ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

Amended under s67A on 05 Feburary 2013 [Approval has Expired]

Date signed: 25 May 2007

Application code:	GMF06001
Application type:	Field test in containment any genetically modified organism under the Hazardous Substances and New Organisms (HSNO) Act 1996
Applicant:	New Zealand Institute for Crop & Food Research Limited
Purpose:	To assess the agronomic performance, in the Lincoln region, up to 10 years of vegetable and forage brassicas, specifically cabbage, broccoli, cauliflower and kale, modified for resistance to caterpillar pests like cabbage white butterfly and diamondback moth**.**
Date received:	30 October 2006
Hearing date:	11 – 13 April 2007
Decision date:	25 May 2007
Considered by:	A Committee of the Environmental Risk Management Authority

Summary of Decision

1. The application to field test the following organisms is **approved with controls** (specified in Appendix 1) having been considered in accordance with the relevant provisions of the Hazardous Substances and New Organisms Act 1996 (the Act) and of the HSNO (Methodology) Order 1998 (the Methodology):

   Brassica oleracea L. (1753) vegetable and forage cultivars, limited to those commonly known as cabbage, cauliflower, broccoli and forage kale, each modified by *Agrobacterium tumefaciens* mediated transformation for the introduction of one or more *cry* genes, which confer resistance to lepidopteran caterpillars (like diamondback moth and cabbage white butterfly), and selectable marker and/or reporter genes.

   The approved organisms may contain some or all of the following:

   (a) One or more crystalline protein genes (*cry* genes) encoding insect resistance derived from *Bacillus thuringiensis*.

   - These insecticidal *cry* genes may utilise plant preferred codons.

(b) Any gene regulatory elements including promoters and terminators may be derived from plants, including *Brassica* species, *Arabidopsis thaliana*, tobacco and other crop species.

- Tissue specific promoters may be used to target *cry* gene expression for example, the chlorophyll AB binding protein promoter.

(c) Regulatory elements derived from vertebrates, invertebrates, fungi, bacteria and viruses are limited to those that have established use in plant transformation and are commercially available:

- These may include the CaMV35S promoter and the CaMV35S polyadenylation region, sourced from *Cauliflower mosaic virus* (CaMV) and/or the Octopine synthase (OCS) and Nopaline synthase (NOS) promoters and terminators derived from *Agrobacterium tumefaciens*.

- Experimental or unproven regulatory elements from these sources will not be used in the development of GM brassicas which are to be field tested.

(d) Antibiotic resistance markers or selectable markers such as hygromycin phosphotransferase II (*hptII*), neomycin phosphotransferase (*nptIII*) and phosphinotricin acetyl transferase (*bar*) or other antibiotic and selectable markers commonly used in plant transformation.

- These include markers available from research groups or companies, on request to researchers.

- The use of markers is limited to those used to select GM plants in the laboratory and may not be used to confer additional traits such as herbicide resistance.

(e) Other markers and reporters such as the uidA gene (GUS) and fluorescent proteins including Green Fluorescent Protein (GFP) and DsRed commonly used in plant transformation.

(f) The foreign DNA will be contained in the T-DNA regions within the binary vectors. This region between the Left and Right border is transferred into the plant genome by disarmed *Agrobacterium tumefaciens* strains.

(g) The following are excluded:

- Genetic material from native flora and fauna.
- Developments that result in expression of vertebrate toxins with $LD_{50} < 100$ µg/kg.

2. The controls imposed on the approved organisms are set out in Appendix 1 to this decision. The controls provide for the adequate containment of the organisms, and for the management of any risks. In particular the controls provide for:

    - the specification of the field test site (the field test containment facility), being a location in the region around Lincoln;
    - the containment of the genetically modified organisms and any heritable material from these organisms;
    - the control and securing of the facility in regard to the entry and exit of people;
    - limitation of the duration of the approval to ten years;
    - disposal of brassica plant material;
    - removal of all brassicas from the field test site before flower bud opening (and thus pollen release) can occur;
    - a prohibition on ingestion of the brassicas in any form, by people and animals; and
    - monitoring and inspections both during the field test and after its completion.

3. In considering the application, all identified potentially significant adverse effects (risks and costs) of the organisms were assessed as negligible, taking into account containment provisions and other controls required by this decision.

4. Concerns raised by Māori, and particularly Te Rūnanga o Ngāi Tahu, were considered to be ameliorated by the controls, including the control requiring specific annual reporting.

5. The principal benefits were considered to be the enhancement of knowledge and understanding of agronomic practices associated with those brassicas genetically modified for *Bt*[1] expression, and upskilling of staff and increased experience in working with gene technology in the field. These two benefits were assessed as non-negligible.

6. The Committee approves this application in accordance with section 45 of the Act. The Committee notes that since all risks and costs were negligible, taking into account the risk management measures imposed by the controls, clause 26 of the Methodology applies. The Committee concluded that the benefits of the application outweigh the risks and costs.

[1]An abbreviation used to denote plants expressing Cry toxins derived from *Bacillus thuringiensis*.

Full Decision

1 Application Process

1.1 Legislative criteria for application

1.1.1 The application was lodged pursuant to section 40(1)(c) of the Act. The decision was made in accordance with section 45 of the Act taking into account additional matters to be considered under sections 37, 44 and 44A, and matters relevant to the purpose of the Act, as specified under Part II of the Act. Unless otherwise stated, references to section numbers in this decision refer to sections of the Act.

1.1.2 Consideration of the application followed the relevant provisions of the Methodology with particular regard to clauses 12 (dealing with assessment of risks) and 13 (dealing with assessment of costs and benefits). Unless otherwise stated, references to clauses in this decision refer to clauses of the Methodology.

1.2 Receipt of application

1.2.1 The application was formally received on 30 October 2006. Prior to formal receipt, the application was checked as required under section 52(1) and was considered to meet the information requirements for consideration. The Minister for the Environment was advised of the receipt of the application on 30 October 2006.

1.3 Decision-making Committee

1.3.1 In accordance with section 19(2)(b) of the Act and clause 43 of the First Schedule to the Act, the New Zealand Environmental Risk Management Authority (the Authority) appointed a Decision-making Committee on 10 November 2006 to consider the application. The Authority delegated to the Committee all necessary powers to determine the application. The Committee comprised the following members of the Authority: Kieran Elborough (Chair), Max Suckling, Manuka Henare and Neil Walter. References to the Committee in the remainder of this decision mean the Decision-making Committee appointed to undertake the consideration.

1.4 Public notification

1.4.1 The application was publicly notified on 31 October 2006 in accordance with section 53(1)(d). Notification was made in accordance with clause 7 and the method of public notification was that determined by the Authority pursuant to section 53A. An alert notice was posted on the ERMA New Zealand website[2] and printed in *The Dominion Post*, *The New Zealand Herald*, and *The Otago Daily Times* on 1 November 2006 and in *The Press* on 4 November 2006.

[2] http://www.ermanz.govt.nz/

1.5 Submissions

1.5.1 Public submissions were open from 31 October 2006 until 12 December 2006. Submissions under section 54 were received from 959 submitters, of which 159 submitters indicated that they wished to be heard at a hearing. At the hearing, 42 submitters spoke on behalf of their own submission and/or on behalf of another person's submission; the names of these submitters are listed in section 1.8 of this decision. A list of all submitters can be found in Appendix 3 of the Evaluation and Review (E&R) report, available on the ERMA New Zealand website, or on request from the Wellington office of ERMA New Zealand.

1.6 Consultation with government departments

1.6.1 In accordance with section 53(4) and clause 5, and for the purpose of section 58(1)(c), various government departments and other agencies including district and regional councils were notified of the receipt of the application. A submission was received from the Department of Conservation (DOC). A complete list of the government departments notified of this application can be found in Appendix 2 of the E&R report.

1.7 Experts

1.7.1 In line with the provision for obtaining expert advice under section 58(1)(a) of the Act and clauses 17 and 18 of the Methodology, Associate Professor Jo Putterill, Plant Molecular Science, School of Biological Sciences, University of Auckland, assessed the scientific robustness of the E&R report, with particular regard to the adequacy of the assessment and evaluation of the risks.

1.8 Hearing

1.8.1 A public hearing[3] was held in Christchurch between 11 and 13 April 2007. Christchurch was selected as a venue by the Committee based on an analysis of likely attendance by submitters and the fact that Christchurch is the closest main centre to the location of the field test. Selection of this venue allowed for the participation of those most likely to be affected. To enable submitters who were outside the region to be heard, the Committee also allowed telephone conferencing.

1.8.2 Submissions were presented to the Committee at the hearing by the following persons:

For the applicant:

- Mary Christey (Scientist, Crop & Food Research)

Supported by:

- Nick Ashby (Science Group Manager, Crop & Food Research)
- Michael Brownbridge (Senior Scientist - Biocontrol and Biosecurity, AgResearch, Lincoln)
- Tony Conner (Scientist, Crop & Food Research)
- Colin Eady (Scientist, Crop & Food Research)
- Christian Walter (Research Leader, Scion, Rotorua)

For the Agency:

- Jenny Khoo (Project Leader)

Supported by:

[3] Section 60 of the Act and clause 2(2)(b) of the Methodology.

- Andrew Allen (Senior Legal Advisor)
- Janet Gough (Senior Policy Analyst)
- Andrea McNeill (Environmental Risk Advisor)
- Linda Robinson (General Manager, Māori)

For Ngā Kaihautū Tikanga Taiao:[4]

- Bella-Ann Tuau

For submitters: Speaking on their own behalf and/or on behalf of other submitters:

- Shushila Ajani
- Peter Bacchus
- Jocelyn Bieleski
- Jody Bisschops
- Claire Bleakley

  Supported by:
  - Judy Carman
  - Joe Cummins
  - Julie Newman
- Beverly Blyth
- Jennifer Blyth
- Jenni Boulton
- Shirin Brown
- Steffan Browning
- Jon Carapiet
- Duncan Currie
- Katherine Dewar
- Elvira Domissee
- Charles Drace
- Ryan Garland
- Jan Gerritsen
- Andrew Gillanders
- Russell Goddard
- Lois Griffiths
- Ann Harper
- George Hendry
- Terry Higginson
- Ella Lawton
- Susie Lees
- Seager Mason
- Kim Merry
- Barbara Mountier
- Angela O'Donnell
- Rebecca Potts

[4] Ngā Kaihautū Tikanga Taiao is formally established as a Māori Advisory Committee under section 24A of the Act, to advise the Authority on how to take account of issues of concern to Māori (particularly in relation to sections 6(d) and 8 of the Act).

- Matthew Prockter
- Martin Robinson
- William Rolleston
- Jay Scanlon
- Ken Shirley
- Simon Terry (supported by David Williams)
- Phyllis Tichinin
- Martina Tschirky
- Christian Walter
- Sarah Walters
- Susan Washington
- Adrian White

1.9 Information available for the consideration

1.9.1 The information available for consideration by the Committee comprised:

- the application submitted by the applicant (including information contained in confidential appendices);
- written submissions received from submitters;
- the E&R Report prepared by the Agency (including comments from DOC);
- the report from the ERMA Māori Advisory Committee, Ngā Kaihautū Tikanga Taiao;
- further information provided by the applicant at the hearing; and
- further information and evidence provided by submitters at the hearing.

1.9.2 The Authority requested further information as provided for under section 58. In order to complete the E&R report containing this information, the requirement to convene a hearing within 30 working days from the close of submissions (section 59(1)(d)) was waived with the consent of the applicant.

2 Consideration

2.1 Summary of the application

2.1.1 The application is for approval to field test in containment vegetable and forage brassicas, specifically cabbage, broccoli, cauliflower and forage kale, modified for resistance to caterpillar pests like cabbage white butterfly (CWB) and diamondback moth (DBM). In this decision, these plants are referred to as genetically modified (GM) brassicas.

2.1.2 In the lodged application, the purpose of the field test was described as to assess the agronomic performance of these genetically modified plants under field conditions, in particular, their response to CWB and DBM. The field test would also be used to study the environmental impacts of *Bt*-containing plants with reference to the soil microflora, non-target beneficial invertebrates, horizontal gene transfer (HGT) and persistence of transgenic DNA in the soil.

2.1.3 In the hearing, the applicant further elaborated on the purpose of the field test. Under agronomic performance, GM brassica marketable heads would be tested for equivalency to the non-GM counterparts. In addition, the applicant provided more

detail on the environmental impacts research that would be carried out in collaboration with other Crown Research Institutes (CRIs), noting that the field test would allow for testing and identification of GM brassica plant lines for such environmental impacts research.

2.1.4 The GM brassicas that are the subject of this approval have been, or are in the process of being, developed in accordance with an approval given by the Crop & Food Research Institutional Biological Safety Committee (IBSC) at Lincoln and assigned the approval code GMD000814. Once the GM brassicas are transferred on to the field test site they come under this field test approval. When the plants are held under this field test approval, they are not subject to approval GMD000814. The Committee notes that this developmental approval (GMD000814) covers a wider range of organisms than are approved in this decision. The Committee notes that the organisms described in this field test approval are the only organisms that can be field tested.

2.1.5 The Committee notes that any GM brassicas developed or imported into containment under other HSNO containment approvals could also be field tested provided that the purpose and the range of genetic modifications fit within the purpose of this field test and the organism description on pages 1 and 2 of this decision.

2.1.6 The field test involves planting out brassica seedlings in a secured contained field test site in the Lincoln region, occupying up to 0.4 hectares. The release of genetic material would be prevented by not allowing any *Brassica oleracea* plants to produce open flowers in the field test site. Plants identified as initiating bolting (a visually significant event before flowering) would be removed from the site and either destroyed or returned to containment for further analysis.

2.1.7 Non-transgenic progeny of GM plants or isogenic lines, ie plants derived originally from GM plants but shown not to contain the *cry* gene(s), may be used as control plants in this field test. Although these plants do not contain the transgene(s), they are still considered GM plants under the Act.

2.1.8 After considering the application, the Committee is satisfied that the purpose of this application is a valid purpose under section 39(1)(b) of the Act, field testing of any new organism.

2.1.9 The field test site must be approved by MAF Biosecurity New Zealand in accordance with section 39 of the Biosecurity Act 1993. Further, the field test site must comply at all times with the controls specified in this decision.

2.2 Sequence of the consideration

2.2.1 In accordance with clause 8 of the Methodology the Committee considered the information provided from the sources listed in section 1.9 above. The approach adopted by the Committee was to look sequentially at identification, assessment and the combined evaluation of risks, and of costs and benefits. Identification of potential risks and costs took into account the matters in clauses 9 and 10. Interposed with this were the consideration of the proposed management regime, and the ability of the organisms to escape and form self-sustaining populations. Controls were considered in relation to the identified risks and those risks identified as significant were assessed (clause 12). Costs and benefits were assessed in accordance with clause 13.

2.2.2 Finally, taking account of the risk characteristics established in accordance with clause 33, the combined impact of risks, costs and benefits was evaluated in accordance with clause 34.

2.3 Identification of the potentially significant adverse effects (risks and costs) of the organism

2.3.1 In accordance with clauses 9 and 10 of the Methodology, which incorporates sections 5, 6 and 8 of the Act, the Committee identified significant risks and costs for assessment and evaluation.

2.3.2 The Committee categorised the potential adverse effects of this application in relation to the following areas of impact: the environment, human health and safety, the relationship of Māori to the environment, Treaty of Waitangi principles, society and community, and market economy in accordance with sections 5 and 6 of the Act and clause 9 of the Methodology. The potential adverse effects include those that might arise from the transfer of genetic elements (section 44A(2)(c) of the Act).

2.3.3 In order to identify the potentially significant adverse effects (risks and costs) of this organism, the Committee identified the sources of the effect (hazard), the pathways for exposure and the areas of impact based on the information provided.

Potentially significant adverse effects on the environment

2.3.4 The Committee identified the following potentially significant adverse effects on the environment. These effects are assessed in section 2.8.6 - 2.8.57 of this decision.

- Development of resistance to *Bt* toxins (Cry toxins) in diamondback moth (DBM) and cabbage white butterfly (CWB).
- Harm to non-target organisms such as:
  - harm to animals (direct toxic effects on (all) animals from eating plants, and indirect effects on animals from antibiotic resistance passed through soil micro-organisms);
  - indirect toxic effects on parasitoids and predators of CWB and DBM;
  - direct toxic effect on beneficial insects or native or valued species such as bees and other insects (pollinators), especially lepidopterans; and
  - direct or indirect toxic effects on birds.
- Spread of insect resistant traits, conferred by *cry* genes, to nearby brassicas (crops or wild relatives) providing a comparative advantage – increased weediness.
- Reduction in soil biodiversity (localised).
- Contamination of aquifers with *Bt* toxins.

Potentially significant adverse effects on human health and safety

2.3.5 The Committee identified increased allergic or toxic reactions in humans (environmental /occupational exposure) as potentially significant adverse effects on human health and safety. This effect is assessed in section 2.8.58 - 2.8.62 of this decision.

2.3.6 The Committee noted that many submitters had expressed concerns that GM brassicas expressing Cry proteins (*Bt* toxins) could potentially be toxic to humans if eaten, and that testing for food safety should occur before the application could be considered.

2.3.7 The Committee agrees that it is essential that food testing occurs before GM crops are considered for human consumption. The Committee considers that this concern

is addressed by control 5.4 which will prevent GM brassicas from entering the human food chain or being fed to livestock. Therefore the Committee considers that this effect does not require further assessment. The Committee also notes that the New Zealand Food Safety Authority (NZFSA) would require food safety testing information prior to the release of any commercial GM food crop.

Potentially significant adverse effects on the relationship of Māori to the environment

2.3.8 The Committee identified the following potentially significant adverse effects on the relationship of Māori to the environment. These effects are assessed in section 2.8.63 - 2.8.69 of this decision.

- Adverse impact on tikanga and mātauranga Māori through the alteration of whakapapa, mauri and tapu.
- Adverse impacts on kaitiakitanga through the:
  - disruption of mauri, tapu and mana;
  - unanticipated genetic transfer; and
  - increased insect resistance to *Bt* toxins.

Potentially significant adverse effects on the principles of Te Tiriti o Waitangi/ Treaty of Waitangi

2.3.9 The Committee identified the following potentially significant adverse effects on the principles of Te Tiriti o Waitangi/Treaty of Waitangi. These effects are assessed in section 2.8.70 - 2.8.72 of this decision.

- Inconsistency with the principles of Te Tiriti o Waitangi/Treaty of Waitangi

Potentially significant adverse effects on society and community

2.3.10 The Committee reviewed the information supplied by the applicant, the information in the E&R report, and further information received at the public hearing.

2.3.11 Given the contained nature of this field test, the Committee did not identify any significant adverse effects on society and community.

2.3.12 The Committee acknowledges submitters' concerns about food safety and food choices. The Committee notes that GM brassicas will be prevented from entering the human food chain and a further application to the Authority for a release approval would be necessary before effects on food safety and food choice would arise. Therefore, the Committee did not consider the effects on food safety and food choices further for this application.

Potentially significant adverse effects on the market economy

2.3.13 The Committee concurs with the Agency that since this application is for a small-scale contained field test with a fixed time period after which all plants will be removed, the potentially significant adverse and beneficial effects associated with this application are not economic in nature.

2.3.14 The Committee notes that submitters raised concerns about opportunity costs arising from this approval.

2.3.15 The purpose of the Act is to "protect the environment, and the health and safety of people and communities by preventing or managing the adverse effects of [..] new organisms". The Committee acknowledges that opportunity costs in terms of alternative uses of resources are relevant to achieving the purpose of the Act. However, in the context of a small scale 'impermanent' field test, such that all material will be removed at the conclusion, consideration of alternative uses of resources is primarily the domain of the applicant. Further, it is not the Committee's role to influence funding allocation decisions either by the applicant or by external funding sources through decisions on applications. The Committee observes that for any future application to conditionally release or release such organisms, the opportunity costs (of all factors) which would be considered in terms of the 'with' and 'without' scenarios may be relevant to the consideration.

2.3.16 Submitters raised concerns that gene flow from GM brassicas to non-GM brassicas (including organic brassicas) could contribute to economic losses for the affected growers. The Committee considers that the pathway for this to occur is through pollen escape from GM brassicas. Given the controls on this approval, the likelihood of pollen escape is highly improbable (section 2.5.17 - 2.5.20). Therefore the adverse effect of economic loss is considered not to be potentially significant and the Committee has not addressed this matter any further.

2.3.17 Submitters also raised concerns about liability resulting from any breach of containment and subsequent environmental, human health, cultural, social or economic damage. The Committee notes that this approval is subject to controls designed to prevent the escape of any material capable of causing monetary losses and that sections 124A to 124I of the Act specifically address matters of pecuniary penalties and civil liability for breaches relating to new organisms. The Committee considers that these adequately address the concerns raised. Beyond this liability for a breach of the controls, any person who has suffered loss as a result of negligence may make a claim through the Courts based on common law principles.

Potentially significant unanticipated adverse effects due to the genetic modification process

2.3.18 The Committee considered the risk of potentially significant unanticipated adverse effects resulting from the genetic manipulations during the development of the GM brassicas.

2.3.19 The Committee notes that unanticipated effects may potentially occur within the genetically modified plants as a result of the genetic modification process. One or more random insertions of genes into the genomic DNA may, in addition to the intended effect, result in unexpected changes in the concentrations of nutrients or secondary metabolites or, in theory, even to the formation of new toxins or viruses.

2.3.20 The Committee heard evidence of concerns held by some submitters that, as a promoter originally derived from a plant virus has been used in the genetic construct inserted into the brassica, unanticipated effects, such as silencing and viral recombination may arise.

2.3.21 The Committee notes that genes controlled by the CaMV promoter may be subject to silencing when plants are infected with CaMV (Gressel, 1999). The Committee considers that one of the rationales for conducting field testing is to identify any unanticipated effects. At the hearing, the applicant stated that a virologist would monitor the plants for CaMV infection. Furthermore, the Committee notes that it is the applicant's intention to use non-viral derived, plant tissue specific promoters in future GM brassica lines.

2.3.22 The Committee notes that homologous recombination between gene sequences can occur. However, such recombination would not be expected to result in the generation of a new virus if an existing virus was not involved in the recombination. Even if a virus acquired a promoter sequence, it is highly improbable that a new pathogen would develop since the host range or pathogenicity of the virus is not usually affected by the promoter sequence.

2.3.23 The Committee notes the concern of submitters regarding the use of highly modified synthetic versions of bacterial *cry* genes and the possibility that the resulting proteins will have different properties compared with the bacterial Cry toxin.

2.3.24 The Committee considers that scientific analysis and field testing of GM brassicas will help to identify unanticipated adverse or beneficial effects of the GM brassicas. In addition, the containment controls will limit the degree to which any altered brassica plants will be exposed to the environment. For this reason the potential for unanticipated effects is not required to be assessed further.

2.4 Identification of the potentially significant beneficial effects (benefits) of the organisms

2.4.1 The Committee notes that at the hearing, the following benefits were identified by the applicant:

- Keeping options open for GM technologies in New Zealand in line with the Royal Commission on Genetic Modification's recommendation that New Zealand "proceed carefully, minimising and managing risks".
- Providing New Zealand relevant agronomic and environmental impacts data.
- Enhancing scientific knowledge.

2.4.2 In accordance with clauses 9 and 10 of the Methodology, which incorporates sections 5, 6 and 8 of the Act, the Committee considered the beneficial effects of field testing GM brassicas, as listed below, as being potentially significant. These effects are assessed in section 2.9 of this decision.

- Enhancement of knowledge and understanding of agronomic practices for these brassicas genetically modified for *Bt* expression.
- Upskilling of staff and increased experience in working with gene technology in the field.

2.4.3 The Committee concurs with the Agency's view expressed in the E&R report that there are no potentially significant beneficial effects on the environment, human health and safety, the relationship of Maori to the environment, Te Tiriti o Waitangi/Treaty of Waitangi, or the market economy, associated with this application.

2.5 Proposed containment and controls and their adequacy

2.5.1 The Committee considered the adequacy of containment for the purpose of section 45(1)(a)(iii) of the Act, and the magnitude and probability of the risks, costs and benefits at the same time and in an integrated fashion. This is because the former interact with the latter and this is recognised in clause 12(d) of the Methodology and in section 45(1)(a)(ii) of the Act. For convenience in setting out the decision, the adequacy of containment is discussed first. This discussion includes options and proposals for managing risks[5].

2.5.2 In accordance with sections 37 and 44 of the Act and clauses 10(e) and (f) of the Methodology, the Committee has considered the ability of the organism(s) or any heritable material to escape containment and to establish an undesirable self-sustaining population, and the ease with which these could be eradicated if such populations were established. Other matters relating to controls were also considered.

[5] Clause 12(d) of the Methodology.

Ability to adequately contain the organism

2.5.3 The field test will be conducted in accordance with the MAF/ERMA New Zealand Standard 155.04.09: Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species (the Plant Containment Standard) (control 1.1). This Standard stipulates that no plants, viable or heritable plant material[6] may be removed from the field test site except under conditions specified by the Authority in the containment controls (controls 1.4, 1.6, 1.8, 1.9 and 1.11).

2.5.4 The Committee has identified and assessed the following pathways by which the GM brassicas may escape from containment.

Removal of brassicas by unauthorised persons

2.5.5 Given the high profile nature of field tests of genetically modified plants, the Committee considers that there is a possibility of sabotage associated with this field test which could lead to GM brassica material being unlawfully taken out of containment. For this reason the location of the field test site will remain confidential.

2.5.6 To address the issue of removal of GM brassicas by unauthorised persons, control 2.1 requires that access to the field test site be restricted to persons authorised by the facility Operator[7]. The field test site shall be enclosed by a perimeter fence to prevent public access, and gates must be closed at all times and locked when there are no authorised persons on site.

2.5.7 Given the above containment measures, the Committee considers that it is highly improbable that unauthorised persons could intentionally remove GM brassica plants from the field test site.

Escape from containment during transit.

2.5.8 The Committee considers that there is potential for GM brassicas to escape containment during transit (between the field test site and the containment laboratories).

2.5.9 The Committee notes that adherence to the Plant Containment Standard (sections 4.5 and 4.6) requirements for transfer and transport of plants or viable plant material will reduce the risk of loss during transit. In addition, the Committee has imposed the following controls that address the movement of GM brassicas between facilities. Control 1.9 requires that approval be sought from the MAF Inspector before any transfer of GM brassicas between facilities. While in transit the plants are to be held in secure containers to prevent spillage. The register of plants, required by section 4.8 of the Plant Containment Standard and by control 1.15 would ensure that in the event of spillage in transit, it would be possible to check exactly what was lost and whether all lost material was recovered. Control 1.11 (an inventory to be used during all transits of plants) is a measure to ensure that any GM plants spilt can be accounted for. The Committee considers that in an event of a spillage during transit, it is very likely that plant material could be recovered from the site of the spillage.

[6] Heritable material is defined in section 2 of the Act and in this context means brassica pollen and seeds.

[7] The person who has overall responsibility for the containment facility, its maintenance and operation, in terms of section 40 of the Biosecurity Act, 1993.

2.5.10 The Committee considered that seed would provide a pathway for escape during transit. Control 7.3 ensures that no seeds of GM brassicas will be sown or inadvertently planted in the field test site. Furthermore, to prevent non-germinated GM seeds being transported to the field test site, control 1.10 requires all seed to be accounted for prior to seedlings being transferred into the field test site.

2.5.11 Given the above containment measures, the Committee considers that it is highly improbable that GM plants would escape from containment during transit.

Unintentional removal by human activity

2.5.12 The Committee considers that there is potential for GM brassicas to escape containment through handling errors by workers, and/or by adherence to machinery or equipment.

2.5.13 The Committee notes that all planting and harvesting of GM brassicas will be performed by hand. Furthermore, all equipment used on the field test site must be cleaned after use (control 4.2).

2.5.14 The plant register (control 1.15) and the monitoring regime (controls 6.3 and 6.4) would provide a mechanism by which any loss of GM brassicas would be detected. Control 5.2 requires that the applicant has procedures in place to retrieve any material accidentally removed from the field test site.

2.5.15 Controls 4.3 and 4.4 require all personnel involved in the handling of the organisms to be informed of the Authority's controls and that training of personnel working in the field test site shall be in accordance with section 3.4 of the Plant Containment Standard. Inexperienced staff and visitors to the field test site must be accompanied by trained personnel at all times.

2.5.16 Given the above containment measures, the Committee considers that it is highly improbable that GM brassicas will escape from containment through handling errors by workers and/or by adherence to machinery or equipment.

Flowering and pollen dispersal

2.5.17 The Committee considers that there is potential for GM brassicas to escape containment through flowering and pollen dispersal. The escape of pollen from GM brassicas is addressed by control 1.8. This control states that *Brassica oleracea* plants shall be prevented from producing open flowers in the field test site. Plants initiating bolting must either be moved back into a containment structure (control 1.4) or killed (control 1.12).

2.5.18 During the hearing, the Committee heard evidence of the possibility that brassicas plants such as broccoli could produce open flowers before bolting of the plant commences. The Committee considered that such events, also influenced by changes in the weather and climate, may not be effectively captured by a monitoring regime where inspection of plants is specified to occur at 3 to 4 day intervals or less. Since containment of GM brassicas depends largely on the ability to monitor for flowering, the Committee has imposed a control stating that monitoring shall be performed using a scientifically validated method and staff trained in that method. The monitoring intervals shall be appropriate to the developmental stages of the brassicas to detect the onset of bolting or early flower opening (control 6.3). A log which records the details and findings of each monitoring visit shall also be maintained (control 6.4). The Committee considers that these requirements would

mean that the Operator could identify and remove all flowering GM brassicas in advance of pollen being dispersed.

2.5.19 The Committee notes that plants derived directly from callus[8] can have altered properties, for example altered flowering properties due to changes in gene expression patterns. Therefore, plants derived directly from callus may provide a pathway by which early flowering could occur within the field test site. As the containment of the GM brassicas depends largely on preventing the opening of flower buds within the field test site, the Committee considered that only seedlings, or cuttings derived from plants grown from seed or cuttings from *in vitro* shoots, but not plants regenerated directly from callus, may be planted in the field test site (control 7.3). Furthermore, the Committee notes that the monitoring required by control 6.3 will ensure that any unusual events such as early flowering are detected before flower buds open.

2.5.20 The Committee considers that these containment measures would ensure that it is highly improbable that GM brassicas plants could escape from containment through flowering and dispersal of pollen.

Removal or destruction of heritable material

2.5.21 The Committee considers that there is potential for GM brassicas to escape containment through heritable material. Brassicas do not naturally reproduce through vegetative reproduction but through the production of seeds. Heritable material of brassicas consists of pollen and seeds. Flowering and dispersal of pollen has been addressed in the previous section.

2.5.22 The Committee considered the potential for ungerminated seeds to be inadvertently transferred into the field test site when brassicas seedlings are transplanted from the glasshouse to the field test site. To ensure that this does not occur, control 1.10 requires that all seed be accounted for before seedlings are planted in the field. Furthermore, control 7.3 states that seeds of the GM brassicas shall not be sown or inadvertently planted in the field test site.

2.5.23 The Committee notes the concerns raised by submitters regarding the collection and disposal of seeds. The field test approval only permits field testing of GM brassicas until marketable heads are formed or bolting begins. Therefore, seed collection of any field tested GM brassicas can only occur under other HSNO Act approvals (control 1.4). Furthermore, the Committee notes that in line with New Zealand's obligations under the Cartagena Protocol[9] any export of GM brassica seeds for release in another country would require Ministerial approval.

2.5.24 The Committee notes the concerns of submitters regarding GM brassicas entering the food chain. Control 5.4 prevents any GM brassicas or food crops grown in the field test site, during the period of the field test and post-harvest monitoring, from entering the food chain. Therefore, for the duration of the field test and post-harvest monitoring period, all buffer row plants and any rotational crops grown within the field test site should be composted on site or ploughed into the field test site (control 7.5). The Committee notes that to ensure the proper disposal of plants used in the buffer rows, these shall be phenotypically different from the GM brassica plants (control 7.4).

[8] A mass of proliferating tissue consisting predominately of parenchymatous cells, but in which differentiation may occur under suitable conditions..

[9] The Cartagena Protocol on Biosafety is a multinational agreement set up under the United Nations Convention on Biological Diversity, to regulate the international trade of living modified organisms.

2.5.25 The Committee notes that under section 45A of the Act, approvals for field testing of genetically modified organisms must include controls to remove or destroy the organism and any heritable material from the organism (section 45A(2)(a)), and may include controls to ensure that, some or all of the genetic elements remaining from the organism are removed or destroyed[10] (section 45A(2)(b)) after the end of the field test. In order to fulfil these requirements, the Committee has specified controls 1.8, 1.12, 6.5, 6.6).

2.5.26 The Committee notes that control 1.12 requires that at the end of each growing season, all GM brassica plants have to be removed from the field test site, and those not retained for research purposes, shall be disposed of using a scientifically validated method.

2.5.27 Controls 6.5 and 6.6 require visual inspection of the site following removal of brassicas at the end of each growing season and at the completion of the field test at monthly intervals. Control 6.6 requires the removal of any heritable material including volunteer brassica plants after the field testing has been completed. To ensure that volunteer brassica plants are detected, the control prohibits brassica plants being planted in the field test site for the duration of the final post harvest monitoring. The final post-harvest monitoring period will initially be for one year after the completion of the field test. However, if any GM brassica volunteers are detected within that year, then an additional 5 years of post-harvest monitoring would be implemented. This additional monitoring period would start from the date of detection of the last volunteer GM brassica plant on site.

2.5.28 Submitters raised concerns about the ability to remove heritable material from the field test site, referring to a previous field trial of tamarillos genetically modified for resistance to the tamarillo mosaic virus.

2.5.29 This GM tamarillo field test pre-dates ERMA New Zealand's role in decision making for the field testing of new organisms. This field test was approved by the Minister of the Environment on 9 January 1998, on the recommendation of the Interim Assessment Group (IAG). In February 2001, after the completion of the field test, but during the post-harvest monitoring period, ERMA New Zealand reviewed the controls imposed by the IAG. ERMA New Zealand commented that, in retrospect it may have been prudent to bag flowers and require hand pollination to remove the potential for bee-mediated transfer of GM pollen. However, it was also noted that the isolation distance of 400 m between the trial site and the nearest commercial tamarillo orchard would have mitigated the risk of cross pollination.

2.5.30 The Committee considers ERMA New Zealand's containment controls with regards to the containment of heritable material are more robust due to the knowledge and experience gained from previous field tests.

2.5.31 The issue of removing any heritable material is addressed by the controls requiring the removal of all heritable material at the end of each growing season (controls 1.8, 1.12 and 1.14) and inspection of the site for any heritable material left behind (controls 6.5 and 6.6). The issue of genetic elements from the GM brassicas remaining in the field test site is addressed by leaving any remaining genetic elements to break down or become inactive at the site and monitoring to detect and remove any subsequent re-growth or seedling germination (controls 6.5 and 6.6). The Committee considers this appropriate as brassicas do not regenerate through vegetative reproduction (root stock or material left in the soil).

[10] In section 45A(2), destroyed includes leaving genetic elements to break down or become inactive at the site of the field test.

2.5.32 Taking into account the containment measures associated with this approval, the Committee concludes it is highly improbable that any heritable material will escape from containment.

Removal of plant material by animals (rodents, escaped stock, birds)

2.5.33 The Committee considered that there is a potential for GM brassicas to escape from containment through removal by animals such as grazing stock, rabbits, hares and birds consuming plant material.

2.5.34 The Committee is satisfied that larger animals such as sheep and cattle are likely to be effectively excluded from the field test site by fences (control 2.1) and it is highly improbable that wandering stock could gain access to the field test site. Control 3.2 requires grazing animals to be excluded from the field test site and control 3.3 requires the Operator of the field test to monitor the integrity of the fencing regularly. In addition, vermin and pest control measures which include surveillance and control activities, are required by section 4.9 of the Plant Containment Standard.

2.5.35 The Committee considers that the removal of seedlings by smaller animals such as rabbits, hares and birds, may be a pathway for escape of whole plants. Control 1.13 requires the implementation of such practical measures as are necessary to reduce the likelihood of removal of GM brassica seedlings from the field test site by animals. Further, the Committee notes that consumption of plant material is not a significant pathway of escape. The Committee considers that, with the exception of seed (which cannot be planted or produced on the field test site), plant material will be digested (killed) within the animal's gut.

2.5.36 Given the above measures, the Committee considers that it is highly improbable that GM brassicas will escape containment through removal by animals.

Loss from the site by natural events

2.5.37 The Committee considers that there is a potential for GM brassicas to escape containment due to natural events (for example strong winds and flooding).

2.5.38 The Committee notes that the field test site location, where only surface flooding has been observed over the last 20 years, and the security and monitoring procedures in place will ensure that the likelihood of natural events leading to plant removal is highly improbable and any missing plants can be quickly identified. The Plant Containment Standard requires the preparation of a contingency plan to deal with such events (control 1.5) and the contingency plan to be implemented immediately to prevent further release, and where possible, recover the released plants (control 5.2).

2.5.39 The Committee notes that localised flooding could occur in the field test site through a burst irrigation pipe with the resultant displacement of GM plants off-site. The Committee considers that such events would be easily observed by workers on the field test site and retrieval of any displaced GM brassica plants could be undertaken. The register of plants in the field test site (control 1.15) would provide a means of ensuring that all GM plants were accounted for following such an event.

2.5.40 Given the proposed containment measures, the Committee considers that it is highly improbable that GM brassicas will escape containment by natural events.

Horizontal Gene Transfer (HGT)

2.5.41 The Committee notes that there is a potential for GM brassica genetic elements to escape containment through HGT. HGT is defined as the transfer of genetic material from one organism to another organism that is outside of the context of parent to offspring (ie vertical) reproduction (Heinemann, 2003).

2.5.42 The Committee considers that HGT of the gene constructs from GM brassicas is theoretically possible but, based on current knowledge including previous studies in the laboratory and in the field, such events are extremely rare.

2.5.43 The Committee notes the submitters concerns that though based on current techniques it is highly improbable that HGT would be detected, this inability to detect HGT does not mean that it will not occur within the field test site. However, the Committee considers that HGT is a rare event, and while there are techniques which could detect the occurrence of HGT, this would involve sampling of impractically large amounts of soil.

2.5.44 Given HGT is an extremely rare event, the Committee considers that it is highly improbable that GM brassica genetic elements will escape containment through HGT. Further information on HGT is set out in the E&R Report[11] and the ERMA New Zealand report on HGT (ERMA New Zealand, 2006).

Other containment controls

Duration of the approval

2.5.45 The Committee considers that the risks posed by this field test are unlikely to change over time, provided that the field test is conducted in accordance with this approval and with the controls imposed on the organism. Therefore the Committee has determined that the duration of the approval shall be up to ten (10) years from the date of the first planting (control 1.6). The Committee considers this to be sufficient time for the applicant to carry out the proposed work. In conjunction with this control, the field test must commence within five (5) years of the approval being granted. Furthermore, the applicant must notify both ERMA New Zealand and MAF Biosecurity New Zealand of their intention to commence field testing (control 7.1). In addition, control 7.9 states that upon completion of all post-harvest monitoring, the field test site will be deregistered following MAF Biosecurity New Zealand approval.

Monitoring and inspection

2.5.46 Clause 6A of the Third Schedule to the Act states that controls may specify inspection of the site before field testing commences. The Committee considers that such a control is not required.

2.5.47 To ensure that the GM brassicas to be field tested meet the requirements of the approved organism description, the approval holder shall provide MAF Biosecurity New Zealand with details of all lines to be tested, at least 30 working days prior to the proposed planting date. Prior to planting, MAF Biosecurity New Zealand will verify the details of lines to be tested against the approved organism description and confirm with the Operator (control 7.2).

2.5.48 The Committee considers that inspection of the field test site should occur during significant stages of the plant's life cycle. Control 6.2 specifies that the inspection of the site and audit of the operation should occur twice during the growing season,

[11] Refer to section 4.4.36 – 4.4.45 of the E&R Report.

including at least once during the period when flowering could occur. Inspections by the MAF Inspector[12] may also occur at any other time to ensure that the field test is being carried out in compliance with this approval.

Annual reports on field test

2.5.49 Control 7.7 requires an annual report to be provided to ERMA New Zealand. This report will help the Authority monitor the operation and progress of the field test.

2.5.50 In order to recognise and provide for the role of Te Rūnanga o Ngāi Tahu and Te Taumutu Rūnanga as ngā kaitiaki in the region, the Operator of the field test shall ensure that specifically written annual updates are provided to those parties, and a copy of these reports is provided to Ngā Kaihautū Tikanga Taiao (control 7.8).

Duty to report any matters relevant to management of test

2.5.51 Control 7.6 requires the Operator of the containment facility to inform the MAF Inspector and ERMA New Zealand of any matters that may affect the long term management of the field test. The purpose of this control is to assist the relevant authorities with ongoing monitoring of the field test.

Conclusions on the adequacy of containment

2.5.52 The Committee considered all of the controls set out in Appendix 1, and did so in the context both of preventing the escape of the organisms and effectively managing any risks. The Committee considers that escape of the GM brassicas from containment is highly improbable, based upon an assessment of the containment measures, the controls imposed by this approval, the biological characteristics of the GM brassicas and the identified pathways by which an escape could occur. The Committee was satisfied that the GM brassicas and any heritable GM brassica material would be adequately contained.

2.6 Ability of organism to escape and to establish an undesirable self-sustaining population

2.6.1 In accordance with sections 44 and 37 of the Act, the Committee considered the ability of the organisms to escape and to establish an undesirable self-sustaining population, and the ease with which such a population could be eradicated.

2.6.2 The possible sources of a self-sustaining population of GM brassica plants are through seed left in the ground after harvest, the release of the whole plants or release of genetic material through pollen or seed dispersal. The Committee has concluded (section 2.5.52 of this decision) that it is highly improbable that any GM brassica material could escape (or to be lost from containment) given the proposed containment measures and the characteristics of *Brassica oleracea*.

2.6.3 The conditions for establishment of an undesirable self sustaining population would require viable plant material to leave the field test site, to remain unnoticed, and to grow off-site. The Committee also considers that the genetic modification is unlikely to contribute to the brassica becoming weedy and establishing an undesirable self-sustaining population.

[12] A person appointed as an inspector under the Biosecurity Act, 1993.

2.6.4 Many brassicas, including broccoli, cabbage, cauliflower and forage kale, are self-incompatible and require cross pollination to set seed. Therefore, if the GM plants escaped and produced pollen, there would have to be sexually compatible wild relatives or other *Brassica* crops in the vincinity for fertile hybrids to form.

2.6.5 The Committee notes that there is considerable taxonomic and morphological diversity of *Brassica* species naturalised in Canterbury and that crop escapes are an important part of this diversity (Heenan et al, 2004). Field observations suggest that land disturbance and the open habitat it creates is amongst the most crucial factors in the establishment of *Brassica* (Heenan et al, 2004). The distribution of naturalised *Brassica* has been described as sparse and infrequent. Many of the small populations that occur appear to comprise casual crop escapees that do not form persistent natural populations.

2.6.6 The Committee recognises that crop escapees may contribute to the naturalised brassica population. However, for this to occur with the GM brassica plants in this field test, there needs to be both a pathway for the plants to escape from containment and a suitable habitat including positive selection pressures.

2.6.7 The Committee concluded that the likelihood of GM-brassica plants or any associated heritable material escaping containment is highly improbable, taking into account the containment measures in place (section 2.5.52). Since there is no positive selection pressure for establishment of GM brassica plants, except in areas of high-insect feeding, the Committee considers that it is, at worst, improbable that a self-sustaining population would be established, if GM brassica plants were to escape from containment.

2.7 Ease of eradication of an undesirable self-sustaining population

2.7.1 The Committee considers that the presence of any GM brassica outside of the field test site is undesirable. The Committee considers that the eradication of an undesirable self-sustaining population of these GM brassicas would be technically possible. An appropriate herbicide (for example Glyphosate), or roguing (pull out and destroy) and autoclaving, could effectively eliminate such individuals.

2.7.2 If a self-sustaining population did establish, the identification of this could be difficult because, apart from the lack of feeding damage under normal to heavy CWB and DBM caterpillar infestation, GM brassicas would not be phenotypically different from non-GM brassica plants. Identification would require specific testing for the transgenic construct used in the field test.

2.8 Assessment of the potentially significant adverse effects (risks and costs) of the organism

Approach and coverage

2.8.1 The adverse effects (risks and costs) assessed below are those identified as potentially significant, having regard for those matters set out in clauses 9 and 10 of the Methodology and sections 5 and 6 of the Act. Risks were considered in terms of the requirements of clause 12 of the Methodology, including especially the assessment of the magnitude of the consequences and probabilities of their occurrence, the nature and impact of uncertainty and the impact of risk management. The evidence available to the Committee was evaluated in accordance with clause 25 of the Methodology.

2.8.2 For each adverse effect the Committee has addressed the following considerations, as set out in the Methodology, as far as is reasonably practicable considering the particular nature of each risk:

- The nature of the adverse effect (clause 12(a)).
- An assessment and evaluation of likelihood and consequence of the adverse effect (clause 12(b)).
- Where possible, an assessment of the level of risk as a combination of the likelihood of occurrence and the magnitude of the adverse effect (clause 12(c)).
- The risk management proposals and their effect on both the risk and the uncertainty associated with the risk (clause 12(d)).
- An assessment of all the effects of the organism should the organism escape containment (section 45).
- An explicit consideration of the uncertainty bounds on the estimates (clause 12(e)) and how uncertainty affects the assessment of the risk (clause 25 - scientific and technical uncertainty, clause 29 - materiality of uncertainty, and clause 30 - need for caution where not resolved).

2.8.3 A “cost” is defined in the Methodology as “the value of a particular adverse effect expressed in monetary or non-monetary terms”. Costs are generally expressed as risks, that is, they are assessed as having a magnitude and a probability. Where costs

are certain this probability is one. The Methodology and the Act both call for consideration of monetary and non-monetary costs (clause 13 and section 9). In most field test cases, the direct costs are those associated with conducting the trial and will accrue to the applicant. Consideration of costs includes:

- Whether the cost is monetary or non-monetary (clause 13(a)).
- An estimate of the magnitude of the cost (clause 13(b)).
- The distributional effects over time, space and groups in the community (clause 13(c)).

2.8.4 Explicit consideration of the uncertainty associated with the estimate (clause 25 scientific and technical uncertainty, clause 29 materiality of uncertainty and clause 30 need for caution where not resolved) may also be required.

2.8.5 The assessments set out below apply to those risks identified in section 2.3 of this decision.

Potentially significant adverse effects on the environment

Development of resistance to Cry toxins in diamondback moth (DBM) and cabbage white butterfly (CWB)

2.8.6 The Committee considered the potential for the development of resistance to *Bt* toxins in DBM and CWB, and consequential threat to the future use of *Bt* foliar sprays and their effectiveness for controlling these pests. This could result in potential costs to growers and the Committee considers that exposure to this risk is involuntary.

2.8.7 The Committee notes that resistance to *Bt* sprays has developed in field populations of DBM in Hawaii, and in Asia. Also, that there has been no report of insect resistance developing as a result of the use of *Bt* transgenic crops (see E&R report[13]).

2.8.8 For a resistant population of DBM or CWB to develop, there has to be selection pressure favouring the survival and reproductive success of insects that carry alleles which confer resistance trait(s) to Cry toxin. With continual selection pressure, ensuing generations will eventually be comprised largely of resistant individuals as the alleles that confer the resistance trait(s) become more predominant in the population resulting in a resistant population.

2.8.9 Several submitters were also concerned about the effectiveness of visual monitoring for caterpillars on brassica plants, a measure proposed by the applicant to prevent resistance from developing. If rare caterpillars which could survive on *Bt* plants were missed, these survivors could complete their development and pass on resistance traits to the next generation.

2.8.10 A submitter noted that even for a small field test site, resistance in these insect pests could arise as the alleles that confer the resistance traits, although rare, can persist within populations in accordance with the principles of population genetics (Hardy Weinberg principle). However, the Committee notes that to date, there are no reports of insect resistance developing from the use of *Bt* expressing crops.

2.8.11 The Committee considered that the magnitude of the effect is minimal because selection for *Bt* resistant individuals is confined to the field test site, and limited to the duration when GM brassica plants are in the ground. Further, there are

[13] Section 7.1.14

alternatives to manage insect resistance, such as the use of other pesticides, should resistance to *Bt* develop in these insect pests.

2.8.12 The field test site is restricted to a 0.4 hectare size plot and is likely to be surrounded by land undergoing other cropping regimes (a large refuge where there is no selection pressure for *Bt* resistant individuals). Therefore, the possibility of development of individuals homozygous[14] for the *Bt* resistant traits is highly improbable as the selection pressure is affecting a small group of individuals from a very large pool that constitutes the rest of the farm land in the Canterbury district.

2.8.13 The Committee considers that this effect is minimal in consequence (magnitude) and it is highly improbable in likelihood. Therefore, this effect is considered to be negligible.

Reduction in soil biodiversity

2.8.14 The Committee considered the risk that Cry toxins released from root exudates and decomposing GM brassica material could be toxic to soil biota either through ingestion or contact, causing a reduction in soil biodiversity.

2.8.15 The Committee heard and considered evidence presented at the hearing that larger differences in soil biota were observed in field trials comparing different maize cultivars (non *Bt*) and crops compared to the differences observed between *Bt* and non *Bt* maize plants of the same cultivar (Griffiths et al, 2005).

2.8.16 The Committee also noted that a small but significant change in the soil biota was observed in glasshouse trials of *Bt* maize compared to non *Bt* maize. However, the difference was no greater than that observed using the current best practice, ie insecticide treatment (Griffiths et al, 2006).

2.8.17 The Committee notes that soil communities are already exposed to *Bt* toxin as *Bacillus thuringiensis* is a naturally occurring soil organism and therefore is already constantly available for ingestion by all soil invertebrates. However, higher levels of Cry toxins may occur in the field test site for a limited period of time. Furthermore the field test site will have different cover crops over the life of the field test. Therefore, the soil biota will not be exposed to *Bt* brassicas continuously.

2.8.18 Taking into account that the Cry proteins will degrade, toxicity effects, if any, would be localised, temporary and reversible. The Committee considered that the consequence (magnitude) of this effect is minimal and would be very unlikely to occur. Therefore, the effect is considered to be negligible.

Harm to non-target organisms

2.8.19 The Committee considered the potential for the GM brassicas to be harmful to non-target organisms because of the novel gene products expressed in the plants. The risk to groups of non-target organisms is assessed in the following sections (2.8.21 – 2.8.46).

2.8.20 Several submitters raised concerns regarding the risks of *Bt* plants to grazing animals, natural predators, parasitoids, non-target organisms such as aphids, earthworms and birds and beneficial insects such as bees. The Committee considered that a contained field test will provide an opportunity to evaluate the effects on non-target organisms on a small scale.

[14] A documented case of resistance to the use of foliar *Bt* sprays has been attributed largely to a single autosomal recessive locus (Schnepf et al, 1998).

Harm to grazing animals

2.8.21 The Committee considered that GM brassica plants could potentially be harmful to grazing animals if ingested. Animals that eat GM brassicas may have an allergic or other adverse reaction to the Cry proteins or other expressed proteins as a result of the genetic modifications.

2.8.22 While the Committee notes that *Bt* toxins have a long history of safe use as insecticidal sprays with applications to a broad range of crops, several submitters have presented evidence concerning toxic effects of *Bt* cotton plants on sheep, and the results of feeding trials of GM plants on rats and mice.

2.8.23 The Committee notes that no toxicity and allergenic studies have been carried out with the GM brassicas. However, to have an adverse effect, grazing animals would need to enter the field test site and consume GM brassicas. The Committee considers that any direct toxic effects to the animals would be localised and easily reversible.

2.8.24 The Committee notes that animals such as grazing stock and other large herbivores are specifically excluded from the field test site by fencing (control 3.2) and no GM brassicas (or any part thereof) are to be deliberately fed to animals (control 5.4).

2.8.25 Animal pathogens found in the soil within the field test site could potentially develop antibiotic resistance via HGT from the GM brassicas and cause harm to any stock that came in contact with them. However, the Committee considered the likelihood of GM brassica genetic elements escaping containment through HGT as highly improbable (section 2.5.44).

2.8.26 The Committee considers that given the containment measure, a direct toxic effect on grazing animals would be minimal in effect and highly improbable in likelihood. Therefore, the risk is considered to be negligible.

Indirect or direct toxic effects causing harm to parasitoids and predators

2.8.27 The Committee considered the potential for GM brassicas to be harmful to organisms other than the lepidopteran pests such as CWB and DBM to which the toxin is targeted. GM brassicas could have direct or indirect toxic effects on non-target organisms which include natural biological control agents such as parasitoids or predators of the CWB and DBM.

2.8.28 The Committee notes that parasitoids and predators of Lepidoptera are unlikely to be susceptible to direct toxic effects of *Bt* expressing brassica. However, the Committee considers that parasitoids and predators could be affected indirectly through effects on their hosts. Any effect on parasitoids and predators would be limited by the relatively small size (0.4 hectare) of the field test.

2.8.29 The Committee considers that although specific *cry* genes have not been named in the application, the scope of the field test limits the use of *cry* genes to those that target lepidopteran caterpillars.

2.8.30 The Committee also notes that other pest control methods, including the use of insecticides such as *Bt* based insecticides, would also be expected to exhibit a similar adverse effect on the populations of parasitoids and predators.

2.8.31 The Committee considers that a direct or indirect toxic effect on predators and parasitoids would be minimal and very unlikely due to the limited size and scope of the field test. The risk is thus considered to be negligible.

Direct toxic effects on non-target pest insect species (excluding lepidopteran species)

2.8.32 The Committee considered the potential for the Cry protein products of the GM brassicas to have a direct toxic effect on non-target pest species that are not expected to be controlled by the Cry proteins. These are non-lepidopteran, and include pests such as aphids and grass grub.

2.8.33 The Committee notes that it is highly likely that any non-target pest herbivores feeding on the GM brassicas within the field test site will be exposed to the Cry toxins. The Committee notes that there are *cry* gene products that target dipterans and coleopterans. However, the organism description restricts the use of *cry* genes to those that target lepidopteran caterpillars and given the known specificity of these toxins, these are unlikely to affect non-lepidopteran insects.

2.8.34 Given that the application is for a small scale field test (0.4 hectare) in size, the Committee considers the magnitude of the effect on non-target pest species is minimal. The likelihood that the GM brassicas may have direct toxic effects on non-target pest species is very unlikely. This risk is thus considered to be negligible.

Direct toxic effects on other non-target lepidopteran pest insect species including native lepidopterans

2.8.35 The organism description restricts the use of *cry* genes to those that target lepidopteran brassica pests like DBM and CWB caterpillars. The Committee considers that these gene products could potentially also affect other non-target lepidopteran pest insect species. There is, however, some uncertainty relating to this assessment as the exact *cry* genes to be tested have not been specified nor is the activity against lepidopterans other than DBM and CWB known without further testing.

2.8.36 Any non-target herbivorous insects feeding within the field test site are likely to be considered potential crop pests and may cause yield losses or crop damage. It is also noted that other pest control methods, including the use of insecticides such as *Bt*-based insecticides, would also be expected to exhibit a similar adverse effect on these populations.

2.8.37 Since the application is for a small scale field test (0.4 hectare in size), the Committee considers the magnitude of the effect on these non-target pest species is minimal and the likelihood of this occurring is considered to be very unlikely. This risk is therefore considered to be negligible.

Direct toxic effect on beneficial insects or native insects (including honey bees and other pollinators)

2.8.38 Many insect species have beneficial ecological functions and are known to act as pollinators of crops and wild plants. In addition, butterflies are considered to be species with high aesthetic value and native insects are of importance for conservation value. The Committee considered the potential for the Cry protein products of the GM brassicas to have a direct toxic effect on these beneficial insects.

2.8.39 The applicant has identified honey bees as the main pollinators of brassica crops with bumble bees also playing a role in pollination. The Committee notes that pollen feeding is the most likely route of exposure to the Cry protein product for the pollinators.

2.8.40 Some submitters had expressed concerns that Colony Collapse Disorder (CCD) could occur as a result of the field test. This phenomenon is poorly understood but involves a dying off of a beehive or bee colony. Although the cause of this disorder

is still unknown, factors such as consumption of GM pollen linked with parasitism have been suggested. The Committee notes that since GM brassicas will not be allowed to produce open flowers in this field test (control 1.8), the likelihood of exposure to pollen from these plants is highly improbable.

2.8.41 Several submitters have referred to papers indicating that exposure to pollen from *Bt* maize can have adverse effects on larvae of non-target butterflies in particular the monarch butterfly (*Danaus plexippus*). The Committee notes, however, that these results are not conclusive, with other laboratory and field studies demonstrating no toxic effects at pollen densities that would be encountered in the field. Further, as noted in section 2.8.40, it is highly improbable that larvae of non-target butterflies will be exposed to pollen from this field test.

2.8.42 The Committee considers that any direct toxic effect to beneficial insects would be limited to the 0.4 hectare field test site and therefore minimal. Since GM brassicas will not be allowed to produce open flowers in this field test (control 1.8), the likelihood of exposure to pollen from these plants is highly improbable. Therefore, the risk to beneficial insects is considered to be negligible.

Direct or indirect toxic effects on birds

2.8.43 The Committee considered the potential toxic effects that GM brassica plants could pose to birds. Several submitters raised concerns that toxic effects could occur directly through birds eating GM plant material, or indirectly through eating earthworms within the field test site. The Committee accepts the evidence in the E&R report[15] and notes that no significant toxicity of *Bt* strains to any species of birds have been recorded.

2.8.44 The Committee notes that the Plant Containment Standard requires the implementation of a vermin and pest control programme. The proposed control (control 1.13) also requires the applicant to implement such practical measures as are necessary to reduce the likelihood of removal of GM brassica seedlings from the field test site by animals, thus reducing the likelihood of exposure of birds to the GM plants.

2.8.45 The Committee considers that any direct or indirect toxic effects on birds would be minimal. Taking into account the management options proposed by the applicant, and the information in published literature, the likelihood of any direct or indirect toxic effects on birds is highly improbable. The risk is thus considered to be negligible.

2.8.46 Overall, the Committee considers that given the size of the field test and the controls and management options in place, an adverse effect on non-target organisms is minimal and at worst very unlikely to occur.

GM brassica escapes to become a weed

2.8.47 The Committee considered the potential for GM brassicas to escape from containment and to become a weed. The Committee notes that there are a number of brassica crops that have become naturalised plants species in the Canterbury region, and some of these naturalised populations are considered weeds.

2.8.48 The Committee notes that for this to occur, either viable GM plant material or seeds have to escape from containment. The Committee has previously considered the

[15] Refer to section 7.1.82 to7.1.86

likelihood of escape via these pathways and assessed it as being highly improbable (section 2.5.52). Seeds will not be permitted to be planted in the field test site (control 7.3), and heritable material originating from the field test site has to be disposed of appropriately (control 1.12).

2.8.49 In the highly improbable event that viable GM brassica plant material or seeds escape from containment, these plants would need to have a selective advantage to cause the spread and persistence of GM brassicas. The Committee considers that the expression of Cry proteins would not add a significant competitive advantage over other weeds and result in the GM brassicas becoming an uncontrollable weed. Control would be possible because the plants could be easily eradicated by application of herbicide.

2.8.50 The Committee considers that the effect of GM brassicas escaping to become a weed is minimal. The likelihood of this occuring is highly improbable taking into account the containment measures in place, and the ease of eradication of such plants if found. This risk is thus considered to be negligible.

Lepidopteran resistance trait spreads to other brassica species causing weediness

2.8.51 The Committee considered the potential for the GM brassicas to hybridise with non-modified *Brassica oleracea* or other brassica weed species found in the Lincoln area, causing a weed species to become more 'weedy' than the unmodified species.

2.8.52 The Committee notes that the pathway by which this effect could occur is through escape of the *cry* transgene to another *Brassica* species by pollen escape from the GM brassicas in containment. If pollen were to be released from containment due to a failure in the monitoring regime, it could pollinate other non-modified *Brassica oleracea* or hybridise with closely related *Brassica* species, within the vicinity of the field test site.

2.8.53 After reviewing the evidence presented in submissions and in the E&R report[16], the Committee is satisfied that the proposed containment measures including the control preventing the brassicas from releasing pollen in the field (control 1.8) would make hybridisation highly improbable. The Committee considers that should this event occur, only non-modified brassicas in the region of the field test site will be impacted and thus the effect will be localised and can be managed.

2.8.54 A *Brassica* species expressing Cry proteins might become more 'weedy' than the unmodified species if the 'weediness' of the unmodified species is limited as a result of insect herbivory. While the Committee has found evidence that CWB and DBM are pests in brassica crops, as they affect the marketability of individual plants, there is no evidence that insect herbivory plays a role in reducing the number of brassica individuals. The Committee notes that the magnitude of this effect is also dependent upon the extent to which the weeds are already being managed, for example, through the use of herbicides.

2.8.55 In the improbable event of insect-resistant volunteer brassicas or weeds occurring on the field test site, these could be easily identified and then removed by spraying with herbicide or by hand-weeding. Therefore, the Committee considers that any potential adverse environmental impact would be minimal, and that it is highly improbable that it would occur. The risk of the insect resistance trait spreading to weeds as a result of this field test is thus considered to be negligible.

[16] Refer to section 7.1.92 to 7.1.101

Contamination of aquifers

2.8.56 During the hearing, several submitters voiced concerns that underground aquifers could be potentially contaminated by leaching of *Bt* toxins produced as root exudates, and from decomposition of GM brassica plant material. The Committee considers that this effect is minimal as it could only arise from the 0.4 hectare field test site and thus the amount of *Bt* toxins leaching is limited, compared to the wider environment where different cropping and agronomic practices are occurring.

2.8.57 The Committee notes that *Bt* toxins are most likely to accumulate in soil and retain their insecticidal activity especially when the toxin is bound to surface-active soil particles and thereby becomes resistant to degradation. The persistence of *Bt* toxins will depend on the interactions between many variables such as biotic activity, soil type, agronomic practices, and environmental conditions, and therefore may vary between sites and seasons[17]. The effects are temporary because, though *Bt* toxins may persist in the soil, the toxins will degrade with time. Taking account the size of the field test site, and the biophysical properties of the *Bt* toxins, the Committee considers that it is highly improbable that contamination of aquifers would occur. This risk is thus considered to be negligible.

[17] Refer to section 7.1.27 of the E&R report

Potentially significant adverse effects on human health and safety

Increased allergies or toxic reactions in humans (environmental /occupational exposure)

2.8.58 The Committee considered the potential for GM brassica plants to be more allergenic or toxic to humans than unmodified brassicas.

2.8.59 The Committee has heard and read the evidence presented in submissions regarding potential toxic effects of GM maize and cotton on humans, and the recent findings on genetically modified peas which were shown to cause lung damage in mice as a result of an allergic reaction. The Committee accepts the evidence presented in the E&R report[18] and notes that there have been no reports of adverse effects on the health of humans or animals from the use of *Bt* insecticides as foliar sprays in New Zealand.

2.8.60 The Committee considers that in the highly improbable event that the GM brassicas did cause an increased allergic or toxic reaction in humans that was different from any comparable effect from the use of *Bt* insecticides, the magnitude of the effect is likely to be minimal. Any allergenic or toxic reaction would be highly localised and affect a very small number of people due to the small scale of the field test. Furthermore, any adverse health effects are likely to be of short duration, as any person suffering a reaction, could be rapidly isolated from the source of the allergen or toxin, should it be suspected or found to be the GM brassica plants. Any adverse allergic or toxic effects would be readily treatable.

2.8.61 In accordance with clause 12 of the Methodology, the potential for allergenic or toxic effects of GM brassica has been assessed together with options for reducing the likelihood of exposure of persons to these GM brassicas. The Committee notes that exposure to this risk is voluntary as, in accordance with the proposed controls, only authorised persons would have access to the GM brassica plants in the field tests[19].

2.8.62 Given the small number of people who may have access to these GM brassica, and their training, the Committee considers that any potential allergic or toxic effects on humans due to GM brassicas would be minimal, and that it is highly improbable that they would occur. The risk of increased allergic or toxic reactions in human is thus considered to be negligible**.**

Potentially significant adverse effects on relationship of Māori to the environment

2.8.63 The need to take account of the relationship between Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga is set out in section 6(d) of the Act and in clause 9(c)(iv) of the Methodology.

2.8.64 The Committee recognises the concern raised by iwi/ Māori submitters that genetic modification may be in conflict with tikanga and mātauranga Māori, disrupting the basic structure and integrity of the relationships between generations and between species. The Committee also recognises comment made by iwi/Māori about the lack of research or information on the risk from genetic modification to cultural values and practices such as whakapapa, kaitiakitanga and rangatiratanga.

[18] Refer to section 7.2.4 to 7.2.14

[19] Clause 33(a) of the Methodology requires the Committee to have regard to the extent to which exposure to the risk is involuntary.

2.8.65 Uncertainties about these effects are in part ameliorated by controls ensuring the strict containment of heritable material, but the application did not include mechanisms for addressing the cultural issues noted above.

2.8.66 The Committee considers that the applicant could have worked more closely with Te Rūnanga o Ngāi Tahu and Te Taumutu Rūnanga on these issues in the development of their application. As the kaitiaki iwi and hapū in the region of the proposed field test, the Committee would have liked to have seen evidence of the formalisation of the applicant's relationship with these groups. From that foundation more effective discussion could have been had to develop possible mechanisms for addressing cultural values and practices as part of the research.

2.8.67 Given the applicant's previous and likely future work in this area, the Committee encourages the applicant to further develop its relationship with Te Rūnanga o Ngāi Tahu and Te Taumutu Rūnanga. This relationship should incorporate the mutual interests of both parties and reflect the intention of Te Tiriti o Waitangi/ Treaty of Waitangi ensuring Te Rūnanga o Ngāi Tahu and Te Taumutu Rūnanga are able to continue in the protection of their taonga, and as kaitiaki in the region.

2.8.68 Recognising feedback received from Te Rūnanga o Ngāi Tahu, the Committee considers that controls 7.7(e)and 7.8 go some way to addressing the issues raised, whilst not being unduly burdensome to either party. The Committee also notes the work being supported by the Agency of ERMA New Zealand to further facilitate the establishment of a relationship between the applicant and Ngāi Tahu including processes for effective future engagement.

2.8.69 The measures outlined above will, in the Committee's view, ameliorate impacts to a sufficient degree that they can be considered to be a negligible risk in the context of this contained field test.

Potentially significant adverse effects on the principles of Te Tiriti o Waitangi/ Treaty of Waitangi

2.8.70 Section 8 of the HSNO Act requires the Authority to take into account the principles of Te Tiriti o Waitangi/Treaty of Waitangi. On considering the principles outlined in the Methodology, the Committee recognises that iwi/Māori may have concerns with regard to the active protection of their taonga, particularly mātauranga and tikanga Māori, and native or valued flora and fauna.

2.8.71 In addition, the Committee acknowledges that Te Rūnanga o Ngāi Tahu and Te Taumutu Rūnanga are the mana whenua and kaitiaki in the region of the field test. In this regard the Committee further notes the need for the development of a formal and effective relationship between the applicant and Ngāi Tahu to ensure their cultural issues are appropriately addressed in research of this kind.

2.8.72 Given the contained nature of this field test and the controls set in this approval (particularly those noted in controls 7.7(e) and 7.8), the Committee considers that the impacts are adequately ameliorated to be considered to be negligible.

2.9 Assessment of beneficial effects (benefits)

Approach and coverage

2.9.1 A "benefit" is defined in the Methodology as "the value of a particular positive effect expressed in monetary or non-monetary terms". The benefits of this application were identified, having regard to those matters set out in clauses 9 and 10 of the Methodology, and considered in terms of the requirements of clause 13 of the Methodology. Accordingly, consideration was given to the estimated magnitude and expected value of the benefits, whether the benefit is monetary or non-monetary and the distributional effects over time, space and groups in the community. The materiality of any uncertainty associated with the estimates (clause 32) was also taken into account.

2.9.2 The benefits assessed below are those that were identified as potentially significant in section 2.4 of this decision. The Committee notes that the relevant benefits are those that pertain to this field test, rather than those potential benefits that might accrue from future approvals for conditional release or release of these organisms.

Enhancement of knowledge and understanding of agronomic practices for these brassicas genetically modified for *Bt* expression

2.9.3 The Committee considers that the principal benefit to be derived from this field test is the scientific knowledge expected to be gained in the areas of:

- phenotypic variation exhibited by GM brassica lines;
- the effectiveness of *Bt* expression in GM brassicas in the field;
- agronomic performance of new transgenic brassica lines;
- biological behaviour of GM brassicas; and
- the impact of GM brassicas on the environment.

2.9.4 The Committee notes that while valuable information would be obtained on some of the above aspects, information on other aspects will be limited due to the small size and scale of the field test.

2.9.5 The Committee considered it is very likely that the field test will allow the applicant to assess the GM brassicas for phenotypic variation and to gain information on the performance of the brassicas in natural soil and under natural weather conditions. Information would also be gained on the resistance of the GM brassicas to insect damage under field conditions and their growth equivalency to control brassicas.

2.9.6 The applicant, at the hearing, identified the following research into environmental impacts which would be done in collaboration with other CRIs as part of the proposed field test:

(a) investigating the impacts on biodiversity of the soil biota;
(b) investigating the impacts on non-target organisms; and
(c) measuring the persistence of DNA and Cry proteins in the soil at the field test site.

2.9.7 The Committee heard evidence of preliminary research that was conducted during field tests of GM pine trees and potato involving investigations into the composition of insect populations (pine trees) and culturable bacterial and fungal communities (pine trees and potato) associated with the transgenic plants in the field. Similar studies may be undertaken by collaborators during this field test. It was expected that other groups, such as CRIs, would carry out some of the environmental impacts assessment using existing funding and that additional funding may be sought to carry out specific research projects while the brassica field test was occurring. For this reason the applicant did not provide specific details of what research would be done and how it would be done.

2.9.8 The Committee questioned whether it would be possible to obtain meaningful data on the environmental impacts of the GM brassicas given the small scale of the field test and the uncertain availability of funding. The Committee notes that, based on the size of the field test, the possibility of obtaining meaningful data is greater for some environmental impacts, for example, effects on soil biota, than for others, such as, effects on non-target organisms. The Committee anticipates that this field test will provide an opportunity for some environmental impacts research to be undertaken and considers that such studies would be highly valuable. However, due to the lack of information regarding funding, the Committee cannot fully assess this benefit. Nevertheless, the Committee recognises that this field test provides a valuable opportunity for experimental work to assess the impacts of GM brassica plants on the soil biota, non-target organisms, and the persistence of DNA sequences and Cry proteins in the soil.

2.9.9 Scientific knowledge is primarily a non-monetary benefit and while the results obtained from this field test may or may not be used in the future, as the basis for future research, or to realise commercial objectives, for current purposes, the benefit of enhanced scientific knowledge is assessed only as a research outcome of the field test. The Committee considers that an enhancement of knowledge and understanding of agronomic practices for these brassicas genetically modified for *Bt* expression is likely. This beneficial effect will accrue to the applicant and the staff involved in this field test and is considered to be of minimal value. A public benefit accruing to the wider scientific community when papers are published describing the research and its results (particularly in the area of impacts on the soil biota of GM plants) would be of minor value. However, this may be very unlikely to be realised. Overall, the Committee considers the enhancement of knowledge and understanding of agronomic practices for GM brassicas to be a non-negligible benefit

Upskilling of staff and increased experience in working with gene technology in the field

2.9.10 The second significant beneficial effect identified is that of upskilling of staff and increased experience in working with gene technology in the field. These are also non-monetary benefits. In particular, the following skills have been identified:

- the development of skills and experience in working with GM brassica crops; and
- the development of skills and the establishment of a framework for assessing GM crops.

2.9.11 The Committee notes that New Zealand, as a nation that is reliant on a knowledge-based economy and the agricultural and horticultural industries, needs to have scientists with expertise in developmental and applied research including working with gene technology in the field. It is possible that in the future, problems or opportunities will arise, which can most effectively be addressed using genetic modification techniques. In that situation it would be useful to have scientists with skills and experience working with gene technology. Such scientists would not only have the skills required to identify GM as a solution, but would also have the skills needed to set up the required research.

2.9.12 However, the Committee notes that it is difficult to assess the value of this benefit, as while the beneficial effects are acknowledged, these will accrue to only a few individuals, and there is no guarantee that these staff will remain in New Zealand. Therefore, while the Committee considers that upskilling of staff and an increase in experience of working with gene technology in the field is likely, the magnitude of the effects is considered to be at most minimal. Nevertheless, the Committee concludes that this benefit is non-negligible.

2.10 Alternative methods of achieving the research objective

2.10.1 In accordance with section 44A(2)(b) of the Act the Committee considered alternative methods of achieving the research objective that have fewer adverse effects than the field test on human health and safety, and the environment, in particular ecosystems and their constituent parts.

2.10.2 The Committee considers that the primary goals of this field test are to assess the agronomic performance of these GM plants under natural environmental conditions, the resistance of GM brassicas to insect pests, and to assess the environmental impacts of these GM brassicas.

2.10.3 All identified adverse effects were assessed as being negligible and the combined adverse effects were also considered to be negligible. Therefore, in reviewing alternatives the Committee recognised that the adverse effects of any alternative means of achieving the research objectives would also need to be negligible for further consideration.

2.10.4 Submitters suggested that as an alternative to field testing of GM brassicas in New Zealand, the research could either be:

- done overseas;
- performed in a glasshouse;
- the entire site could be covered with wire mesh; or
- the site could be lined with polythene.

2.10.5 The Committee considers that performing the field test employing any of these alternative means would impede the research objectives of this project which rely on the GM brassicas being exposed to natural environmental conditions in New Zealand.

2.10.6 The Committee considers that one of the benefits of this research is to provide an enhancement of knowledge and understanding, by obtaining agronomic and impacts data that is relevant to New Zealand. The Committee considers that field testing in New Zealand is the only way to generate scientifically meaningful data to directly address this objective because of the difficulties in replicating natural environmental conditions present in a field site, in an indoor containment facility.

2.10.7 The Committee notes that there is some uncertainty regarding the potential for meaningful information on the environmental impacts of growing GM brassicas to be obtained given the limitations of scale inherent in this field test (section 2.9). However, the Committee recognises that for the purpose of conducting environmental impacts research in a field situation, plants must be placed into the field, so it is doubtful if any alternative means could be found, other than a field test, to do the work.

2.10.8 The Committee's view is that the proposed approach is broadly appropriate to achieving the research objectives and that the adverse effects are sufficiently low for this not to be material in looking at alternatives. Given the Committee's view that no alternative methods for achieving the same objectives have been identified, there is thus no reason under section 44A(2)(b) of the Act to decline the application.

2.11 Establishment of the approach to risk in the light of risk characteristics

2.11.1 Clause 33 of the Methodology requires the Authority to have regard for the extent to which a specified set of risk characteristics exist when considering applications. The intention of this provision is to provide a route for determining how cautious or risk averse the Authority will be in managing the risks and in weighing up risks and costs against benefits. However, in the case of the present application, the relevance of clause 33 is reduced because the application is "in containment" and it has been concluded that the containment provisions and other controls will reduce identified adverse effects (risks) to a negligible level.

2.11.2 Therefore, while specific consideration of clause 33 is not required for individual risks, the Committee notes that in the context of management of the combined risks, the duration of the approval is limited and none of the significant risks identified are considered to persist over time. It is also considered that the risks are not subject to uncontrollable spread nor are they likely to have effects extending beyond the immediate location of incidence. Futhermore, the containment measures limit the extent to which exposure to the risks is involuntary. Given the nature of the risks identified, it is considered that they are not irreversible.

2.11.3 In conclusion, in establishing the proposed containment regime the Committee has reflected a cautious approach to managing the risks.

2.12 Adequacy of containment and overall evaluation of risks, costs and benefits

Adequacy of containment

2.12.1 Section 45 of the Act requires the Committee to be satisfied that the genetically modified organisms can be adequately contained. The Committee considered all of the controls finally proposed, as set out in Appendix 1, and did so in the context both of preventing the escape of the organisms and effectively managing any risks.

2.12.2 The Committee also determined that controls were in place as required by section 45A(2)(a) of the Act, but that no specific controls were required to deal with genetic elements, as set out in section 45A(2)(b) of the Act. The Committee confirmed that controls were in place as required by clause 6A of the Third Schedule to the Act.

2.12.3 Having regard to all of the above, the Committee is satisfied that the GM brassicas will be adequately contained.

Combining and weighing of risks, costs and benefits

2.12.4 The following overall evaluation of risks and costs (incorporating adverse effects) and benefits (incorporating beneficial or positive effects) was carried out having regard to clauses 22 and 34 of the Methodology, and in accordance with the tests in clause 26 of the Methodology and section 45 of the Act. Clause 26 of the Methodology is the appropriate reference for making the decision since all identified potentially significant risks have been assessed as being negligible.

2.12.5 Risks and costs considered but found to be negligible were those associated with effects on the environment, effects on human health and safety, the relationships of Māori to the environment and Te Tiriti o Waitangi/Treaty of Waitangi, society and community, and market economy. In making these assessments the Committee considered both the impact of containment and other controls and the effects of the GM brassicas if they were to escape from containment. In aggregate, all risks were considered to be negligible.

2.12.6 The Committee concluded that the primary benefits accruing from the field test are the enhancement of knowledge and understanding of agronomic practices associated with these brassicas genetically modified for *Bt* expression, and upskilling of staff and increased experience in working with gene technology in the field. The Committee assessed these benefits as non-negligible.

2.12.7 The Committee noted all external costs are negligible and that after considering the impact of the combined controls the organisms can be adequately contained. Consequently, the Committee determined that the benefits outweigh the costs of the application.

2.13 References

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3 Decision

3.1.1 Pursuant to section 45(1)(a)(i) of the Act, the Committee is satisfied that this application is for one of the purposes specified in section 39(1) of the Act, being section(s) 39(1)(b): Field testing any new organism.

3.1.2 Having considered all the possible effects in accordance with sections 45(1)(a)(ii) and section 44A(2)(c) and pursuant to clause 26 of the Methodology, and based on consideration and analysis of the information provided and taking into account the application of risk management controls specified in this decision, the view of the Committee is that the risks and costs (adverse effects) associated with the field testing in containment of the following organism are outweighed by the benefits (beneficial effects) of conducting the research:

Brassica oleracea L. (1753) vegetable and forage cultivars, limited to those commonly known as cabbage, cauliflower, broccoli and forage kale, each modified by *Agrobacterium tumefaciens* mediated transformation for the introduction of one or more *cry* genes, which confer resistance to lepidopteran caterpillars (like diamondback moth and cabbage white butterfly), and selectable marker and/or reporter genes.

The approved organisms may contain some or all of the following:

(a) One or more crystalline protein genes (*cry* genes) encoding insect resistance derived from *Bacillus thuringiensis*.

- These insecticidal *cry* genes may utilise plant preferred codons.

(b) Any gene regulatory elements including promoters and terminators may be derived from plants, including *Brassica* species, *Arabidopsis thaliana*, tobacco and other crop species.

- Tissue specific promoters may be used to target *cry* gene expression for example, the chlorophyll AB binding protein promoter.

(c) Regulatory elements derived from vertebrates, invertebrates, fungi, bacteria and viruses are limited to those that have established use in plant transformation and are commercially available:

- These may include the CaMV35S promoter and the CaMV35S polyadenylation region, sourced from *Cauliflower mosaic virus* (CaMV) and/or the Octopine synthase (OCS) and Nopaline synthase (NOS) promoters and terminators derived from *Agrobacterium tumefaciens*.
- Experimental or unproven regulatory elements from these sources will not be used in the development of GM brassicas which are to be field tested.

(d) Antibiotic resistance markers or selectable markers such as hygromycin phosphotransferase II (*hptII*), neomycin phosphotransferase (*nptIII*) and phosphinotricin acetyl transferase (*bar*) or other antibiotic and selectable markers commonly used in plant transformation.

- These include markers available from research groups or companies, on request to researchers.
- The use of markers is limited to those used to select GM plants in the laboratory and may not be used to confer additional traits such as herbicide resistance.

(e) Other markers and reporters such as the uidA gene (GUS) and fluorescent proteins including Green Fluorescent Protein (GFP) and DsRed commonly used in plant transformation.

(f) The foreign DNA will be contained in the T-DNA regions within the binary vectors. This region between the Left and Right border is transferred into the plant genome by disarmed *Agrobacterium tumefaciens* strains.

(g) The following are excluded:

- Genetic material from native flora and fauna.
- Developments that result in expression of vertebrate toxins with $LD_{50} < 100$ µg/kg.

3.1.3 The Committee is satisfied that the controls, as set out in Appendix 1, will adequately contain the organisms as required by section 45(1)(a)(iii) of the Act. The Committee is also satisfied that the specific requirements set out in section 45A(2) and clause 6A of the Third Schedule to the Act are met by the controls.

3.1.4 In accordance with section 44A(2)(b) of the Act the Committee is satisfied that there are no alternative methods of achieving the research objectives that have fewer adverse effects, and that, accordingly, there is no basis under this section for declining the application.

3.1.5 In accordance with clause 36(2)(b) of the Methodology the Committee records that, in reaching this conclusion, it has applied the balancing tests in section 45 of the Act and clause 26 of the Methodology and has relied in particular on the criteria set out in the following sections of the Act:

- section 44 additional matters to be considered;
- section 45 determination of application;
- section 44A additional matters to be considered for field tests of genetically modified organisms;
- section 45A controls required for field tests of genetically modified organisms; and
- clause 6A of the Third Schedule-inspection and monitoring.

3.1.6 The Committee has also applied the following criteria in the Methodology:

- clause 9 - equivalent of sections 5, 6 and 8;
- clause 10 - equivalent of sections 36 and 37;
- clause 12 – evaluation of assessment of risks;
- clause 13 – evaluation of assessment of costs and benefits;
- clause 21 – the decision accords with the requirements of the Act and regulations;
- clause 22 – the evaluation of risks, costs and benefits – relevant considerations;
- clause 24 – the use of recognised risk identification, assessment, evaluation and management techniques;
- clause 25 – the evaluation of risks;
- clause 26 - all risks are negligible;
- clause 33 – the risk characteristics; and
- clause 34 – the aggregation and comparison of risks, costs and benefits.

3.1.7 The application for field testing of *Brassica oleracea* L. (1753) vegetable and forage cultivars, limited to those commonly known as cabbage, cauliflower, broccoli and forage kale, genetically modified as described in section 3.1.2 above, is thus approved, with the controls set out in Appendix 1.

_____ _____

Dr Kieran Elborough Date: 25 May 2007

Chair, Decision Making Committee

Approval code: GMF000041 BCH number: 39268

1st Amendment: February 2013

To amend control 1.6 and 1.7 to reflect that the field test has been terminated early, and expire this HSNO approval.

_____ _____

Dr Val Orchard Date: 05 February 2013

Chair, Decision Making Committee

Appendix 1: Controls

In order to provide for the matters detailed in Part I of the Third Schedule to the Act, *Containment Controls for Importing, Developing or Field Testing of Genetically Modified Organisms*, the approved organisms are subject to the controls set out below.

In this Appendix:

1. References to providing information or reports to ERMA New Zealand shall mean the Chief Executive of ERMA New Zealand or any such other person nominated by the Authority for this purpose.

2. The terms Operator and Inspector have the meanings given in the MAF/ERMA New Zealand Standard 155.04.09: *Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species*.

3. The terms 'containment structure' and 'containment facility' have the same meaning as defined in section 2(1) of the Act, namely:

> *"Containment facility" means,-*
> *(a) in relation to new organisms (other than genetically modified organisms), a facility registered as a containment facility under the Biosecurity Act 1993:*
> *(b) in relation to genetically modified organisms, a facility which complies with the controls imposed by an approval granted under [any of sections 42, 42A, 42B, or 45.]*
> *"Containment structure" means a containment facility that is a vehicle, room, building, or other structure, set aside and equipped for the development of genetically modified organisms*

1 To limit the likelihood of any accidental release of any organism or any viable genetic material[20]:

Containment facility

1.1 The containment facility for the field test ('the field test site') shall be operated and maintained in accordance with all of the following controls, including the MAF/ERMA Standard 155.04.09 *Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species*[21] (the Plant Containment Standard).

1.2 Responsibility for conducting the field test shall be held by an Operator approved in accordance with section 40 of the Biosecurity Act 1993, and the Operator shall be responsible for ensuring that all controls are complied with.

1.3 The field test site is limited to 0.4 hectares in size. The boundaries of the containment facility in which the field test is conducted shall be marked by a permanent feature (or GPS location details).

[20] Viable Genetic Material is biological material that can be resuscitated to grow into tissues or organisms. It can be defined to mean biological material capable of growth even though resuscitation procedures may be required, for example, when organisms or parts thereof are sublethally damaged by being frozen, dried, heated, or affected by chemicals

[21] Any reference to this standard in these controls refers to any subsequent version approved or endorsed by ERMA New Zealand

1.4 The GM brassicas, once removed from the field test site back into a containment structure, shall be subject to the relevant HSNO Act containment approval for these organisms.

1.5 The containment facility manual, approved according to the requirements in the Plant Containment Standard, shall be updated to incorporate all these controls. The contingency plan proposed in accordance with this manual shall describe the contingency plans in place to take account of any accidental loss of, or release of plants outside the field test site, or any other emergency, and shall include a procedure to prevent further release and where possible recover or eradicate the released plants.

1.6 After no more than ten (10) consecutive calendar years from the first planting, all GM brassicas shall be removed from the field test site and final post-harvest monitoring shall commence (control 6.6). This approval will expire after final post-harvest monitoring has been completed and the field test containment facility approval is cancelled..

1.7 The field test site shall be managed and registered as a containment facility, approved under section 39 of the Biosecurity Act 1993, for the duration of the field test and the post-harvest monitoring period (control 6.6).

1.8 *Brassica oleracea* plants shall be prevented from producing open flowers in the field test site. Plants identified as initiating bolting must either be immediately moved back into a containment structure (control 1.4) or killed (control 1.12).

1.9 When transferring GM brassica plants, which includes seedlings, and plants harvested from the field test site, into or out of the field test site, the Operator shall ensure that:

(a) the plants are secured and double contained; and

(b) a permit from the MAF Inspector in accordance with the procedure specified in the Plant Containment Standard listed in control 1.1 is obtained.

1.10 To ensure that no non-germinated GM seeds are planted in the field test site, all seed must be accounted for before seedlings are transferred into the field test site (control 7.3).

1.11 An inventory of GM brassica plants taken out of the containment structure and transferred to the field test site and from the field test site to the containment structure shall be checked on arrival to ensure that no plants are lost in transit. If a discrepancy is noted, the contingency plan referred to in control 1.5 above, shall be implemented (control 5.2).

1.12 All living brassica vegetative material the subject of this approval and not retained for research purposes shall be killed by composting, autoclaving or another scientifically validated method.

1.13 The Operator shall take such practical measures as are necessary to minimise the likelihood of removal of GM brassica seedlings from the field test site by animals.

1.14 At the completion of the field test, or in the event of premature ending of the field test, all GM brassica plants not retained for research purposes shall be killed in accordance with control 1.12 and the field test site shall be monitored in accordance with control 6.6.

Register of Plants

1.15 A register of GM brassica lines planted and grown in the field test site shall be maintained. The following records shall be kept for each plant line:

(a) the identity of the plant line (species, cultivar or breeding line and details of genetic modification);

(b) the identity of the person responsible for the plant(s);

(c) the date of planting in the field test site;

(d) the position of each plant within the field test site;

(e) the date of transfer of plant(s) or viable plant material to and from the containment structure and the field test site; and

(f) the date and method of final disposal of plant(s).

2 To exclude unauthorised people from the field test site:

2.1 At all times only persons authorised by the Operator shall have access to the field test site. The Operator shall maintain measures to restrict unauthorised access to the site that include:

(a) a fence that prevents public access into the field test site shall enclose the site. Gates shall be closed at all times and locked whenever there are no authorised persons present; and

(b) a log of all persons accessing the field test site.

2.2 The identification of entrances, numbers of and access to entrances, and security requirements for the entrances and the field test site shall be in compliance with the Plant Containment Standard.

3 To exclude other organisms from the field test site and to control undesirable and unwanted organisms within the field test site:

3.1 Construction and operation of the field test site shall comply with the requirements of the Plant Containment Standard relating to the exclusion of other organisms from the field test site and the control of undesirable and unwanted organisms within the field test site.

3.2 Grazing animals (for example sheep, cattle and other large herbivores) shall be excluded from the field test site.

3.3 Security monitoring of the field test site shall be carried out regularly to ensure the integrity of the fence.

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

4.1 Operation of the field test site shall comply with the requirements of the Plant Containment Standard relating to the prevention of accidental removal of plant material.

4.2 All equipment used in conjunction with the field test site shall be cleaned after use to prevent the accidental release of living vegetative GM brassica material.

4.3 The Operator shall inform all personnel involved in handling the organisms of the controls set out in this Appendix.

4.4 The training of personnel working in the field test site shall be in compliance with the Plant Containment Standard.

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

5.1 Construction and operation of the field test site shall comply with the requirements of the Plant Containment Standard relating to controlling the effects of any accidental release or escape of an organism.

5.2 In the event of any release from containment of GM plants from the field test site, the contingency plan for the retrieval or killing of any viable material of the organism that has escaped shall be implemented immediately (control 1.5). The contingency plan shall be included in the containment manual in accordance with the requirements of the Plant Containment Standard.

5.3 If any interference with the field test site or any non-compliance with the controls occurs, whether an approved organism escapes from containment or not, the Operator must ensure that the MAF Inspector responsible for supervision of the field test site has received notification of the relevant event within 24 hours.

5.4 No GM brassicas (or any part thereof), nor any other food crops grown in the field test site during the field test or in the post-harvest monitoring period, shall under any circumstances be permitted to be consumed by any person, or be deliberately fed to animals (other than the insect species that are the subject of this field test and related research).

6 Controls addressing inspection and monitoring requirements including any inspection required before, during and after the field test:

6.1 The operation of the field test site shall comply with the requirements contained in the Plant Containment Standard relating to the inspection and monitoring requirements for containment facilities.

6.2 The MAF Inspector may inspect and audit the field test site at any time to ensure the field test site is complying with this approval. The Operator shall arrange for inspection of the field test site and auditing of its operation to occur:

(a) twice during the growing season, including at least once during the period when flowering could occur; and

(b) once during the winter season if GM brassicas are planted in the field test site over the winter.

6.3 During the period when GM brassicas are present in the field test site, the site shall be monitored to detect the onset of bolting or early flower opening using a scientifically validated method and staff appropriately trained in that method. Monitoring intervals shall be appropriate to the developmental stages of the brassicas to detect the onset of bolting or early flower opening. Any plants detected as initiating bolting or with early flower opening will be contained as set out in control 1.8.

6.4 A monitoring log shall be kept and shall be available for inspection by the MAF Inspector. This log shall include:

(a) the date of monitoring inspections and the name of the person undertaking the monitoring;

(b) the number of bolting or early flowering plants detected, and the action taken to contain the bolting or early flowering plants;

(c) any unanticipated discrepancy in the number of GM brassica plants remaining in the field test site. If an unanticipated discrepancy is found the Operator must ensure that the MAF Inspector responsible for supervision of the field test site has received notification of the event within 24 hours; and

(d) a record of any non-test *Brassica oleracea* plants found. If any non-test *Brassica oleracea* plants are found within the field test site they shall be managed and disposed of in accordance with control 1.12.

6.5 At the end of each growing season, the entire field test site shall be monitored monthly to detect any GM volunteer plants. A log of these monitoring events shall be maintained and it shall record the date, details of any GM *Brassica* plants found and any action taken. Any volunteer GM plants found shall be removed and killed in accordance with control 1.12.

6.6 At the completion of the field test, the final post-harvest monitoring period shall begin. This monitoring period will initially be for one (1) calendar year. This will be extended for a further five (5) years from the date when the last volunteer GM brassica plant is found if, during the initial monitoring period, any volunteer GM brassica plants are found. For the duration of this monitoring period, no brassicas shall be planted and the entire field test site shall be monitored monthly to detect any GM volunteer plants. A log of these monitoring events shall be maintained and it shall record the date, any GM brassica plants found and any action taken. Any volunteer GM plants found shall be removed and killed in accordance with control 1.12.

7 Additional controls

7.1 ERMA New Zealand and the MAF Inspector responsible for supervision of the field test site must be notified in writing when this approval is used for the first time. This field test must commence within five (5) years of the date of this decision.

7.2 The Operator shall supply MAF Biosecurity New Zealand with details of all brassica lines to be tested, at least thirty (30) working days prior to the proposed planting date. Prior to planting, MAF Biosecurity New Zealand will verify the details of lines to be tested against the approved organism description and confirm with the Operator.

7.3 GM seedlings, or GM cuttings derived from plants grown from seed or cuttings from in vitro shoots, but not plants regenerated directly from callus, may be planted in the field test site. Seeds of the GM brassica shall not be sown or inadvertently planted in the field test site (control 1.10).

7.4 Any brassicas used in the buffer rows[22] shall not be genetically modified and shall be phenotypically different, for example, have different foliage or head colour, from the GM brassicas planted at the same location.

7.5 For the duration of the field test (including the final post-harvest monitoring period), all buffer row plants and any rotational crops planted within the field test site should be composted on the field test site, or ploughed into the field test site.

7.6 The Operator shall promptly inform the MAF Inspector and ERMA New Zealand of any matters which may affect the long term management of the field test including:

(a) changes in the key personnel such as the principal investigator or Operator responsible for the field test;

(b) changes in the management structure of the applicant, being Crop & Food Research that may affect the management of the field test;

(c) any event or circumstance that would affect the capacity of the applicant to meet the requirements of the controls set out in this Appendix; and

(d) changes in the land use or ownership.

7.7 A written report on the progress of the field test shall be provided to ERMA New Zealand by 31 July of each year during the approval and monitoring period. Information requirements will be as agreed with ERMA New Zealand and may include, but not be limited to, the following:

(a) field test activities;

(b) any unanticipated events;

(c) any issues with controls;

(d) proposed activities for the next year where relevant;

(e) any relationship development and management initiatives undertaken with Te Rūnanga o Ngāi Tahu and Te Taumutu Rūnanga;

(f) all educational and public awareness activities undertaken with Māori more generally;

(g) all educational and public awareness activities undertaken with community groups; and

(h) all scientific publications, conference presentations and key findings resulting from this field test, including impacts research.

7.8 The applicant shall provide a specifically written annual update to Te Rūnanga o Ngāi Tahu and Te Taumutu Rūnanga by 31 July each year during the approval period. This update shall provide information on the progress of the field test and explain how the

[22] Plants that are grown around the experimental plots to control for any edge effects. These are planted as part of the experimental design and serve no containment or risk mitigation purposes.

applicant is addressing any cultural issues raised by Ngāi Tahu in relation to the field test research. A copy of this report should also be provided to Ngā Kaihautū Tikanga Taiao.

7.9 At the conclusion of the field test and upon completion of all post-harvest monitoring, the field test site will be deregistered following MAF approval.