

Chair

Cabinet Business Committee

MANAGEMENT OF GENETIC MODIFICATION IN NEW ZEALAND

PROPOSAL

1. The purpose of this paper is to give effect to the Labour-led Government Co-operation Agreement with the Green Party of Aotearoa New Zealand on genetically modified organisms (GMOs) and to report back to Cabinet on the domestic liability regime for living modified organisms (LMOs) [CBC Min (08)13/24].

EXECUTIVE SUMMARY

2. The government Co-operation Agreement with the Green Party states “*during this term of Parliament work will be undertaken to increase the certainty around the ability of non-GM producers to maintain GM free production and be able to identify their products as such to meet market access requirements*”. The Green Party has discussed with me several detailed proposals which it considers would achieve this aspect of the Agreement. In light of those conversations, and focusing proposed changes on genetically modified (GM) crops, I propose:
 - an open register of GM crops and location controls dictated under approvals for GM crops and other GMOs;
 - a new segregation and traceability regime for GM crops;
 - an enhanced public register of non-compliance with GM controls;
 - mandatory labelling of GM propagative material at point of sale.
3. An open register of GM crops and a public register of non-compliance can be readily implemented. Similarly, a template code of practice for segregation has been drafted and, subject to consultation with industry, could be used to develop crop-specific codes as required. The current European Union (EU) framework for traceability could be further developed for New Zealand conditions. Mandatory labelling of any GM propagative material at point of sale could occur through Consumer Information Standards (CIS) regulations under the Fair Trading Act but is likely to take more than a year to implement.
4. Section 17 of the Hazardous Substances and New Organisms (HSNO) Act 1996 limits the extent to which I can direct the Environmental Risk Management Authority (ERMA). This means that implementing the template code of practice and the framework for traceability as mandatory controls would require legislative change. Alternatively, implementing these proposals via a change to the Hazardous Substances and New Organisms (Methodology) Order 1998 may stray beyond the scope of the empowering provision in the HSNO Act and therefore

could be challenged as *ultra vires* or the subject of a complaint to the Regulations Review Committee under Standing Order 315.

5. These issues notwithstanding, I propose to recommend amending the Hazardous Substances and New Organisms (Methodology) Order 1998, or promulgate new regulations under section 140(1) of the HSNO Act (or both if necessary) to prescribe requirements for any conditionally released GMO, particularly in relation to segregation for GM crops. I intend to submit that legislation to the Cabinet Legislation Committee for consideration by 31 August 2008.
6. It is important to note that, as it is an autonomous Crown Entity, ERMA will not have to impose such prescribed controls as it has discretion under the HSNO Act to impose controls on a case-by-case basis. However the regulations will strongly suggest to ERMA the government's intention in this regard.
7. Amendment to the Methodology Order or new regulations would require prior public consultation to comply with statutory obligations, although new regulations would require more limited consultation under section 141 of the HSNO Act.
8. There has also been requests for support for local government involvement in GM crop management in their local area. Advice can be provided to local government about possible drafting of district plan changes under the Resource Management Act (RMA) 1991 to restrict the planting of GM crops in their local area. However, current lack of scientific evidence for the need to impose such controls would make it unlikely that such a plan change would be successful. While advice on making plan changes can be provided, changes to legislation or regulations in this area are not supported.
9. This paper also reports back to Cabinet on its invitation that I “provide a paper on a proposed domestic liability regime for [living modified organisms]” [CBC Min (08) 13/24 refers] arising from the Cabinet paper titled “International Negotiations on Liability Rules for Damage Resulting from Transboundary Movements of Genetically Modified Organisms” [CBC (08) 182 refers].
10. This paper describes the current domestic liability framework that applies to GMOs and the state of negotiations on liability and redress rules for damage resulting from living modified organisms (LMOs) under the Cartagena Biosafety Protocol (the Protocol). LMOs are essentially GMOs, which in New Zealand are regulated as new organisms under the HSNO Act (this paper therefore uses the term GMO throughout). The paper notes also that Parties to the Protocol recently agreed to work towards legally binding rules and procedures on an “administrative approach” aimed at remediating damage and non-binding guidelines (with a legally binding component) on civil liability.
11. Pending conclusion of that work, I recommend inviting the Minister for the Environment and the Minister of Justice to report back to Cabinet with recommendations on a system which involves strict liability and redress with primary responsibility being directed to the producer or importer of the GMOs.
12. Officials have expressed concern that the additional controls outlined in this paper could effectively and significantly restrict future research and innovation in GM crops in New Zealand. That is neither my intention nor my expectation. The range of options included here is aimed at providing a greater level of transparency, increased accountability and greater public openness of GM crop management, should GM crops be approved for use in New Zealand. It is aimed at ensuring that non-GM growers have a heightened level of assurance about the integrity and marketability of their product, while still allowing GM crops to be approved by

ERMA subject to its standard assessment practices based around associated risks and benefits.

BACKGROUND

GM management options

13. In July 2001, the Royal Commission on Genetic Modification (RCGM) reported to the government on the issues surrounding genetic modification in New Zealand. The RCGM recommended a precautionary approach which preserved options for the future. Following extensive public consultation, government endorsed that approach and initiated a work programme across government to support its policy of proceeding with caution with genetic modification while preserving opportunities. The Royal Commissioner's final report noted:

“Our recommendations aim to encourage the coexistence of all forms of agriculture. The different production systems should not be seen as being in opposition to each other, but rather as contributing in their own ways to the overall benefit of New Zealand.”

14. In addition to conventional agriculture, those other production systems referred to were organic, integrated pest management and the use of genetic modification.
15. In February 2003 the government announced its proposed amendments to the HSNO Act. These came into force in October 2003.
16. The Labour-led government Cooperation Agreement includes a section on GMOs:

“The Green Party remains opposed to the outdoors release of any GMOs. The government has legislated for a process to ensure any such release is subject to strict conditions. Both parties to this agreement accept that it is important that New Zealand consumers and producers must maintain the right to grow and/or choose to consume GE free products. To this end it is agreed that during this term of Parliament work will be undertaken to increase the certainty around the ability of non GM producers to maintain GM Free production and be able to identify their product as such to meet market access requirements.”
17. This paper provides Cabinet with options on how to manage GMOs in the future in line with this Co-operation Agreement. There are consequential implementation issues associated with those decisions.

Domestic liability regime

18. On 12 May 2008, Cabinet Business Committee considered a paper from the Minister of Foreign Affairs on international negotiations on liability rules for damage resulting from trans-boundary movements of LMOs. The Committee [CBC Min (08) 13/24 refers]:
 - agreed to maintain an open mind towards the development of an international liability regime, emphasising that rules should be practical and workable, and not restrict the import or export of LMOs where such activities meet New Zealand domestic standards;
 - noted that New Zealand has yet to finalise a domestic liability regime for LMOs, inviting me to provide a paper on such a regime; and
 - agreed that New Zealand be ready to support a continuation of the negotiations past MOP-4.

19. This paper, in part, responds to the invitation to report to Cabinet on a proposed domestic liability regime for LMOs.

COMMENT

Minister for the Environment's powers to direct ERMA

20. In 2003 on considering the RCGM's report, Cabinet considered whether specific controls should be made mandatory. Such an approach was considered "neither practical nor compatible with the evolving nature of the theme proceeding with caution". Accordingly, Cabinet agreed "that ERMA be given broad discretion to impose appropriate conditions on a new organism which it approves for conditional release" [CAB Min (03)4/3 refers].
21. Therefore, ERMA is currently required under Part 5 of the HSNO Act to consider each GM application on a case-by-case basis. Controls are imposed to adequately and appropriately manage the risks associated with the specific new organism.
22. Section 9 of the HSNO Act authorises the Governor-General to make an Order in Council to establish a Methodology for ERMA when making decisions under Part 5 (Assessments). This section also requires ERMA to consistently apply this Methodology when making such decisions.
23. The Hazardous Substances and New Organisms (Methodology) Order 1998 describes the process and procedure for ERMA's decision-making in terms of the assessment of risks, costs and benefits. It has been suggested that changing this Methodology Order might be a way to implement some of the proposals outlined in this paper, without the need for legislative amendment.
24. However, the Methodology Order, as a regulation, is limited as to its scope by its empowering authority in the HSNO Act, and therefore any changes to the Methodology Order relating to substantive matters (such as the mandatory controls outlined in this paper) may extend the scope of the Order beyond what section 9 of the HSNO Act allows. This would be risky as those provisions could be challenged as *ultra vires* section 9 of the HSNO Act, or possibly be the subject of a complaint to the Regulations Review Committee for consideration under standing order 315.
25. Section 17 of the HSNO Act prohibits me from giving any "direction under section 104 of the Crown Entities Act 2004 that relates to the exercise of any power, duty, or function of the Authority under Part 5" of the Act. As such, my ability to require ERMA to impose any mandatory control on any GMO (or any new organism or hazardous substance) is limited. I propose to recommend an amendment to the Methodology Order, or new regulations under section 140(1) of the HSNO Act (or both if necessary) to prescribe requirements for conditionally released GMOs, particularly for segregation of GM crops. I intend to submit draft legislation to the Cabinet Legislation Committee for consideration by 31 August 2008.

Controls imposed on GMOs under the HSNO Act

26. It is important to note however that ERMA, as an autonomous Crown Entity, will not have to impose those prescribed controls as mandatory. ERMA has a discretion under the HSNO Act to impose controls. The conditional release scheme for new organisms provisions was included in the HSNO Act through the HSNO Amendment Act 2003. Section 38D provides that ERMA *may* impose controls when approving a conditional release. Subsection (1)(c) authorises

ERMA to impose obligations on applicants to comply with codes of practice or standards. An example of an obligation included in that provision is "meeting particular co-existence requirements". ERMA could therefore, on a case-by-case basis, exercise its discretion to impose controls on segregation and traceability.

27. While an amendment to the Methodology Order or new regulations would elevate appropriate across the board controls to subsidiary legislation, it will still not overcome the statutory restraints, of ERMA's discretion and a case-by-case approach, for the government. Subsidiary legislation will, nevertheless, strongly suggest to ERMA the government's intention in this regard.
28. If I am to require ERMA to give effect to the changes outlined in this paper (particularly where mandatory controls are required) then there are three options, all of which will require legislative change:
 - repeal or otherwise amend section 17 of the HSNO Act, to enable me to legally give specific direction to ERMA;
 - repeal or otherwise amend section 9 of the HSNO Act to broaden the scope of the Methodology Order to include substantive matters as well as process; or
 - make these proposals mandatory controls that ERMA must impose on any conditional release of a GM crop through amendment of (e.g. section 38D) of the HSNO Act.
29. Should any of these options be agreed, officials would need to be tasked to provide further advice on how this could best be implemented.

Public register of GMO approval locations

30. Officials have provided me with advice on a range of options for implementing a public register of GM crop activity. This paper proposes implementation of an open public register that would give effect to the relevant section of the Co-operation Agreement with the Green Party.
31. The primary purpose of a GM crop location register would be to provide non-GM producers with information to help them make management choices about their non-GM production systems. It could also be used by beekeepers wishing to make choices about how to manage their hives, if they wished to reduce the chances of GM pollen being incorporated into their products.
32. Controls imposed by ERMA on a GM approval should be sufficient to manage risks to an acceptable level such that nearby non-GM producers are not required to take any additional action of their own. However, knowledge of the use of GM crops in the locality would give non-GM producers greater personal control over the security of their own produce.
33. A public register would provide a list of GM crop locations or location controls dictated under conditional release approvals for GM crops and other GMOs where practicable. The most straightforward and accessible mechanism would be a list on a government website. A simple, web-based table of locations and organisms would be quick to establish as currently there are no conditional releases of any GMOs approved by ERMA. The administrative costs of establishing and maintaining a simple website register of GM crop locations should be relatively inexpensive for up to approximately 200 entries.

34. The fully open public register I propose focuses on conditional releases of GM crops. More analysis is required to consider if, and how, this could be applied to “full” releases both of GM crops and of other types of GMOs (for example animals and micro-organisms) as these organisms would no longer be classified as “new organisms” under the control of the HSNO Act.
35. Officials recommend that field tests are excluded from any fully open register. Cross-pollination from GM field tests to neighbouring non-GM crops is unlikely as, under the HSNO Act, such tests are biologically contained and all heritable material arising from the field test is retrieved or destroyed at the end of the trial. Including the locations of field tests in the register would add to administrative costs for the government agency tasked with this work with no perceivable gain to non-GM producers. The alternative view is that, as there have been sufficient breaches of containment in field tests so far, that they ought to be included.

Implementation

36. Officials have advised that there is a potential risk of intentional damage to GM crops or threats to GM growers if location information is available for GM crops. In New Zealand the locations of GM crop field tests have never been published. As such, it is impossible to provide explicit evidence that publishing the locations of GM crops is correlated with an increase in intentional damage of those crops. Appendix 1 does, however, give New Zealand examples of intentional damage to GM crops and threats to GM growers, illustrating that some people opposed to GM crops, who have been able to obtain this information, are prepared to act on it. In the EU a number of member states have experienced problems with intentional damage and have been considering whether they will change the format of their registers to attempt to prevent future intentional damage of GM crops (see Appendix 2).
37. The establishment and operation of a register of GM crops would be best undertaken by the Ministry of Agriculture and Forestry (MAF) as it holds the most relevant and up-to-date “active” location information through its enforcement role for new organisms under the HSNO Act. Although ERMA holds a register of GM approvals this register is not required to reflect what GM crops are in the ground at any given time. MAF’s records relate to containment facilities and field tests, and so this would be easily adapted to relate to locations of conditional releases if and when they occur. A further advantage of MAF undertaking this work is that this can be done via a Ministerial direction. This process would not be as straightforward if ERMA were to be required to establish and maintain the register and may even require changes to legislation.
38. Provision of detailed site information may not be possible with current containment approvals (field tests), given the requirements of the Privacy Act 1993 or given existing confidentiality arrangements. These privacy concerns may be avoided if, in the future, ERMA was to inform prospective conditional release applicants that GM crop location information would be made available to the public.

Code of practice for segregation

39. Officials have drafted a code of practice “template” for the seed crop industry, based on the principles and best practice for segregation. The template is presented as a “fill-in-the-blanks” document covering field management best

practice, pollination management, seed processing management and traceability provisions (Appendix 3).

40. The template would be filled in as appropriate to develop crop-specific codes of practice for the segregation of GM crops. Information from both domestic and international guidelines, such as the Organisation for Economic Cooperation and Development (OECD) guidelines for minimum crop isolation distances, could be used to fill in the blanks.

Implementation

41. An amendment to the Methodology Order 1998 or new regulations under section 140(1) of the HSNO Act could be drafted to reflect the current code of practice "template" for the seed crop industry. Although, as indicated above, it would not be mandatory for ERMA to impose regulations on any applicant, they would nevertheless reflect best practice and, as a consequence, be persuasive of across the board controls to achieve desirable segregation and traceability.
42. Finalising the draft generic template will require consultation with the New Zealand cropping and arable industries for a period of six weeks. Officials are able to begin consulting on this template immediately if so directed. There may need to be wider consultation later on individual codes of practices.
43. Applicants wanting to conditionally release a GM seed crop would be able to use the template to develop a crop-specific code of practice, which ERMA could require as a control. If such a code of practice was available ERMA would be likely to require this as a way of managing risks for any conditional release. However, under current legislation, ERMA would treat each application on a case-by-case basis and could not be *required* to use this code of practice as part of its controls. Section 17 of the HSNO Act prevents the Minister from directing ERMA to make this a mandatory requirement of any approval.
44. A change to the HSNO Act would be needed if use of specific codes of practice for GM crop management were to be mandatory controls for ERMA GM conditional release approvals.

Framework for traceability

45. EU Regulation (EC) 1830/2003 provides a framework for the traceability and labelling of GMOs. It requires EU member states to implement GMO traceability and labelling measures for products placed on the market, although member states are at liberty to establish for themselves how they implement those measures.
46. The key elements of the EU traceability framework are paraphrased below.
 - The traceability framework applies from the point of production and ends at the final consumer.
 - A system to develop and assign unique identifiers to GMOs must be established before traceability can be implemented.
 - The presence of GMOs and their unique identifiers must be transmitted in writing and everyone handling this information must hold it for five years.
 - The traceability requirements do not apply to small elements of GMOs in products provided these are adventitious or technically unavoidable, nor to medicinal products for human use or veterinary use.

- Provision for inspection and compliance measures, penalties and review are required.
- The framework also applies to products of GMOs.

Adapting the EU traceability and labelling of GMOs framework for New Zealand

47. ERMA could currently require applicants wanting to conditionally release a GMO for commercial use to describe how they would implement a framework of traceability objectives. ERMA and MAF would then need to be satisfied with the proposed implementation before that application could be granted. ERMA could then require implementation measures as controls on the approval. Any such controls would sit within New Zealand's existing compliance and enforcement systems, so separate provisions within the traceability framework (as in the EU system) would not be needed.
48. Should this option be agreed, officials will need to be asked to provide further information particularly about how adventitious or technically unavoidable presence of GMOs is to be determined and any other issues around adapting the system for use in New Zealand, including possible application to veterinary and human medicines that are or contain GMOs or other GMOs, if practicable.
49. A change to the HSNO Act would be required if ERMA were to be directed to make compliance with a traceability framework mandatory for anyone applying to conditionally release a GM crop.

Public register of non-compliance

50. ERMA's website includes a public register of incidents involving new organisms that may have resulted from non-compliance with regulatory requirements and/or cause adverse effects to human health and safety, or the environment. The register includes a brief summary of the incident; date and the source of the report; where it happened; effects on the environment, health and safety; how the incident was managed and any follow up actions taken by the enforcement agency or by the approval holder.
51. I have asked officials to provide advice on implementing an enhanced non-compliance register for all field-tests and conditional release approvals for new organisms that:
 - continues to provide annual reports on non-compliance;
 - summarises audit findings on compliance with requirements;
 - notifies reasons for non-compliance;
 - notifies any new or additional controls as a result of non-compliance.
52. Such a register would be relatively straightforward to establish for both field tests and conditional releases. The register could be hosted on either the ERMA or MAF websites and a link provided on both websites to the register.
53. MAF has developed a reporting template (Appendix 4) that could be used to summarise audit and compliance information following the completion of field test and conditional release audits. This information could be integrated with the existing notification of annual reports, and any new or additional controls resulting from non-compliance, on a website register. Links to extrinsic documents referred to in the approval decision could also be provided in the register. Additional links

could be provided, where relevant, between ERMA's website and MAF's public register of GM crop locations.

54. Officials could deliver this form of register for existing GM field tests within a 6 week time-frame if directed to do so, as it falls outside the scope of the restriction on Ministerial direction in section 17 of the HSNO Act.

Labelling of GM propagative material

55. Mandatory labelling of GM propagative material at point of sale could occur by means of Consumer Information Standards (CIS) regulations prescribed in accordance with section 27 of the Fair Trading Act.
56. The purpose of a CIS regulation would be to provide a labelling system for GM propagative material that has been approved for release by ERMA under the HSNO Act and its associated regulations. Propagative material means any plant material intended for planting or growing such as seeds, nursery plants, bulbs and buds. The primary objective of the regulations would be to provide clear information to consumers that seeds, bulbs or plants have been genetically modified thus allowing consumers to make an informed purchase decision.
57. Before the Minister of Consumer Affairs can recommend CIS regulations, section 27(3) of the Fair Trading Act requires that the Minister must consult with persons the Minister considers will be "substantially affected" by the implementation of the regulations and must consider all comments received.
58. It has been suggested that mandatory labelling could be based on a previous industry voluntary scheme that has not yet been implemented. There have been no applications in New Zealand to conditionally release or release GM plants, so there are currently no GM plants for sale here. The Ministry of Consumer Affairs (MCA) has made a quick review of the industry scheme and suggests it is unnecessarily complex. MCA favours a simple labelling scheme with the clear purpose as stated above.

Timeframe to implement mandatory labelling

59. MCA has estimated that it could not complete CIS regulations before October 2009, nor implement them before October 2010, as the Fair Trading Act sets out strict process rules that must be met regarding consultation. Given the nature of the GM debate, there will likely be considerable interest from consumer groups and industry associations in the proposed regulations and this would need to be followed by further consultation on WTO trade issues. MCA also notes that to meet this deadline it would need to delay other projects already identified as government priorities.

Local government in GM crop management

60. The RMA does not prevent councils from restricting or preventing the use of GMOs in their district or region. However, section 32 of the RMA requires a council to demonstrate that its rules are the most appropriate way of achieving the purpose of the Act and have regard to their efficiency and effectiveness.
61. Crown Law opinion is that, given that the risks of any adverse environmental effects are explicitly dealt with under the HSNO Act, additional restrictions or prohibition by territorial authorities may be hard to justify. Further, Crown Law advises that should a territorial authority successfully restrict the use of GMOs in

their region, the territorial authority would then assume the liability for any lack of adherence to this control. Given the difficulty of detecting GMOs, officials believe that the territorial authority would be assuming a heavy risk in acting in this way.

62. Plan provisions and the section 32 report associated with these are subject to challenge through public submissions and appeals to the Environment Court. To withstand such challenge, proposals to manage and control GMOs in statutory RMA plans would need to be robustly based on strong scientific evidence and facts.
63. The Ministry for the Environment (MfE) is aware that territorial authorities continue to be lobbied by environmental and community groups to introduce controls on GMOs through their district plans. MfE's position has been that GMOs are strictly controlled by national legislation (the HSNO Act) and it would be difficult for territorial authorities to identify any issues associated with GMOs that would not be adequately and most appropriately addressed by the HSNO Act and ERMA.
64. The RCGM looked at the possibility of regional GM free zones under the RMA and saw "considerable practical difficulties" with the proposals and preferred approaches under the HSNO Act and MAF-led Codes of Practice.
65. Nevertheless, to provide guidance a template of some model plan provisions and an outline for a section 32 report is attached to this paper for information (Appendix 5). Note that officials consider, however, that any such proposed changes are likely to be successfully challenged on a lack of good grounds for implementing such a change. It is considered highly unlikely that territorial authorities would be able to identify actual environmental effects and risks that have not already been addressed by ERMA.

Domestic liability regime for LMOs

Terminology - LMO (living modified organism)

66. LMO is the term used under the Cartagena Protocol. As well as GMOs, it includes organisms produced by fusing cells from organisms from different taxonomic families. However, the primary focus is on GMOs and for the purposes of this paper, we treat LMOs and GMOs as the same.

Liability – government's response to the Royal Commission

67. New Zealand has a general domestic liability regime that applies to harm caused by LMOs that are GMOs (as well as harm caused by other new organisms). The regime was reviewed and revised by the government in 2003 in responding to the RCGM.
68. The RCGM considered liability issues in the context of GMOs and recommended that, for now, there be no change to existing liability rules. Officials then undertook detailed analysis to determine whether GMOs raise any unique liability issues and whether any change to the law was required (Appendix 6).
69. The analysis noted that regulatory regimes such as the HSNO Act promote the same objectives as liability rules, especially in encouraging precaution to reduce the risk of harm, provided there are strong incentives to comply with the regulatory regimes.
70. On 3 February 2003, Cabinet Business Committee (having Power to Act) noted that while existing liability rules will not always operate effectively to encourage

precaution and provide compensation in relation to GM, this is not unique to GM and so devising a liability regime solely on the basis of a GM/non-GM distinction would not be sound in principle.

71. The Committee then agreed, in order to strengthen incentives to comply with the HSNO regime, to amend the Act in respect of all new organisms to include a strict civil liability rule for harm caused by non-complying activities and civil pecuniary penalties for breaches [CBC Min (03) 3/16].

Detail of current liability regime

Liability rules

72. Under the general common law, if a person were to suffer harm caused by an activity involving a GMO, the person may be able to bring a claim to recover their loss under grounds including negligence, nuisance and breach of statutory duty.
73. Claims may potentially be brought against users, suppliers or manufacturers of the relevant GMOs or GM products, the person who obtained consent for the release and/or the directors and responsible executives of companies engaged in such activities. A regulatory agency such as ERMA may also potentially be liable in negligence or breach of statutory duty if proper care is not taken when approving a GMO or GM product for release.

Post-2003 HSNO Act provisions

74. Since 2003 the HSNO Act has provided for civil pecuniary penalties for breaches concerning any new organism. The advantages over liability rules include no need to wait until harm occurs before bringing proceedings to prove a causal link between an activity and any harm. There is also no need to prove negligence.
75. Strict civil liability (liability without fault with defences for the injurer) applies for harm caused by an activity in breach of the HSNO Act. Defences are available to excuse inadvertent breaches. This provides strong incentives to comply with the HSNO Act while not deterring authorised activities, improves access to compensation for those harmed by non-complying activities and may facilitate remediation.

Cartagena Biosafety Protocol

76. The Cartagena Protocol on Biosafety (the Protocol) establishes international procedures for the trans-boundary movement, transit, handling and use of all LMOs (GMOs) that may have adverse effects on the conservation and sustainable use of biological diversity. The Protocol dealt with liability by requiring the first meeting of the parties to adopt a process for the elaboration of international rules and procedures on liability and redress and to endeavour to complete this process within four years, namely by the 4th Meeting of the Parties (MOP-4) held in May 2008 in Bonn. That deadline has not been met.
77. One of the key reasons why the negotiations have not concluded has been the sharply polarised views on whether there is any need for binding international rules on civil liability. In a compromise at MOP-4, Parties agreed to work towards rules and procedures that will include legally binding rules on an “administrative approach” aimed at remediating damage and non-binding guidelines on civil liability, but with a binding element prescribing the key features of any civil liability

regime. The negotiations are to resume in early 2009. The final instrument will not be formally settled until MOP-5 in 2010.

78. Much of the detail of the rules and procedures is still subject to further negotiation. However, the administrative approach will apply only to damage to the conservation and sustainable use of biological diversity and is likely to require parties to provide a domestic framework that:
- requires an operator to immediately inform a competent authority of damage and to take appropriate response measures;
 - allows/requires a competent authority to implement appropriate measures (which may include response measures) where an operator fails to do so and to recover costs from the operator.
79. The non-binding guidelines on civil liability are likely to cover a broader range of damage. While the detail of the guidelines and of the binding element has also yet to be negotiated, on the basis of the discussions so far, it seems likely that New Zealand's current liability regime would comply with these aspects.
80. The administrative approach being negotiated under the Cartagena Protocol is similar in concept to the full enforcement order process for environmental damage under the RMA. It is also likely to be consistent with the government's 2003 decisions on liability, which recognised that liability rules generally don't work well for environmental damage.

Other options considered in 2003

Strict liability for GM harm

81. The strict civil liability rule added to the HSNO Act in 2003 only applies to non-complying activities. Strict liability for complying activities would involve imposing liability for all harm caused by GM related activities (i.e. including harm resulting from activities that comply with the HSNO Act), without proof of fault. Such an approach was not supported in 2003 as it was considered contrary to the conclusion that there is no principled basis for enhanced liability rules for GM-related activities and could cut across the government policy on GM of proceeding with caution while preserving opportunities. It was also considered that imposing the more stringent standard of strict liability for all harm could deter socially beneficial activities and, consequently, stifle innovation and economic growth contrary to government policy.
82. It was noted at that time that the imposition of strict liability would create incentives to pursue non-GM options in preference to GM options, even if a GM option were socially preferable. Since many other countries, in particular Australia, do not impose strict liability for GM activities there would be, other things being equal, strong incentives for GM innovation to take place abroad rather than in New Zealand, even where such innovations would benefit New Zealand if undertaken here.
83. Nonetheless, and pending conclusion of the Cartagena Protocol negotiations, I recommend that Cabinet invite the Minister for the Environment and the Minister of Justice to report back to Cabinet by 1 December 2008 with recommendations on a system which involves strict liability and redress with primary responsibility being directed to the producer or importer of the GMOs.

Compulsory insurance, statutory compensation or remediation funds

84. These options were not and are not favoured. Compulsory insurance is not a viable option, as insurance for GM harm is not currently available. It is also not clear whether insurers will be able to adequately monitor precaution taken by insureds and reflect it in the terms of insurance, by pricing to reflect risk and precaution, or by denying cover where certain forms of precaution are not taken. If insurers cannot do this the cost of insurance is driven up to prohibitive levels (resulting in fewer people engage in the activity) or insurance becomes unavailable (making the requirement a de facto prohibition).
85. Statutory compensation or remediation funds will not enhance the precaution objective. Such funds may reduce incentives for those who may be harmed to take precaution to protect themselves since they will be compensated regardless. The funds may also reduce incentives for potential injurers to take precaution if their liability is reduced or excluded, unless the fund takes over the victim's right to claim.

Requiring ERMA to consider imposing insurance or a bond as a condition of approval

86. Assessing when and how to use such discretion and the amount of any insurance or bond would, generally, be a highly speculative exercise, involving consideration of a range of difficult issues. There is a risk that socially beneficial activities might be deterred and capital be tied up when it could be put to more productive uses.
87. Moreover, given the uncertainties surrounding the use of a bond, such a power would very likely expose ERMA to increased applications for judicial review of its decisions by those who disagree with conditions imposed on them, or those who consider that ERMA should have imposed a bond or insurance and did not. This could have significant resourcing implications for ERMA and result in delays.
88. Finally, any requirement or option to impose financial securities may raise questions of consistency with the WTO as a non-tariff barrier to trade.
89. ERMA has a wide authority to impose controls on conditional release under section 38D(2) of the HSNO Act. This authority arguably includes the discretion to impose a bond on applicants. ERMA has never exercised this power and therefore its legal authority to impose bonds has not been tested. However, the absence of an express reference to the ability to impose bonds makes any such requirement liable to legal challenge for the following reasons:
 - the wide power would be read with the specific controls in subsection (1), which are limited;
 - when section 38D(2) was inserted into HSNO it could have expressly referred to bonds (as is the case in the RMA) but it was not government policy to do so at that time; and
 - the government's response to the RCGM rejected the requirement of bonds.
90. The RMA has been cited as allowing conditions of consent which require a bond to be entered into with the consent authority. This is to ensure the performance of any one or more conditions of a resource consent. However, under the RMA, bonds are discretionary, apply only to foreseeable and quantifiable harm, and must be tailored to the specific circumstances of each activity.

91. As noted earlier in this paper, requiring ERMA to impose insurance or a bond as a condition of approval would require legislative change.

GENERAL

92. Officials have expressed concern that the additional controls outlined in this paper could effectively impose a ban on future research and innovation in GM crops in New Zealand. They argue that New Zealand already has the most comprehensive and robust GM management regime in the world. This is evidenced by the decreased number of field test applications in New Zealand since the 2003 amendments to the HSNO Act and the total absence of any conditional releases of GMOs. In contrast, internationally, there have been increasing numbers of field tests and both controlled and full releases of GM crops. Officials argue that tightening the regime further would effectively change the balance of government's overall strategy of proceeding with caution while preserving opportunities.
93. That is not the intention of this paper. The range of options included here is aimed at providing a greater level of transparency, increased accountability and greater public openness of GM crop management. It is aimed at ensuring that non-GM growers have a heightened level of assurance about the integrity and marketability of their product, while still allowing GM crops to be approved by ERMA subject to their standard assessment practices based around associated risks and benefits.

CONSULTATION

94. The Ministry of Agriculture and Forestry; Ministry of Economic Development (MED); Ministry of Foreign Affairs and Trade; Ministry of Justice; Treasury; Ministry of Research, Science and Technology (MoRST); Ministry of Consumer Affairs; Te Puni Kokiri; Department of Conservation; Environmental Risk Management Authority and the Commerce Commission have been consulted. The Department of the Prime Minister and Cabinet has also been informed.
95. Specific comments provided by MAF, MoRST, Treasury and MED are below.
- MAF, MoRST, Treasury and MED consider that it is important to strike a balance between risk management and innovation. Some of the proposals in this paper are likely to be perceived by innovators and investors as increasing the costs and uncertainty of GM-related innovation, without managing any significant risk.
 - MAF, MoRST, Treasury and MED do not support proposed actions involving Ministerial direction of ERMA's actions. This would be a departure from the case-by-case assessment and management of risks of new organisms that Cabinet endorsed in 2003 in the government's response to the RCGM and that ERMA currently undertakes. Furthermore, changing the HSNO Act to give the Minister for the Environment more power to direct ERMA would reduce the perceived independence of ERMA.
 - MAF, MoRST, Treasury and MED do not support public disclosure of GM crop locations. They consider that this would raise fears of intentional damage or personal intimidation. These fears, and the costs of increased security measures to allay them, would act as significant deterrents to anyone applying to conditionally release a GM crop. They therefore recommend continuing with the status quo, where publication of GM crop locations is not an automatic requirement and ERMA imposes controls on uses of new

organisms on a case-by-case basis to manage the risks they pose to an acceptable level.

96. The Ministry of Justice does not consider a case has been made for further work on liability rules and their application to GMOs at this time. As noted in 2003, devising a liability regime solely on a GM/non GM distinction would not be sound in principle. The consequences of imposing strict liability, such as encouraging GM innovation to take place abroad, rather than in New Zealand (as outlined in paragraph 82) are live concerns. Moreover, directing primary responsibility to the producer or importer of a GMO has the potential to skew the incentives others have to take appropriate precaution to reduce or avoid the risk of harm.

FINANCIAL IMPLICATIONS

97. Note that there will be financial implications of implementing some of the proposals in this paper but that these would be met under existing departmental baselines.

HUMAN RIGHTS

98. There are no inconsistencies between these proposals and the Human Rights Act 1993.

LEGISLATIVE IMPLICATIONS

99. The proposals contained in this paper would result in either amendment to the Hazardous Substances and New Organisms (Methodology) Order 1998, or new regulations under section 140(1) of the Hazardous Substances and New Organisms Act or both, to prescribe requirements for segregation and traceability schemes that ERMA would have particular regard to imposing as controls when considering any application to conditionally release a GM crop.

REGULATORY IMPACT ANALYSIS

100. A regulatory impact analysis has not been prepared for this paper. The Ministry for the Environment does not confirm that the principles of the Code of Good Regulatory Practice and the regulatory impact analysis requirements, including the consultation RIS requirements, have been complied with. The Ministry notes, however, that the full regulatory impacts of these proposals can not be identified until the Ministry for the Environment, Ministry of Agriculture and Forestry and Environmental Risk Management Authority have undertaken the consultation with affected parties proposed in this paper. Further analysis following that consultation will inform a comprehensive regulatory impact statement to be provided on submission of specific proposals for legislative amendments to address the policy proposals contained in this paper.
101. Additionally, should Cabinet decide to proceed with a Consumer Information Standard under the Fair Trading Act or any other option requiring legislative change, a regulatory impact analysis would be conducted as part of the development of those changes. A regulatory impact statement would then be provided when policy approval is sought for actual regulatory changes.

GENDER IMPLICATIONS

102. There are no gender implications in this paper.

DISABILITY PERSPECTIVE

103. There are no disability perspectives associated with this paper.

PUBLICITY

104. There will be no publicity associated with this paper. However, I propose that this paper should be released publicly once Cabinet has made a decision and that public and media announcements about this decision should be made at the relevant time.

RECOMMENDATIONS

I recommend that the Committee:

Background

1. **note** that the Royal Commission on Genetic Modification (RCGM) recommended a precautionary approach which preserved options for the future;
2. **note** that the Government Co-operation Agreement with the Green Party states that
“during this term of Parliament work will be undertaken to increase the certainty around the non-GM producers to maintain GM free production and be able to identify their products as such to meet market access requirements”;
3. **note** that reference to “GM crops” in this paper includes other genetically modified organisms (GMOs), including veterinary and human medicines that are or contain GMOs, where that is practicable;

Controls imposed on GMOs under the HSNO Act

4. **invite** the Minister for the Environment to submit to the Cabinet Legislation Committee, by 31 August 2008, following necessary consultation:
 - (a) amendment to the Hazardous Substances and New Organisms (Methodology) Order 1998; or
 - (b) new regulations under section 140(1) of the Hazardous Substances and New Organisms (HSNO) Act 1996; or
 - (c) both (a) and (b),
to prescribe requirements for segregation and traceability schemes, that the Environmental Risk Management Authority (ERMA) would have particular regard to imposing as controls when considering applications to conditionally release a GMO, particularly any genetically modified (GM) crop;

5. **invite** the Minister for the Environment to provide drafting instructions to the Parliamentary Counsel Office to give effect to the legislative amendments or new regulations (or both) referred to in recommendation 4 (above) and recommendation 6 (below);
6. **note** that I propose that the amendment to the Methodology Order or new regulations (or both) would reflect the requirements of the current draft code of practice template for the seed crop industry following consultation in that context;
7. **note** an amendment to the Methodology Order or new regulations (or both) may not be able to require ERMA to impose mandatory controls, as ERMA has a discretionary power under section 38D of the HSNO Act to impose controls in respect of conditional release approvals for new organisms;
8. **note** that any amendment to the Methodology Order, imposed by ERMA as a condition on an application, might be open to challenge as being *ultra vires* section 9 of the HSNO Act, and further, that the amending order, or regulations (or both) could be the subject of a complaint to the Regulations Review Committee under Standing Order 315;
9. **note** that the Minister for the Environment's powers to direct ERMA are limited and that to implement some of these proposals as mandatory controls legislative amendment would be required;
10. **direct** Ministry for the Environment (MfE) officials to provide further advice by 1 December 2008 on any amendments to the HSNO Act required to implement these proposals as mandatory;

Public register of GMO approval locations

11. **direct** officials to:
EITHER
 - a. implement a public register of GM crop site locations and location controls dictated under future GMO approvals, including contained field tests;OR
 - b. implement a public register of GM crop site locations and location controls dictated under future GMO approvals, excluding contained field tests;
12. **note** that officials consider that inclusion of contained field trials in any public register of GMO approval locations would increase the administrative burden but offer no perceivable gain to nearby non-GM producers, whereas the alternative view is that there have been sufficient breaches of containment in field tests so far that they ought to be included;
13. **note** that such a register would be held by the Ministry of Agriculture and Forestry (MAF) as MAF would hold the most up-to-date site locations for field tests and sites of release for conditional releases of GMOs;

Code of practice for segregation

14. **note** that a segregation model exists based on the principles and best practice for segregation of crops;

15. **direct** MAF officials to publicly consult on the proposed new model for mandatory segregation (6 week consultation period, with immediate start);
16. **note** that section 17 of the HSNO Act prevents the Minister from directing ERMA to make adherence to a Code of Practice a mandatory requirement of any approval and a change to the HSNO Act would be required to change this limitation;
17. **note** the amendment to the Methodology Order or new regulations (or both) proposed in recommendation 4 to prescribe requirements for segregation and traceability schemes that ERMA would have particular regard to imposing as controls when considering any application to conditionally release a GM crop;

Framework for traceability

18. **note** that the European Union (EU) has a traceability framework for GM crops;
19. **direct** officials to report back to Cabinet Policy Committee by 31 August 2008 about how to adapt the EU's traceability framework to be consistent with New Zealand's regulatory system;
20. **note** that section 17 of the HSNO Act prevents the Minister from directing ERMA to make any specific control a mandatory requirement of any approval and a change to HSNO Act would be required to change this limitation;
21. **note** the amendment to the Methodology Order or new regulations (or both) proposed in recommendation 4 to prescribe requirements for segregation and traceability schemes that ERMA would have particular regard to imposing as controls when considering any application to conditionally release a GM crop;

Public register of non-compliance

22. **direct** officials to enhance the current non-compliance register for all field-tests and conditional release approvals for new organisms so as to:
 - continue to provide annual reports on non-compliance;
 - summarise audit findings on compliance with requirements;
 - notify reasons for non-compliance; and
 - notify any new or additional controls as a result of non-compliance;
23. **direct** officials to provide for links, where relevant, between the public register of GM crop locations on the MAF website (referred to in recommendations 11 and 13, above) and the enhanced non-compliance register on the ERMA website (referred to in recommendation 22);

Labelling of GM propagative material

24. **note** that officials from the Ministry of Consumer Affairs have advised that consultation requirements of the Fair Trading Act mean that Consumer Information Standard regulations could not be implemented before October 2010;
25. **direct** officials, led by the Ministry of Consumer Affairs, to draft a Consumer Information Standard under the Fair Trading Act for the labelling of GM propagative material for implementation as soon as is practicable and to report back to Cabinet to gain approval for the consultation required by statute;

Local government in GM crop management

26. **note** that template models of district plan changes and section 32 processes under the RMA have been developed;
27. **note** that officials advise that district plan changes using the template models might not survive a challenge unless territorial authorities are able to provide evidence of environmental effects and risks that have not already been addressed by ERMA – an unlikely event in the view of officials;

Domestic liability regime for living modified organisms (LMOs)

28. **note** that following the RCGM report, the government gave detailed consideration to a range of additional controls including strict liability for harm caused by GM, compulsory insurances, statutory compensation, remediation funds and the imposition of bonds and decided not to support any of those options;
29. **note** that on 3 February 2003 the Cabinet Business Committee, having Power to Act [CAB Min (03) 3/2-8]:
 - a. noted that while existing liability rules will not always operate effectively to encourage precaution and provide compensation in relation to GM, this is not unique to GM and so devising a liability regime solely on the basis of a GM/non-GM distinction would not be sound in principle; and
 - b. agreed that to strengthen incentives to comply with the regime, the HSNO Act 1996 should be amended to cover new organisms, to include a strict civil liability rule for harm caused by non-complying activities and a civil penalty regime for breaches [CBC Min (03) 3/16];
30. **note** that on 12 May 2008 Cabinet Business Committee:
 - a. noted that New Zealand has yet to finalise a domestic liability regime for LMOs [CBC Min (08) 13/24 para 5]; and
 - b. invited the Minister for the Environment to provide a paper to Cabinet on a proposed domestic liability regime for LMOs, as soon as practicable [CBC Min (08) 13/24 para 6];
31. **note** that New Zealand's existing common law liability framework applies to harm caused by GM activities and that this is supplemented by a civil penalty regime for breaches of the HSNO Act and strict civil liability regime for harm caused by activities in breach of the HSNO Act involving new organisms;
32. **note** that New Zealand has participated in negotiations on liability and redress for damage resulting from the trans-boundary movement of GMOs under the Cartagena Protocol on Biosafety; that the recent meeting of the parties agreed to work towards legally binding rules and procedures on an "administrative approach" aimed at remediating damage to the conservation and sustainable use of biological diversity and non-binding guidelines on civil liability (with a legally binding component that would identify key elements of a civil liability regime) but that the final instrument will not be formally settled until early 2010;
33. **invite** the Minister for the Environment and the Minister of Justice to report back to Cabinet by 1 December 2008 with recommendations on a system which involves strict liability and redress with primary responsibility being directed to the producer or importer of the GMOs;

Publicity

34. **agree** that the Minister for the Environment may publicly release this paper, including Cabinet decisions, once Cabinet has made a decision;
35. **agree** that the Minister for the Environment may make public and media announcements about this decision at the relevant time.

Hon Trevor Mallard
Minister for the Environment

Date

Appendix 1: Intentional damage to GM crops in New Zealand

The main concern about an open register genetically modified (GM) crops is that location information could be used by individuals or groups to interfere with, damage or destroy crops or other organisms, or to intimidate those involved with the management of the GM crops or other genetically modified organisms (GMOs). There are no conditional releases or releases of GMOs currently in New Zealand. Although specific location information about GM field tests has not been made public, some individuals have demonstrated in the illegal, intentional damage of GM field tests that they can deduce the location of GM research plots. The locations of the organisations involved (for example, Crown Research Institutes) and the controls placed on GM field tests are both on public record. The extra security required of GM field tests, for example, can act as an indicator of which plot contains GMOs.

Examples of damage relating to New Zealand GM research are shown below:

Crop & Food Research, Lincoln

- 1999 – A field test of potatoes modified for soft rot resistance was dug up and destroyed.
- 2002 – A containment glasshouse was broken into and more than 1000 plants from three research projects were damaged. Many of the plants were not GM.

Scion Research, Rotorua (Forest Research)

- 2008 - Scion Research - 17 GM pine trees and 2 control trees were destroyed after people had cut through a security fence. This has resulted in a delay in the research programme, including making information available on the environmental effects of GM trees.

AgResearch

- 2001 – A scientist who was undertaking research on transgenic cows had his car damaged and he and his family were threatened because of his research.
- 2001 – Two Molotov cocktails started a fire beside an AgResearch fence line and anti-GE graffiti was sprayed on a nearby shed.

Corson Grain

- Following the finding of the “Corngate” GM corn growing in New Zealand, there was an attack on two cars parked near the Corson general manager’s house. In fact the damaged cars belonged to a neighbour.

Officials are also aware of a recent media release in New Zealand in which a spokesperson from the Soil & Health Association suggested in reference to Crop & Food Research’s recent application to field test genetically modified onions, spring onions, garlic and leeks that individuals would be “better off” pulling out these GM crops than making a submission to ERMA. GE Free (NZ) also released a press statement expressing concern about ERMA’s approach to consideration of GM field test applications stating that “If the system continues to [ignore public concerns and] is not corrected, the result is likely to be legitimate concerns get pushed underground with other forms of protest arising”.

As the measures proposed could apply in future to GMOs other than crops, potentially including GM animals, it is important to mention that there has been ongoing damage to research facilities and threats to persons by animal rights activists. These incidents relate to research involving both GM and non-GM animals. The seriousness of the actions and threats made by animal rights activists was considered by the Ombudsman when he considered whether to release the names of people appointed to Animal Ethics Committees under the Animal Welfare Act 1999. He agreed to withhold member’s names from the applicant because of the threats. There is no evidence that damage or harassment would be less likely if location information was publicised.

Appendix 2: International experiences with GM register

European Union Directive 2001/ 18/ EC, Article 31 3(a) and 3(b) sets out the requirements for a register of GMOs for deliberate release. 3(a) covers releases for a purpose other than placing on the market (for example, field tests, which in the EU are a form of release) and 3(b) covers releases for the purpose of placing on the market (for example, commercial releases). In general, both registers must be public.

It is important to note that the degree of specificity around the location of GMOs deliberately released is not prescribed in the Directive. This is reflected in the range of ways in which member states have implemented their registers. For example, the information may refer to regions or districts where GMOs are located, and some EU members do not specify information until after the GM crops are harvested.

According to the Second Report from the Commission to the Council and the European Parliament "On the experience of Member States with GMOs placed on the market under Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. {SEC(2007) 274}", industry expressed concern about the release of the exact location of field tests on the basis that this often resulted in the harassment of farmers and ultimately in the destruction of the tests by anti-GM activists. The report notes that most EU member states provide the location of the field trial at the level of the municipality or town rather than the exact location in order to reduce the possibility of destruction of sites.

A personal communication between the United Kingdom's Department for Environment, Food and Rural Affairs (Defra) and ERMA indicates that France has recently referred a domestic legal case on this issue to the European Court of Justice for a ruling (expected by late 2009) on whether a precise location reference has to be given for GM tests, or whether and to what extent less precise location details can be provided to take account of the risk of intentional damage. Information from Defra and from a recent paper in the Swiss Journal of Consumer Protection and Food Safety indicates that, as a result of intentional damage of GM crops, several EU member states are reviewing the precision of information made available about GM crop locations.

In addition, a recent cable from New Zealand representatives in Paris indicates that the French government intends to enact new Biotechnology Legislation. As a balance to provisions to make location information on GM crops or tests publicly available, the French government proposes to create a crime for the unauthorised destruction of GM crops. The crime is punishable by two years imprisonment for commercial crops and three years for research crops.

In Australia, the Australian Office of the Gene Technology Regulator provides a record of field trial locations. The purpose is to show the location of all field tests involving the intentional release of GMOs into the environment under limited and controlled conditions. The site includes information on both current and previous (post-harvest) tests that are currently regulated by the Gene Technology Regulator across Australia. The maps provide approximate latitude and longitude coordinates. Information on locations of commercial crops is not provided.

Appendix 3 Draft generic template for a code of practice for segregation of GM crops

CROP SPECIES				
1.0 SEED IDENTIFICATION				
1.1.1 Traceability: Unique reference code (BCH number); origin; quality; variety; regulation; technology provider terms (e.g. Bt Stewardship); and treatments.				
2.0 SEED PRODUCTION				
2.1 FIELD MANAGEMENT				
2.1.1 Crop production area: Location; paddock history – rotation; paddock identification; and identification of neighbouring crops (use of mapping tools such as SCID, the New Zealand Seed Crop Isolation Distance Mapping System). Paddock inspection – weed species, volunteer identification and control, fence line buffers.				
2.1.2 Field planting: Equipment, pre-sowing machinery inspections; post-sowing machinery clean-down; documentation Machinery and equipment clean-down procedures (validated).				
2.1.3 Field harvesting: Equipment, machinery inspections; clean, secure, leak-proof transport; on farm storage inspections; identity labelling for harvested seed; and documentation of management procedures. Machinery and equipment clean-down procedures (validated).				
2.1.4 Post-harvest field management: Management of hard-seed, volunteers, crop rotation, inspection and monitoring, and documenting the management procedures.				
Crop rotation needed?	Year 1 ____ crop	Year 2 ____ crop	Year 3 ____ crop	Year 4 ____ crop

2.2 POLLINATION MANAGEMENT		
2.2.1 Fertility mechanism:	Self-fertile / Outcrossing potential:	
2.2.2 Pollen production:	___ days from planting	___ days duration
2.2.3 Pollen longevity:	___ hours	
2.2.4 Pollination Vector:	(a) Bee/Insect pollinated: Y/N	Pollen distribution (by bee/insect): Maximum distance ___ km
	(b) Wind pollinated: Y/N	Pollen distribution (by wind): Maximum distance ___ m
2.3 POLLINATION ISOLATION		
3.3.1 Spatial Isolation	Isolation distance required by OECD seed certification scheme/ other:	Minimum distance ___ m
3.3.2 Physical Isolation	Additional physical buffers/barriers to pollen flow may be required	Windbreaks/hedgerows Buffer rows Local beehive management
3.3.3 Temporal isolation:	Share cropping information with neighbours. Inter-fertile crops/ feral plants within isolation boundary? Y/N Adjust planting dates so crops do not pollinate at the same time as neighbouring crops.	
3.0 SEED PROCESSING		
3.1 WORK FLOW and CRITICAL CONTROL POINTS		
For individual organisations and sites, identify work flow issues and Critical Control Points which could lead to the loss of identification and traceability, contribute to commingling, result in accidental substitution, non-representative sampling, spoilage or pest contamination.		

3.2 EQUIPMENT & MACHINERY	
For each piece of equipment used in seed production and processing (in the following section) document:	<ul style="list-style-type: none"> a) Whether the company owns or will rent/borrow it? b) Whether it is dedicated GM or dual-use? c) The Standard Operating Procedure for its cleaning and maintenance, and how this procedure was validated.
3.3 DOCUMENTATION	
Document all harvesting and handling activities. With good records, you will have a better chance of identifying causes of problems should commingling occur.	<ul style="list-style-type: none"> 1) Field records, location, planting date, harvesting date, management 2) Equipment records, cleaning activities 3) Handling activities, e.g. Seed cleaning and dressing, testing, treatments 4) Test results, storage, transport, sales
3.3.1 Field equipment:	Planters; Harvesters; Tractors; Augers
3.3.2 Transport equipment:	Trailers; Trucks
3.3.3 Storage:	Drying bins; Grain dryers; Storage Bins
3.3.4 Seed Processing:	Seed Cleaning/Dressing Equipment, Huskers, Shellers; Augers; Elevators; Seed treatments
3.3.5 Testing and Certification:	Seed sampling equipment
4.0 TRACEABILITY	

Appendix 4:

Reporting template for Audit and Compliance Information



**Submission Form to Compliance Co-ordinator , ERMA New Zealand
for Audits of Field Tests (& Conditional Releases)**

Compliance

Co-ordinator Contact:

**MAF Auditor contact
for further information**

Approval Code:

Approval Holder Name:

Approval Category:

Approval Title:

Date of Audit:

Seasonal? (ie. 1 of 3)

Next audit date:

FIELD-TEST (CONDITIONAL RELEASE) COMPLIANCE WITH REQUIREMENTS

Compliance Control / Reference	Details of Non- compliance	Follow-up Action taken
1.		
2.		
3.		

Appendix 5: Model Plan Change Provisions - Genetic Modification

District Plan Provisions

ISSUE: [Optional – Not a mandatory part of the plan]

The unintended or unmanaged release of genetically modified plants, organisms, or material into the environment of [INSERT NAME OF DISTRICT OR CITY] can adversely affect flora and fauna and the health and wellbeing of local residents.

OBJECTIVE:

To ensure the unintended or unmanaged release of genetically modified plants, organisms or material does not expose flora, fauna or residents in [INSERT NAME OF DISTRICT OR CITY] to adverse effects.

POLICIES:

Policy 1:

The growing, propagation, farming, harvesting, or breeding of genetically modified crops and organisms shall be managed in such a way that avoids the:

- (a) Unintended cross contamination with flora and fauna outside the *approved genetic modification facility*;
- (b) Unintended release of genetically modified plants or organisms

Policy 2:

Transportation of genetically modified plants, organisms, or material within the [INSERT NAME OF DISTRICT OR CITY] shall be managed in such a way that avoids any possibility of unintended release or dispersal.

METHODS: [Optional – Not a mandatory part of the plan]

RMA methods shall include:

- (a) Rules in the district plan that control growing, propagation, farming, harvesting, breeding, release or transportation of genetically modified crops and organisms
- (b) Rules in the district plan to manage the location of *approved genetic modification facilities*

Other methods include:

- (c) Working with the regional council to develop rules for inclusion in regional plans to manage any unintended discharge or genetic modified materials into air or water.

RULES:

Discretionary Activities:

Rule 1

The following shall be discretionary activities throughout the [INSERT NAME OF DISTRICT OR CITY]:

- (a) growing, propagation, farming, harvesting, or breeding of genetically modified crops and organisms
- (b) transportation of genetically modified crops and organisms to and from any *approved genetic modification facility*

Rule 2

In considering an application for a resource consent under rule 1, the [INSERT NAME OF DISTRICT OR CITY] shall have particular regard to:

- (a) The design and location of the *approved genetic modification facility* and the degree to which it prevents the unintended release or distribution of genetically modified material; and
- (b) The degree to which restrictions placed on the use, storage, or movement of genetically modified plants, organisms or material through other legislation are able to be complied with.

Prohibited Activity:

The planting, propagation, growing, farming, harvesting, transportation or distribution through any means of genetically modified plants or organisms outside *approved genetic modification facilities* is a prohibited activity in the [INSERT NAME OF DISTRICT OR CITY].

Definitions:

Approved genetic modification facilities in the context of this plan shall mean a site or building that has been approved by ERMA as being appropriate for the growing, propagation, farming, harvesting, release, or storage of genetically modified plants or organisms.

Transportation: for the purposes this plan, movement or carriage of genetically modified material by any means including discharges into air or water.

Section 32 Template:

Environmental Issue to be addressed through the plan change:

[Insert issue here]

Background

[Introduction to the issue, why it needs to be managed through the plan, relationship to any other legislation, definitions of any terms used in the report etc.]

Nature of effects

[Description of the effects that are to be managed, including why they need to be managed].

Objective

[Insert Objective Here]

The extent to which the objective[s] is the most appropriate way to achieve the purpose of the RMA

[Insert comment and background information to show the objective achieves the purpose of the RMA (s.5)].

Policies

Risk of acting or not acting if there is uncertain or insufficient information:

[Insert commentary on what would happen if nothing was done or information was inadequate]

	Efficiency	Effectiveness	Benefits	Costs
Policy 1				
Policy 2				

Comment

[Insert commentary summarising the evaluation and any alternative rules or methods that have been considered].

Rules and other methods:

Risk of acting or not acting if there is uncertain or insufficient information

[Insert commentary on what would happen if nothing was done or information was inadequate]

		Efficiency	Effectiveness	Benefits	Costs
Rule Method: 1	or				
Rule Method: 2	or				

Comment

[Insert commentary summarising the evaluation and any alternative rules or methods that have been considered].

Appendix 6: Liability rules

Under current law, persons suffering any harm caused by a GM activity or technology (or generally) may be able to bring a claim to recover their loss under grounds including negligence, nuisance and breach of statutory duty. However, liability rules do not provide compensation for every kind of harm – only personal injury, property damage and certain forms of economic loss. They are generally less effective in addressing harm to many individuals or the environment in situations where it is difficult to show causation and they are not capable of addressing harm that cannot be easily quantified or compensated in monetary terms. Therefore cultural, ethical and spiritual issues related to GM that arise are not ones that can be addressed by liability rules. They need to be addressed in other ways, such as through the regulatory process that applies to GM activities or industry management procedures.

The main objectives of liability rules are to encourage precaution, provide compensation for harm and put right (or remediate) damage. Imposing an obligation on those engaging in an activity to pay for harm caused provides incentives to reduce the risk of harm, provided it is cheaper to do so than pay for the expected cost of the harm. The ability of a person harmed to claim damages by way of compensation underpins and reinforces the precaution objective. The incentives for a potential injurer to take precautions will be reduced if he or she is not likely to bear the full cost of the harm they cause.

For liability rules to work well, it is therefore important that persons suffering harm bring a claim to recover the cost of that harm and that the claim is likely to be successful, with the injurer meeting the costs of harm. The following table indicates when liability rules are likely to work well, and when they are not.

<i>Liability rules will be effective where:</i>	<i>Liability rules will be less effective where:</i>
The harm is to a few individuals	The damage is diffuse
It is easy to identify the injurer	It is difficult to identify the injurer
It is easy to establish causation	It is difficult to establish causation
The loss is easy to quantify	It is difficult to quantify the loss
The harm is foreseeable	The harm is not foreseeable
The injurer can pay for cost of harm	The injurer cannot pay the cost
There is no time lag between act and harm	There is a time lag between act and harm
The likely outcome of the claim is clear	The likely outcome of the claim is uncertain
Costs of pursuing the claim are modest	The costs of pursuing a claim are high

Certain GM activities that may potentially cause harm were assessed against these indicators. Some non-GM activities that have parallels to GM activities were also assessed against the indicators, as were other activities without a direct GM counterpart.

This assessment indicated that, within the range of GM activities, liability rules will be effective in some cases and will be less effective in others. They will tend to be less effective where, for example, harm is to many individuals or the environment, it is difficult to show causation and the injurer is not easy to identify.

This result is the same for non-GM activities – liability rules will sometimes be effective and sometimes will not – for the same reasons that apply in the GM context. For this reason there does not appear to be a principled basis for devising a special liability regime solely on the basis of a GM/non-GM distinction.