

# **ERMA New Zealand Evaluation & Review Report**

Application for Approval to Field  
Test in Containment any Genetically  
Modified Organism

**Application Numbers:  
GMF98005, GMF98006**

Genetically Modified Herbicide and Insect Tolerant  
Maize (*Zea mays*)

## Key Issues

As containment applications the key issues relate to the adequacy of containment and proposed controls to manage risks, and whether the residual risks are either of negligible significance, or are outweighed by the benefits of the field trial.

The applicant has identified as a benefit the survival of the plant breeding station in New Zealand that depends on the continued breeding of crops for overseas clients. This breeding programme, according to the applicant, provides employment to up to 25 people. ERMA New Zealand notes that the applicant has not identified what number of employees or percentage of funding is allocated to the production of the transgenic hybrids.

ERMA New Zealand understands that the transgenic lines of maize proposed for field test in New Zealand are derived from the same lines as have been released for general use in the Northern Hemisphere. The Authority may wish to consider the necessity of a field trial in New Zealand of lines approved for release overseas unless there is an intention to monitor non-target effects on an ongoing basis. The benefits to be derived from the production of transgenic seed for export from a 0.4 hectare field trial should be considered in the context that the same lines of seed can be bought in bulk in the Northern Hemisphere.

The issues that relate to the proposed field trials are the potential for:

- horizontal gene transfer
- development of resistance to *Bt* in Lepidoptera in New Zealand
- secondary poisoning of beneficial insects
- benefit to New Zealand

The issue of gene transfer to non-target organisms has, *inter alia*, been raised in submissions also.

The small scale of the trial (0.4ha each), the isolation from other maize crops by at least 400m, the use of paper bags to prevent pollen escape, regular inspections, and the post harvest monitoring, included in the proposed controls are designed to minimise unintended/accidental escape of transgenes from containment, should the application be approved.

These applications involve the importation of transgenic maize seed and then field trial of the same. In this respect these applications are similar to the sugarbeet applications NOC98003 (importation into containment) and GMF98004 (field trial of a GMO). The import of the maize seed is not requested prior to any decision on the field test so both the import and field test have been dealt within the field test applications. The Authority may wish to consider the implication that a decision to approve the field trials would also imply an approval to import the transgenic maize seed into containment prior to sowing.

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# 1. Introduction

## Application Brief

- 1.1 Pioneer New Zealand Inc, a subsidiary of Pioneer Hi-Bred International, is seeking approval to import and field test genetically modified organisms in containment under *section 40(1)(a)* and *(c)* of the Hazardous Substances and New Organisms (HSNO) Act 1996.

The applicant proposes to import seed and perform two seasons (1999/2000 and 2000/2001) of small scale field tests of herbicide and insect tolerant maize at Pukekohe, in the Waikato region, for the purpose of increasing inbred seed and developing hybrid seed containing the PAT and *Bt* genes. The seed would be exported to France following each harvest.

The herbicide tolerant maize line T25 (GMF98005) is modified by the p35S/AC plasmid which includes the *pat* gene of synthetic origin for glufosinate herbicide (Buster) resistance based on the *pat* gene of *Streptomyces viridochromogenes*. It also contains an ampicillin resistance gene (*ampR*) of *Escherichia coli* origin, which is not expressed in plants.

The insect tolerant maize line MON 810 (GMF98006) was produced by two plasmid vectors PV-ZMBK07 and PB-ZMGT10. The application states that MON 810 line expresses only the *cryIA(b)* insect control protein derived from the common soil bacterium *Bacillus thuringiensis* subsp. *Kurstaki* specific to Lepidoptera larvae.

The purpose of this application falls under *section 39(1)(b)* of the HSNO Act 1996; *Field testing any new organism*.

The containment measures proposed include the isolation of the transgenic maize from commercial maize crops by at least 400m and the containment of the tassels (male flowers) in bags to prevent pollen dispersal.

Although the applications were submitted separately many of the issues are the same for both applications, and the submitters and their written comments are largely the same for both applications. Therefore the applications are dealt within one ERMA Evaluation and Review (E & R) Report. Where issues do differ, such as risks associated with the nature of the modifications, the maize line is clearly identified.

## Project Team

- 1.2 The **project team** consists of the following ERMA New Zealand and external members:

Project Leader (Operations Group)	Denise McDonald
Scientific Advisor (Science & Research Group)	Dr Abdul Moeed
Scientific Advisor (Science & Research Group)	Dr Deborah Read

Policy Advisor (Policy & Analysis Group)	Janet Gough
Policy Advisor (Policy & Analysis Group)	Bevan Tipene-Matua
External Scientific Advisor	Dr Clive Ronson (University of Otago)
Report Sign-off Manager	Dr Donald Hannah

## Purpose of the Evaluation & Review Report

1.3 The purpose of the E&R Report is to assist and support decision-making by the Authority by:

- consolidating the information provided by the applicant and submitters, and obtained from other sources, into a common format which enables conflicts and similarities to be readily identified;
- presenting the relevant information in a format and sequence which is consistent with the decision-making requirements of the Act and of the Methodology;
- evaluating the information (and assessments) provided to give an opinion on its quality and credibility, to identify gaps and to analyse overlaps and conflicts;
- identifying key issues arising from the evaluation relevant to the Authority's consideration of applications; and
- where controls or conditions may be applied, providing technical advice on the control or condition options available.

The advice contained in the E&R Report is given solely on the basis of an objective and expert review of the application and the assessments of risks, costs and benefits provided in relation to that application. It does not make recommendations, nor direct or prejudge the decision that the Authority might make on the application.

## 2. Process and Information Provided

- 2.1 The application was formally received in terms of statutory timing on **23 September 1998** and following verification by ERMA New Zealand was publicly notified on the 26 September 1999. Submissions closed on **9 November 1998**.
- 2.2 In undertaking the review and evaluation of the application ERMA New Zealand identified a number of deficiencies in the information. Further information was sought from the applicant on 4 November 1998, in accordance with *section 58(1)* of the HSNO Act.
- 2.3 The application was *stalled* with respect to statutory timeframes on 16 December 1998, pending receipt and review of the further information.
- 2.4 Further information, provided on 6 November 1998 and 22 February 1999 (*Appendix 4 and 5*), was reviewed by ERMA New Zealand and it was considered insufficient for the application to proceed. Specifically the applicant was requested to provide further information on the following matters:
  - Information to support claims regarding pollen dispersal and lack of insect interest.
  - Information on the field trial management and harvesting procedures.
  - Additional information on the financial benefits to New Zealand associated with the proposal.
- 2.5 This information was provided on 14 May 1999 (*Appendix 6*).
- 2.6 The applicant provided, on 21 July 1999, information regarding recent research on the effects of *Bt* pollen on Monarch caterpillars (*Appendix 7*).

### Reports from other Government Agencies

- 2.7 Various government agencies were notified of the receipt of the application under *section 53(4)* of the Act.

### Agencies consulted with

- 2.8 The **Department of Conservation** provided comment on the application in a fax dated 10 November 1998. Refer to *Appendix 1* of this report. Michael Cameron, New Organisms Officer, identified the following issues which ERMA should take into account in its consideration:
  - Ensuring the maintenance of refugia of non-transgenic corn to prevent any potential for susceptible insects to acquire resistance to *Bt* insecticide.
  - Ensure the adequacy of containment of the pollen within the paper bags and establishing whether 400m is sufficient isolation distance.

- Examining the potential for genetic material to escape through means other than sexual reproduction.
- 2.9 Refer to section 5, *pages 16-26* and *Appendix 2* and *3* of this report for further discussion of these issues.

## Submissions

- 2.10 A total of **10** submissions were received on application GMF98005, and **9** on GMF98006. Of which **4** submitters in total indicated that they wish to be heard in support of their submissions.

Submissions were received from the following parties, of which all submitted on both applications except R.A.G.E who only submitted on GMF98005.

**Table 1: Summary of Submissions Received**

Submitter No. GMF98005/ GMF98006	Submitter Name	Organisation / Contact	Contact Details	Wish to be Heard?
1/1	Walter Treitag	Private	28 Moana Road Days Bay Eastbourne	No
2/2	Tony Phillips	Private	1/10 King Street Nelson	No
3/3	Jane Hunter	Private	1/10 King Street Nelson	No
4/4	Berylla Berylla	Private	24 Montcalm Street Nelson	Yes
5/5	Susie Lees	Private	17 Alton Street Nelson	Yes
6/6	Nelson Soil & Health Group	Sol Morgan	31 Quebec Road Nelson	No
7/-	R.A.G.E. Revolt Against Genetic Engineering	Mary Anne Howard-Clarke	P O Box 30762 Lower Hutt	Yes
8/7	Oraina Jones	Private	47 Ellis Street Brightwater	Yes
9/8	Federated Farmers of New Zealand (Inc)	Bronwyn McMillan	P O Box 715 Wellington	No
10/9	Catherine Johnson	Private	Main Road South Wakefield Nelson	No

Copies of all submissions received are attached to this report. The *Summary of Submissions Reports* is included as *Appendix 2*. Refer also to section 5, *pages 16-26* of this report for further discussion of issues raised in submissions.

## Supporting Documentation for the E&R Report

- 2.11 No **Confidential information** was provided as part of the application.

2.12 The following documents were available for the evaluation and review of the applications:

1. **Application Forms 4:** (ER-AF-NO4-3 9/98) Field Test (Including Large Scale Fermentation) in Containment any Genetically Modified Organism.
2. Documents in support of the applications (including site maps).
3. Copies of cited literature in the applications and additional information.
4. Public submissions received.
5. Department of Conservation comment (Appendix 1 of this report).
6. *Summary of Submissions Reports* (Appendix 2 of this report).
7. Further Information received from the Applicant (Appendices 4-7 of this report).

### **Additional Information**

2.13 Additional information could be sought with respect to the following issues if the Authority concludes these are material issues or ones that mean that insufficient information is available for a decision to be made:

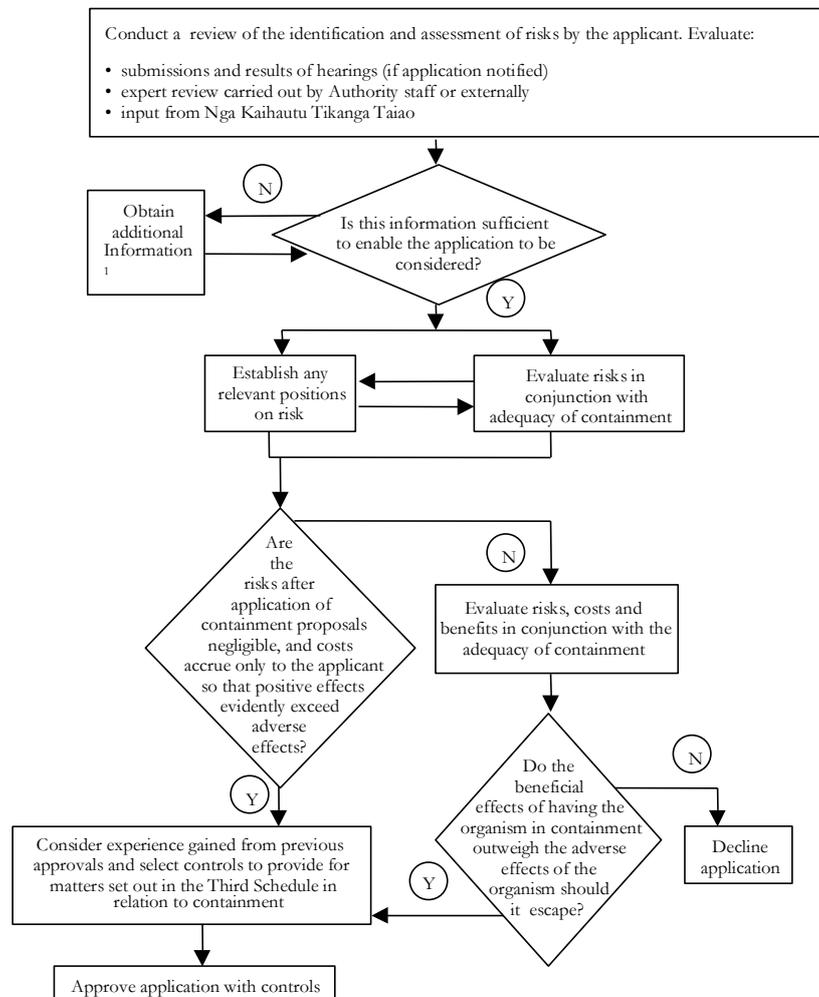
- Formal identification and consideration of all the possible risks and risk pathways and costs and benefits.
- Information on what susceptible Lepidoptera occur in New Zealand and whether they occur in the area proposed for the field trials.
- Detailed procedures to show how containment is assured during seed import and transport and during offsite processing of the seed prior to export.

### 3. Consideration of the Application

- 3.1 This application is to be considered via the decision path, *Figure 3* in the ERMA New Zealand Protocol 7, *Decision Paths*. This decision path relates to applications to develop/import/field test any new organism in containment. A copy of the relevant decision path is included as **Figure 3**, and also as a foldout page at the back of this report.
- 3.2 Following the initial steps in the decision path, the application was received and deemed appropriate and valid. An initial review of the identification and assessment of risks by the applicant was undertaken by ERMA New Zealand and is presented in the following sections.

**Figure 3 Decision path for applications to develop/import/field test any new organism in containment (section 40)**

Note <sup>1</sup>: The Authority may decline an application if insufficient information is available to enable it to determine the adverse effects.



## 4. Issues Raised in Submissions

4.1 The following table presents a summary of the key issues raised in submissions. Refer also to the *Summary of Submissions Report* included as *Appendix 1* of this report for a complete breakdown of specific issues raised under each heading identified in **Table 2**.

**Table 2: Summary Table of Issues Raised in Submissions**

Issue Number	Issue
1	Risk of Gene Transfer
2	Risks to Human Health
3	Containment System and Procedures
4	Adequacy of Risk Assessment
5	Economic Risks
6	Environmental Issues
7	Benefits
8	Issues of Knowledge and Ethics

4.2 Significant issues identified in Table 2 above have been further analysed by ERMA New Zealand below.

### Issue 1: Risks of Gene Transfer

4.3 Many submissions noted their concern regarding the transfer of the insect and herbicide genes to other species and cross pollination to conventional maize crops.

The issue of risk of gene transfer is further discussed in section 5 of this report, *page 22* and below in section 4.6 with regards to the potential for transfer of antibiotic resistance.

### Issue 2: Risks to Human Health

4.4 Although the purpose of the field trial is to increase inbred seed and develop hybrid seed for export, submitters have raised risks to human health arising from consumption.

4.5 Depending on the refining process used there is usually no, or very little, DNA and protein resulting from the genetic modification present in highly refined food ingredients such as oil and starch (European Commission Scientific Committee for Food, 1999). However, ERMA New Zealand notes that DNA and protein will be present in whole kernels and corn meal.

4.6 There is no known adverse health effect from the human consumption of processed transgenic maize. The application includes a copy of the assessment of the European Union Scientific Committee on Plants (1998) that summarises their review of available data. The main points of the Scientific Committee with respect to health are:

- No toxic effects have been observed in acute toxicity studies.

- Use of the natural *Btk* insecticides has not produced evidence of allergenic responses.
  - *Btk* toxin and PAT protein do not have homology to known allergens.
  - Transgenic maize is substantially equivalent to non-transgenic maize.
  - There is no  $\beta$  lactamase activity confirming no risk of transfer of ampicillin resistance from the bacterial ampicillin resistance gene in herbicide tolerant maize.
  - In the unlikely event that there was transfer of the PAT gene to gut bacteria, expression is not likely to occur as the gene is under the control of a plant promoter that is not functional in bacteria.
  - In the remote event that the PAT gene was to be expressed in gut micro-organisms or in human or animal cells no negative effects are expected as the only known substrate of PAT is glufosinate ammonium.
  - There was no effect on growth performance and body composition of broiler chickens fed herbicide tolerant maize.
  - The glufosinate-derived residues do not concentrate in any maize processed fractions that are relevant to food or feed items. No residues above the limit of detection are to be expected in food of animal origin derived from livestock fed with transgenic maize treated with glufosinate ammonium.
- 4.7 The Committee commented however that applied *in vitro* methodology to study the survival of *Btk* toxin and PAT can be improved, and use of an isolated protein in toxicity studies does not adequately model degradation of the same protein when fed as an integral component of the diet.
- 4.8 The Committee concluded *'that there is no evidence to indicate that the seeds of insect-resistant maize when grown, imported and processed in the manner indicated, are likely to cause adverse effects on human or animal health ...'* and *'that there is no evidence to indicate that the use of genetically modified maize as any other maize, is likely to cause adverse effects on human or animal health ...'*
- 4.9 ERMA New Zealand notes that a recent field study<sup>1</sup> has however indicated that under some conditions insect tolerant maize may enhance maize's safety for human and animal consumption as a result of lower concentrations of a class of mycotoxins, fumonisins. Fumonisin is classified by the International Agency for Research on Cancer as a probable human carcinogen.

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<sup>1</sup> Munkvold G, Hellmich R and Rice L. Comparison of fumonisin concentrations in kernels of transgenic Bt maize hybrids and nontransgenic hybrids. Plant Dis 1999; 83:130-8.

- 4.10 ERMA New Zealand notes that each proposed field trial is small scale (0.4 hectare) and seed will not enter the food chain. All seed will be either destroyed, or exported for future breeding efforts or testing.

### **Issue 3: Containment System and Procedures**

- 4.11 Several submitters questioned the adequacy of containment and whether the pollen can be fully contained by the use of paper bags over the tassels in all weather conditions. The Federated Farmers noted that they are *Satisfied with the protocols of the proposed biosecurity controls for this application.*
- 4.12 The Applicant has stated in *Appendix 6* that the bags are secure and unable to be removed by climatic conditions and the bags prevent all access to the pollen by insects. ERMA New Zealand notes that the issue of birds or rodents damaging the bags, as raised in the comments from the Department of Conservation (*Appendix 1*), has not been addressed by the applicant but can be addressed through controls requiring monitoring and remedying any such occurrence.
- 4.13 The issue of adequacy of the containment system and procedures is further discussed in section 5 of this report, *page 20*.

### **Issue 6: Environmental Issues**

- 4.14 Increased herbicide use and its negative impact on ecosystems was an issue raised in submissions on application GMF98005 for maize line T25. The applicant has addressed the safety of using glufosinate herbicide and has suggested the likely positive agronomic and environmental impacts of glufosinate tolerant maize (application, *question 13*). The applicant has not explained whether the herbicide will be used in weed control for the proposed field trial.
- 4.15 Submitters on application GMF98006 for maize line MON810 raised concerns regarding the effect on beneficial organisms and development of resistance to *Bt* sprays used by organic farmers.
- 4.16 ERMA New Zealand notes that prolonged exposure of susceptible insects to insect tolerant maize may lead to the development of resistance to *Bt*, and consequential reduced efficacy of *Bt* -based biopesticides such as Dipel. The application does not present information on susceptible insects likely to feed on maize line MON810 at the trial site. However the small size of the trial and the inclusion of non-modified maize rows will act as a refuge to minimise the risk of resistance developing.
- 4.17 Submitters raised the concern of the development of super weeds. ERMA New Zealand notes that maize is a cultivated crop and does not have weedy tendencies nor do the modifications confer any potential for weediness. Also, there are no close relatives of maize in the wild in New Zealand and given compliance with the proposed controls the risk of the insect or herbicide resistance genes being transferred, either by cross breeding or by gene transfer, would be remote.

## Issue 7: Benefits

- 4.18 A number of submitters questioned whether the purpose of the trials for using New Zealand, as an off-season nursery, with little benefit to New Zealand, is a valid reason to allow the possible contamination of New Zealand with modified maize.
- 4.19 The Federated Farmers recognised that although the trials will have little immediate benefit to New Zealand growers that *'it is important to demonstrate our commitment to this technology in order that we do not preclude ourselves from any long term benefits'*.
- 4.20 Refer to Assessment of Benefits section 5.11, *page 27*.

## 5. Identification, Assessment and Evaluation of Risks, Costs and Benefits

- 5.1 The applicant is required to identify and assess risks, costs and benefits. ERMA New Zealand's role is to evaluate the information, looking for completeness of the identification, and the accuracy and completeness of the assessment. As part of this evaluation ERMA New Zealand may identify risks, costs and benefits not addressed by the applicant.

This section therefore contains an identification, assessment and evaluation of risks, costs and benefits associated with this application. This section also identifies any significant omissions, conflicts or gaps in the information provided.

- 5.2 The applicant has not indicated the method used to identify risks, nor is there evidence of a systematic approach to identifying risks.

### Identification of Risks

- 5.3 The following table presents an identification of risks associated with this application, following the format laid out in the *Methodology*. This includes risks identified in the application, submissions, by the external scientific reviewer and by ERMA New Zealand.

In identifying risks in the application the **applicant** has made no explicit reference to a number of the matters identified as being relevant in the *Methodology* and the HSNO Act.

These include:

- The life-supporting capacity of air, water, soil and ecosystems [*clause 9(a)* of the *Methodology*].
- Significant displacement of any native species within its natural habitat [*clause 10(a)*].
- Significant deterioration of natural habitats [*clause 10(b)*].
- Significant adverse effects on New Zealand's inherent genetic diversity [*clause 10(d)*].
- The ability to cause disease, be parasitic, or become a vector for human, animal or plant disease [*clause 10(g)*].

- 5.4 Risks identified by the applicant that impact on these factors have been included in Table 3. Additional risks identified by ERMA New Zealand staff and the external reviewer, but not identified by the applicant, have been included in Table 3.

**Table 3: Identification of Risks**

(Source: *Annotated Methodology for the consideration of applications for Hazardous Substances and New Organisms under the HSNO Act 1996, August 1998*)

Name of the Risk	Statutory Reference (refers to relevant clauses of the <i>Methodology</i> )	Reference Note
<p><b>Social and Community Risks</b></p> <ol style="list-style-type: none"> <li>General unease of some sectors of society to crop field test applications.</li> <li>General unease of some sectors of society on the general issue of genetic engineering.</li> </ol>	<p>9(b) The maintenance and enhancement of the capacity of people and communities to provide for their economic, social, and cultural well being; and the reasonably foreseeable needs of future generations.</p>	<p>Refer to the <i>Summary of Submissions Reports, Appendix 2</i> of this report.</p>
<p><b>Containment Risks (also see 14. below)</b></p> <ol style="list-style-type: none"> <li>Escape and dispersal of transgenic material via birds, rodents, insects and people.</li> <li>Gene transfer to wild weed species through pollen escape.</li> <li>Regeneration from seed left in the trial area subsequent to the completion of monitoring.</li> </ol> <p><b>Ecological Risk (also see 12. below)</b></p> <ol style="list-style-type: none"> <li>Potential harmful effect on non-target organisms. (ie risk of development of Bt resistance in susceptible insects).</li> </ol>	<p>9(c)(i) The sustainability of all native and valued introduced flora and fauna.</p> <p>(ii) The intrinsic value of ecosystems.</p>	<p>Refer to <i>section 5.6 and 5.8 page 20</i> of this report.</p> <p>Refer to application <i>section 5 and 8</i>.</p> <p>Refer to the <i>Summary of Submissions Report, Appendix 1</i> of this report.</p> <p>Refer to <i>Additional Information, Appendix 6 and 7</i> of this report.</p> <p>Refer to <i>Department of Conservation's comment, Appendix 1</i> of this report.</p>
<p><b>Health Risks</b></p> <ol style="list-style-type: none"> <li>Potential harm resulting from the consumption of transgenic maize following escape and entry into the human food chain.</li> <li>Potential harm from use of antibiotic marker genes.</li> </ol>	<p>(iii) Public health.</p>	<p>Refer to <i>section 4.5-4.11, page 12</i> of this report.</p> <p>Refer to application <i>section 11-12</i>.</p> <p>Refer to the <i>Summary of Submissions Report, Appendix 2</i> of this report.</p>

Name of the Risk	Statutory Reference (refers to relevant clauses of the <i>Methodology</i> )	Reference Note
<p><b>Cultural Risks</b></p> <p>9. Potential harm to the relationships of Maori culture and traditions with their taonga</p>	<p>(iv) The relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga.</p>	<p>Refer to <i>section 5, page 26</i> of this report.</p> <p>Refer to application <i>section 11-12</i>.</p>
<p><b>Economic Risks</b></p> <p>10. Risk to New Zealand’s ‘clean green’ image</p> <p>11. Potential loss of the effectiveness of <i>Bt</i> as an organic pesticide.</p>	<p>(v) The economic and related benefits to be derived from the use of a particular hazardous substance or new organism.</p>	<p>Refer to <i>section 5.8.15, page 25</i> of this report.</p> <p>Refer to applications <i>section 11-12</i>.</p> <p>Refer to the <i>Summary of Submissions Report, Appendix 1</i> of this report.</p> <p>Refer to <i>Additional Information, Appendix 6</i> of this report.</p>
	<p>(vi) New Zealand’s international obligations.</p>	<p>ERMA New Zealand notes that there appears to be no implications in the context of this application.</p>
<p>Refer to 9(c)(iii) above.</p>	<p>10(c) The significant adverse effects on human health and safety.</p>	<p>Refer to 9(c)(iii) above.</p>
<p><b>Ecological Risks</b></p> <p>12. Herbicide resistant plants developing as super weeds.</p> <p>13. Insect resistant plants developing as super weeds.</p>	<p>10(d) Significant adverse effects on New Zealand’s inherent genetic diversity.</p>	<p>Refer to <i>section 4.17, page 14</i> of this report.</p> <p>Refer to applications <i>section 5</i>.</p> <p>Refer to the <i>Summary of Submissions Report, Appendix 2</i> of this report.</p> <p>Refer to <i>Additional Information, Appendix 5</i> of this report.</p>
<p><b>Containment Risks</b></p> <p>14. The maize seeds escape, establish and form self-sustaining populations.</p> <p>15. Maize pollen escapes and crosses, undetected, with conventional maize crops.</p>	<p>10(e) The ability of the organism to establish an undesirable self-sustaining population anywhere in New Zealand.</p>	<p>Refer to <i>section 5, page 20</i> of this report.</p> <p>Refer to application <i>section 5</i>.</p> <p>Refer to the <i>Summary of Submissions Report, Appendix 2</i> of this report.</p> <p>Refer to <i>Additional Information, Appendix 5 and 6</i> of this report.</p>

Name of the Risk	Statutory Reference (refers to relevant clauses of the <i>Methodology</i> )	Reference Note
16. The maize, following an escape is unable to be eradicated (detected).	10(f) The ease with which the organism could be eradicated if it established an undesirable self-sustaining population.	Refer to <i>section 5.6.6, page 21</i> of this report. Refer to application <i>section 11-12</i> .
17. Ease of eradication reduced due to herbicide resistance (including multiple resistances developing).		Refer to the <i>Summary of Submissions Report, Appendix 2</i> of this report.

## Assessment and Evaluation of Risks

5.5 Of the risks identified in **Table 3** above, ERMA New Zealand considers that a number of these risks are significant and require further analysis. The risks identified have been further analysed in the following broad groups:

- i. Issues related to the capacity of transgenic maize to escape, establish and disseminate.
- ii. Potential for gene transfer
- iii. Potential harmful effects on other organisms, including development of *Bt* resistance in susceptible insects and effect of *Bt* pollen on insects.
- iv. Potential harm to the relationships of Maori culture and traditions with their taonga.

### Issues related to the capacity of transgenic maize lines to escape, establish and disseminate

5.6 The following assessment relates to risks associated with the ability of the transgenic maize lines to escape from containment (via pollen or seed), establish and disseminate.

#### Assessment and Evaluation of Risks, Uncertainty, and the Distribution of Effects

5.6.1 The applicant, in assessing the risks of escape, has highlighted mechanisms for escape of modified material. The applicant has identified potential methods of escape of seed and pollen by:

- transport of seed from the site via animals (ie. birds, rodents and humans)
- transport of pollen via insects
- transport of pollen via wind

5.6.2 The applicant has assessed the potential for dispersal of transgenic material via these pathways and considered that the proposed field trial management procedures as below in section 5.6.10 and the following characteristics of maize would make any escape unlikely:

- maize is wind pollinated only
- pollen is not likely to be transported further than 200m by wind
- pollen remains viable for only 30 minutes
- maize seed does not persist in soil from one season to the next

- maize has no seed dispersal mechanisms and cannot disseminate without human intervention
- any seed consumed by animals would be devitalised in the digestive tract and would not be dispersed
- maize does not exhibit weedy tendencies
- the modifications for herbicide and insect tolerance have no effect on the weedy characteristics or survivability of the plant or the seed.

5.6.3 Taking into account the biological characteristics of maize, ERMA New Zealand is of the view that the proposed containment controls will minimise the risk of unintended/accidental release from containment.

5.6.4 ERMA New Zealand considers that the applicant has not addressed, with sufficient detail, how containment of the seed will be maintained throughout the offsite processing of the seed prior to export.

5.6.5 The applicant did not explicitly identify what the consequences would be if the organism escaped and became established, or whether it could be eradicated, but has noted that due to the small scale of the trials and the management procedures that:

*'we anticipate no impact, positive or negative, on tangata whenua, human or animal health, agricultural production, non target organisms in the area, the general ecology, or environmental quality and pollution in the area'.* (Applications question 11-12).

5.6.6 ERMA New Zealand considers that adherence to the proposed controls should ensure that any likely effects are minimised. This includes a requirement for an eradication plan should the organism escape from containment.

### **Approach to Risk**

5.6.7 Risks associated with the field trial are linked to the escape of the transgenic maize. ERMA New Zealand considers the applicant has experience in managing such trials, however should any containment fail there is little experience in managing potential adverse effects.

### **Method of Risk Management (including to what degree can the risk be managed by risk management)**

5.6.8 The application proposes the following procedures to manage the risk of escape of transgenic pollen and seeds:

- Pioneer personnel only will have access to the trial site , which is not visible from the road, is surrounded by shelter trees and is only accessible by passing the owner's house
- Small scale trials of 0.4ha each

- Isolation zone of at least 400m from other commercial maize crops
- Secure bagging of transgenic pollen tassels to prevent pollen dispersal
- Secure packaging of seed for transport to drying facility and during import and export
- Site monitored for a season following the trials to detect and destroy any maize volunteers.

### **Impact of Risk Management**

- 5.6.9 The impact of risk management is to reduce the likelihood of escape and ERMA New Zealand considers that compliance with the proposed in section 10 of this report will minimise the likelihood of such an occurrence.

### **Potential for gene transfer**

- 5.7 The following assessment relates to the potential effect on the environment should the maize genes be transferred to maize and other organisms through means of pollen escape and via horizontal transfer.

#### **Assessment and Evaluation of Risks, Uncertainty, and the Distribution of Effects**

- 5.7.1 The applicant has noted that *'since sexually compatible relatives of maize are not found in New Zealand we anticipate no potential for gene transfer to wild or woody species'* (Applications, *Question 5*).
- 5.7.2 ERMA New Zealand notes that pollen is reported to remain viable for only 30 minutes therefore limiting inadvertent transfer via insects or on clothing. The bagging of the pollen tassels and 400m isolation distance provides additional assurances that transgenic pollen is very unlikely to be transported to other maize crops.
- 5.7.3 According to the applicant, maize is not an invasive crop and has limited ability to disperse seed. The risk of volunteer maize surviving and dispersing modified pollen following harvest is considered unlikely due to the post harvest monitoring for volunteer maize and the inability of the seed to remain viable if buried.
- 5.7.4 While the risk of horizontal gene transfer is not covered explicitly in the applications, in the attachments to *questions 16* the European Union on Scientific Committee on Plants considered there was no risk associated with gene transfer between organisms for both maize lines T25 and MON810.

### **Potential harmful effects on other organisms**

- 5.8 The following assessment relates to the effects on other organisms arising from any consumption of transgenic maize or the development of *Bt* resistance in susceptible insects.

## Assessment and Evaluation of Risks, Uncertainty, and the Distribution of Effects

### Effects on Non Target Organisms

- 5.8.1 The application for maize line MON810 addresses the risk of effects of the *Bt* protein on target and non target organisms in Question 11 and 12. It is stated that the maize line MON180 expressing the *Bt* protein has no deleterious effects against representative species.
- 5.8.2 ERMA New Zealand notes<sup>2</sup> that concern has been expressed about the effects of genetically modified maize on monarch butterflies (*Danaus plexippus*). A well publicised laboratory experiment by Losey *et al.* (1999)<sup>3</sup> of Cornell University showed that *Bt* (*Bacillus thuringiensis*) maize pollen had a negative effect on viability of monarch butterfly larvae. A preliminary finding obtained from one assay triggered the widespread debate that ensued. Further work will be needed to evaluate the long term implications in natural situations.
- 5.8.3 ERMA New Zealand is of the view that it is not surprising that the *Bt* maize specifically developed to protect it from attacks by the European corn borer could also affect other Lepidoptera that may feed on the transgenic maize. As noted in Appendix 3 of this report the toxins encoded by the *cry* 1 genes are toxic to insect Order Lepidoptera and are not species specific.
- 5.8.4 In this context and according to the London Free Press report of 15 July 1999 a newly announced Canadian research aims to understand how the Cornell University findings relate to outdoor conditions in Ontario. The report attributed to Art Schaafsma, a researcher at the University of Guelph, says that they want to develop strategies for further reducing potential risks to butterflies and other beneficial insects while retaining the benefits of *Bt* maize for farmers, consumers and the environment.
- 5.8.5 ERMA New Zealand notes that monarch butterfly in North America is well known for its twice yearly migration across the continent and according to reports is an unofficial symbol of conservation in the US and has been dubbed the 'Bambi of the insect world'. Monarch numbers have been reported to be declining for decades and consequently the recent *Nature* report served to further heighten fear that genetic engineering in general and *Bt* maize, in particular, pose a potential threat to monarchs as well as biodiversity in general.
- 5.8.6 ERMA New Zealand notes that in the context of this application, the following is relevant:

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<sup>2</sup> Also refer to *Appendix 3* of this report: ERMA New Zealand Review of the effects of Maize line MON180 on other organisms.

<sup>3</sup> Losey J E, Rayor L S, and Carter M E 1999: Transgenic pollen harms monarch larvae. *Nature* 399: 214.

- 5.8.7 *Bt* maize is designed to affect Lepidoptera feeding on the modified crop. Maize does not appear to be a food plant of monarch caterpillars. Secondary impact due to maize pollen spreading to other plants and then affecting other Lepidoptera (e.g. monarch butterflies) that feed on those plants is difficult to determine without knowing the occurrence of these other Lepidoptera food plants in the immediate vicinity of the trial site and the ability of the maize pollen to settle on those plants.
- 5.8.8 The applicant has confirmed that two swanplants that exist in New Zealand, are the same family as the milkweed (*Asclepias curassavica*) used in the Cornell laboratory study. According to the applicant swanplants do not occur in the vicinity of the trial site (*Appendix 7*) and have not been recorded in the wild.
- 5.8.9 However, the publication Parsons et al. 1998<sup>4</sup> lists the two species of the *Asclepias* family referred to in *Appendix 7*, both called 'swan plant': the first, *Gomphocarpus fruticosus* (L.) R.Br. is considered to be naturalised in both the North and South Islands, and the second, *G. physocarpus* (E. Meyer) is found as a casual in Auckland (*pers comms Dr M. Parsons*).
- 5.8.10 ERMA New Zealand notes that the distribution of monarch butterflies in New Zealand suggests that their activity would coincide with the growing season of maize. The issue with respect to effect on the butterflies would relate to the presence of their food plants in or in the vicinity of the trial site.
- 5.8.11 In relation to the potential negative effects on other Lepidoptera ERMA New Zealand notes that the European corn borer appears not to be present in New Zealand. However, other Lepidoptera regarded as pests of maize in New Zealand (Watson R N and Hill M G 1985)<sup>5</sup> include the cosmopolitan armyworm (*Mythimna separata*), southern armyworm (*Persectania aversa*), tomato fruitworm (= corn earworm) (*Helicoverpa armigera confertta* and *H. punctigera*), and green looper (*Chrysodeixis erisoma*). Other insect pests of maize reported by Watson and Hill (1985) include flies (Diptera), beetles and weevils (Coleoptera), and aphids (Hemiptera).
- 5.8.12 Effects on beneficial insects that are natural predators of insect pests, e.g. lacewings (Neuroptera) (*New Scientist* of May 1998) and ladybird beetles (Coleoptera) (*New Scientist* of November 1997) due to secondary poisoning has been raised as a concern. The argument is that mass cultivation of *Bt* transgenic crops would adversely affect beneficial insect populations because these populations will be harmed if they fed on the pests killed by toxins introduced in the transgenic crops. However, any effect on beneficial insects due to insecticidal sprays to control insect pests is an area needing consideration while evaluating the effects on beneficial insects resulting from *Bt* resistant transgenic crops. Given the small scale nature of the proposed trial, ERMA New Zealand

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<sup>4</sup> Parsons et al. 1998 Current Plant Names for Wild Plants in New Zealand. Manaaki Whenua Press.

<sup>5</sup> Watson R N and Hill M G 1985: Pests of maize in New Zealand. In *Maize: management to market*. Eagles H A and Wratt G S (eds). Agronomy Society of New Zealand, Special Publication No. 4.

has not evaluated the relative effects of using *Bt* and other pesticides on beneficial insects.

### Development of Bt Resistance

- 5.8.13 The threat of widespread development of resistance to *Bt* because of large scale planting of *Bt* resistant modified crops is a concern because *Bt* has been used as a natural pesticide for pest management. In order to reduce the possibility of the development of resistance, refugia of non-transgenic maize are being established in which susceptible insects can propagate without exposure to *Bt*.
- 5.8.14 For this strategy to work the insect genes encoding resistance to *Bt* must be recessive. However, recent work by Huang *et al.* (1999)<sup>6</sup> has suggested that resistance to *Bt* is genetically dominant in the European corn borer. This is in contrast to findings in other insect pests. This suggests that new strategies may be needed to sustain the insecticidal value of *Bt* expressing crops.
- 5.8.15 ERMA New Zealand notes that the refugia strategy assumes that the development of resistance in European corn borer will be recessive so that when these insects mate with the non-resistant European corn borers in the refugia, the progeny will be killed if they fed on *Bt* maize. However, if some dominant mutants appear, the progeny that results from these mutants mating with normal European corn borers in the refugia will be resistant and could survive by feeding on the *Bt* maize. In the New Zealand context where European corn borer is not a pest of maize, implications to other Lepidoptera that feed on maize need to be considered. If these caterpillars become resistant to the *Bt* toxin, the future use of *Bt* as a biopesticide for these pests could be jeopardised.
- 5.8.16 In the above context, the Authority may wish to consider that the area of transgenic *Bt* maize to be planted in this field trial is very small (0.4 hectare) and therefore how relevant some of the above issues are for this particular application.
- 5.8.17 The applicant notes that maize line T25 does not have any pesticidal mode of action and therefore no target species on which to act. The regulatory approval documents in the application and the additional information in *Appendix 5* of this report conclude that line T25 is unlikely to have adverse effects on animal health and that '*unconfined release of line T25 will not result in altered impacts on interacting organisms...when compared with currently commercialise counterparts*'. (Canadian Food Inspection Agency, Decision Document 98-22, *Appendix 5*)

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<sup>6</sup> Huang F, Buschman L L, Higgins R A, and McGaughey W H 1999: Inheritance of resistance to *Bacillus thuringiensis* toxin (Dipel ES) in the European corn borer. *Science* **284**: 965-67.

### **Method of Risk Management (including to what degree can the risk be managed by risk management)**

- 5.8.18 The applicant proposes to perform controlled pollinations in which the pollen is contained within bags. ERMA New Zealand notes there is some inconsistency as to the applicant's view on effectiveness of the pollen containment method referred to within the additional material, as to whether the technique prevents or minimises pollen dispersal, ie. the additional information in *Appendix 6* states that the use of the paper bags '*ensures that **no** pollen from the transgenic plants is able to spread*' while in *Appendix 7* it is stated that the controlled pollinations '*will be made using techniques proven to **minimise** the risk of pollen dissemination*'.
- 5.8.19 The field trial design also involves a total of 147 rows of maize at one site with only 36 rows being maize line MON810. This extensive refuge, the small scale and short duration of the trial would minimise the likelihood of large scale resistance developing in Lepidoptera insects.

### **Impact of Risk Management**

- 5.8.20 The impact of risk management is to reduce the likelihood of escape.

### **Relationship of Maori and their Culture and Traditions with Taonga**

- 5.9 The following assessment relates to the effects on the relationship of Māori and their culture and traditions with taonga (*section 6(d)* of the Act) resulting from this application.

#### **ERMA New Zealand Evaluation of Adequacy of Consultation**

- 5.9.1 Consultation by the applicant has been at the local level.
- 5.9.2 The applicant has used three meetings with the tangata whenua group Huakina Development Trust, from Tainui, as their primary source of information.
- 5.9.3 The applicant held discussions with a small group from Huakina headed by Mr Dennis Ngātaki. ERMA New Zealand has confirmed that this consultation took place and that the Huakina Development Trust is satisfied with the consultation process.
- 5.9.4 ERMA New Zealand also considers that the consultation on this application has been as extensive as could be reasonably expected, and a decision on risks to Māori should be made on the basis of the information available.

#### **ERMA New Zealand Evaluation of the Identification of the Risks (including significance of the risks)**

- 5.9.5 Huakina Development Trust has not raised any concerns about this application.

- 5.9.6 Subsequently, the applicant has not identified any risks to the relationship of Māori culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga.
- 5.9.7 ERMA New Zealand has not identified any risks posed by this application to the relationship of Māori culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga.

### **Assessment of Costs**

- 5.10 The applicant has not explicitly identified any costs. ERMA New Zealand notes that primary monetary costs will be associated with the crop production and maintenance, plus transport and certification fees.

### **Assessment of Benefits**

- 5.11 The applicant has identified that for the survival of the plant breeding station in New Zealand that it is essential for them to produce corn with transgenic traits. The applicant identified that the station employs 25 people, and with full funding from the USA they are dependant on being able to provide such services for the international company (*Appendix 6*). ERMA New Zealand notes that the applicant has not identified what number of employees or percentage of funding is allocated to the production of the transgenic hybrids.
- 5.12 The applicant has identified non-monetary benefits linked to the agronomic effects of the two lines of transgenic maize. Since New Zealand does not grow these transgenic crops commercially none of these benefits of simplified weed management or insect control accrue to New Zealand.
- 5.13 ERMA New Zealand understands that the transgenic lines of maize proposed for field test in New Zealand are derived from the same lines as have been released for general use in the Northern Hemisphere. The Authority may wish to consider the necessity of a field trial in New Zealand of lines approved for release overseas unless there is an intention to monitor non-target effects on an ongoing basis. Production of transgenic seed for export from a 0.4 hectare field trial does not seem a worthwhile venture when the same lines of seed can be bought in bulk in the Northern Hemisphere.

## 6. Application of Controls

- 6.1 The Third Schedule of the HSNO Act 1996, Part I, identifies *Matters to be Addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* (GMOs).
- 6.2 Controls can be designed with the aim of reducing the probability of any escape from containment, and reducing the likelihood that a self-sustaining population may form in the event of an escape. However, such controls cannot totally eliminate the possibility that escape will occur, as complete compliance cannot be guaranteed.
- 6.3 The controls set out below are designed to manage the risks associated with field testing of transgenic maize. Specifically, they relate to the maintenance of the transgenic maize in secure containment so as to prevent unintended release of any heritable material. These controls are put forward as the basis for assessing the risks associated with approving the *field testing of genetically modified cattle in containment*. The Authority may wish to amend these controls (in order to make them more or less ‘strict’) to achieve a level of probability of escape that is appropriate for the application.
- 6.4 If approval is granted, operation of the containment facilities must specifically ensure the following (with respect to the matters identified in the Third Schedule of the HSNO Act):

**Table 5: Proposed Controls according to the Third Schedule of the HSNO Act 1996**

(Source: *Hazardous Substances and New Organisms Act 1996 Third Schedule Part I Matters to be Addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms*)

1. To limit the likelihood of any accidental release of any organism or any viable genetic material:

Matters to be addressed	Proposed Controls or Options for Controls
1(a) Requirements for treatment and decontamination to prevent escape by way of expelled air, discharge of water or liquid waste, removal of solid waste or goods, or breaches in facility boundary.	<p>1.1 The applicant shall gain approval of the field trial site as a containment facility from the Ministry of Agriculture and Forestry under the Biosecurity Act 1993.</p> <p>1.2 The method of handling the transgenic maize seeds during planting shall ensure that there is no spillage outside the field trial site.</p> <p>1.3 The field trial site shall be used solely for the proposed field trials of transgenic maize involving maize line MON810 and T25 and non-modified maize.</p> <p>1.4 Maize pollen tassels on transgenic plants shall be fully contained within secure weatherproof bags prior to pollen shed.</p> <p>1.5 Immediately following pollination transgenic plants shall be destroyed by cultivation and burial prior.</p>

	<p>1.6 Non-transgenic recipient plants shall be securely bagged in waterproof bags following hand pollination.</p> <p>1.7 All ears produced by hand pollination shall be hand harvested and transported to the drying facility in secure bags to ensure no transgenic material is dispersed.</p> <p>1.8 The ears from which kernels have been removed shall be destroyed by incineration immediately after kernels have been removed (preferably daily).</p> <p>1.9 Following harvest the non-transgenic plants shall be mulched, the field rotary hoed, and deep ploughed to ensure plant material is destroyed and buried.</p> <p>1.10 All seed produced shall be exported or destroyed by incineration.</p>
1(b) Equipment and requirements for facility construction to enable the requirements for treatment and decontamination to be readily met	1.11 The applicant shall adhere to the trial design and experimental procedures as detailed in the application, except as otherwise required by these controls.
1(c) Requirements to be complied with for the access of persons to the facility	<p>1.12 Only persons authorised by the applicant shall have access to the field trial site.</p> <p>1.13 The trial site shall be monitored for interference other than by authorised personnel and it shall be secured to ensure that unauthorised persons do not have unrestricted access to it.</p>
1(d) Procedures and requirements for transport, identification, and packaging for all biological material to and from the facility and within the facility	<p>1.14 All transgenic maize material shall be properly and adequately identified at all times.</p> <p>1.15 Any object or material that is likely to contain viable transgenic maize shall be disposed of by incineration or autoclaving, to prevent unintended release.</p> <p>1.16 Transgenic maize seed shall be imported into a locked seed store, in accordance with the packaging requirements of the International Air Transport Association (IATA). All containers used must be clearly labelled with the name, address, and phone number of both the sender and the recipient. During storage, the transgenic maize seed shall be kept separate from all other seed stock at all times. The seed packets shall not be opened and shall remain at the seed storage facilities in Pukekohe until planting.</p>
1(e) Requirements for the disposal of any biological material.	<p>1.17 All imported seed not used in the field trial shall be exported or destroyed by incineration.</p> <p>1.18 No plant material from the trial shall be used for animal feed or for human consumption or, except for seed, removed from the trial site.</p>
1(f) Requirements for facility	See 1(a) above.

construction	
1(g) Requirements to secure the facility and openings, including securing against failure in the event of foreseeable hazards	1.19 The applicant shall ensure that the bags on tassels are monitored for bird or rodent damage and any damage detected shall be remedied to prevent pollen escape.

2. To exclude unauthorised people from the facility:

Matters to be addressed	Proposed Controls or Options for Controls
2(a) Means of identification of all entrances to the facility	See 1(c) above.
2(b) The numbers of entrances and access to the facility	See 1(c) above.
2(c) Security requirements for the entrances and the facility	See 1(c) above.

3. To exclude other organisms from the facility and to control undesirable and unwanted organisms within the facility:

Matters to be addressed	Proposed Controls or Options for Controls
3(a) Monitoring requirements to establish the presence of other organisms	3.1 The applicant shall prevent seed-eaters having access to transgenic maize seed during or prior to germination.
3(b) Phytosanitary requirements	See 1(a) above.
3(c) Requirements to secure the facility and openings against likely unwanted organisms	See 1(a) above.

4. To prevent unintended release of the organism by experimenters working with the organism:

Matters to be addressed	Proposed Controls or Options for Controls
4(a) Requirements to prevent the contamination of work surfaces, equipment, clothing and the facility generally	4.1 Equipment and clothing used in the field testing of transgenic maize shall be thoroughly cleaned at the containment location to prevent any viable transgenic maize material leaving the containment location.  4.2 All equipment and clothing used in the offsite processing of transgenic maize shall be thoroughly cleaned to prevent any viable transgenic maize material escaping the trial site.

4(b) Requirements for laboratory practice to control infection by ingestion or breaks in skin cover	Not applicable.
4(c) Means to control infection by inhalation	Not applicable.

5. To control the effects of any accidental release or escape of an organism:

Matters to be addressed	Proposed Controls or Options for Controls
5(a) Eradication plan for escaped organisms	5.1 The applicant shall include in the management plan the procedures to be implemented in the event of the loss of containment of any transgenic material. The eradication procedure shall ensure that no viable transgenic maize material remains in the environment.
5(b) Requirements to limit the likelihood of an escaped organism spreading, surviving and breeding, including, but not limited to:	See 1(a) above.
(i) Exclusion zones (spatial or temporal)	5.2 The applicant shall maintain a minimum isolation distance of 400m between the transgenic maize field trials and any non-modified maize not involved in the trials.
(ii) Location of the facility outside the usual habitat range of the organism	5.3 The applicant has noted that the proposed site is in an area which traditionally, except for a Pioneer maize crop, no other maize is grown.

6. Inspection and monitoring requirements:

Matters to be addressed	Proposed Controls or Options for Controls
6 Inspection and monitoring requirements for containment facilities (including any inspection required before commencement of the development or field testing)	<p>6.1 The Authority or its authorised agent or properly authorised enforcement officers, may inspect the field trial site at any reasonable time.</p> <p>6.2 The field trial site shall be monitored for at least 1 year from the date the plants are mulched following harvest. Any volunteer plants shall be destroyed by manual or chemical means prior to reproductive elements forming.</p> <p>6.3 The manager responsible for the contained field trial shall report immediately to MAF, ERMA New Zealand on any event that is likely to be in the public interest, eg escape or removal or destruction of transgenic material.</p> <p>6.4 The applicant shall:</p>

	<ul style="list-style-type: none"> <li>(i) Keep an inventory of all transgenic maize material imported, harvested, destroyed, and exported.</li> <li>(ii) Advise the Authority of planting and harvest dates.</li> <li>(iii) Provide a comprehensive report to ERMA New Zealand within four months of the harvest and export of the transgenic seed or at any other time if requested by ERMA New Zealand detailing progress and outcomes of the field test; and extent of compliance with the controls</li> <li>(iv) Provide reports to ERMA New Zealand within four months of the completion of each 1 year monitoring period on the monitoring activities and occurrence of volunteers.</li> </ul>
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7. Implementation of controls:

Matters to be addressed	Proposed Controls or Options for Controls.
7(a) The qualifications required of the person responsible for implementing the controls imposed by an approval	7.1 The applicant shall inform all personnel involved in the development and field trial of transgenic maize of the controls imposed in this decision.
7(b) The provision of a management plan specifying procedures for implementing controls imposed by an approval.	7.2 The applicant shall prepare and use a management plan to implement the controls imposed by this approval. The plan shall specify the containment system both at the trial site and for off-site processing. It shall also include the post field test monitoring regime and the destruction of volunteers as required by these controls and defined in the applications and the additional information. The management plan shall be  Note: The controls 1.1 to 7.2 inclusive constitute the standard applicable to the approval of a place as a containment facility for the purposes of <i>section 39</i> of the Biosecurity Act 1993.

## 7. Commentary on Other Issues

### Previous Considerations

- 7.1 The applicant has noted that the field trials proposed in this application are a repeat of those approved by the Minister for the Environment, application numbers 46 and 47, on 10 November 1999.
- 7.2 A copy of the previous approvals as gazetted as a deemed approval under HSNO is included in the report as *Appendix 8*. The final report on these field trials harvested on 9 April 1998 is also included in the further information of *Appendix 4* of this report.

### Consideration of the organism by another Country

- 7.3 Included in the applications in Section 16 are tables listing the regulatory clearances held by transgenic maize lines MON180 and T25. The application and additional information also includes the full decision documents and assessments of a selection of the government approval agencies.

## 8. Status of Associated Approvals

- 8.1 The applicant has indicated that the maize will require an import permit under the Biosecurity Act 1993 from the Ministry of Agriculture and Forestry.

## 9. Precedents

- 9.1 The Authority must consider each application on its merits, and is therefore not bound by the stance it has taken in previous decisions. However the Authority may wish to reflect on statements it has made in previous decisions where these involve similar issues to those raised by these applications.
- 9.2 In its decisions approving the applications **GMF98007** and **GMF98008**, *to field test genetically modified potato cultivars*, the Authority commented on the issue of horizontal gene transfer.

Both decisions stated that:

*In considering the likelihood of escape of genetic material by horizontal gene transfer to soil micro-organisms, the Authority noted that while the scientific evidence available is inconclusive, horizontal gene transfer from transgenic plants to soil micro-organism is unlikely.'*

- 9.3 The decision on GMF98008 also provides information on the consideration of the development of *Bt* resistance in Lepidoptera populations and effects on beneficial organisms:

*The Authority considered the possibility of the development of resistance within populations of Lepidoptera (specifically the potato tuber moth) to the cry proteins derived from the soil bacterium*

*Bacillus thuringiensis*, and any adverse effects on beneficial organisms, specifically insects, which may occur as a result of consuming the toxin.

*Based on the available scientific evidence the Authority concluded that the probability of Lepidoptera populations developing resistance to cry proteins, in the context of the proposed small-scale field test, was very low. Moreover, the origin of any resistance developed would be difficult to determine because of the current use of Bt toxin as an organic insecticide.'*

*In addition the Authority considered that any adverse effects on populations of beneficial organisms, such as ladybirds and lacewings, would in the context of the proposed field test be insignificant.'*

## 10. Overall Evaluation

- 10.1 Having considered the risks identified in *section 5* in conjunction with the adequacy of containment, as described in *section 6*, the decision path obliges the Authority to form a view as to whether the risks after the application of containment controls are *negligible*<sup>7</sup> and costs accrue only to the applicant.
- 10.2 The risks associated with the development and field trial of a genetically modified organism in containment relate primarily to the potential for the organism or any heritable material escaping into the uncontrolled environment. The principal issue to be considered is therefore whether controls can be imposed that would effectively contain the organism and its heritable material from escaping containment. The proposed containment regime and compliance with controls imposed would ensure to minimise the likelihood of transgenic maize or any heritable material escaping into the uncontrolled environment.
- 10.3 If the Authority is of the view that the risks are not negligible it must weigh risks and costs against benefits. The risks, costs and benefits as assessed by the applicant are outlined in *section 5* of this report. If the Authority deems that a full risk-cost-benefit assessment is appropriate it may wish to consider whether there is sufficient information to proceed.

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<sup>7</sup> The *Annotated Methodology* defines *negligible risks* as *risks which are of such little significance in terms of their likelihood and effect that they do not require active management and/or after the application of risk management do not need to be justified by counter-balancing benefits.*

# Appendix 1

## Comment from the Department of Conservation

## **Appendix 2**

### **Summary of Submissions Reports**

## **Appendix 3**

### **ERMA New Zealand Review of the effects of Maize line MON180 on other organisms**

## **Appendix 4**

**Additional information received from the applicant-6 November 1998  
Report on 1996/97 Field trials**

## **Appendix 5**

**Additional information received from the applicant -22 February 1999**

## **Appendix 6**

**Additional information received from the applicant-14 May 1999**

## **Appendix 7**

**Additional information received from the applicant-21 July 1999**

## **Appendix 8**

**1997/98 maize field trials conditions on approval: NZ Gazette Issue 101**