled 'Growing the Biotechnology Sector in New Zealand: A Framework for Action'. The report was made public and recommended 28 actions. Key recommendations regarding GMO release include:

> Action 15 recommends:
> Government to undertake a biennial review of the compliance costs associated with biotechnology, bearing in mind the processes required to accelerate any regulatory reform identified.
>
> Action 18 recommends:
> That the following changes be made to the ERMA hearings and HSNO Act approval processes to ensure New Zealand has a world-class regulatory system that meets environmental protection requirements and is quick and cost efficient:
> - ERMA to adopt stricter compliance with rules of evidence procedures within its hearing process;
> - Channel all generic submissions not specifically related to an application for HSNO Act approval through an appropriate ethics council (e.g. bioethics) on the basis that a mechanism should be in place to ensure all year round response; and
> - Adopt a more balanced cost recovery practice in the operation of the approval process. [underline added](where is the underline?)

5. In practice these actions were about enhancing innovation rather than assurance, for example:
   - Looks to ensure innovation is not stifled by unnecessary cost and complexity in the regulatory regime, and
   - The overall intent being to ensure that implementation of the HSNO Act is not a barrier to innovation.

6. In addition, it is important to note that the Taskforce's growth targets focussed on innovation and growth and not assurance. Notably, over the next ten years, the targets were to:

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[61] Royal Commission on Genetic Modification, Recommendation 14.3, page 360
[62] Royal Commission on Genetic Modification, Recommendation 14.3, page 360
[63] The Biotechnology Taskforce, Growing the Biotechnology Sector in New Zealand: A Framework for Action, Minister's Foreword, May 2003

- triple the size of the biotechnology community from 350 to over 1,000 organisations;
- increase total cluster employment from around 3,900 to over 18,000;
- increase five-fold the number of core biotechnology companies from 40 to over 200;
- improve performance from both research organisations and private companies resulting in increased export values from the current base of $250 million to over $1 billion per annum.[64]

7. Also, in May 2003 the Government released its Biotechnology Strategy. The strategy set out a vision and direction for the development of biotechnology in New Zealand under the theme of 'a foundation for development with care'. It recommended action in three areas:
   - community engagement
   - growing the sector
   - regulation that provides robust safeguards and allows innovation[65].

8. At this time Hon Pete Hodgson noted that:

> Wrestling with the opportunities and challenges presented by a fast-moving and complex sector is not easy, but standing still is not an option. That's why the strategy calls for action in three areas — growth, community engagement and effective regulation.[66]

9. One of the key goals of the strategy was:
   'Manage the development and introduction of new biotechnologies with a regulatory system that provides robust safeguards and allows innovation'.[67]

10. The objectives of this goal were:

    1) Ensure regulation effectively assesses and manages risks from the introduction of new biotechnologies.
    2) Complete and implement the reviews of the Patents Act, the Plant Variety Rights Act and bioprospecting regulation.
    3) Promote greater transparency and best regulatory practice in the sector.
    4) Maintain an overview of the biotechnology-related regulatory system to ensure effectiveness and efficiency, and provide for assessments of how well it is achieving a balance between assurance and innovation.[68]

11. In relation to objective 4, oversight of the regulatory system to ensure effectiveness and efficiency was assigned to MoRST. The strategy noted:

> While, as the sector taskforce has noted, it is in our trading interests to keep a gold standard for safety, we must do so in a way that supports innovation and does not load the system with unnecessary complexity and costs….There is, however, a need to assign responsibility for oversight of the system as a whole, to consider the multiple and dynamic links, and particularly the interactions between regulation and innovation. ..In line with MoRST's whole-of-government co-ordination role for biotechnology, it is appropriate to assign overview to MoRST, in liaison with other key agencies and industry.
> As part of this overview activity, the Government has made provision for the conduct of periodic independently contracted system audits to assess whether the regulatory regime and its operation are achieving an appropriate balance between assurance and innovation.[69]

12. The strategy assigned two key actions to objective 4, being:

    1) Assign MoRST an overview role in relation to biotechnology-related regulation, in liaison with key agencies and sector bodies.

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[64] MORST, Implementing the Biotechnology Taskforce's Recommendations, April 2004 Update, page 1
[65] MORST web site
http://www.morst.govt.nz/?CHANNEL=BIOTECHNOLOGY+STRATEGY&PAGE=Biotechnology+Strategy
[66] Hon Pete Hodgson Press Statement - A Biotechnology Strategy for New Zealand, 25 May 2003
[67] Biotechnology Strategy 2003, page 27
[68] Biotechnology Strategy 2003, page 27
[69] Biotechnology Strategy 2003, page 32

2) Conduct periodic independently contracted system audits to assess whether the regulatory regime and its operation are achieving an appropriate balance between assurance and innovation. [70]

13. The Ministry of Research Science and Technology's 2003/4 work program contributes to these two key actions, which link back to each of the three areas stated in the Biotechnology strategy, discussed earlier. Their web site lists the following actions as part of the program.

- Developed a Biotechnology Education Hub to provide quality teaching resources for schools. The hub involves input from science education researchers and the biotechnology community (researchers and industry), will fit with schools' curriculum, and will be launched toward the end of 2004.
- Started to develop a systems' view of the biotechnology regulatory system and the way it handles both risk management and innovation. This work will be developing indicators to allow periodic reviews of the biotechnology regulatory system.
- Developed our Futurewatch[71] capability to help Government's responsiveness to emerging biotechnology issues and opportunities.
- Identified the range of pathways to market for New Zealand's biotechnology products and services to support the best practice commercialisation of biotechnology research.
- Helped build closer ties with Australia in biotechnology to provide opportunities for collaborative research and development.
- Consulted with the sector to identify ways to better coordinate the planning, purchase and usage of large equipment needed for biotechnology research.
- Coordinated cross-government action toward the Biotechnology Strategy and Biotechnology Taskforce actions.

14. Apart from the second point, which mentions risk management, these actions are again strongly focussed on innovation rather than assurance.

15. The Biotechnology Taskforce met on 5 April 2004 to discuss progress. MoRST prepared an update[72] for this meeting. Notably, the context was again focussed on innovation rather than assurance.

16. This is an important finding considering both the NZ Cabinet and the UK Cabinet Office acknowledge that the nature of the regulatory system may/will have an important bearing on our ability to analyse risks and rewards of GM Crops.

17. To conclude, the public policy landscape remains focussed on barriers to innovation, consequently, there is likely to be pressure on government to reduce assurance. In order to ensure quality decisions are made in regard to innovation and assurance, it would be valuable to provide an innovation and assurance framework to provide clarity in the debate. A suggested framework is attached in Appendix 3/Figure 1.

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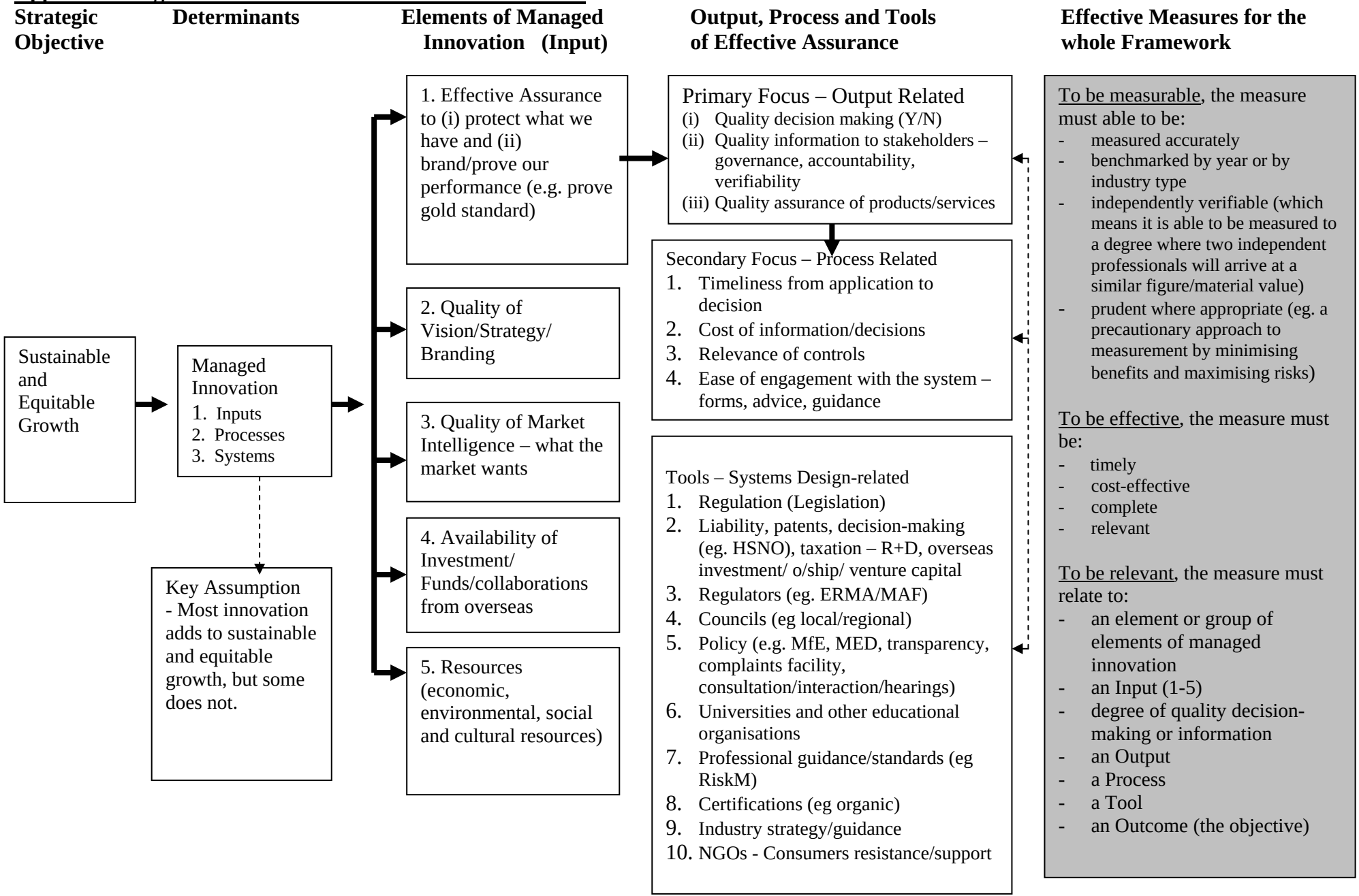
[70] Biotechnology Strategy 2003, page 32

[71] Futurewatch as defined by MORST: MoRST's new Futurewatch work program, aims to build government's awareness and preparedness for emerging science and technologies and the sort of implications – opportunities and risks – that they present to NZ. Futurewatch can be thought of as a kind of a 'radar', a way of systematically scanning the external environment. A key aim is to find things that are new or unusual that may be signposts to important changes in the environment. It also has a role in identifying certainties and helping to describe probable futures.

[72] http://www.morst.govt.nz/?CHANNEL=BIOTECHNOLOGY+TASKFORCE&PAGE=Biotechnology+Taskforce

Appendix 3: Figure 1: Innovation and Assurance Framework



Appendix 4: Cabinet Policy Committee Minute – POL Min (03) 8/5 – 9 April 2003

Government Response to the Royal Commission on Genetic Modification: Economic Analysis Results and HSNO Act Implications commented on economic modelling results – April 2003

Economic modelling results

1 **noted** that previous international studies have produced mixed evidence of the economic implications of genetically modified (GM) crops;

2 **noted** that these previous international studies have considered crops that are not economically significant to New Zealand;

3 **noted** that the economic modelling undertaken with New Zealand-specific GM organism release applications indicates a range of possible positive and negative impacts on Gross Domestic Product (GDP), depending on the productivity improvements, price impacts and types of technology modelled;

4 **noted** that officials' analysis of the modelling results suggests that foregoing the release of GM organisms is likely to have a more significant negative impact on GDP than any of the GM organism release scenarios;

5 **noted** that the analysis suggests that the two major determinants of whether the economic impact of releasing GM organisms is positive or negative in New Zealand are:

5.1. the effect of a release of a GM organism on the international price of New Zealand produce; and

5.2. the size of the productivity gain that can be achieved through the release of a GM organism.

6 **noted** that Government policy interventions, such as maintenance of a robust regulatory regime and promotion of domestic biotechnology research, can have a significant impact on the determinants in paragraph 5 above;

7 **noted** that the scenarios considered likely to lead to positive impacts on GDP reflect current Government policy of a rigorous regulatory regime, international confidence in that regulatory regime, a case by case approach to assessing applications, and successful co-existence between GM and non-GM production methods;

8 **noted** that the results suggest that the release of GM organisms closer to the human food chain poses greater economic risks than releases for medical or pest control purposes.

HSNO decision-making processes

9 **noted** that there is a requirement in the Hazardous Substances and New Organisms (HSNO) Act and HSNO Methodology for the Environmental Risk Management Authority to take account of economic costs, benefits, and risks when considering an application for release of a new organism, including national level effects;

10 **noted** that Ministers have previously agreed to make a number of changes to the HSNO Act largely in respect of the management of new organisms;

11 **agreed** that no further changes, beyond those noted in paragraph 10, are required to either the HSNO Act or the HSNO Methodology to ensure that the economic consequences of a new organism application are appropriately considered;

12 **agreed** that further work be undertaken by ERMA, in consultation with relevant departments, on how it would approach its assessment of economic impacts within the context of the proposed co-existence mechanisms;

13 **directed** officials to report back to Cabinet Policy Committee (POL) by 31 July 2003 on the funding implications of the further work referred to in paragraph 12, in the context of the wider review of ERMA capability;

14 **directed** officials from MAF and MfE to report back to POL by 31 October 2004, on any policy implications arising from the work referred to in paragraph 12.

Appendix 5: Excerpts from the Legislation

The methodology for economic analysis is contained in the Hazardous Substances and New Organisms legislation. The legislation contains two key tests for ERMA.

14. For containment of GMO's (including field tests), the key section is the HSNO Act 1996 (section 45) and the HSNO (Methodology) Order 1998 (clauses 26 and 27).

Section 45(a) [ERMA may] approve the application if –
(ii) After taking into account all effects of the organism and any inseparable organism, ….the beneficial effects of having the organism in containment outweigh the adverse effects of the organism and any inseparable organism should the organism escape; and
(iii) the Authority is satisfied that the organism is adequately contained;…

Clause 26. Taking into account the measures available (if any) for risk management, the Authority may approve an application where a substance or organism poses negligible risks to the environment and health and safety if it is evident that the benefits associated with that substance or organism outweigh the costs.

Clause 27(1). Where clause 26 does not apply, the Authority must take into account the extent to which the risks and any costs associated with that substance or organism may be outweighed by the benefits.

15. For import or release (and conditional releases) the key sections are contained in the HSNO Amendment Act 2003.

Section 38(C). The Authority may …grant a conditional release approval with controls, but only if the Authority determines that -
(a) after taking into account…the organism meets the minimum standards set out in section 36; and
(b) there is sufficient information available to assess the adverse effects of the organism; and
(c) after taking into account ….., the positive effects of the organism outweigh the adverse effects of the organism and any inseparable organism.

Section 36. The Authority shall decline the application, if the organism is likely to -
(a) cause any significant displacement of any native species within its natural habitat; or
(b) cause any significant deterioration of the natural habitats; or
(c) cause any significant adverse effects on human health and safety; or
(d) cause any significant adverse effect on New Zealand's inherent genetic biodiversity; or
(e) cause disease, be parasitic, or become a vector for human, animal, or plant disease, unless the purpose of that importation or release be a parasite, or a vector for disease.

16. The current HSNO (Methodology) Order 1998 defines risk, cost and benefit as:

"Risk" means the combination of the magnitude of an adverse effect and the probability of its occurrence.
"Cost" means the value of a particular adverse effect expressed in monetary and non-monetary terms.
"Benefit" means the value of a particular positive effect expressed in monetary and non-monetary terms. [73]

17. Key Amendments Relevant to Economic Analysis

Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2002

In deciding whether to approve or decline an application, the Authority must take into account -
(d) any adverse effects of developing or field testing the organism on
(i) health and safety; and

[73] HSNO (Methodology) Order 1998 - Interpretation

(ii) the environment, in particular ecosystems and their constituent parts; and

(e) any alternative method of achieving the research objective that has fewer adverse effects on the matters referred to in paragraph (a) than the development or field test; and

(f) any effects resulting from the transfer of any genetic elements to other organisms in or around the site of the development or field test.

Hazardous Substances and New Organisms Amendment Act 2003, Section 6

Matters relevant to purpose of Act -
and substituting the following paragraph:

(e) the economic and related benefits and costs of using a particular hazardous substance or new organism

Appendix 6: Excerpts from the Australian/New Zealand Risk Management Standard 4360:2004 (AS/NZS 4360:2004)

Selected Definitions

- Risk - the chance of something happening that will have an impact on objectives
- Risk analysis - systematic process to understand the nature of and to deduce the level of risk
- Risk assessment - the overall process of risk identification, risk analysis and risk evaluation
- Risk avoidance - a decision not to become involved in, or to withdraw from, a risk situation
- Risk criteria - terms of reference by which the significance of risk is assessed. NOTE: Risk criteria can include associated cost and benefits, legal and statutory requirements, socioeconomic and environmental aspects, the concerns of stakeholders, priorities and other inputs to the assessment.
- Risk evaluation - process of comparing the level of risk against risk criteria
- Risk identification - the process of determining what, where, when, why and how something could happen
- Risk management - the culture, processes and structures that are directed towards realizing potential opportunities whilst managing adverse effects
- Risk management process - the systematic application of management policies, procedures and practices to the tasks of communicating, establishing the context, identifying, analysing, evaluating, treating, monitoring and reviewing risk
- Risk management framework - set of elements of an organization's management system concerned with managing risk
- Stakeholders - those people and organizations who may affect, be affected by, or perceive themselves to be affected by a decision, activity or risk.[74]

[74] AS/NZS 4360:2004, Page 4,5 and 6

Appendix 7: Application: GMF03001 (excerpt – as contained in the full application)

Purpose:

To field test onions modified for tolerance to the herbicide glyphosate, and to evaluate their environmental impact; herbicide tolerance; agronomic performance; development as cultivars and equivalency to non-genetically modified onions.

Risk identification, assessment and impact table – pages 35-38

The following table addresses potential concerns of the genetically modified trial and organism and the likelihood that such concerns will have an adverse effect according to section 5.2A-E, and assesses the harm that might be caused through such an adverse affect (section 5.3A-E).

Name of Potential Concern/risk (relevant section)	Risk rating (likelihood) and reason	Consequence (impact) of risk and reason
1. The genetically modified onion becomes a weed (5.2&5.3 A)	Negligible - Onion is completely unsuited to become a weed species (Rubin 1990). The proposed trial site is closely monitored and all plants and flowers will be accounted for. All pollinations will be performed within a PC2 contained glasshouse	Harmless - Herbicide tolerant plants arise naturally and the consequence of a herbicide tolerant onion weed arising through genetically modified would be no greater than it arising through non-GM methods (see Conner *et al*. 2003)
2. Will genetically modified onions have negative ecological impacts in this trial (5.2&5.3 A)	Negligible - Because of the safe nature of the gene product (see appendix B2) and the weak competitive nature of the host plant chosen for this work (see section 5). As measures to stop pollen spread (pollination in PC2 contained glasshouse) and vegetative spread (weekly monitoring, records of all plants on the site and measures to prevent sabotage) are in place, the only variable from a similar non-GM herbicide spray test is the genetically modified onion, which as we have described (above) carries negligible risk compared to a non genetically modified onion, and will be removed after the duration of the trial. The herbicide treatments proposed are no different to those used for other crops or in many areas in order to get rid of weeds.	Harmless – Any negative ecological impact of the field trial would be removed at the end of the trial with the removal of the genetically modified onions. As the land is cropping land it is anticipated that upon removal of the last onion the land would be returned to its original state.
3. Will the genetically modified onion trial affect biodiversity (5.2&5.3 A)	Negligible – See above	Harmless - New Zealand accidentally introduces many species each year. Most have much more potential than an onion to cause environmental harm therefore relative to what is occurring already (the baseline) this trial offers no increased risk of harm

Name of Potential Concern/risk (relevant section)	Risk rating (likelihood) and reason	Consequence (impact) of risk and reason
4. The genetically modified organism and trial will have adverse health affects (5.2&5.3B)	Negligible - From a scientific perspective, no adverse effects on human health and safety of these transgenic lines can be envisaged from the proposed small scale field trials as the *CP4 EPSPS* gene product has been extensively assessed in other plant systems and shown to have no adverse effects and has been approved safe for human consumption (Appendix B3). No human feeding trials are proposed in this trial. In contrast, some benefical effects should result, in the longer term, from the agricultural use of these transgenic onions (see below)	Harmless – Even if it did eventuate that the glyphosate tolerant onion had detrimental human health effects then the breeding lines that result from this trial could easily be destroyed if necessary
5. The genetically modified onion transfers the trait to a related allium species (5.2&5.3 C)	Negligible - Onion is not readily fertile with any of the other allium species present in New Zealand (Kik 2002, Healy and Edgar 1980). All pollinations will be performed within a PC2 contained glasshouse. If any pipes and umbels are produced they will be removed from the trial before flower opening	Harmless - Herbicide tolerant plants arise naturally and the consequence of a herbicide tolerant onion weed arising through genetically modified would be no greater than it arising through non-GM methods (see Conner *et al.* 2003)
6. Horizontal gene transfer will occur from the genetically modified onion to unrelated species (5.2&5.3 C)	Negligible - Several studies have looked at this and none so far have found it, except for rare transfer to plant associated fungi, but there is no evidence of stable integration and inheritance (Conner et al 2003). The probability of transfer is further reduced in onions because it has a very large genome therefore the transgene constitutes relatively a much smaller fraction than the genome than for most other plant species. For it to have any possibility of consequence it would have to express the gene product and confer a selective advantage.	Harmless – The *CP4 EPSPS* gene is present in plant and bacterial genomes and so could just as easily become integrated horizontally from these species. For it to be actively maintained within a foreign genome it would need to confer a selective advantage. If it did then it would probably already have arisen (as it has in the organisms in which it is already present). For it to then cause harm the selective advantage it conferred would have to be detrimental to the environment. The *CP4 EPSPS* gene product has been extensively studied and shown to be non toxic so it is hard to envisage such a detrimental effect
7. Potential adverse effects on the relationship of Maori and their culture and traditions with their ancestrol lands, waters, sites waahi tapu, valued flora and fauna and other taonga (5.2&5.3 D)	Negligible - Our intention is not to adversely affect Maori relationships with the environment or belief systems. It is not expected that the proposed release would have any effect on Maori traditional resources. The onion is an introduced crop plant and the plants which have been genetically modified and whose release is being sought represent commonly grown cultivars.As demonstrated in 5.2 & 5.3 A,B,C, & E the impacts of this field trial are designed to have negligible adverse effects on humankind (of any culture) and the environment. It is designed to be harmless should adverse consequences arise again regardless of location and the culture within that location	Harmless - See 5.3 A,B,C, & E we see no reason why this field trial should cause harm. The trial is a test only, and in the future similar onions may deliver benefit to society and the environment as a whole
8. Will the genetically modified onion trial lead to	Negligible - Glyphosate resistance is rare despite 28 years of use on millions of hectares. Currently 5 resistant species have been reported	Harmless - Should such a superweed arise, then it would only be 'super' against glyphosate. There are many alternative management

Name of Potential Concern/risk (relevant section)	Risk rating (likelihood) and reason	Consequence (impact) of risk and reason
the development of a superweed (5.2&5.3 E)	(Hortzler, 2003) that have arisen through natural means (not transfer of the *CP4 EPSPS* gene) (Heck *et al.* 2002). Thus glyphosate resistance can occur just as it can for other herbicides. For glyphosate this is a rare occurrence. For the purposes of this trial, amounts of glyphosate similar to that used by many home gardeners (3 applications/year) are proposed. Thus, there is a similar risk of a superweed arising from the home use of glyphosate as from this trial	and cropping strategies available to counter such a superweed (Heck *et al.* 2002). These strategies are likely to be less costly than current weed control practices in onion and therefore relatively harmless compared to existing practices.
9. Will the genetically modified onion trial affect the purity of other onion crops (5.2&5.3 E)	Negligible – No pollen or flowers from the onion will be present in the trial	Harmless – even if the *CP4 EPSPS* gene product did accidentally get into onion crops it would not be maintained as major growers buy new seed each year. Very few people maintain their own onion seed. Even if they did, for the trait to persist it would have to confer an advantage to the onion in the environment in which it is grown otherwise in all probability the trait will be lost due to random sampling (Griffiths *et al.* 1996. Introduction to genetic analysis page 807-808). This would only occur if the grower sprayed the crop with glyphosate, something that is not normal practice.
10. The field site is sabotaged. (5.2&5.3 E)	Unlikely – Guarded location and security measures (confidential Appendix A2) are in place to prevent sabotage. Whilst this is a risk to the research, the plants themselves represent no risk to the environment or human health (see above)	Harmless – From an environmental and human health perspective (see above). However, from a research perspective such an eventuality could cause a delay in information gathering. Fortunately we are doing this in collaboration with international partners and so damage at one site would not compromise the ultimate goals of the research. However, it may negatively impact upon the development of New Zealand and Australasian cultivars which are being predominantly developed using this trial.