

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY

# THE BULLETIN

*The Bulletin is the Authority's formal record of applications and decisions. If you are not already on the 'key stakeholder' list and would like to receive a copy please contact ERMA New Zealand. The Bulletin is also available on the ERMA New Zealand website: [www.ermanz.govt.nz](http://www.ermanz.govt.nz)*

## INTRODUCTION

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Under the Hazardous Substances and New Organisms (HSNO) Act 1996, applications for new organisms and genetically modified organisms for release, field testing of new organisms and genetically modified organisms, and use of a new organism in an emergency must be publicly notified. Public notices are placed in the *New Zealand Herald*, *The Dominion*, *The Press* and *The Otago Daily Times*.

A public register of all applications received is also available on the ERMA New Zealand website [www.ermanz.govt.nz](http://www.ermanz.govt.nz). The register includes a brief description of the application. An executive summary is available on the website. The full application document is available on request.

Any person may make a submission on a notified application. Please check individual application details for the closing date for submissions. ERMA New Zealand's *Quick Guide No. 4* has information on how to make a submission and a sample submission form. Submissions must be in writing, signed by the submitter and include the following:

- submitter's name, postal address, telephone and fax number
- details of the application the submission is about
- reasons for the submission
- whether the submitter wishes to speak at a hearing.

Submitters may also note any decision they would like the Authority to make.

Lower risk applications, such as those to import a new organism into containment or to develop a genetically modified organism in containment, are not required to be publicly notified under the HSNO Act. Non-notified applications are included in *The Bulletin* for information only – there is no opportunity to make a submission on these applications.

## SCHEDULED HEARINGS

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**Date:** 10 August 2000

**Code:** NOR99004

**Applicant:** Auckland Regional Council

**Purpose:** To release from containment the mist flower gall fly, *Procecidochares alani* (Steyskal), for the purpose of biological control of mist flower (*Argemone riparia*)

## NON NOTIFIED APPLICATIONS RECEIVED

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**Application Code:** GMC00004

**Applicant:** Genesis Research and Development Corporation Ltd

**Purpose:** To import into containment defective clones of Tomato Bushy Stunt Virus (TBSV) for uses as expression vectors to test and characterise novel gene function in plant cells

**Date Application Received:** 2 July 2000

**Application Code:** NOC99023

**Applicant:** Landcare Research Institute

**Purpose:** To import into containment microorganisms for the International Collection of Microorganisms from Plants (ICMP) as a reference collection in the investigation of plant quarantine outbreaks of plant diseases and for international and NZ research use

**Date Application Received:** 12 July 2000

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*Please feel free to photocopy this material. Acknowledgement of ERMA New Zealand would be appreciated.*

**ERMA NEW ZEALAND**

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**Application Code:** GMD00079

**Applicant:** Auckland Healthcare

**Purpose:** To isolate cloned human DNA in order to be used as probes for molecular-based diagnostics

**Date Application Received:** 13 July 2000

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**Application Code:** GMD00080

**Applicant:** Auckland Healthcare

**Purpose:** To develop in containment genetically modified *E. coli* as part of a diagnostic service for patients with congenital immune deficiency disorders and for prognostic purposes to improve medical services for children with genetic defects of the immune system

**Date Application Received:** 13 July 2000

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**Application Code:** NOC99015

**Applicant:** HortResearch, Ruakura Research Centre

**Purpose:** To gain approval under section 259 of the HSNO Act 1996 for microorganisms lawfully in use to be held under secure conditions for future reference purposes

**Date Application Received:** 27 July 2000

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## NOTIFIED APPLICATIONS

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**Application Code:** GMF99001

**Applicant:** New Zealand Forest Research Institute

**Purpose:** To field test, in the Bay of Plenty (Rotorua), over a period of 20 years, *Pinus radiata* plants with genetic modifications in genes controlling reproductive development. The total duration of this project including a post-trial monitoring phase is 22 years

**Date Application Received:** 18 June 1999

**Date Application Notified:** 19 July 2000

**Submissions Close:** 30 August 2000

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**Application Code:** GMF99005

**Applicant:** New Zealand Forest Research Institute

**Purpose:** To field test, in the Bay of Plenty (Rotorua), over a period of 10 years, *Pinus radiata* and *Picea abies* plants genetically engineered in herbicide resistance. The total duration of this project is 11 years

**Date Application Received:** 18 June 1999

**Date Application Notified:** 19 July 2000

**Submissions Close:** 30 August 2000

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## STALLED APPLICATIONS

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**Application Code:** GMD00054

**Applicant:** Victoria University of Wellington

**Purpose:** To transform *E. coli* bacteria to amplify single molecules of plant ITS DNA so that mixtures can be separated into their constituent component strands for sequencing

**Date Application Stalled:** 20 June 2000

**Reason for Stalling:** Under section 52 of the HSNO Act the Authority considers that the applicant is able to provide further relevant information

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**Application Code:** GMD00055

**Applicant:** Victoria University of Wellington

**Purpose:** To investigate the molecular population genetic structuring of greenshell mussels throughout New Zealand

**Date Application Stalled:** 20 June 2000

**Reason for Stalling:** Under section 52 of the HSNO Act the Authority considers that the applicant is able to provide further relevant information

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## DECISIONS ON APPLICATIONS

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The Environmental Risk Management Authority reached a decision on the following application on 9 June 2000

**Application Code:** GMD00006

**Applicant:** University of Otago

**Purpose:** To maintain and develop genetically modified laboratory mice strains through conventional breeding techniques

**Description of organisms:**

The organisms approved are genetically modified mice (*Mus musculus*) resulting from:

A. Crosses between the following strains (including subsequent sibling-sibling matings and backcrosses to the parental strains):

1. PPENK and C57BL/6
2. CD1 and C57BL/6
3. B6AaO and C57BL/6
4. Line 318 and C57BL/6<sup>bm13</sup>  
(natural mutant of C57BL/6 - non GMO)
5. Line 318 and C57BL/6
6. Mkk6 and B10A/SgSnJ
7. Mkk6 and C57BL/6
8. OTII and C57BL/6
9. NF $\times$  $\beta$ -luc and B10A/SgSnJ
10. AP1-luc and C57BL/6
11. NFAT-luc and C57BL/6
12. JNK and C57BL/6
13. C57BL/6-Pfp<sup>tm1Sdz</sup> and C57BL/6
14. C57BL/6-Ifng<sup>tm1T3</sup> and C57BL/6
15. 5CC.7 and B10A/SgSnJ

B. Crosses between the following strains to generate animals carrying two genetically modified traits (including subsequent sibling-

sibling matings and backcrosses to the parental strains and the non-modified strain C57BL/6): This list includes animals that have been crossed to improve background strain purity, or for improved breeding purposes, from the list 1-15 above.

16. PPENK and OTII
17. PPENK and Line 318
18. Line 318 and C57BL/6-Ifng<sup>tm1Ts</sup>
19. NFAT-luc and NF $\times$  $\beta$ -luc
20. NFAT-luc and Line 318
21. C57BL/6-Pfp<sup>tm1Sdz</sup> and Line 318
22. NFAT-luc and OTII
23. NF $\times$  $\beta$ -luc and OTII
24. NF $\times$  $\beta$ -luc and Line 318
25. AP1-luc and Line 318
26. AP1-luc and OTII
27. 5CC.7 and AP1-luc
28. C57BL/6-TgN(Mog) and B6,129-tgCTLA4/CD28
29. C57BL/6-TgN(Mog) and C57BL/6-*Cd28*<sup>tm1Mak</sup>
30. C57BL/6-TgN(Mog) and C57BL/6-*114*<sup>tm1NnT</sup>
31. C57BL/6-TgN(Mog) and C57BL/6-Ifng<sup>tm1Ts</sup>
32. C57BL/6-TgN(Mog) and C57BL/6-Jnk2<sup>tm1</sup>
33. C57BL/6-TgN(Mog) and C57BL/6-Cd152<sup>tm1</sup>
34. C57BL/6-TgN(Mog) and C57BL/6-Rag1<sup>tm1Mom</sup>

Matings between genetically modified mice other than those listed and described above are not approved.

**Decision:** Approved with Controls

**ERMA approval codes:** GMD000411-GMD000444

#### Controls:

In order to satisfy the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approval of this application is subject to the following controls:

#### 1. To limit the likelihood of any accidental release of any organism or any viable genetic material<sup>1</sup>:

- 1.1. The operation and management of the containment facility<sup>2</sup> shall be in accordance with:
  - i the Ministry of Agriculture and Forestry (MAF) Regulatory Authority/ERMA New Zealand Standard 154.03.03: *Containment Facilities for Vertebrate Laboratory Animals*; and
  - ii Australian New Zealand Standard AS/NZS 2243.3:1995 *Safety in Laboratories*: Part 3: *Microbiology*, at Animal House Physical Containment Level 2 (PC2).

- 1.2. The facility shall be approved by MAF as a containment facility in accordance with the MAF/ERMA New Zealand Standard 154.03.03 prior to the development of any genetically modified mice that are the subject of this approval.
- 1.3. The maximum number of genetically modified mice in the containment facility shall not exceed the capacity of the facility, and/or any requirements of the relevant Animal Ethics Committee.
- 1.4. Detailed and accurate records of all matings performed under this approval shall be maintained and be available for inspection.

#### 2. To exclude unauthorised people from the facility:

- 2.1 The applicant shall comply with the requirements of the standards listed in control 1.1 relating to identification of entrances, numbers of and access to entrances, and security requirements for the entrances and the facility.

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

- 3.1 The applicant shall comply with the requirements of the standards listed in control 1.1 relating to exclusion of other organisms from the facility and the control of undesirable and unwanted organisms within the facility.

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

- 4.1 The applicant shall comply with the requirements of the standards listed in control 1.1 relating to the prevention of unintended release of the organisms by experimenters working with the organisms.

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

- 5.1 If for any reason a breach of containment occurs the applicant shall notify the facility supervisor<sup>3</sup> (MAF) and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected).

- 5.2 The applicant shall comply with the requirements of the standards listed in control 1.1 relating to the maintenance of records demonstrating compliance with the Standard (154.03.03), as required by the quality assurance programme, and documented in the containment manual.

#### 6. Inspection and monitoring requirements for containment facilities:

- 6.1 The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facility at any reasonable time.

#### 7. Qualifications required of the persons responsible for implementing those controls:

- 7.1 The applicant shall comply with the requirements of the standards listed in control 1.1 relating to the training of personnel working in the facility.

1 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, eg when organisms or parts thereof are sublethally damaged by being frozen, dried, heated, or affected by chemical.

2 *Containment facility* means a place approved in accordance with section 39 for holding organisms that should not, whether for the time being or ever, become established in New Zealand. *Biosecurity Act 1993*

3 An inspector appointed under the Biosecurity Act.

The Environmental Risk Management Authority reached a decision on the following applications on 22 June 2000

**Application Code:** GMD00003

**Purpose:** To develop genetically modified bacteriophage containing plasmid PSK genes and to introduce these into laboratory strains of *Escherichia coli*, *Salmonella typhimurium* and *S. brandenburg* as a method for non-antibiotic microbial control

**Application Code:** GMD00004

**Purpose:** To develop in containment genetically modified *E. coli*, *A. tumefaciens* and *S. cerevisiae* for studying the natural processes of horizontal gene transfer, for medical research into the genetic basis of disease and risk of gene transfer

**Application Code:** GMD00005

**Purpose:** To develop in containment genetically modified *E. coli* K12, *Salmonella typhimurium* and Mardin Darby Canine Kidney (MDCK) cell lines to determine the extent of activity of natural gene transfer mechanisms during bacterial infections of mammalian cells

**Applicant:** University of Canterbury

**Description of organisms:**

GMD00003:

*Escherichia coli* K12 and its derivatives, Phage T1, T3, T4, T5, T7, λ, P22 and *Salmonella typhimurium*, *Salmonella brandenburg* modified by identified plasmid PSK genes and phage genes sourced from T1, T3, T4, T5, T7, λ and P22.

GMD00004:

Laboratory strains of *Saccharomyces cerevisiae*, *Agrobacterium tumefaciens* and *Escherichia coli* K12 and derivatives modified by various plasmids, marker genes, antibiotic resistance and nucleic acids as described and listed in the application.

GMD00005:

*Escherichia coli* K12 and derivatives, *Salmonella typhimurium*, Mardin Darby Canine Kidney (MDCK) cell line as modified by various plasmids, marker genes, antibiotic resistance and nucleic acids as described and listed in the application.

(For full descriptions of modifications in applications GMD00003, 4, and 5 refer to the ERMA NZ register)

**Decision:** Approved with Controls

**ERMA approval codes:** GMD000445-GMD000460

**Controls:**

### Physical Containment 1

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approval of the organisms requiring PC1 containment is subject to the following controls:

1. The operation, management and construction of the facility shall be in accordance with the:
  - i. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*
  - ii. Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories*: Part 3: *Microbiology*, at Physical Containment Level 1 (PC1).
2. The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and controls imposed by the Authority.
3. If for any reason a breach of containment occurs the applicant shall notify the facility supervisor<sup>4</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
4. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

**Controls:**

### Physical Containment 2

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approval of the organisms requiring PC2 containment is subject to the following controls:

1. The operation, management and construction of the facility shall be in accordance with the:
  - i. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*
  - ii. Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories*: Part 3: *Microbiology*, at Physical Containment Level 2 (PC2).
2. The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and controls imposed by the Authority.
3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>4</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
4. The Authority or its authorised agent or properly

<sup>4</sup> An inspector appointed under the Biosecurity Act.

authorised enforcement officers, may inspect the facilities at any reasonable time.

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The Environmental Risk Management Authority reached a decision on the following application on

**Application Code:** GMD00073

**Applicant:** Landcare Research Limited

**Purpose:** To modify *Escherichia coli* with DNA from selected bacteria to establish the extent to which genes may be transferred between bacterial species in nature and to develop specific diagnostic probes for plant pathogenic bacteria of significance to NZ's biosecurity.

**Description of organisms:** *Escherichia coli* strains DH10B and DH5 alpha as modified by pGEM, pBluescript, and pDONR cloning vectors containing genomic DNA fragments from the following bacteria:

- i. *Pseudomonas* spp
- ii. *Acidovorax* spp
- iii. *Agrobacterium* spp
- iv. *Burkholderia* spp
- v. *Clavibacter* spp
- vi. *Curtobacterium* spp
- vii. *Erwinia* spp
- viii. *Xanthomonas* spp
- ix. *Xylella* spp

The development of these genetically modified organisms involve Schedule 2 approved host/vector systems and meet the requirements of Category A – A(a) – for DNA from non-pathogenic donors, or Category B experiments – B(b)(v)(B) – where the donors are able to cause disease, under the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

**Decision:** Approved with Controls  
**ERMA approval codes:** GMD000461

**Controls:**

In consideration of the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approvals of the organisms are subject to the following controls:

1. The operation, management and construction of the facility shall be in accordance with the:
  - i. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*.
  - ii. Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories*: Part 3: *Microbiology*, at Physical Containment Level 1 (PC1).

2. The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and controls imposed by the Authority.
3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>5</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
4. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

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The Environmental Risk Management Authority reached a decision on the following application on 15 July 2000

**Application Code:** NOC99011

**Applicant:** University of Otago

**Purpose:** To import into containment, for research purposes, genetically modified *Saccharomyces cerevisiae* laboratory strains that contain fragments of DNA cloned from other species.

**Description of organisms:** *Saccharomyces cerevisiae*<sup>a</sup> as modified by nucleic acids sourced from organisms<sup>b</sup> as specified in Annex 1 (application Appendix 1) and vectors<sup>c</sup> in Annex 2 (application Appendix 2), and being organisms developed under Category A or B experiments as defined in the Hazardous Substances and New Organisms Act (Low-Risk Genetic Modification) Regulations 1998.

<sup>a</sup> Laboratory strains containing linear plasmids that can be transmitted to other *Saccharomyces* and that produce toxins against other yeasts ('killer toxins') shall not be included.

<sup>b</sup> Donor organisms shall not include New Zealand native macroflora and macrofauna (including fungi) or species valued by Māori, except where such material is sourced from overseas native populations.

Donor organisms shall not include species endemic<sup>6</sup> to New Zealand.

<sup>c</sup> The approved vectors shall not include those that are conjugative.

**Decision:** Approved with Controls  
**ERMA Approvals Code:** NOC000705

**Controls:**

In consideration of the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approval of this application is subject to the following controls on importation:

<sup>5</sup> An inspector appointed under the Biosecurity Act.

<sup>6</sup> Endemic: Often synonymous with indigenous (as in 'New Zealand has many endemic species'), but also used for more local specifications. An organism may be endemic to New Zealand, not naturally occurring anywhere else (eg kiwi), but may also be endemic in a particular part of the country. In common usage the expression 'a native species' often refers to an indigenous or endemic species. For organisms that only occur naturally in New Zealand the term endemic is preferred over native. (*ERMA New Zealand Intranet Glossary, March 2000*)

1. **To limit the likelihood of any accidental release of any organism or any viable genetic material<sup>7</sup>:**
  - 1.1. The operation and management of the containment facility shall be in accordance with the:
    - i Ministry of Agriculture and Forestry (MAF) Biosecurity Authority/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*.
    - ii Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories*: Part 3: *Microbiology*, at Physical Containment Level 1 (PC1).
  - 1.2. The facility shall be approved by MAF as a containment facility in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02, and the controls of the Authority, prior to the import into containment of any genetically modified organisms that are the subject of this approval.
2. **To exclude unauthorised people from the facility:**
  - 2.1. The applicants shall comply with the requirements contained in the standards listed in control 1.1 relating to identification of entrances, numbers of and access to entrances, and security requirements for the entrances and the facility.
3. **To exclude other organisms from the facility and to control undesirable and unwanted organisms within the facility:**
  - 3.1. The applicants shall comply with the requirements contained in the standards listed in control 1.1 relating to exclusion of other organisms from the facility and the control of undesirable and unwanted organisms within the facility
4. **To prevent unintended release of the organism by experimenters working with the organism:**
  - 4.1. The applicants shall comply with the requirements contained in the standards listed in control 1.1 relating to the prevention of unintended release of the organisms by experimenters working with the organisms.
5. **To control the effects of any accidental release or escape of an organism:**
  - 5.1. The applicants shall comply with the requirements of the standards listed in control 1.1 relating to the provision of an eradication plan to deal with an accidental release or spillage of microorganisms both within and outside the facility.
  - 5.2. If for any reason a breach of containment occurs the applicants shall notify the facility Supervisor<sup>8</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected).
6. **Inspection and monitoring requirements for containment facilities:**
  - 6.1. The Authority or its authorised agent or properly

authorised enforcement officers, may inspect the facilities at any reasonable time.

7. **Qualifications required of the persons responsible for implementing those controls:**
  - 7.1. The applicant shall comply with the requirements of the standards listed in control 1.1 relating to the training of personnel working in the facility.
8. **The applicant shall notify the Supervisor and ERMA New Zealand if there are any changes in ownership of property housing the containment facility maintaining organisms under this approval.**

The Environmental Risk Management Authority reached a decision on the following application on 18 July 2000

**Application Code:** GMD00026

**Purpose:** To develop in containment genetically modified variants of *Escherichia coli*, *Pseudomonas*, *Erwinia* and *Serratia* species. These are central to our understanding of the natural mechanisms by which potential biocontrol agents interact with various phytopathogens

**Application Code:** GMD00063

**Purpose:** Demonstration of basic molecular/microbial genetic techniques to second year students in the Plant and Microbial Sciences and Zoology departments involving experiments to determine the presence of transforming DNA by expression of marker genes and properties under investigation

**Applicant:** University of Canterbury

**Description of organisms:** The organisms approved are the genetically modified microorganisms as listed below:

**A. Application GMD00026**

**A1. *Escherichia coli* strain K12 derivatives<sup>a</sup>** modified by the pLAFR3 cosmid vector, pBR322/pUC-derived plasmid vectors<sup>b</sup>, or pACYC184<sup>b</sup> containing DNA from:

- i. *Serratia entomophila*
- ii. *Pseudomonas aureofaciens*
- iii. *Pseudomonas viridflava*
- iv. *Erwinia herbicola*
- v. *Erwinia amylovora*

The development of these genetically modified organisms shall meet the requirements of Category B experiments – B(b)(v)(B) – in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

**Containment A1:** The development of organisms described in A1, where conjugative plasmids are not involved requires PC1 level containment, plus the additional requirements as listed in the controls.

The vectors and donor DNA listed above can be transferred from their *E. coli* hosts only to the host cells as described below, using conjugative

<sup>7</sup> 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, eg when organisms or parts thereof are sublethally damaged by being frozen, dried, heated, or affected by chemical.

<sup>8</sup> An inspector appointed under the Biosecurity Act.

plasmids derived from plasmid RP4:

**A2.** Mutated strains of *Serratia entomophila* as modified by pLAFR3, pBR322/pUC-derived plasmid vectors<sup>b</sup>, or pACYC184<sup>b</sup> containing DNA from *Serratia entomophila*.

**A3.** Mutated strains of *Pseudomonas aureofaciens* as modified by pLAFR3, pBR322/pUC-derived plasmid vectors<sup>b</sup>, or pACYC184<sup>b</sup> containing DNA from *Pseudomonas aureofaciens*.

**A4.** Mutated strains of *Pseudomonas viridflava* as modified by pLAFR3, pBR322/pUC-derived plasmid vectors<sup>b</sup>, or pACYC184<sup>b</sup> containing DNA from *Pseudomonas viridflava*.

**A5.** Mutated strains of *Erwinia herbicola* as modified by pLAFR3, pBR322/pUC-derived plasmid vectors<sup>b</sup>, or pACYC184<sup>b</sup> containing DNA from *Erwinia herbicola*.

**A6.** Mutated strains of *Erwinia amylovora* as modified by pLAFR3, pBR322/pUC-derived plasmid vectors<sup>b</sup>, or pACYC184<sup>b</sup> containing DNA from *Erwinia amylovora*.

The development of these genetically modified organisms shall meet the requirements of Category B experiments – B(b)(i) – in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

<sup>a</sup> The host cells shall not contain generalised transducing phages.

<sup>b</sup> These vectors shall be non-conjugative.

**Containment A2-A6:** The development of organisms described in A2-A6, involving the use of hosts not in Schedule 2 of the low risk genetic modification regulations and conjugative plasmids (as described above), require PC2 level containment, plus the additional requirements as listed in the controls.

## **B. Application GMD00063**

**B1.** *Escherichia coli* strain K12 derivatives<sup>a</sup> modified by the non-conjugative plasmids pHK11, pHK11-1, pHK11-2, pHK11-3, pHK11-4, or pHK11-5, and not containing any additional foreign DNA, where the development of these genetically modified organisms meet the requirements of Category A experiments – A(a) – in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

<sup>a</sup> The host cells shall not contain conjugative plasmids or generalized transducing phages.

**Containment B1:** The development of organisms described in B1, which does not involve the use of conjugative plasmids, requires PC1 level containment, plus the additional requirements as listed in the controls.

**B2.** *Escherichia coli* strain K12 derivatives<sup>a</sup>

modified by the conjugative plasmid pColV-K30, and where the development of the genetically modified organisms meet the requirements of Category A or B experiments – B(b)(iv)A – in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

<sup>a</sup> The host cells shall not contain generalized transducing phages.

**Containment B2:** The development of organisms described in B2, involving conjugative plasmids, shall be conducted under PC2 level containment, plus the additional requirements as listed in the controls.

**B3.** *Salmonella typhimurium* strain DB7136 as modified by the transducing phage P22 derived from *S. typhimurium* strain LT2, and where the development of the genetically modified organisms meet the requirements of Category B experiments – B(b)(i) – in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

**Containment B3:** The development of organisms described in B3, involving a host that is not in Schedule 2 of the low-risk regulations, requires PC2 level containment, plus the additional requirements as listed in the controls.

**Decision:** Approved with Controls

**ERMA approval code:** GMD000581-GMD000589

## **Controls:**

### **Physical Containment 1 (Organisms A1 and B1 as listed above)**

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approvals of the organisms **requiring PC1 containment** are subject to the following controls:

1. The operation, management and construction of the facility shall be in accordance with the:
  - 1.1. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*.
  - 1.2. Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories*: Part 3: *Microbiology*, at Physical Containment Level 1 (PC1).
2. The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and controls imposed by the Authority.
3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>9</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a

contingency plan for the recovery and eradication of any organisms or viable material that has escaped.

4. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

**Physical Containment 2 (Organisms A2-A6, B2 and B3 as listed above)**

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approvals of the organisms **requiring PC2 containment** are subject to the following controls:

1. The operation, management and construction of the facility shall be in accordance with the:
  - 1.1. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*.
  - 1.2. Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories*: Part 3: *Microbiology*, at Physical Containment Level 2 (PC2).
2. The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and controls imposed by the Authority.
3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>10</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
4. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

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The Environmental Risk Management Authority reached a decision on the following application on 18 July 2000

**Application Code:** GMD00065

**Applicant:** University of Canterbury

**Purpose:** To generate modified *Escherichia coli*, using *Arabidopsis thaliana* and *Pinus radiata* cDNAs, as research tools to assist investigations into the regulation of gene expression in plant cells

**Description of organisms:**

The organisms approved are:

*Escherichia coli* strain K12 derivatives<sup>a</sup> modified by non-conjugative general bacterial cloning plasmid vectors containing:

1. Leucine aminopeptidase cDNA from *Arabidopsis thaliana*
2. cDNA from *Pinus radiata* root tissues

The development of these genetically modified organisms shall meet the requirements of

Category A experiments – A(a) – in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

<sup>a</sup> The host cells shall not contain conjugative plasmids or generalized transducing phages.

**Decision:** Approved with Controls

**ERMA approval code:** GMD000590

**Controls:**

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approvals of the organisms **requiring PC1 containment** are subject to the following controls:

1. The operation, management and construction of the facility shall be in accordance with the:
  - 1.1. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*.
  - 1.2. Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories*: Part 3: *Microbiology*, at Physical Containment Level 1 (PC1).
2. The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and controls imposed by the Authority.
3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>11</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
4. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

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The Environmental Risk Management Authority reached a decision on the following application on 18 July 2000

**Application Code:** GMD00066

**Applicant:** University of Canterbury

**Purpose:** To develop microsatellite markers from non-native vertebrate and invertebrate species for population studies.

**Description of organisms:**

The organisms approved are:

**A1.** *Escherichia coli* strain K12 derivatives that do not contain conjugative plasmids or generalized transducing phages (eg DH5 $\alpha$ ) modified by non-conjugative general bacterial cloning plasmid vectors and lambda phage vectors containing DNA sourced from non-

<sup>10</sup> An inspector appointed under the Biosecurity Act.

<sup>11</sup> An inspector appointed under the Biosecurity Act.

native vertebrate<sup>a</sup> and non-native invertebrate species<sup>b</sup>, where the development of the genetically modified organisms meet the requirements of Category A experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

**A2. *Escherichia coli* strain K12 derivatives** that do not contain generalised transducing phages but may contain conjugative plasmids (eg XL1-Blue) modified by non-conjugative general bacterial cloning plasmid vectors and lambda phage vectors containing DNA sourced from non-native vertebrate<sup>a</sup> and non-native invertebrate species<sup>b</sup>, where the development of the genetically modified organisms meet the requirements of Category B experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

<sup>a</sup> Genetic material sourced from Māori people shall not be used.

<sup>b</sup> Genetic material shall not be sourced from organisms listed as unwanted or prohibited for the purposes of the Biosecurity Act. Prior to import of genetic material from CITES-listed species the applicant shall ensure that they have the correct documentation from the exporting country and written approval from the Department of Conservation that the requirements of CITES have been met. Alternatively, an import can be organised between registered institutions for CITES scientific transfers.

**Containment A1:** The development of organisms described in A1, where conjugative plasmids are not involved requires PC1 level containment, plus the additional requirements as listed in the controls.

**Containment A2:** The development of organisms described in A2, where conjugative plasmids are involved requires PC2 level containment, plus the additional requirements as listed in the controls.

**Decision:** Approved with Controls

**ERMA approval code:** GMD000591-GMD000592

**Controls:**

#### **Physical Containment 1 (Organisms A1 as listed above)**

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approvals of the organisms **requiring PC1 containment** are subject to the following controls:

1. The operation, management and construction of the facility shall be in accordance with the:
  - 1.1. Ministry of Agriculture and Forestry

(MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*.

- 1.2. Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories: Part 3: Microbiology*, at Physical Containment Level 1 (PC1).
2. The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and controls imposed by the Authority.
3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>12</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
4. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

#### **Physical Containment 2 (Organisms A2 as listed above)**

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approvals of the organisms **requiring PC2 containment** are subject to the following controls:

1. The operation, management and construction of the facility shall be in accordance with the:
  - 1.1. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*.
  - 1.2. Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories: Part 3: Microbiology*, at Physical Containment Level 2 (PC2).
2. The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and controls imposed by the Authority.
3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>13</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
4. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

<sup>12</sup> An inspector appointed under the Biosecurity Act.

<sup>13</sup> An inspector appointed under the Biosecurity Act.

The Environmental Risk Management Authority reached a decision on the following application on 18 July 2000

**Application Code:** GMD00067

**Applicant:** University of Canterbury

**Purpose:** The use of kanamycin resistant *Hieracium praealtum* as a rapid assay for levels of zygotic as compared with apomictic embryogenesis

**Description of organisms:**

The organisms approved are:

Hybrid plants resulting from the pollination of non-modified *Hieracium pilosella* with pollen from genetically modified *H. praealtum* containing the nptII gene on an *Agrobacterium tumefaciens* Ti-plasmid integrated into the plant's genome.

The development of these genetically modified organisms meet the requirements of Category B – B(b)(iii) – experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998, and the genetically modified plants shall be contained under PC2 level containment.

**Decision:** Approved with Controls

**ERMA approval code:** GMD000593

**Controls:**

**Physical Containment 2**

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approvals of breeding the genetically modified *Hieracium praealtum* plants are subject to the following controls:

1. The containment facilities used to contain genetically modified *Hieracium praealtum* developed as a part of this approval shall be registered by the Ministry of Agriculture and Forestry (MAF) as containment facilities under the Biosecurity Act 1993.
2. The operation, management and construction of the Laboratory containment facility used when germinating seeds, shall be in accordance with the:
  - 2.1. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*, and
  - 2.2. Australian New Zealand Standard AS/NZS 2243.3:1995 *Safety in Laboratories*: Part 3: *Microbiology*, at Physical Containment Level 2 (PC2), and the controls imposed in this decision.
3. Prior to the development of any reproductive structures the plants shall be transferred from the PC2 laboratory to a Plant House containment facility operated, managed and constructed in accordance with the:
  - 3.1. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard

155.04.09: *Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species*, and

- 3.2. Australian New Zealand Standard AS/NZS 2243.3:1995 *Safety in Laboratories*: Part 3: *Microbiology*, at Plant House Physical Containment Level 2 (PC2), and the controls imposed in this decision.
4. Prior to inflorescence maturity appropriate measures shall be taken to separate the plants from other plants and to prevent pollen and/or seed being dispersed beyond the specified area or escaping from the plant house. This should at least include screening to inhibit dispersal, but may require bagging of the plants if screening is considered to be, or is, ineffective. Disposal of pollen and seed not required for subsequent analysis shall be treated as microbiological waste and disposed of by autoclaving as described in the Australian New Zealand Standard AS/NZS 2243.3:1995.
5. The applicant shall ensure that pollen and seed are not transported out of the containment facility on workers clothing and that all laboratory coats used shall remain in the facility, except during cleaning. When laboratory coats are to be cleaned they shall be transported within a closed bag or container in a manner that does not allow for the escape of viable genetic material. Pockets on laboratory coats shall be removed.
6. All people working within the containment facility shall at all times wear slip-on disposable over-shoes to prevent the loss of genetically modified pollen or seed from the containment facility. Over-shoes shall be disposed of in a manner that does not allow the escape of viable genetic material.
7. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>14</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
8. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

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The Environmental Risk Management Authority reached a decision on the following application on 18 July 2000

**Application Code:** GMD00068

**Applicant:** Forest Research Institute

**Purpose:** To develop in containment modified microorganisms which will form the genetic stock of the molecular biology research programme for use in the genetic engineering of conifer species and to further develop and improve transformation methods

**Description of organisms:**

The organisms approved are:

A. *Escherichia coli* strain K-12 and derivatives\* as

14 An inspector appointed under the Biosecurity Act.

modified by non-conjugative plasmid vectors containing one or more of the following, and where the development of the genetically modified organisms meet the requirements of Category A experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998:

1. Selectable marker and reporter genes
2. Genes conferring resistance to insect pests of plants sourced from bacteria and eukaryotes<sup>b</sup>
3. Genes conferring resistance to plant pathogens sourced from bacteria and eukaryotes<sup>b</sup>
4. Genes involved with responses to environmental stress (eg heat, cold, and drought) sourced from bacteria and eukaryotes<sup>b</sup>
5. Genes involved in cell maintenance, cell structure, or replication sourced from bacteria and plants<sup>b</sup>
6. Genes associated with plant metabolism, sourced from bacteria and plants<sup>b</sup>
7. Genes involved in wood development and structure, sourced from plants<sup>b</sup>
8. Virulence genes and left and right T-DNA border sequences from the Ti plasmid of *Agrobacterium tumefaciens*
9. Promoters sourced from plant viruses, plants, yeast, mammals and bacteria
10. Origins of replication derived from bacterial plasmids, bacteriophage, and yeast

<sup>a</sup> Host cells shall not contain conjugative plasmids of generalised transducing phages.

<sup>b</sup> Genetic material sourced from native flora and fauna, or from Māori or Polynesian people, shall not be used. Genetic material sourced from organisms listed as prohibited or unwanted for the purposes of the Biosecurity Act shall not be used. Genetic material sourced from CITES-listed organisms shall not be used without written approval from the Department of Conservation.

**B.** Disarmed strains of *Agrobacterium tumefaciens* as modified by Ti-plasmid vectors containing one or more of the following, and where the development of the genetically modified organisms meet the requirements of Category A experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998:

1. Selectable marker and reporter genes
2. Genes conferring resistance to insect pests of plants sourced from bacteria and eukaryotes<sup>a</sup>
3. Genes conferring resistance to plant pathogens sourced from bacteria and eukaryotes<sup>a</sup>
4. Genes involved with responses to environmental stress (eg heat, cold, and

drought) sourced from bacteria and eukaryotes<sup>a</sup>

5. Genes involved in cell maintenance, cell structure, or replication sourced from bacteria and plants<sup>a</sup>
6. Genes associated with plant metabolism, sourced from bacteria and plants<sup>a</sup>
7. Genes involved in wood development and structure, sourced from plants<sup>a</sup>
8. Virulence genes and left and right T-DNA border sequences from the Ti plasmid of *Agrobacterium tumefaciens*
9. Promoters sourced from plant viruses, plants, yeast, mammals and bacteria
- a Genetic material sourced from native flora Māori or Polynesian people, shall not be used. Genetic material sourced from organisms listed as prohibited or unwanted for the purposes of the Biosecurity Act shall not be used. Genetic material sourced from CITES-listed organisms shall not be used without written approval from the Department of Conservation.

**C.** *Saccharomyces cerevisiae* laboratory strains modified by yeast plasmid vectors and non-conjugative *E. coli*/yeast plasmid shuttle vectors containing one or more of the following, and where the development of the genetically modified organisms meet the requirements of Category A experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998:

1. Selectable marker and reporter genes
2. Genes conferring resistance to insect pests of plants sourced from bacteria and eukaryotes<sup>a</sup>
3. Genes conferring resistance to plant pathogens sourced from bacteria and eukaryotes<sup>a</sup>
4. Genes involved with responses to environmental stress (eg heat, cold, and drought) sourced from bacteria and eukaryotes<sup>a</sup>
5. Genes involved in cell maintenance, cell structure, or replication sourced from bacteria and plants<sup>a</sup>
6. Genes associated with plant metabolism, sourced from bacteria and plants<sup>a</sup>
7. Genes involved in wood development and structure, sourced from plants<sup>a</sup>
8. Virulence genes and left and right T-DNA border sequences from the Ti plasmid of *Agrobacterium tumefaciens*
9. Promoters sourced from plant viruses, plants, yeast, mammals and bacteria
10. Origins of replication derived from bacterial plasmids, bacteriophage, and yeast
- <sup>a</sup> Genetic material sourced from native flora and fauna, or from Māori or Polynesian people, shall not be used. Genetic material

sourced from organisms listed as prohibited or unwanted for the purposes of the Biosecurity Act shall not be used. Genetic material sourced from CITES-listed organisms shall not be used without written approval from the Department of Conservation.

**Decision:** Approved with Controls

**ERMA approval code:** GMD000607-GMD000609

**Controls:**

#### Physical Containment 1

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approvals of the organisms are subject to the following controls:

1. The operation, management and construction of the facility shall be in accordance with the:
  - 1.1. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*.
  - 1.2. Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories: Part 3: Microbiology*, at Physical Containment Level 1 (PC1).
2. The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and controls imposed by the Authority.
3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>15</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
4. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

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The Environmental Risk Management Authority reached a decision on the following application on 18 July 2000

**Application Code:** GMD00069

**Applicant:** Forest Research Institute

**Purpose:** To develop in containment modified *Nicotiana tabacum* and *A. thaliana* to be used as model plant organisms to assess the expression characteristics of promoters and the function of a range of genes

**Description of organisms:**

The organisms approved are:

**A. *Arabidopsis thaliana*** as modified by disarmed *Agrobacterium tumefaciens* Ti-plasmid vectors containing only elements comprising one or

more of the following, and where the development of the genetically modified organisms meet the requirements of Category B – B(b)(iii) – experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998:

1. Reporter and selectable marker genes
2. Genes involved in plant reproductive development<sup>a</sup>
3. Genes involved in plant biochemical and physiological processes<sup>a</sup>
4. Gene promoters involved in the regulation of plant developmental processes derived from *Pinus radiata* and other organisms<sup>a</sup>
5. The CaMV35S promoter and the CaMV35S-polyA terminator
6. Promoters for functional analyses sourced from plants<sup>a</sup>

<sup>a</sup> Genetic material sourced from native flora shall not be used. Genetic material sourced from organisms listed as prohibited or unwanted for the purposes of the Biosecurity Act shall not be used. Genetic material sourced from CITES-listed organisms shall not be used without written approval from the Department of Conservation.

**B. *Nicotiana tabacum*** as modified by disarmed *Agrobacterium tumefaciens* Ti-plasmid vectors containing only one or more of the following, and where the development of the genetically modified organisms meet the requirements of Category B – B(b)(iii) – experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998:

1. Reporter and selectable marker genes
2. Genes involved in plant reproductive development<sup>a</sup>
3. Genes involved in plant biochemical and physiological processes<sup>a</sup>
4. Gene promoters involved in the regulation of plant developmental processes derived from *Pinus radiata* and other organisms<sup>a</sup>
5. The CaMV35S promoter and the CaMV35S-polyA terminator
6. Promoters for functional analyses sourced from plants<sup>a</sup>

<sup>a</sup> Genetic material sourced from native flora shall not be used. Genetic material sourced from organisms listed as prohibited or unwanted for the purposes of the Biosecurity Act shall not be used. Genetic material sourced from CITES-listed organisms shall not be used without written approval from the Department of Conservation.

**Decision:** Approved with Controls

**ERMA approval code:** GMD000610-GMD000611

<sup>15</sup> An inspector appointed under the Biosecurity Act.

## Controls:

### Physical Containment 1

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approvals of the organisms are subject to the following controls:

1. The operation, management and construction of the facility shall be in accordance with the:
  - 1.1. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*.
  - 1.2. Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories*: Part 3: *Microbiology*, at Physical Containment Level 1 (PC1).
2. The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and controls imposed by the Authority.
3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>16</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
4. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

### Physical Containment 2

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approvals of genetically modified *Arabidopsis thaliana* and *Nicotiana tabacum* plants are subject to the following controls:

1. The containment facilities used to contain genetically modified *Arabidopsis thaliana* and *Nicotiana tabacum* developed as a part of this approval shall be registered by the Ministry of Agriculture and Forestry (MAF) as containment facilities under the Biosecurity Act 1993.
2. The operation, management and construction of the Laboratory containment facility where genetically modified whole plants are grown, shall be in accordance with the:
  - 2.1. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*, and
  - 2.2. Australian New Zealand Standard AS/NZS 2243.3:1995 *Safety in Laboratories*: Part 3: *Microbiology*, at Physical Containment Level 2 (PC2), and the controls imposed in this decision.

3. Prior to the development of any reproductive structures the plants shall be transferred from the PC2 laboratory to a Plant House containment facility operated, managed and constructed in accordance with the:
  - 3.1. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 155.04.09: *Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species*, and
  - 3.2. Australian New Zealand Standard AS/NZS 2243.3:1995 *Safety in Laboratories*: Part 3: *Microbiology*, at Plant House Physical Containment Level 2 (PC2), and the controls imposed in this decision.
4. Prior to inflorescence maturity appropriate measures shall be taken to separate the plants from other plants and to prevent pollen and/or seed being dispersed beyond the specified area or escaping from the plant house. This should at least include screening to inhibit dispersal, but may require bagging of the plants if screening is considered to be, or is, ineffective. Disposal of pollen and seed not required for subsequent analysis shall be treated as microbiological waste and disposed of by autoclaving as described in the Australian New Zealand Standard AS/NZS 2243.3:1995.
5. The applicant shall ensure that pollen and seed are not transported out of the containment facility on workers clothing and that all laboratory coats used shall remain in the facility, except during cleaning. When laboratory coats are to be cleaned they shall be transported within a closed bag or container in a manner that does not allow for the escape of viable genetic material. Pockets on laboratory coats shall be removed.
6. All people working within the plant house shall at all times wear slip-on disposable over-shoes to prevent the removal of genetically modified pollen or seed from the containment facility. Over-shoes shall be disposed of in a manner that does not allow the escape of viable genetic material.
7. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>17</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
8. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

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The Environmental Risk Management Authority reached a decision on the following application on 18 July 2000

**Application Code:** GMD00070

**Applicant:** Forest Research Institute

**Purpose:** To develop in containment modified *Pinus radiata* and *Picea abies* with genes related to pest and disease and wood quality traits to assess gene

<sup>16</sup> An inspector appointed under the Biosecurity Act.

<sup>17</sup> An inspector appointed under the Biosecurity Act.

expression patterns and characteristics and evaluate a transgenic approach to improve forest tree value

#### Description of organisms:

The organisms approved are:

A. *Pinus radiata* as modified by DNA derived from non-conjugative plasmid vectors of *Escherichia coli* introduced using biolistic transformation and containing only elements comprising one or more of the following, and where the development of the genetically modified organisms meet the requirements of Category B – B(b)(iii) – experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998:

1. Selectable marker and reporter genes
2. Genes conferring resistance to insect and fungal pests of plants sourced from bacteria and eukaryotes<sup>a</sup>
3. Plant<sup>a</sup> genes associated with wood characteristics
4. Plant<sup>a</sup> genes regulating wood development
5. Promoters sourced from plant viruses, plants<sup>a</sup>, and bacteria
6. Origins of replication derived from bacterial plasmids and bacteriophage

<sup>a</sup> Genetic material sourced from native flora or fauna shall not be used. Genetic material sourced from organisms listed as prohibited or unwanted for the purposes of the Biosecurity Act shall not be used. Genetic material sourced from CITES-listed organisms shall not be used without written approval from the Department of Conservation.

B. *Picea abies* as modified by non-conjugative plasmid vectors of *Escherichia coli* introduced using biolistic transformation and containing only elements comprising one or more of the following, and where the development of the genetically modified organisms meet the requirements of Category B – B(b)(iii) – experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998:

1. Selectable marker and reporter genes
2. Genes conferring resistance to insect and fungal pests of plants sourced from bacteria and eukaryotes<sup>a</sup>
3. Plant<sup>a</sup> genes associated with wood characteristics
4. Plant<sup>a</sup> genes regulating wood development
5. Promoters sourced from plant viruses, plants<sup>a</sup>, and bacteria
6. Origins of replication derived from bacterial plasmids and bacteriophage

<sup>a</sup> Genetic material sourced from native flora or fauna shall not be used. Genetic material

sourced from organisms listed as prohibited or unwanted for the purposes of the Biosecurity Act shall not be used. Genetic material sourced from CITES-listed organisms shall not be used without written approval from the Department of Conservation.

**Decision:** Approved with Controls

**ERMA approval code:** GMD000612-GMD000613

**Controls:**

#### Physical Containment 1

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approvals of the organisms are subject to the following controls:

1. The operation, management and construction of the facility shall be in accordance with the:
  - 1.1. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*.
  - 1.2. Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories*: Part 3: *Microbiology*, at Physical Containment Level 1 (PC1).
2. The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and controls imposed by the Authority.
3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>18</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
4. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

#### Physical Containment 2

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approvals of genetically modified *Pinus radiata* and *Picea abies* plants are subject to the following controls:

1. The containment facilities used to contain genetically modified *Pinus radiata* and *Picea abies* developed as a part of this approval shall be registered by the Ministry of Agriculture and Forestry (MAF) as containment facilities under the Biosecurity Act 1993.
2. The operation, management and construction of the Laboratory containment facility where genetically modified whole plants are grown, shall be in accordance with the:
  - 2.1. Ministry of Agriculture and Forestry

<sup>18</sup> An inspector appointed under the Biosecurity Act.

(MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*, and

- 2.2. Australian New Zealand Standard AS/NZS 2243.3:1995 *Safety in Laboratories: Part 3: Microbiology*, at Physical Containment Level 2 (PC2), and the controls imposed in this decision.
3. Prior to the development of any reproductive structures the plants shall be transferred from the PC2 laboratory to a Plant House containment facility operated, managed and constructed in accordance with the:
  - 3.1. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 155.04.09: *Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species*, and
  - 3.2. Australian New Zealand Standard AS/NZS 2243.3:1995 *Safety in Laboratories: Part 3: Microbiology*, at Plant House Physical Containment Level 2 (PC2), and the controls imposed in this decision.
4. Prior to inflorescence maturity appropriate measures shall be taken to separate the plants from other plants and to prevent pollen and/or seed being dispersed beyond the specified area or escaping from the plant house. This should at least include screening to inhibit dispersal, but may require bagging of the plants if screening is considered to be, or is, ineffective. Disposal of pollen and seed not required for subsequent analysis shall be treated as microbiological waste and disposed of by autoclaving as described in the Australian New Zealand Standard AS/NZS 2243.3:1995.
5. The applicant shall ensure that pollen and seed are not transported out of the containment facility on workers clothing and that all laboratory coats used shall remain in the facility, except during cleaning. When laboratory coats are to be cleaned they shall be transported within a closed bag or container in a manner that does not allow for the escape of viable genetic material. Pockets on laboratory coats shall be removed.
6. All people working within the plant house shall at all times wear slip-on disposable over-shoes to prevent the loss of genetically modified pollen or seed from the containment facility. Over-shoes shall be disposed of in a manner that does not allow the escape of viable genetic material.
7. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>19</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
8. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

The Environmental Risk Management Authority reached a decision on the following application on 18 July 2000

**Application Code:** GMD00071

**Purpose:** To modify *Saccharomyces cerevisiae* and *Escherichia coli* with *S. cerevisiae* DNA to determine what genes are involved in the natural processes of amino acid transport in yeast

**Application Code:** GMD00072

**Purpose:** To modify *Escherichia coli* to determine how genes are naturally transferred between microorganisms and how that process influences the evolution of plants

**Applicant:** University of Canterbury

**Description of organisms:**

The organisms approved are:

**GMD00071**

1. *Escherichia coli* strain K12 derivatives<sup>a</sup> as modified by non-conjugative general bacterial plasmid vectors or *E. coli*/yeast shuttle vectors containing genes sourced from *Saccharomyces cerevisiae*.

2. *Saccharomyces cerevisiae* laboratory strains as modified by yeast plasmid vectors or non-conjugative *E. coli*/yeast shuttle vectors containing genes sourced from *Saccharomyces cerevisiae*.

The development of these genetically modified organisms shall meet the requirements of Category A experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

<sup>a</sup> The host cells shall not contain conjugative plasmids or generalized transducing phages.

**GMD00072**

1. *Escherichia coli* strain K12 derivatives<sup>a</sup> as modified by conjugative and non-conjugative bacterial plasmid vectors containing PSK/ABI genes sourced from *E. coli* and from plasmids and phage of *E. coli*.

The development of these genetically modified organisms shall meet the requirements of Category A or B experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

<sup>a</sup> The host cells shall not contain generalized transducing phages.

**Decision:** Approved with Controls

**ERMA approval code:** GMD000594-GMD000596

**Controls:**

#### **Physical Containment 1**

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approvals of the organisms **requiring PC1 containment** are subject to the following controls:

<sup>19</sup> An inspector appointed under the Biosecurity Act.

1. The operation, management and construction of the facility shall be in accordance with the:
  - 1.1. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*.
  - 1.2. Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories: Part 3: Microbiology*, at Physical Containment Level 1 (PC1).
2. The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and controls imposed by the Authority.
3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>20</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
4. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

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The Environmental Risk Management Authority reached a decision on the following application on 18 July 2000

**Application Code:** GMD00056

**Applicant:** Victoria University of Wellington

**Purpose:** To modify *Escherichia coli* for the purpose of propagating recombinant DNA, required to make diagnostic probes for the detection of human mutations and polymorphisms, and to generate target sequences to validate the probes (positive controls)

**Description of organisms:**

*Escherichia coli* strain K12 and derivatives<sup>a</sup> as modified by non-conjugative plasmid cloning vectors containing DNA for the following sequences sourced from humans<sup>b</sup>, and where the development of the genetically modified organisms meet the requirements of Category A experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998:

- a) Human 21-hydroxylase genes (CYP21/CYP21P)
- b) CFTR gene
- c) Centromeric alphoid repeat sequences
- d) Telomeric repeat sequences

<sup>a</sup> The host cells shall not contain conjugative plasmids or generalized transducing phages

<sup>b</sup> Genetic material sourced from Māori shall not be used.

**Decision:** Approved with Controls

**ERMA Approvals Code:** GMD000597

<sup>20</sup> An inspector appointed under the Biosecurity Act.

<sup>21</sup> An inspector appointed under the Biosecurity Act.

**Controls:**

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approvals of the organisms **requiring PC1 containment** are subject to the following controls:

1. The operation, management and construction of the facility shall be in accordance with the:
  - 1.1. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*.
  - 1.2. Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories: Part 3: Microbiology*, at Physical Containment Level 1 (PC1).
2. The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and controls imposed by the Authority.
3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>21</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
4. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

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The Environmental Risk Management Authority reached a decision on the following applications on 18 July 2000

**Application Code:** GMD00058

**Purpose:** To study the function and regulation of the epithelial sodium channel

**Application Code:** GMD00059

**Purpose:** To apply mammalian cell transfection to produce proteins in mammalian cells to study the function and regulation of the epithelial sodium channel

**Application Code:** GMD00060

**Purpose:** To apply recombinant DNA technology to clone and express genes of interest as tools to produce proteins in either mammalian cells or oocytes to study the function and regulation of the epithelial sodium channel

**Application Code:** GMD00061

**Purpose:** To apply routine recombinant DNA technology to clone and express genes of interest as tools to produce protein in either bacterial or mammalian cells to study the function and regulation of H-cadherin

**Application Code:** GMD00062

**Purpose:** Transient transfection of mammalian cells

**Applicant:** Victoria University of Wellington

## Description of Organisms:

1. *Escherichia coli* strain K12 and derivatives that do not contain conjugative plasmids or generalized transducing phage, as modified by non-conjugative plasmid vectors of the following types:

- i. General *E. coli* cloning vectors eg pBluescript, pGEM, pCRII vectors
- ii. *E. coli* expression plasmid vectors eg pProEx HT, pRSET, pGEX series vectors
- iii. *E. coli*/mammalian expression plasmid vectors eg pMT3, pHM6, pcDNA3, pGL3
- iv. *E. coli*/yeast shuttle vectors eg pGAD424, pGBT9

And containing:

- i. genomic or cDNA from human<sup>a</sup>, rat, mouse or sheep for the purposes of identifying and/or expressing:
  - a. genes associated with sodium channel function; or
  - b. genes associated with H-cadherin function
- ii. the *Saccharomyces cerevisiae* ubiquitin gene
- iii. genomic or cDNA from chicken (*Gallus gallus*) genes associated with H-cadherin function

The development of these genetically modified organisms shall meet the requirements of Category A experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

<sup>a</sup> Genetic material sourced from Māori shall not be used.

2. **Laboratory strains of *Saccharomyces cerevisiae*** as modified by yeast plasmid vectors containing:

- i. genomic or cDNA from human<sup>a</sup>, rat, mouse or sheep for the purposes of identifying and/or expressing:
  - a) genes associated with sodium channel function; or
  - b) genes associated with H-cadherin function
- ii. the *Saccharomyces cerevisiae* ubiquitin gene
- iii. genomic or cDNA from chicken (*Gallus gallus*) genes associated with H-cadherin function

The development of these genetically modified organisms shall meet the requirements of Category A experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

<sup>a</sup> Genetic material sourced from Māori shall not be used.

3. **Mammalian cell lines<sup>a</sup>** derived from:

- i. Dog (*Canis familiaris*), eg MDCK (Mardin-Darby canine kidney)
- ii. Pig (*Sus scrofa*), eg LLC-PK1 pig proximal kidney

iii. Mouse (*Mus musculus*), eg CommaD mouse mammary

iv. Rat (*Rattus norvegicus*)

v. Sheep (*Ovis aries*)

vi. The Cos-7 green monkey kidney cell line

Human cell lines will also be used but since human beings and genetic structures derived from human beings are not organisms for the purposes of the HSNO Act, approval for the genetic modification of human cell lines is not required under the HSNO Act.

As modified by mammalian expression plasmid vectors containing:

- i. genomic or cDNA from human<sup>b</sup>, rat, mouse or sheep for the purposes of expressing:
  - a) genes associated with sodium channel function; or
  - b) genes associated with H-cadherin function
- ii. the *Saccharomyces cerevisiae* ubiquitin gene
- iii. genomic or cDNA from chicken (*Gallus gallus*) genes associated with H-cadherin function

The development of these genetically modified organisms shall meet the requirements of Category A experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

<sup>a</sup> Cell lines shall be free of viruses or viral vectors that are capable of infecting humans

<sup>b</sup> Genetic material sourced from Māori shall not be used.

**Decision:** Approved with Controls

**ERMA Approval Codes:** GMD000598-GMD000605

### Controls:

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approvals of the organisms **requiring PC1 containment** are subject to the following controls:

1. The operation, management and construction of the facility shall be in accordance with the:
  - 1.1. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*.
  - 1.2. Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories*: Part 3: *Microbiology*; at Physical Containment Level 1 (PC1).
2. The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and controls imposed by the Authority.
3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>22</sup> and

<sup>22</sup> An inspector appointed under the Biosecurity Act.

- ERMA New Zealand immediately the event is noticed (and at least within
4. 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
  5. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

The Environmental Risk Management Authority reached a decision on the following application on 18 July 2000

**Application Code:** GMD00074

**Applicant:** Victoria University of Wellington

**Purpose:** To modify *E. coli* for the purpose of propagating recombinant DNA. The recombinant DNA is required to make diagnostic probes for the production of FISH probes. The probes will be used in studies analysing development expression patterns in rats

**Description of organisms:**

***Escherichia coli* strain K12 and derivatives<sup>a</sup>** as modified by non-conjugative plasmid cloning vectors containing genomic or cDNA sourced from laboratory rat (*Rattus norvegicus*) brains, where the development of the genetically modified organisms meet the requirements of Category A experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.

<sup>a</sup> The host cells shall not contain conjugative plasmids or generalized transducing phages

**Decision:** Approved with Controls

**ERMA Approvals Code:** GMD000606

**Controls:**

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, the Authority's approvals of the organisms **requiring PC1 containment** are subject to the following controls:

1. The operation, management and construction of the facility shall be in accordance with the:
  - 1.1. Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms*.
  - 1.2. Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories*: Part 3: *Microbiology*, at Physical Containment Level 1 (PC1).
2. The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and controls imposed by the Authority.

3. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor<sup>23</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.
4. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

The Environmental Risk Management Authority reached a decision on the following application on 29 July 2000

**Application Code:** GMD99002

**Applicant:** University of Otago

**Purpose:** To develop in containment replication-deficient recombinant retroviruses containing a range of DNA. The retroviruses will be inserted into cell lines to study the role of viral and cellular proteins in cell cycle control

**1. Description of organisms:**

*Escherichia coli* strains K12 and B and their derivatives that do not contain conjugative plasmids or generalised transducing phages, as modified by cloning vectors<sup>a</sup> as listed in Annex 1<sup>24</sup> and containing nucleic acids sourced from the following items:

- i. Papillomavirus genes E1, E2, E4, E5, E6, E7, L1, and L2.
- ii. Adenovirus genes E1, E2, E3, E4
- iii. The ribosome entry site sequence expression cassette from pIRES1neo
- iv. Genes that are involved with cell cycle control<sup>b</sup>, sourced from eukaryotes<sup>c</sup> and being organisms developed under Category A or B experiments as defined in the Hazardous Substances and New Organisms Act (Low-Risk Genetic Modification) Regulations 1998.

**2. Replication defective but infection-competent retroviral (Retroviridae) vectors as modified by:**

- i. (a) Papillomavirus genes E1, E2, E4, E5, E6, E7, L1, and L2, or
- (b) Adenovirus genes E1, E2, E3, E4
- ii. The ribosome entry site sequence expression cassette from pIRES1neo
- iii. Genes that are involved with cell cycle control<sup>b</sup>, sourced from eukaryotes<sup>c</sup>

**Under no circumstances shall two known oncogenes be included within the same vector.**

3. Epitheloid and fibroblast cells from mouse (*Mus musculus*), rat (*Rattus norvegicus*), and human as modified by the retroviral vectors identified in 2 above.
4. Epitheloid and fibroblast cells from mouse (*Mus musculus*), rat (*Rattus norvegicus*), and human as modified by E1b deficient adenoviruses and the retroviral vectors identified in 2 above.

<sup>23</sup> An inspector appointed under the Biosecurity Act.

<sup>24</sup> Annex 1 refers to the *Appendix 1* of the application GMD99002

5. Mouse and human<sup>d</sup> retrovirus packaging cell lines.

<sup>a</sup> The approved vectors shall not include plasmids that are able to transfer themselves by conjugation or generalised transducing phages.

<sup>b</sup> Genes involved in cell cycle control are those that play a role in the regulation of cellular growth or that are toxic to mammalian cells.

<sup>c</sup> Genetic material originally sourced from Māori and native or valued flora and fauna shall not be used. Genetic material from CITES-listed species shall not be used without the written permission of the Department of Conservation.

<sup>d</sup> Note that the development of genetically modified human cell lines does not require an approval under the HSNO Act 1996. The definition of organism in the HSNO Act, explicitly, *does not include a human being or a genetic structure derived from a human being.*

**Decision:** Approved with Controls

**ERMA Approvals Code:** GMD000462-GMD000465

**Controls:**

In considering the Third Schedule Part I *Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms* of the Act, this application is approved subject to the following controls:

**1. To limit the likelihood of any accidental release of any organism or any viable genetic material<sup>25</sup> :**

**For the development of genetically modified *E. coli***

1.1. The construction, operation and management of the containment facility shall be in accordance with the:

- i Ministry of Agriculture and Forestry (MAF) Biosecurity Authority/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms.*
- ii Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories: Part 3: Microbiology*, at Physical Containment Level 1 (PC1).

**For the development of genetically modified *Retroviridae* and genetically modified cell lines**

1.2. The construction, operation and management of the containment facility shall be in accordance with the:

- i MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms.*
- ii Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories: Part 3: Microbiology*, at Physical Containment Level 2 (PC2).

1.3. The facilities shall be approved by MAF as containment facilities in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and

the controls of the Authority, prior to the development of any genetically modified organisms that are the subject of this approval.

- 1.4. A biological safety cabinet of class II (refer AS 2252.2<sup>26</sup>) shall be used for all experiments requiring PC2 containment involving the handling of retroviruses.
- 1.5. Dishes and plates of cells containing human-infectious viruses shall be handled in larger plates (or inverted lids) to provide traps for accidental spills.
- 1.6. All pipettes, glassware, plasticware, and other used equipment shall be decontaminated by submersion in a suitable disinfectant or by placing in polyethylene bags that should subsequently be sealed and autoclaved. Sharps (eg needles and scalpel blades), shall be disposed of in puncture-resistant containers (refer AS 4031<sup>27</sup>) and incinerated.
- 1.7. Tissue cultures infected with human-infectious or potentially human-infectious viruses shall be kept in incubators dedicated to the use of human-infectious viruses.
- 1.8. Human-infectious viruses or infected cell lines shall be stored in a section of the freezer specifically designated for this purpose and clearly marked to this effect. Similarly, ampoules of frozen infected cell lines shall be stored in a separate section of the liquid nitrogen tank.

**2. To exclude unauthorised people from the facility:**

2.1. The applicants shall comply with the requirements contained in the standards listed in controls 1.1 and 1.2 relating to identification of entrances, numbers of and access to entrances, and security requirements for the entrances and the facility.

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

3.1. The applicants shall comply with the requirements contained in the standards listed in control 1.1 and 1.2 relating to exclusion of other organisms from the facility and the control of undesirable and unwanted organisms within the facility.

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

- 4.1. The applicants shall comply with the requirements contained in the standards listed in control 1.1 and 1.2 relating to the prevention of unintended release of the organisms by experimenters working with the organisms.
- 4.2. Under no circumstances should investigators be infecting cultures of their own cells, or of their immediate relatives, or those of other members of the laboratory.

<sup>25</sup> 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, eg when organisms or parts thereof are sublethally damaged by being frozen, dried, heated, or affected by chemical.

<sup>26</sup> AS 2252.2 Part 2: *Laminar flow biological safety cabinets (Class II) for personnel and product protection*

<sup>27</sup> AS 4031 *Non-reusable containers for the collection of sharp medical items in health care areas*

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

- 5.1. The applicants shall comply with the requirements of the standards listed in control 1.1 and 1.2 relating to the provision of an eradication plan to deal with an accidental release beyond the facility and into the uncontrolled environment or spillage of microorganisms within the facility.
- 5.2. If for any reason a breach of containment occurs the applicant [or facility Operator] shall notify the facility Supervisor<sup>28</sup> and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected), and notify the measures taken to mitigate its effects.

**6. Inspection and monitoring requirements for containment facilities:**

- 6.1. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facility at any reasonable time.

**7. Qualifications required of the persons responsible for implementing those controls:**

- 7.1. The applicant shall comply with the requirements of the standards listed in control 1.1 and 1.2 relating to the training of personnel working in the facility.
- 7.2. The facility Operator, in consultation with the Institutional Biological Safety Committee (IBSC), shall ensure that only suitably trained individuals will handle human-infectious recombinant viruses covered under this approval.
- 7.3. The facility Operator shall record the qualifications and training undertaken of all personnel working with organisms under this approval, and make these records available for examination by the Inspector.
- 7.4. The Operator shall ensure that every individual working with organisms under this approval:

- i has read and understood the requirements of standards identified in controls 1.1 and 1.2, and the additional controls specified in this approval, and in particular those provisions relating to the safety of personnel working with human-infectious recombinant viruses.

In order to achieve this, the applicant shall prepare a laboratory operations manual (containment manual) for all persons working with organisms under this approval, which is derived from AS/NZS 2243.3 at PC1 and PC2, and the additional controls identified as a part of this approval.

This manual shall be available to all personnel working in the containment facility at all times.

- ii has signed a declaration that states that they have read and understood the standards identified in controls 1.1 and 1.2, and the additional controls specified in this approval.

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The Environmental Risk Management Authority reached a decision on the following application on 29 July 2000

**Application Code:** GMF98009

**Applicant:** New Zealand Pastoral Agricultural Research Institute Ltd (AgResearch)

**Purpose:** To field test, in Waikato, genetically modified cattle with extra bovine genes, the insertion of the human myelin basic protein gene, and the deletion of the bovine  $\beta$ -lactoglobulin gene. Genes will be expressed in the milk of the cattle

**Description of organisms:**

*Bos taurus* (cattle): Construct: Myelin Basic Protein (MBP) cattle (insertion of sequence coding for human myelin basic protein); Phenotype: expression of the human myelin basic protein in the milk of genetically modified cattle. This decision is for one of the three constructs for approval sought under application GMF98009. The following two constructs were approved by the Authority on 18 November 1999:

1. *Bos taurus* (cattle): Construct: casein<sup>plus</sup> (insertion of additional cattle milk casein protein genes); Phenotype: enhanced expression of casein in the milk of genetically modified cattle to increase the casein content of milk relative to that of total solids.
2. *Bos taurus* (cattle): Construct: BLG<sup>minus</sup> (disruption of the cattle  $\beta$ -lactoglobulin locus, to inactivate the gene); Phenotype: reduced  $\beta$ -lactoglobulin content of milk of genetically modified cattle relative to total solids.

**Decision:** Approved with Controls

**ERMA Approvals Code:** GMF000026

**Controls:**

In considering the Third Schedule Part I Matters to be addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms of the Act, the approved organisms are subject to the following controls:

**1. To limit the likelihood of any accidental release of any organism or any viable genetic material<sup>29</sup>:**

- 1.1. The applicant before field testing cattle containing any construct not yet developed, shall obtain development approval, under the Hazardous Substances and New Organisms (HSNO) Act 1996, from the AgResearch Ruakura Institutional Biological Safety Committee (IBSC) and provide a declaration in writing to the Authority verifying that:

- i the construct and genetically modified embryo has been developed in accordance with an

<sup>28</sup> An inspector appointed under the Biosecurity Act.

<sup>29</sup> 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, eg when organisms or parts thereof are sublethally damaged by being frozen, dried, heated, or affected by chemical.

- approval under section 39(1)(a) of the Act
- ii the construct and genetically modified embryo complies with the requirements detailed in the schedule attached to this decision (Schedule 1)
  - iii the genetically modified cell line (nuclear donor) from which the embryo is produced contains the transgene [verified by methods including, but not limited to, the Polymerase Chain Reaction (PCR) or Southern hybridisation analysis].
- 1.2. The field test of genetically modified cattle shall be carried out in a containment facility<sup>30</sup> registered by the Ministry of Agriculture and Forestry (MAF) under the Biosecurity Act 1993, in accordance with the MAF Biosecurity Authority Animal Health and Welfare Standard 154.03.06: *Containment Standard for Field Testing Farm Animals*.
  - 1.3. The applicant shall provide ERMA New Zealand and the facility Supervisor<sup>31</sup>(MAF) with a timetable for the production and field testing of genetically modified cattle approved under this decision, and shall notify ERMA New Zealand and the facility Supervisor, in writing, of any changes to that timetable.
  - 1.4. The production and maintenance of genetically modified cattle in the containment facility shall be in accordance with the relevant sections and regulations of the Animal Welfare Act 1999, the Animal Welfare Advisory Committee (AWAC) and National Animal Ethics Advisory Committee (NAEAC) guidelines administered by MAF, and the relevant AgResearch Animal Ethics Committee (AEC).
  - 1.5. The maximum number of cattle<sup>32</sup> in the field test shall not exceed the capacity of the containment facility as approved under the MAF Biosecurity Authority Standard 154.03.06, and/or any requirements of the relevant AEC, and should at all times be the minimum number of animals required to obtain statistically significant results.
  - 1.6. The total number of cattle in the field test (including cattle containing casein<sup>plus</sup> and BLG<sup>minus</sup> constructs approved in November 1999) shall not at any one time exceed 200 animals.
  - 1.7. At all times only persons authorised by the Operator or the Manager shall have access to the containment facility.
  - 1.8. All conventional cattle in the field test shall be double tagged (ie by two different ear tags). All genetically modified cattle shall be individually identified by an ear tag for visible identification and also implanted with a subcutaneous electronic microchip to enable individual electronic identification. In the event that subcutaneous microchips cannot be inserted until cattle reach a certain age, cattle shall have two different types of ear tag in place at all times, allowing for immediate identification.
  - 1.9. The identification system for genetically modified cattle shall enable the information on the genotype and generation (T0, T1 etc) to be derived from a database maintained by the applicant.
  - 1.10. The applicant shall maintain a register with records of identity and fate of all cattle in the field test.
  - 1.11. No genetically modified cattle are permitted to leave the containment facility except in accordance with the provisions specified in the MAF Biosecurity Authority Standard 154.03.06, as described in control 1.2.
  - 1.12. Milking of genetically modified cattle shall be performed within the containment facility and the milk shall be transported, in secure containers to prevent spill, to the laboratory (a *containment facility* registered by MAF in accordance with the MAF Biosecurity Authority Standard 154.03.02 *Containment Facilities for Microorganisms*) for evaluation. A log of the quantity of milk obtained and its fate shall be maintained and recorded in a register.
  - 1.13. All genetically modified cattle no longer required for breeding and any biological material (including semen and ova) derived from genetically modified cattle no longer required for the purpose of this application shall be disposed of on-site<sup>33</sup> by burial, in such a manner which minimises leaching to defined aquifers, and following consultation with Ngāti Wairere.
  - 1.14. In the event that operations involving genetically modified cattle cease, all genetically modified cattle in the containment facility shall be destroyed and disposed of in accordance with the provisions specified in control 1.13 above.
  - 1.15. Conventional cattle may be disposed of off-site, but shall not leave the containment facility until 50 days after the third negative pregnancy test, ie performed at approximately 28, 35 and 50 days post-embryo transfer.
  - 1.16. All waste milk, skim milk, and cream shall be disposed of on-site by either an effluent treatment digester, incineration, or by spraying onto pasture following treatment in order to destroy any cells present in the milk.
  - 1.17. The containment facility shall be enclosed by double 2-metre high perimeter fences constructed in accordance with the requirements specified in MAF Biosecurity Authority Standard 154.03.06. The inner perimeter fence shall be *electronically monitored and alarmed* (in order that

<sup>30</sup> The *containment facility* refers to the area where the genetically modified cattle are to be maintained, and that is registered by MAF under the Biosecurity Act 1993.

<sup>31</sup> An Inspector appointed under the Biosecurity Act.

<sup>32</sup> Including: genetically modified cattle, non-modified cattle and conventional cattle.

<sup>33</sup> On-site refers to any place on AgResearch property within the Ruakura Research Centre.

the location of any breach of containment is detected immediately), stock-proof and capable of preventing entry and escape of cattle.

**2. To exclude unauthorised people from the facility:**

The applicant shall comply with the requirements contained in the standard listed in control 1.2 relating to identification of entrances, numbers of, and access to entrances, and security requirements for the entrances and the facility.

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

3.1. The applicant shall comply with the requirements contained in the standard listed in control 1.2 relating to exclusion of other organisms from the facilities and the control of undesirable and unwanted organisms within the facilities.

3.2. In the event of mortality in genetically modified cattle in the containment facility, carcasses shall be immediately removed to prevent access by scavengers and the carcasses shall be disposed of in accordance with the provisions specified in control 1.13.

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

4.1. The applicant shall comply with the requirements contained in the standard listed in control 1.2 relating to the prevention of unintended release of genetically modified cattle by experimenters working with the cattle.

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

5.1. In case of unintended or accidental release or escape of genetically modified cattle involved in the field test, the applicant shall recover the escaped cattle to the containment facility. If there has been any possibility of mating occurring, steps shall be taken to abort any possible resulting pregnancies. If abortion is not successful, the affected cattle shall be slaughtered and disposed of in accordance with the provisions specified in control 1.13. Alternatively, potentially affected cows shall be identified and destroyed, and be disposed of in the same manner.

5.2. If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected).

**6. Inspection and monitoring requirements for containment facilities:**

6.1. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the containment facility at any reasonable time.

6.2. The Operator responsible for maintaining genetically modified cattle in the containment facility, shall report immediately to ERMA New

Zealand and the Supervisor (at least within 24 hours) on any event that is likely to be in the public interest, eg unexpected mortality in genetically modified cattle or a breach in security.

6.3. The applicant shall provide a comprehensive report to ERMA New Zealand in each December on the progress in the production and field testing of genetically modified cattle, including an inventory, with particular reference to the topics listed in section 4.13 of the MAF Biosecurity Authority Standard 154.03.06. This report shall also include:

i information on animal welfare issues including; behaviour traits of genetically modified cattle as against unmodified cattle in the field test, number and explanation of caesarean sections performed for genetically modified cattle; and issues associated with the induced lactation of genetically modified calves.

ii information on the stability of the genetic constructs used in genetically modified cattle.

iii any reports provided to the local AgResearch AEC.

6.4. The applicant shall provide a final report to ERMA New Zealand at the conclusion of the approval period, being five years from the date of this decision. This shall include:

i information on the items listed in section 4.13 of the MAF Biosecurity Authority Standard 154.03.06.

ii information on animal welfare issues including; behaviour traits of genetically modified cattle as against unmodified cattle in the field test, number and explanation of caesarean sections performed for genetically modified cattle; and issues associated with the induced lactation of genetically modified calves.

iii information on the stability of the genetic constructs used in genetically modified cattle.

iv any reports provided to the local AgResearch AEC.

6.5. The applicant shall establish and facilitate a Working Group with Ngāti Wairere, to enable Ngāti Wairere to monitor the implementation and progress of the field test, and to provide a forum for the exchange of information on the science of genetic modification.

**7. Qualifications required of the persons responsible for implementing those controls:**

7.1. The applicant shall comply with the requirements of the standards listed in control 1.2 relating to the training of personnel working in the facility.

7.2. The applicant shall notify the Supervisor and ERMA New Zealand if there are any changes in ownership of the property housing the containment facility in which organisms under this approval are maintained.

## DELEGATED AUTHORITY

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### The following applications were decided by institutions acting under delegated powers from the Authority

**Applicant:** University of Otago

**Institution application code:** GMO00/UO020

**Purpose:** The purpose of this application is to use *Escherichia coli* expression systems to produce specific streptococcal adhesin polypeptides for research purposes

**ERMA Approval code:** GMD000466-467

**Description of organism:** A panel of isogenic *Saccharomyces cerevisiae* strains with ATF1, ATF2 and/or OLE1 genes disrupted with marker genes and *Escherichia coli* K12 derivatives used in the construction of *Saccharomyces cerevisiae* GMO00/UO020

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA002

**Purpose:** To understand causative role of polymorphisms in the pathogenesis of Type II Diabetes in Māori

**ERMA Approval code:** GMD000468-469

**Description of organism:** *E. coli* and mammalian cell lines as modified by human genomic DNAs encoding parts of the amylin, glucokinase and HNF-1 genes

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA016

**Purpose:** Diagnosis of Haemophilia A and Haemochromatosis and a study of the genetic basis of these diseases with the long-term goal of improving diagnostic methods

**ERMA Approval code:** GMD000470

**Description of organism:** *E. coli* (K12 strains) as modified by genes encoding human blood clotting factors, blood physiological factors and blood cell clonal markers

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA018

**Purpose:** To develop in vitro systems to investigate the interaction of Hepatitis B virus with hepatocytes

**ERMA Approval code:** GMD000471

**Description of organism:** *E. coli* (K12 strains) as modified by HBV pre S1 and core proteins

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA024

**Purpose:** To study the genes controlling cell growth which may be targets for future drug therapies

**ERMA Approval code:** GMD000472-473

**Description of organism:** *E. coli* (K12 strains) and mammalian cell lines as modified by cDNAs encoding phospholipases and their isoforms

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA026

**Purpose:** To understand transporter proteins in prokaryotes and eukaryotes and develop novel therapies for *Helicobacter* infection

**ERMA Approval code:** GMD000474

**Description of organism:** *E. coli* as modified by *Helicobacter* amino acid transporter genes

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA032

**Purpose:** To develop novel therapies for neurological disorders including Parkinson's disease, epilepsy and injury resulting from stroke

**ERMA Approval code:** GMD000475-477

**Description of organism:** *E. coli*, Baculovirus, mouse and rat cell lines (and human cell lines) as modified by AAV vector with therapeutic genes

**Decision:** Approved with controls (PC2)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA036

**Purpose:** To understand the mechanisms of rotavirus infection with the long-term goal of development of vaccines and novel therapies for rotavirus

**ERMA Approval code:** GMD000478-482

**Description of organism:** *E. coli* and mammalian cell lines as modified by rotavirus cDNAs encoding viral proteins 1-11

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA015

**Purpose:** To study the transcriptional regulation of adhesion molecules beta 7 and MadCAM

**ERMA Approval code:** GMD000483-485

**Description of organism:** *E. coli* (K12 strains), insect, and mammalian cell lines as modified by human and mouse adhesion molecule, adhesion promoter and enhancer elements and regulatory nuclear proteins

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA037

**Purpose:** To study the mechanisms of cell adhesion and chronic inflammatory processes

**ERMA Approval code:** GMD000486-488

**Description of organism:** *E. coli* and mammalian cell lines as modified by a luciferase reporter gene and human and mouse genes involved in transcription regulation

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA038

**Purpose:** To investigate the role of protein and peptide

aggregation in neurodegenerative disorders such as Huntington's and Alzheimers disease

**ERMA Approval code:** GMD000489-491

**Description of organism:** *E. coli* and mammalian cell lines as modified by a fluorescent proteins as well as human Huntington's, Abeta, Tau and Tata Binding Protein genes which have been further modified by untranslated and glutamine repeats

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA040

**Purpose:** To study the membrane transport of nutrients and neurotransmitters

**ERMA Approval code:** GMD000492-496, 580

**Description of organism:** *E. coli* and mammalian cell lines (canine monkey, pig, rat and mouse) as modified by mammalian Noradrenaline and Creatinine Transporters as well as Transporter Interacting and Regulating Protein (TIRP) genes

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA041

**Purpose:** To study melanocortin receptors and their possible role in Type II diabetes and obesity

**ERMA Approval code:** GMD000497-500

**Description of organism:** *E. coli* and mammalian cell lines as modified by mammalian melanocortin receptors and reporter genes

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA027

**Purpose:** To understand the regulation of photosynthesis or flowering in *Arabidopsis*

**ERMA Approval code:** GMD000501

**Description of organism:** *Arabidopsis* as modified by genes regulating photosynthesis or flowering in *Arabidopsis*

**Decision:** Approved with controls (PC2)

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**Applicant:** Crop & Food Research

**Institution application code:** GMO00/CFR003

**Purpose:** To use *E. coli* in standard molecular cloning experiments using commercial strains and vectors under manufacturer's guidelines. Donor DNA obtained from *Triticeae* and other grass species – development of DNA markers for identifying sites of gene introgression from wild barley grass into cultivated barley

**ERMA Approval code:** GMD000502

**Description of organism:** *Escherichia coli* (laboratory strains) modified by DNA from grass species *Hordeum vulgare*, *H. bulbosum*, *Secale cereale*, *Triticum species*, *Avena* sp. *Oryza* sp. using pGEM-T plasmids

**Decision:** Approved with controls (PC2)

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**Applicant:** Crop & Food Research

**Institution application code:** GMO00/CFR004

**Purpose:** To study the genes and genetic mechanisms controlling apomixis using *Hieracium* as a model plant. This requires the insertion of certain marker genes to enable the process of asexual reproduction to be tracked. The recombinase genes are used to clip genes in and out of plant chromosomes as required. The use of plant sequences from *Arabidopsis* forms part of an international collaboration to study the action of genes involved in sexual reproduction when introduced into an apomictic plant

**ERMA Approval code:** GMD000503-505

**Description of organism:** *Hieracium* apospecies in the subgenus *Pilosella*, *Agrobacterium tumefaciens* and *E. coli* modified by genes for selection purposes eg antibiotic resistance genes, visual selection genes, recombinase genes and plant sequences from the *Arabidopsis*.

**Decision:** Approved with controls (PC2)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO013

**Purpose:** The purpose of this application is to detect potential protein/protein interactions between viral proteins and host proteins in order to further our knowledge of virus host interactions at the molecular level

**ERMA Approval code:** GMD000506

**Description of organism:** *E. coli* as modified by non conjugative plasmids carrying sequences encoding GAL4 fusion proteins, and *Saccharomyces cerevisiae* expressing GAL4-fusion proteins

**Decision:** Approved with controls (PC1 and PC2: where potential oncogene is inserted)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO005

**Purpose:** To construct strains of *E. coli* for research into vaccines

**ERMA Approval code:** GMD000507

**Description of organism:** *E. coli* K12 and B strains as modified by mouse cytokine, cytokine receptor and antigen peptide cDNA cloned into non-conjugative plasmid vectors

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO016

**Purpose:** The purpose of this application is to generate laboratory strains of the yeast *Saccharomyces cerevisiae* that can be used to study the function of membrane-bound proteins potentially involved in antimicrobial drug resistance

**ERMA Approval code:** GMD000508-509

**Description of organism:** *Saccharomyces cerevisiae* and *Escherichia coli* K12 and B derivatives modified

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by incorporation of genomic DNA cloned from *S. cerevisiae*, *Candida albicans*, *C. glabrata*, *C. krusei*, *C. dubliniensis* or *Cryptococcus neoformans* into a non-conjugative *E. coli*/*S. cerevisiae* shuttle expression vector

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO018

**Purpose:** The purpose of this application is to use *Escherichia coli* expression systems to produce specific streptococcal adhesin polypeptides for research purposes

**ERMA Approval code:** GMD000510

**Description of organism:** *Escherichia coli* K12 or B derivatives with genomic DNA cloned from oral streptococcal species using non-conjugative plasmid or bacteriophage vectors

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO023

**Purpose:** The purpose of this application is to generate RNA probes to research the tissue distribution and cellular localisation of gene expression of cardiovascular hormones and their receptors.

**ERMA Approval code:** GMD000511

**Description of organism:** *Escherichia coli* K12 or B derivatives containing DNA fragments of genes encoding cardiovascular hormones or their receptors in a plasmid vector

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO026

**Purpose:** The application is made to seek approval to clone and express *H. pylori* Lpp20 with the sole purpose of using the recombinant protein in the development of an effective *H. pylori* vaccine

**ERMA Approval code:** GMD000512

**Description of organism:** *E. coli* BL21 derivatives, as modified by insertions of PCR-derived HP1456 (*H. pylori* lipoprotein 20) gene

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO028

**Purpose:** The development of these genetically modified organisms is central to medical research aimed at understanding the genetic basis of the development and function of dendritic cells

**ERMA Approval code:** GMD000513-514

**Description of organism:** *E. coli* K12 derivatives and mammalian cell lines carrying non-conjugative plasmids containing cDNA encoding genes from human dendritic cells

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO030

**Purpose:** The development of these genetically modified organisms is central to biomedical research aimed at understanding the molecular basis of cancer and other human genetic conditions

**ERMA Approval code:** GMD000515

**Description of organism:** *E. coli* K12 derivatives modified by non-conjugative vectors containing human genomic DNA or cDNA of non-Maori origin

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO039

**Purpose:** To develop modified bacteria and cell lines to analyse the way substances cross cell membranes by examining the channels through which they pass (Update of application GMO00/UO028 to include TriplEX2 and 4 new donor species)

**ERMA Approval code:** GMD000516 & 576

**Description of organism:** *Escherichia coli* (K12 and B) and cultured epithelial cell lines (Canine: MDCK, African Green Monkey: COS-7 and Pig: LLCPK1) modified by cDNA from possum (*Trichosurus vulpecula*), mouse (*Mus musculus*), cockroach (*Periplaneta americana*) and cricket (*Teleogryllus commodus*) cloned into TriplEX2 vector (Clontech)

**Decision:** Approved with controls (PC1)

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**Applicant:** Fletcher Challenge Forests Limited

**Institution application code:** GMO00/FC001

**Purpose:** To transform *P. radiata* with a reporter gene and suitable marker, in order to monitor the gene expression during plant development

**ERMA Approval code:** GMD000517-520

**Description of organism:** Modified *Escherichia coli* and *Agrobacterium tumefaciens* will be used to transform *Nicotiana tabacum* and *P. radiata* species with the glucuronidase and neomycin phosphotransferase II genes

**Decision:** Approved with controls (PC2)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO019

**Purpose:** To construct genetic libraries of poxvirus DNA. This will enable genetic and functional analyses of poxvirus to be conducted

**ERMA Approval code:** GMD000521

**Description of organism:** *Escherichia coli* as modified by non-conjugative plasmids carrying poxvirus DNA

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO037

**Purpose:** To clone or subclone DNA encoding specified mammalian cytokines, growth factors and their receptors in *E. coli* K12. This will enable

functional analyses of these factors to be conducted

**ERMA Approval code:** GMD000522

**Description of organism:** *Escherichia coli* strain K12 or B as modified by non-conjugative vectors carrying DNA encoding specified mammalian cytokines, growth factors and their receptors

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO010

**Purpose:** To produce cDNAs from invertebrates in *E. coli* in order to study biological processes such as vision at the molecular level which will contribute to developing an understanding of biological defects

**ERMA Approval code:** GMD000523

**Description of organism:** *Escherichia coli* K12 derivatives as modified by DNA cloned from invertebrate tissues (primarily the squid species *Nototodarus sloanii*, *Loligo forbesi*) into non-conjugative plasmid or phage vectors

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO009

**Purpose:** Application and improvement of a vector to provide gene disruption cassettes that allow the high level expression of membrane proteins from bacterial and non-human and non-indigenous eukaryotic sources in the plasma membranes and secretory vesicles of *Saccharomyces cerevisiae*

**ERMA Approval code:** GMD000524-525

**Description of organism:** *Saccharomyces cerevisiae* strains, and *E. coli* K12 derivatives used in construction, modified by deleting membrane transporters and expressing at high levels homologous and heterologous membrane proteins in the plasma membrane and in secretory vesicles

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO017

**Purpose:** The purpose of this application is to allow development of genetically modified *Pseudomonas aeruginosa* bacteria in order to better understand how this organism causes infection in susceptible patients (update of GMO99/UO022)

**ERMA Approval code:** GMD000526-527

**Description of organism:** *Pseudomonas aeruginosa* and *Escherichia coli* K12 as modified by peptide synthetase genes from other microorganisms

**Decision:** Approved with controls (PC1 and PC2)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO031

**Purpose:** The purpose of this application is to isolate genes that encode for proteins that protect *Mycobacterium smegmatis* from acidic pH. By

understanding this process using *Mycobacterium smegmatis* as a model we may be able to understand how virulent bacteria like *Mycobacterium tuberculosis* cope with extremes of pH (update on GMO99/UO014)

**ERMA Approval code:** GMD000528-529

**Description of organism:** *E. coli* K12 derivatives and *Mycobacterium smegmatis* containing pYUB or pJEM vectors with cloned *Mycobacterium smegmatis* DNA

**Decision:** Approved with controls (PC1 and PC2)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO012

**Purpose:** This application is to apply standard tools (retroviral lineage tracing) to investigate the embryonic origins of cells and tissues in the body

**ERMA Approval code:** GMD000530-539

**Description of organism:** *Escherichia coli* K12 and B derivatives and embryonic *Rattus rattus norvegicus*, *Mus musculus*, *Gallus domesticus*, *Xenopus laevis* as modified by mouse or human retroviral nucleic acid sequences and marker genes

**Decision:** Approved with controls (PC2)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA020

**Purpose:** The use of microbial communities as indicators of environmental perturbation, the role of microorganisms in the degradation of organic matter, wastewater treatment and in industrial bioreactors and the microbial ecology of plants and animals

**ERMA Approval code:** GMD000543

**Description of organism:** *E. coli* (K12 strains) as modified by ribosomal RNA gene sequences from Archeobacteria, Bacteria and Eukaryotic Microorganisms

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA021

**Purpose:** To study the functions of intracellular transport proteins using fluorescent microscopy

**ERMA Approval code:** GMD000544-550

**Description of organism:** *E. coli* (K12 strains), *Saccharomyces cerevisiae* and rat, mouse, monkey, hamster, and insect cell lines as modified by expression vectors with Red Fluorescent protein as well as rat and mouse amylin

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA025

**Purpose:** To understand the brain specific Growth Hormone Receptor signaling pathway with the long-term goal of minimising the severe effects of hypoxic-ischaemic injury to the brain

**ERMA Approval code:** GMD000551-552

**Description of organism:** *E. coli* (K12 strains) and mammalian cell lines modified by normal and truncated forms of rat Growth Hormone Receptor

**Decision:** Approved with controls (PC1)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA013

**Purpose:** To develop effective treatments for cancer (update to GMO99/UA026)

**ERMA Approval code:** GMD000553-554

**Description of organism:** Mice and *E. coli* (K12 strains) as modified by immunoregulatory and tumor reducing agents

**Decision:** Approved with controls (PC1: *E. coli*, PC2: *Mus musculus*)

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**Applicant:** University of Auckland

**Institution application code:** GMO00/UA030

**Purpose:** To develop basic model gene transfer and reporter systems for teaching and research to understand the fundamental molecular biology of plants (Update to UA/85-90)

**ERMA Approval code:** GMD000555-572, 578-579

**Description of organism:** Specified plant species, *E. coli* and *Agrobacterium tumefaciens* as modified by GUS and GFP reporter genes

**Decision:** Approved with controls (PC1 and PC2 Plant House)

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**Applicant:** University of Otago

**Institution application code:** GMO00/UO001

**Purpose:** To identify *Candida albicans* DNA sequences that are either induced or repressed under specific environmental conditions

**ERMA Approval code:** GMD000573-574

**Description of organism:** *Escherichia coli* K12 derivatives and *Candida albicans* modified by incorporation of genomic DNA cloned from *C. albicans* into a non-conjugative plasmid

**Decision:** Approved with controls (PC1 and PC2)

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