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ENVIRONMENTAL RISK MANAGEMENT AUTHORITY

THE BULLETIN

The Bulletin *is published approximately eleven times per year. It is an official record of applications being processed, the Authority's decisions, and other activities under the Hazardous Substances and New Organisms (HSNO) Act 1996.* **The Bulletin** *– and further information on the application process are available on the ERMA New Zealand website: www.ermanz.govt.nz.* **The Bulletin** *can also be ordered by electronic subscription through bulletin@ermanz.govt.nz*

NEW ORGANISMS

DECISIONS ON APPLICATIONS

The Environmental Risk Management Authority reached a decision on the following application on 9 September 2002

Application Code: GMC02005

Applicant: AgResearch Limited – Wallaceville Office

Purpose: To import nematodes and gene libraries for use in investigating parasite drug resistance and to develop methods, including vaccines, to combat nematode diseases in livestock and humans

Description of Organisms: *Caenorhabditis elegans* (Maupas 1900) modified by plasmid pD49.83 containing the rol-6 marker gene and a putative vaccine antigen sequence (confidential information) from the sheep parasitic nematode *Haemonchus contortus*. *Escherichia coli* (Migula 1895) Castellani & Chalmers 1919 strain DH10B modified by:

- EMBL 3 vector containing genomic DNA fragments derived from *Trichostrongylus colubriformis*
- *Escherichia coli* (Migula 1895) Castellani & Chalmers 1919 strain DH10B modified by Lambda DASH vector containing genomic DNA fragments derived from *Ostertagia circumcincta* or *Parastrongyloides trichosuri*
- *Escherichia coli* (Migula 1895) Castellani & Chalmers 1919 strain DH10B modified by Lambda ZAP vector containing cDNA derived from *Caenorhabditis elegans*, *Caenorhabditis briggsae*, *Haemonchus contortus*, *Parastrongyloides trichosuri*, *Onchocerca volvulus* or *Ostertagia circumcincta*
- *Escherichia coli* (Migula 1895) Castellani & Chalmers 1919 strain DH10B modified by pBluescript pGEM-T or pGEM-T Easy vectors containing genomic DNA or cDNA derived from *Caenorhabditis elegans*, *Caenorhabditis briggsae*, *Trichostrongylus colubriformis*, *Haemonchus contortus*, *Parastrongyloides trichosuri*, *Onchocerca volvulus* or *Ostertagia circumcincta*
- Bacteriophage EMBL 3 modified with genomic DNA fragments derived from the sheep parasitic nematode *Trichostrongylus colubriformis*
- Bacteriophage Lambda DASH modified with genomic DNA fragments derived from the sheep parasitic nematode *Ostertagia circumcincta* or the possum parasitic nematode *Parastrongyloides trichosuri*
- Lambda ZAP containing cDNA derived from *Caenorhabditis elegans*, *Caenorhabditis briggsae*, *Haemonchus contortus*, *Parastrongyloides trichosuri*, *Onchocerca volvulus* or *Ostertagia circumcincta*

Decision: Approved with Controls

ERMA Approval Code: GMC001188 – GMC001190

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ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO
ERMA New Zealand

Controls:

In order to satisfactorily address the matters detailed in the Third Schedule Part I: Containment controls for importing, developing or field testing of genetically modified organisms[1] of the HSNO Act, and other matters in order to give effect to the purpose of the HSNO Act (section 45(2)), 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[2]:

1.1 The person responsible for a particular research area and/or the person responsible for the operation of the containment facility shall inform all personnel involved in the handling of the organisms of the Authority's controls.

1.2 The containment facility in which the GM nematodes, *Escherichia coli*, and bacteriophage are maintained shall be registered by the Ministry of Agriculture and Forestry (MAF) Biosecurity Authority in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02 (Containment Facilities for Micro organisms). The organisms shall be maintained at the following Physical Containment Levels as defined in AS/NZS Standard 2243.3.2002. Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities.

- GM *Escherichia coli* and bacteriophage at Physical Containment Level 1 (PC1)
- GM nematodes at Physical Containment Level 2 (PC2)

1.3 The construction and operation of the containment facilities ('the facility') in which the organisms are maintained, shall be in accordance with the relevant standards listed in 1.2 above.

2. To exclude unauthorised people from the facility:

2.1 The identification of entrances, numbers of and access to entrances, and security requirements for the entrances and the facility shall be in compliance with the standards listed in control 1.2.

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

3.1 Construction and operation of the containment facility shall comply with the requirements of the standards listed in control 1.2 relating to the 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 Construction and operation of the containment facility shall comply with the requirements of the standards listed in control 1.2 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 Construction and operation of the containment facility shall comply with the requirements of the standards listed in control 1.2 relating to controlling the effects of any accidental release or escape of an organism.

5.2 If for any reason a breach of containment occurs, the facility Supervisor[3], MAF Biosecurity Authority and ERMA New Zealand shall be notified immediately the event is noticed (and at least within 24 hours of the breach being detected).

5.3 In the event of any breach of containment of the organisms, the contingency plan for the attempted retrieval or destruction of any viable material of the organism that has escaped shall be implemented immediately. The contingency plan shall be included in the containment manual in accordance with the requirements of standards listed in control 1.2.

6. Inspection and monitoring requirements for containment facilities:

6.1 The operation of the containment facilities shall comply with the requirements contained in the standards listed in control 1.2 relating to the inspection and monitoring requirements for containment facilities.

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

6.3 The containment manual shall be updated, as necessary, to address the implementation of the controls imposed by this approval, in accordance with the Standards listed in control 1.2.

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

7.1 The training of personnel working in the facility shall be in compliance with the standards listed in control 1.2.

1 Bold headings refer to Matters to be Addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms, specified in the Third Schedule of the HSNO Act 1996.

2 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.

3 An inspector appointed under the Biosecurity Act.

The Environmental Risk Management Authority reached a decision on the following application on 9 September 2002

Application Code: S2602004

Applicant: Eric Walton

Purpose: Determination whether or not *Musa mannii* is not a new organism under section 26 of the HSNO Act

Description of Organisms: *Musa mannii* H.Wendel. exBaker1893 (Family Musaceae)

Decision: That *Musa mannii* H.Wendel. exBaker1893 (Family Musaceae) is not a new organism under section 26 of the HSNO Act

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The Environmental Risk Management Authority reached a decision on the following application on 9 September 2002

Application Code: S2602008

Applicant: New Zealand Cactus and Succulent Society

Purpose: Determination whether or not *Momordica rostrata* is a new organism under section 26 of the HSNO Act

Description of Organisms: *Momordica rostrata* Zimmermann 1922 (Family Cucurbitaceae)

Decision: That *Momordica rostrata* Zimmermann 1922 (Family Cucurbitaceae) is not a new organism under section 26 of the HSNO Act

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The Environmental Risk Management Authority reached a decision on the following application on 17 September 2002

Application Code: GMD01244

Applicant: Victoria University of Wellington

Purpose: To develop in containment genetically modified *Escherichia coli* (transfer of ACNGT approved organisms to approved status under the HSNO Act)

Description of Organisms: *Escherichia coli* (Migula 1895) Castellani & Chalmers 1919 (Family Enterobacteriaceae) strain K-12 or B derivatives, eg K802, JM101, HB101, C600 by the following vector and donor DNA:

Vector – Non-conjugative plasmids, eg pBR322, pBR325, pSP6. Bacteriophages M13 and Lambda

Donor – DNA from invertebrates and vertebrates other than humans and other than from invertebrate and vertebrate organisms which are native[4] to New Zealand

Decision: Approved with Controls

ERMA Approval Code: GMD002231

Controls:

In considering all the matters to be addressed as detailed in Part I of the Third Schedule of the HSNO Act: Matters to be addressed by containment controls for importation, development and field testing of genetically modified organisms, this approval (on behalf of the Authority) of the organisms are subject to the following controls:

1. To limit the likelihood of any accidental release of any organism or any viable genetic material[5]:

1.1 The person responsible for a particular research area and/or the person responsible for the operation of the containment facilities ('the facility') shall inform all personnel involved in the handling of the organisms of the Authority's controls.

1.2 The Ministry of Agriculture and Forestry (MAF) shall approve the facility in accordance with the MAF/ERMA New Zealand Standard 154.03.02: Containment Facilities for Micro organisms at Laboratory Physical Containment Level 1 (PC1) and the controls of the Authority.

1.3 The operation and management of the containment facilities shall be in accordance with the:

a) Ministry of Agriculture and Forestry (MAF) Regulatory Authority/ERMA New Zealand Standard 154.03.02: Containment Facilities for Micro organisms at Laboratory Physical Containment Level 1 (PC1).

b) Australian New Zealand Standard AS/NZS 2243.3:2002 Safety in Laboratories: Part 3: Microbiological aspects and containment facilities, at the Physical Containment Level 1 (PC1).

2. To exclude unauthorised people from the facility:

2.1 The identification of entrances, numbers of and access to entrances, and security requirements for the entrances and the facility shall be in compliance with the requirements of the standards listed in control 1.3.

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

3.1 The exclusion of other organisms from the facility and the control of undesirable and unwanted organisms within the facility shall be in compliance with the standards listed in control 1.3.

4 'Native' in this context means a species which has an established population and breeds in New Zealand. The term is often used as synonym of both 'endemic' and 'indigenous'. It excludes 'introduced' or 'exotic' species that have been brought into New Zealand by humans or self introduced in recent times.

5 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.

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

4.1 The prevention of unintended release of the organisms by experimenters working with the organisms shall be in compliance with the standards listed in control 1.3.

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

5.1 Control of the effects of any accidental release or escape of the organisms shall be in compliance with the standards listed in control 1.3.

5.2 In the event of any breach of containment the contingency plan for the attempted retrieval or destruction of any viable material of the organisms that have escaped shall be implemented immediately. The contingency plan shall be included in the containment manual in accordance with the Standards 154.03.02 listed in control 1.3(a).

5.3 If for any reason a breach of containment occurs the facility Supervisor[6], MAF Biosecurity Authority and ERMA New Zealand shall be notified immediately the event is noticed (and at least within 24 hours of the breach being detected).

5.4 The applicants shall comply with the requirements of the standards listed in control 1.3 relating to the maintenance of records demonstrating compliance with the Standards 154.03.02, as required by the quality assurance programme, and documented in the containment manual.

6. Inspection and monitoring requirements for containment facilities:

6.1 The inspection and monitoring requirements for containment facilities shall be in compliance with the standards listed in control 1.3.

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

6.3 The containment manuals shall be updated, as necessary, to address the implementation of the controls imposed by this approval, in accordance with the MAF/ERMA New Zealand Standard 154.03.02.

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

7.1 The training of personnel working in the facility shall be in compliance with the standards listed in control 1.3.

7.2 The facility Operator, in consultation with the Institution shall ensure that only suitably trained individuals will handle the material 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.

The Environmental Risk Management Authority reached a decision on the following application on 23 September 2002

Application Code: NOC02002

Applicant: Landcare Research

Purpose: To conduct host specificity testing of four insect species as possible biocontrol agents for weedy species of banana passionfruit in New Zealand

Description of Organisms: *Zapriothrica nr nudiseta* (Wheeler 1956) (Diptera: Drosophilidae) Bud fly

Pyrausta perelegans Hampson, 1899 (Lepidoptera: Pyralidae) Flower moth

Cyanotricha necyria Felder & Rogenhofer, 1875 (Lepidoptera: Notodontidae (Dioptinae)) Foliage-feeding moth

Dasiops caustonae Norrborn & McAlpine, 1997 (Diptera: Lonchaeidae) Fruit-feeding fly

Decision: Approved with Controls

ERMA Approval Code: NOC002275 – NOC002278

Controls:

In order to satisfactorily address the matters detailed in the Third Schedule Part II: Containment controls for new organisms excluding genetically modified organisms[7] of the HSNO Act, and other matters in order to give effect to the purpose of the HSNO Act (section 45(2)), the Committee'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[8]:

1.1 The insects are to be held in containment, and the host specificity tests carried out, only within Landcare Research's Transitional and Containment Facility for Invertebrates at the Canterbury Agriculture and Science Centre, 40 Gerald Street, Lincoln. The construction, operation, and management of the containment facility shall be in accordance with the:

6 An inspector appointed under the Biosecurity Act.

7 Bold headings refer to matters to be addressed by containment controls for new organisms excluding genetically modified organisms, specified in the Third Schedule (Part II) of the HSNO Act 1996.

8 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

a) Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.02.08. Transitional and Containment Facility for Invertebrates;

b) Australian New Zealand Standard AS/NZS 2243:3 2002 Safety in Laboratories: Part 3: (Microbiological aspects and containment facilities), Invertebrate Containment Level 2 (PC2); and the controls of the Authority.

1.2 No organisms, other than those directly connected with the host specificity testing, are to be in the same part of the containment facility at the same time.

1.3 The following protective clothing shall be worn at all times by all people entering the containment facility: plastic overalls covering the entire body, including the head; plastic boots; and a face mask, if the person has a beard. The protective clothing shall be put on and taken off in the containment facility.

2. To exclude unauthorised people from the facility:

2.1 The identification of entrances, numbers of and access to entrances, and the security requirements for the entrances and the facility shall be in compliance with the standards listed in Control 1.1.

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

3.1 Control of the effects of any accidental release or escape of an organism shall be in compliance with the standards listed in Control 1.1.

3.2 If for any reason a breach of containment occurs the facility Supervisor[9], MAF Biosecurity Authority, ERMA New Zealand, and Department of Conservation shall be notified immediately the event is noticed (and at least within 24 hours of the breach being detected).

3.3 In the event of any breach of containment of the organisms, the contingency plan for the attempted retrieval or destruction of any viable material of the organism that has escaped shall be implemented immediately.

3.4 Before any importation of the insects is made, the applicant shall submit to ERMA New Zealand, for approval by the Authority, a revised contingency plan for limiting the likelihood of any of the insects spreading, surviving and breeding, and for eradication of the insects, should any breach of containment occur. The revised plan is to reflect the additional controls imposed by this decision (including, in particular 3.6 and 3.7).

3.5 The revised contingency plan shall be included in the containment manual in accordance with the requirements of standards listed in Control 1.1.

3.6 In the event of an escape of insects from the containment room being detected or suspected, all walls, ceilings and floors of the containment room, corridor and air-lock of the facility are to be sterilised and disinfected.

3.7 Immediately an escape from containment is detected or suspected, potted banana passionfruit plants are to be placed as trap plants in the grounds outside of the containment facility. These plants are to be managed in a manner that maximises the opportunity to restrict the spread and the possibility of destruction any escaped insects.

4. Inspection and monitoring requirements for containment facilities:

4.1 The inspection and monitoring requirements for containment facilities shall be in compliance with the standards listed in Control 1.1.

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

4.3 The containment manual shall be updated, as necessary, to address the implementation of the controls imposed by this approval, in accordance with Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.02.08. Transitional and Containment Facility for Invertebrates.

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

5.1 The training of personnel working in the facility shall be in compliance with the standards listed in Control 1.1.

6. Additional controls:

6.1 The first host specificity studies shall include the native kōhia *Tetrapathaea tetranda*. ERMA New Zealand and the Wairewa Runanga Society Inc are to be notified of the results of these host specificity trials on kōhia. If the testing indicates that kōhia *Tetrapathaea tetranda*, is a potential host for one or more of the species of insects, all further importations of the relevant species of insect shall cease, and all individuals of the relevant species held in containment shall be immediately destroyed.

9 An inspector appointed under the Biosecurity Act.

6.2 All insects used in the research are to be destroyed when the trials are completed or at the end of the approval period (unless a further approval is obtained from the Authority extending the period of the approval, or for release of the insects from containment).

6.3 Members of the Wairewa Runanga are to be invited to accompany Landcare Research staff on their excursions into the takiwa to collect kōhia material for the research. Any kōhia collected is to be used solely for the purposes of the present application.

6.4 Landcare Research is to maintain ongoing liaison with Ngāi Tahu and the Wairewa Runanga to enable monitoring and information exchange related to the banana passionfruit biocontrol research.

6.5 This approval is for a period ending 31 December 2012.

The Environmental Risk Management Authority reached a decision on the following application on 30 September 2002

Application Code: GMC02007

Applicant: University of Otago

Purpose: To import into containment GM mice for use in studying inherited kidney disease and the pathogenesis of childhood heart and muscle disease, with an aim to developing strategies and therapies to combat these diseases

Description of Organisms: *Mus musculus* (Linnaeus 1758) strain C57BL/6, SV40 tsA58 Tag

Mus musculus (Linnaeus 1758) strain C57BL/6, Ozz-/-LacZ

Mus musculus (Linnaeus 1758) strain 129SV, Ozz-/-LacZ

Decision: Approved with Controls

ERMA Approval Code: GMC001193 – GMC001193

Controls:

In order to satisfactorily address the matters detailed in the Third Schedule Part I: Containment controls for importing, developing or field testing of genetically modified organisms[10] of the HSNO Act, and other matters in order to give effect to the purpose of the HSNO Act (section 45(2)), 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[11]:

1.1 The person responsible for a particular research area and/or the person responsible for the operation of the containment facility shall inform all personnel involved in the handling of the organisms of the Authority's controls.

1.2 The containment facility in which the organisms are maintained shall be in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.03. Containment Facilities for Vertebrate Laboratory Animals, at Physical Containment Level 2 (PC2) as defined in AS/NZS Standard 2243.3.2002. Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities.

1.3 The construction and operation of the containment facilities ('the facility') in which the organisms are maintained, shall be in accordance with the relevant standards listed in control 1.2 above.

2. To exclude unauthorised people from the facility:

2.1 The identification of entrances, numbers of and access to entrances, and security requirements for the entrances and the facility shall be in compliance with the standards listed in control 1.2.

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

3.1 Construction and operation of the containment facility shall comply with the requirements of the standards listed in control 1.2 relating to the 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 Construction and operation of the containment facility shall comply with the requirements of the standards listed in control 1.2 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 Construction and operation of the containment facility shall comply with the requirements of the standards listed in control 1.2 relating to controlling the effects of any accidental release or escape of an organism.

10 Bold headings refer to Matters to be Addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms, specified in the Third Schedule of the HSNO Act 1996.

11 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.

5.2 If for any reason a breach of containment occurs, the facility Supervisor[12], MAF Biosecurity Authority and ERMA New Zealand shall be notified immediately the event is noticed (and at least within 24 hours of the breach being detected).

5.3 In the event of any breach of containment of the organisms, the contingency plan for the attempted retrieval or destruction of any viable material of the organism that has escaped shall be implemented immediately. The contingency plan shall be included in the containment manual in accordance with the requirements of standards listed in control 1.2.

6. Inspection and monitoring requirements for containment facilities:

6.1 The operation of the containment facilities shall comply with the requirements contained in the standards listed in control 1.2 relating to the inspection and monitoring requirements for containment facilities.

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

6.3 The containment manual shall be updated, as necessary, to address the implementation of the controls imposed by this approval, in accordance with the Standards listed in control 1.2.

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

7.1 The training of personnel working in the facility shall be in compliance with the standards listed in control 1.2.

The Environmental Risk Management Authority reached a decision on the following application on 30 September 2002

Application Code: GMD02028

Applicant: AgResearch Limited

Purpose: To develop transgenic cattle that can express functional therapeutic foreign proteins in their milk, and to develop transgenic cattle to study gene function and genetic performance

Description of Organisms: *Bos taurus* cells and animals modified with a range of genes derived solely from humans, mice, cattle, deer, sheep, and goats, and other genetic sequences, including reporter and selectable marker genes and expression control sequences, derived from other organisms

Decision: Approved with Controls

ERMA Approval Code: GMD002232

Controls:

In order to satisfactorily address the matters detailed in the Third Schedule Part I: Containment controls for importing, developing or field testing of genetically modified organisms[13] of the HSNO Act, and other matters in order to give effect to the purpose of the HSNO Act (section 45(2)), 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[14]:

1.1 Steps (a) to (d) as specified in the application, shall be carried out in an indoor containment facility approved by the Ministry of Agriculture and Forestry (MAF) under the Biosecurity Act 1993, in accordance with the MAF/ERMA New Zealand Standard 154.03.02 Containment Standard for Micro organisms at Physical Containment Level 1 (PC1).

1.2 The operation and management of the indoor containment facility shall be in accordance with MAF/ERMA New Zealand Standard 154.03.02 Containment Standard for Micro organisms.

1.3 Steps (e) and (f), as specified in the application, shall be carried out in an outdoor containment facility[15] approved by the Ministry of Agriculture and Forestry (MAF) under the Biosecurity Act 1993, in accordance with the MAF/ERMA New Zealand Animal Health and Welfare Standard 154.03.06: Containment Standard for Field Testing Farm Animals.

1.4 The operation and management of the outdoor containment facility shall be in accordance with MAF/ERMA New Zealand Standard 154.03.06: Containment Standard for Field Testing Farm Animals.

1.5 The outdoor containment facility shall be enclosed by double 2 metre high perimeter fences constructed in accordance with the requirements of the standard specified in control 1.4. The inner perimeter fence shall be electronically monitored and alarmed (in order that the location of any breach of containment is detected immediately), stock-proof, and capable of preventing entry and escape of cattle.

12 An inspector appointed under the Biosecurity Act.

13 Bold headings refer to Matters to be Addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms, specified in the Third Schedule of the HSNO Act 1996.

14 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.

15 The outdoor 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 as a containment facility.

1.6 No genetically modified cattle, surrogate mothers (cows carrying GM foetuses to full term or near to full term), or recipient cows (cows that implant a GM embryo but subsequently lose the foetus) are permitted to leave the outdoor containment facility except in accordance with the requirements of the standard listed in control 1.4. All such animals shall be returned to the outdoor containment facility.

1.7 The number of genetically modified male calves shall be kept to a minimum. All genetically modified male calves shall be destroyed after semen has been collected, and disposed of in accordance with control 1.9.

1.8 All genetically modified cattle, surrogate mothers, recipient cows, and non-transgenic calves[16] associated with this approval, no longer required for the development shall be destroyed, and disposed of in accordance with control 1.9. Surrogate mothers and recipient cows are defined by pregnancy to the stage of demonstrable placentation at, or before, the 35 day scan, whether or not they carry the calf to term. Conventional cattle that do not implant a GM embryo can be disposed of off-site.

1.9 Disposal shall be by burial in unlined offal pits. Offal pits are to be located within the outdoor containment facility and shall be positioned to minimise leaching to groundwater. The applicant shall consult with Ngāti Wairere with respect to developing culturally appropriate mechanisms and protocols for disposal, which add to and are consistent with the rest of this control.

1.10 In the event of mortality of genetically modified cattle in the containment facilities, carcasses shall be immediately removed to prevent access by scavengers and the carcasses disposed of in accordance with control 1.9.

1.11 Milking of genetically modified cattle shall be performed within the outdoor containment facility and the milk shall be transported, in secure containers to prevent spill, to the indoor containment facility (approved under control 1.1) for evaluation. A log of the quantity of milk obtained and its fate shall be maintained and recorded in a register.

1.12 All milk, skim milk, and cream shall either be disposed of by an effluent treatment digester or incineration within the indoor facility, or by spraying onto pasture within the outdoor containment facility following treatment in order to destroy any cells present in the milk; or be removed into secure containment in accordance with the MAF/ERMA New Zealand Standard 154.03.02 Containment Facilities for Micro organisms.

1.13 No part or product of genetically modified cows, surrogate mothers or recipient cows (as defined in control 1.8), or non-transgenic calves[17] shall be ingested by any person at any time.

1.14 Any cattle with signs of any exotic disease, including transmissible spongiform encephalopathies, shall be reported to MAF via the Exotic Disease and Pest Emergency Hotline. Disposal of animals will be according to MAF direction.

2. To exclude unauthorised people from the facility:

2.1 The applicant shall comply with the requirements contained in the standards listed in controls 1.2 and 1.4 relating to identification of entrances, numbers of, and access to entrances, and security requirements for the entrances and the facilities.

2.2 At all times only persons authorised by the Operator or the Manager of the containment facilities shall have access to the containment facilities.

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 standards listed in controls 1.2 and 1.4 relating to exclusion of other organisms from the facilities and the control of undesirable and unwanted organisms within the facilities.

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 standards listed in controls 1.2 and 1.4 relating to the prevention of unintended release of genetically modified cattle, cells or embryos by experimenters working with the organisms.

4.2 The maximum number of cattle[18] housed in the outdoor containment facility shall not exceed the capacity of the containment facility as approved under control 1.3 and any requirements of the Ruakura Animal Ethics Committee (RAEC).

4.3 All conventional cattle within the facility 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 for individual electronic identification. In the event that subcutaneous microchips cannot be implanted until cattle reach a certain age, cattle shall have two different types of ear tags in place at all times to allow for immediate identification.

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[19] (MAF) and the Chief Executive of ERMA New Zealand immediately the event is noticed.

5.2 In case of unintended or accidental release or escape of genetically modified cattle, the applicant shall recover the escaped cattle and return them to the outdoor containment facility. If there has been any possibility of mating occurring, steps shall be taken to abort any possible resulting pregnancies, and the foetuses and mothers disposed of in accordance with control 1.9.

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 facilities at any reasonable time.

6.2 The Manager responsible for maintaining genetically modified cattle in the outdoor containment facility, shall report immediately to ERMA New Zealand and the facility 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, a breach in security, or presence of Transmissible Spongiform Encephalopathies (TSE).

6.3 The applicant shall maintain a register with records of identity and fate of all cattle in the development.

6.4 Micro organisms shall be tested for the presence of the introduced genetic modifications at the disposal sites. If horizontal gene transfer (HGT) is detected, genetic modification and disposal of cattle shall be immediately halted and the Chief Executive of ERMA New Zealand informed. A remediation plan to manage the impact of the HGT event shall be developed in consultation with the Chief Executive of ERMA New Zealand.

6.5 The applicant shall provide a comprehensive report to ERMA New Zealand in each December on the progress in the development 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:

a) information on animal welfare issues including any reports to the RAEC in relation to this development;

b) information on progress in relation to investigations of HGT; and

c) a summary of any unforeseen positive or negative effects to the environment, public health, Māori culture, or the economy or society resulting from the research.

6.6 The applicant shall provide a final report to ERMA New Zealand, within six months of the end of the project or the end of the approval period (whichever is sooner). The report shall include:

a) the results of the monitoring under control 6.4;

b) any reports of the RAEC in relation to this development;

c) whether there have been any unforeseen positive or negative effects to the environment, public health, Māori culture and the economy or society resulting from the research; and

d) whether the controls imposed have been practicable and/or effective in their control purpose.

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

7.1 The applicant shall inform all personnel involved in the production and development of genetically modified cattle of the controls imposed in this decision.

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 facilities in which the organisms under this approval are maintained.

8. To ensure that, after the end of the development, heritable material is removed or destroyed:

8.1 In the event that operations involving genetically modified cattle cease, and in any case at the end of the approval period:

16 Non-transgenic calves are animals with no foreign genetic material in their genome, but which have transgenic animals in their line of breeding.

17 Non-transgenic calves are animals with no foreign genetic material in their genome, but which have transgenic animals in their line of breeding.

18 Including all genetically modified and non-genetically modified cattle.

19 An inspector appointed under the Biosecurity Act.

a) all genetically modified cattle, surrogate mothers and recipient cows (as defined in control 1.8) shall be destroyed and disposed of in accordance with control 1.9, unless a further HSNO approval has been obtained; and

b) all heritable material (including semen and ova) derived from genetically modified cattle shall be removed into secure containment or destroyed on-site in accordance with the requirements in control 1.2.

9. Additional controls imposed by the Committee:

9.1 Sequences from the vector backbone shall not be integrated into the bovine genome.

9.2 Before nuclear transplantation, all genetic material in the insert vector shall be characterised (that is, the DNA has been sequenced and there is an understanding of the potential gene products and their function) and the details of the genetic material (including source) and each construct shall be provided to the Chief Executive of ERMA New Zealand.

9.3 Breeding shall be limited to the minimum necessary to complete development. In the case of genetically modified cattle developed to study gene function and gene performance, no breeding of animals is authorised, except where necessary to develop homozygous transgenic cattle. In the case of cattle modified to express therapeutic proteins in milk, genetically modified cattle may be bred, where necessary

a) to produce one subsequent generation to investigate stability of inheritance or

b) to produce two subsequent generations to develop homozygous transgenic cattle. Prior to any breeding of transgenic cattle, the Chief Executive of ERMA New Zealand shall be advised of the intention to breed and the reasons for the breeding.

9.4 The applicant shall facilitate the continued cooperation of the existing monitoring groups with Ngāti Wairere (Ahi Ka and Te Kotuku Whenua), to enable Ngāti Wairere representatives to monitor the implementation and progress of the development, and to develop culturally appropriate mechanisms and protocols, as required. AgResearch shall advise the Chief Executive of ERMA New Zealand if either of these groups are disbanded or cease to operate satisfactorily.

9.5 The production and maintenance of genetically modified cattle in the outdoor 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 RAEC. The husbandry of the animals shall be overseen by an experienced large animal veterinarian, who shall have the power to determine a humane endpoint for any part of the experimental procedures in steps (e) and (f) (ie generating live offspring from cultured embryos and checking gene stability through reproduction).

9.6 The approval is for a period of seven and a half (7.5) years from the date of the signed decision.

AMMENDMENTS TO APPROVALS

Under Section 67A of the HSNO Act the Environmental Risk Management Authority may amend any approval given under Part V of the Act if it considers that the alteration is minor in effect or corrects a minor or technical error.

The following amendment to the controls was made by the Authority on 9 September 2002

Application Code: GMD00302

Applicant: HortResearch Palmerston North

Purpose: To develop in containment potexviruses as expression vectors (amplicons) for use in plants

Original Applicant: The Horticulture and Food Research Institute of New Zealand Limited (HortResearch) and AgResearch Ltd, Grasslands Research Centre

Amended Applicant: The Horticulture and Food Research Institute of New Zealand Limited (HortResearch); AgResearch Ltd, Grasslands Research Centre; and Crop and Food Research Institute

The following amendment to the controls was made by the Authority on 10 September 2002

Application Code: GMD01164

Applicant: Trees and Technology Limited

Purpose: To develop in containment Nicotiana species and Eucalyptus species and hybrids modified with a construct containing a gene coding for avidin which may confer resistance to herbivorous insects, to enable preliminary assessment of the gene's effect

Original Controls:

11.5 Plant material (including seeds), soil samples or leaf litter derived from the genetically modified plants shall be transported in secure containers and in accordance with the packaging requirements: Packaging Instructions No. 650 of the IATA Dangerous Goods Regulations as referred to in AS/NZS 2243.3:1995 Safety in Laboratories: Part 3: (Microbiology). Each transfer shall be recorded in the containment facility register. The applicant shall ensure that no escape of material occurs during this transfer and examination. Prior to the transfer from the containment facility the applicant shall request approval in writing from the Supervisor in accordance with the requirements of the MAF/ERMA New Zealand Standard 154.04.09: Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species.

Amended Controls:

11.5 Whole plants (including seeds), soil samples or leaf litter derived from the genetically modified plants shall be transported in secure containers and in accordance with the packaging requirements: Packaging Instructions No. 602 of the IATA Dangerous Goods Regulations as referred to in AS/NZS 2243.3:2002 Safety in Laboratories: Part 3 'Microbiological aspects and containment facilities' section 13.4(g). Laboratory cultures of genetically modified plant material in tubes and dishes shall be transported in secure containers and in accordance with the packaging requirements: Packaging Instructions No. 913 of the IATA Dangerous Goods Regulations as referred to in AS/NZS 2243.3:2002 Safety in Laboratories: Part 3 'Microbiological aspects and containment facilities' section 13.4(f). Each transfer shall be recorded in the containment facility register. The applicant shall ensure that no escape of material occurs during this transfer and examination. Prior to the transfer from the containment facility the applicant shall request approval in writing from the Supervisor in accordance with the requirements of the MAF/ERMA New Zealand Standard 154.04.09: Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species.

DELEGATED AUTHORITY

The Chief Executive of the Environment Risk Management Authority, acting under delegated power from the Authority, reached a decision on the following application on 9 September 2002

Application Code: GMD02077

Applicant: Fonterra Research Institute formerly New Zealand Dairy Research Institute

Purpose: To genetically modify approved *Escherchia coli* or yeast strains with Dairy Bacteria or *Streptococcus thermophilus* in small-scale laboratory experiments to change the levels of proteins produced by these bacteria, in order to assess the effects of these proteins on dairy product properties.
Update to GMD01001

Description of Organisms: *Escherchia coli* strain K 12 or B derivatives
Saccharyomyces cerevisiae laboratory strains
Pichia pastoris laboratory strains
Lactobacillus acidophilus
Lactobacillus brevis
Lactobacillus bulgaricus
Lactobacillus casei
Lactobacillus crispatus
Lactobacillus fermentum
Lactobacillus gasseri
Lactobacillus helveticus
Lactobacillus johnsonii
Lactobacillus paracasei
Lactobacillus plantarum
Lactobacillus reuteri
Lactobacillus rhamnosus
Lactococcus lactis

Decision: Approved with Controls

ERMA Approval Code: GMD002214 – GMD002230

Controls:

In considering all the matters to be addressed detailed in the Third Schedule Part I Containment Controls for Development and Field Testing of Genetically Modified Organisms of the HSNO Act, the IBSC approval of the organism(s) is subject to the following controls:

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

   a) The MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02: Containment Facilities for Micro organisms

   b) Australian/New Zealand Standard (AS/NZS) 2243.3 Safety in Laboratories: Part 3: Microbiological aspects and containment facilities, at Physical Containment Level 2 (PC2) for *Pichia pastoris, Lactococcus lactis* and the named *Lactobacillus species*

   c) Australian/New Zealand Standard (AS/NZS) 2243.3 Safety in Laboratories: Part 3: Microbiological aspects and containment facilities, at Physical Containment Level 1 (PC1) for *Escherichia coli* and *Saccharomyces cerevisiae*

2. The facility shall be approved and registered by MAF Biosecurity Authority as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standard (154.03.02), (and additional controls as listed below).

3. All culture products and associated materials shall be autoclaved, sterilised, or incinerated before being disposed of.

4. 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) 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 following applications were decided by institutions acting under delegated powers from the Authority

Applicant: Crop and Food Research, Lincoln

Institution application code: GMO02/CFR002

Purpose: To update the mycorrhizal-host organism source material to include liverwort species and roots of native tree species, and to update the vectors used in the construction of genomic DNA libraries.
An update of GMO00/CFR008

ERMA Approval code(s): GMD002233

Description of organism: *Escherichia coli* modified with DNA from fungi associated with liverwort and native tree root samples

Decision: Approved with controls (PC2)

Applicant: Genesis Research and Development

Institution application code: GMO02/GR037

Purpose: To determine the biological function of proteins in bioassays.
Update of GMO/GR019 to extend the sources of DNA used in the assays

ERMA Approval code(s): GMD002234-2241

Description of organism: *Escherichia coli, Arabidopsis thaliana, Eucalyptus grandis, Nicotiana tabacum, Pinus radiata* and *Zinnia elegans* modified with non-conjugative vectors, DNA from specific plants, animals, bacteria or fungi

Saccharomyces cerevisiae modified with vectors (eg pRS 400 Series, Display BAIT, and Display TARGET), DNA from specific plants, animals, bacteria or fungi

Drosophila melanogaster cells modified with vectors (eg pRMHA3), DNA from specific plants, animals, bacteria or fungi

Decision: Approved with controls (PC1 and PC2)

Applicant: HortResearch, Auckland

Institution application code: GMO02/HRA059

Purpose: Organisms will be developed to understand the response in plants to virus infection by studying the mechanistic interplay between the gene silencing, intron splicing and/or translation pathways, in plants using reporter genes to indicate path efficiencies

ERMA Approval code(s): GMD002242-2261

Description of organism: *Actinidia arguta, Actinidia chinensis, Actinidia deliciosa, Actinidia eriantha, Arabidopsis thaliana, Cyphomandra betacea, Escherichia coli* (K12 & B derivatives), *Lycopersicon esculentum, Malus domestica, Nicotiana benthamiana, Nicotiana clevelandi, Nicotiana glutinosa, Nicotiana tabacum, Petunia hybrida, Vaccinium angustifolium, Vaccinium ashei, Vaccinium corymbosum, Vaccinium macrocarpon, Vitis vinifera* modified with specific vectors containing

a) genes of non-human mammalian, insect, fungal, plant, or bacterial origin, or

b) single genes from viruses

Decision: Approved with controls (PC1 and PC2)

Applicant: HortResearch, Auckland

Institution application code: GMO02/HRA060

Purpose: Disarmed strains of *Agrobacterium tumefaciens* will be modified to delete endogenous tetracycline resistance genes and endogenous DNA recombination genes to facilitate the stabilisation and transfer of recombinant DNA into plants

ERMA Approval code(s): GMD002262-2263

Description of organism: *Agrobacterium tumefaciens* modified with tetracycline resistance and recombination genes (Rec. genes and tetA/R locus) deleted

Escherichia coli modified with *Agrobacterium Tetracycline* resistance and recombination genes

Decision: Approved with controls (PC1)

Applicant: HortResearch, Auckland

Institution application code: GMO02/HRA061

Purpose: Cloning mammalian endothelial cell marker proteins into *Escherichia coli* for sequencing and functional cell based assay development to support proof-of-concept studies investigating the potential of incorporating selectivity into the design of new pesticides

ERMA Approval code(s): GMD002264

Description of organism: *Escherichia coli* K12 derivatives modified by pUC-based plasmids containing mammalian endothelial cell marker genes

Decision: Approved with controls (PC1)

Applicant: HortResearch, Auckland

Institution application code: GMO02/HRA062

Purpose: To clone fungal genes involved in pathogenicity, mating-type, biological control, cell wall function and fungicide resistance into *Escherichia coli*.
Update of GMO99/HRA007 and GMO00/HRA033 to expand the types of *Escherichia coli* plasmid cloning vectors being used

ERMA Approval code(s): GMD002265

Description of organism: *Escherichia coli* K12 and B strains and their derivatives modified by DNA from *Glomerella cingulata, Colletotrichum sp, Botrytis cinerea, Venturia sp, Conyotherium minitians, Fusarium solani* and *Neurospora crassa* in the vectors pET22b, pET30a-c.
Update of GMD99125 and GMD00290

Decision: Approved with controls (PC1)

Applicant: HortResearch, Auckland

Institution application code: GMO02/HRA063

Purpose: To use yeast expression to determine the function of plant and fungal genes. Update of GMO00/HRA038 and GMO00/HRA046 to specify two fungi as new sources of DNA

ERMA Approval code(s): GMD002266-2267

Description of organism: *Escherichia coli* K12 derivatives modified with plasmid vectors containing genes from *Venturia inaequalis* and *Neurospora crassa*

Saccharomyces cerevisiae modified with plasmid vectors containing genes from *Venturia inaequalis* and *Neurospora crassa*

Decision: Approved with controls (PC1)

Applicant: HortResearch, Auckland

Institution application code: GMO02/HRA064

Purpose: To establish a high frequency genetic transformation system in ryegrass to investigate gene function

ERMA Approval code(s): GMD002268-2270

Description of organism: *Escherichia coli* K12 derivatives modified with selectable markers, hygromycin or bar, reporter gene gus and/or cloned plant or bacterial genes

Agrobacterium tumefaciens (disarmed strains) modified with selectable markers, hygromycin or bar, reporter gene gus and/or cloned plant or bacterial genes

Lolium perenne modified with selectable markers, hygromycin or bar, reporter gene gus and/or cloned plant or bacterial genes

Decision: Approved with controls (PC1 and PC2)

Applicant: HortResearch, Auckland

Institution application code: GMO02/HRA065

Purpose: Analysis of cDNA and genomic clones of plant origin to determine their function in plant development and plant responses.
Update of GMO00/HRA037

ERMA Approval code(s): GMD002271-2286

Description of organism: *Escherichia coli*, *Agrobacterium tumefaciens* and specific plant species modified with *Antirrhinum majus* or *Zea mays* genes involved in plant development, cell cycle, pathogen response, stress, carbohydrate biosynthesis, mobilisation and transport, flavour, colour; signalling and gene regulation

Decision: Approved with controls (PC1 and PC2)

Applicant: HortResearch, Auckland

Institution application code: GMO02/HRA066

Purpose: To construct libraries of plant genes in suitable vectors for subsequent analysis by high throughput sequencing and for later use in programs aimed at functional analysis of the plant genes.
Update of GMO00/HRA036

ERMA Approval code(s): GMD002287-2288

Description of organism: *Escherichia coli* K12 and B approved non-conjugative hosts and *Escherichia coli* K12 and B non-approved hosts (containing F' and no traD mutation) modified by specific plasmid and lambda vectors containing DNA from specific plant genera

Decision: Approved with controls (PC1 and PC2)

Applicant: Massey University

Institution application code: GMO02/MU004

Purpose To develop transgenic plants of the pasture legume white clover, tobacco and *Arabidopsis thaliana* to study the role of the plant hormone ethylene in regulating leaf senescence (ageing)

ERMA Approval code(s): GMD002289-2293

Description of organism: *Escherichia coli* DH5alpha modified with pBluescript; pGEM; pBin19, and pArt27 containing *Arabidopsis thaliana* and *Trifolium repens*, *Escherichia coli*, *Aequorea* and *Agrobacterium* genes

Arabidopsis thaliana, Nicotiana tabacum and Trifolium repens modified with *Arabidopsis thaliana* and *Trifolium repens*, *Escherichia coli*, *Aequorea* and *Agrobacterium* genes

Agrobacterium tumefaciens LBA4404 modified with pBin19, and pArt27 containing *Arabidopsis thaliana, Trifolium repens*, *Escherichia coli*, *Aequorea* and *Agrobacterium* genes

Decision: Approved with controls (PC2)

Applicant: Massey University

Institution application code: GMO02/MU005

Purpose: To clone plant genes for the purpose of DNA sequencing and the expression of recombinant proteins for subsequent antibody production

ERMA Approval code(s): GMD002294

Description of organism: *Escherichia coli* (DH5alpha, BL-21, TB-1) modified with pBluescript, pGEM, pGEX, and pPROEX containing *Trifolium* spp., *Malus* spp. and *Allium* spp. genes

Decision: Approved with controls (PC2)

Applicant: Massey University

Institution application code: GMO02/MU007

Purpose: To isolate and characterise both plant and fungal genes involved in establishment and maintenance of symbiotic associations between temperate grasses and fungal endophytes

ERMA Approval code(s): GMD002295-2305

Description of organism: *Escherichia coli* (K12 derivatives) modified with non-conjugative vectors (e.g. pUC series, pBLUESCRIPT, GATEWAY) selectable markers blaA, nptII, cat, tett, spc; DNA from yeast, *Epichloe typhinia, Epichloe festucae, Neotyphodium* sp. LpTG-2, *Neotyphodium lolii, Penicillium paxilli, Aspergillus* spp, *Lolium perenne, Festuca pratensis, Festuca arundinaceae,* jellyfish (GFP), *Escherichia coli* (GUS), firefly (LUX)

Agrobacterium tumefaciens (disarmed strains) modified with vectors with bacterial (blaA, nptII, cat, tet, spc) and fungal (hph, nptIII, pyr4, prtA, tub2, trpC) selectable markers, DNA from yeast, *Epichloe typhinia*, *Epichloe festucae, Neotyphodium* sp. LpTG-2, *Neotyphodium lolii, Penicillium paxilli, Aspergillus* spp, *Lolium perenne, Festuca pratensis, Festuca arundinaceae,* jellyfish (GFP), *Escherichia coli* (GUS), firefly (LUX)

Saccharomyces cerevisiae modified with yeast/ *Escherichia coli* shuttle vectors, bacterial selectable markers blaA, nptII, cat, tet; DNA from yeast, *Epichloe typhinia*, *Epichloe festucae, Neotyphodium* sp. LpTG-2, *Neotyphodium lolii, Penicillium paxilli, Aspergillus* spp, *Lolium perenne, Festuca pratensis, Festuca arundinaceae*, jellyfish (GFP), *Escherichia coli* (GUS), firefly (LUX)

Lolium perenne protoplast (all cultivars), *Festuca pratensis* protoplast (all cultivars), and *Festuca arundinaceae* protoplast (all cultivars) modified with transient assays of chacterised DNA from *Lolium perenne*, *Festuca arundinaceae, Festuca pratensis*, jellyfish (GFP), *Escherichia coli* (GUS), firefly (LUX)

Epichloe typhina strain E8, *Epichloe festucae* (all strains), *Neotyphodium* sp. LpTG-2 (all strains), *Neotyphodium lolii* (all strains) and *Penicillium paxilli* (all strains) modified with non-conjugative vectors, T-DNA; DNA from yeast, *Epichloe typhina, Epichloe festucae, Neotyphodium* sp. LpTG-2, *Neotyphodium lolii, Penicillium paxilli, Aspergillus* spp, jellyfish (GFP), *Escherichia coli* (GUS), firefly (LUX) and selectable markers blaA, hph, nptII

Decision: Approved with controls (PC1 and PC2)

Applicant: Massey University

Institution application code: GMO02/MU011

Purpose: To use *Escherichia coli, Pichia pastoris* or insect cell lines (baculovirus system) as heterologous hosts for expression of recombinant eukaryotic PNGases for comparative (with prokaryotic PNGase) structural and biochemical studies

ERMA Approval code(s): GMD002306-2308

Description of organism: *Escherichia coli* modified with pET32; pOPH6; pPICZ series or pPICZalpha series containing PNGase genes from *Schizosaccharomyces pombe, Arabidopsis thaliana* or *Homo sapiens*

Pichia pastoris (strains X-33, GS115, KM71H) modified with pPICZ series or pPICZalpha series containing PNGase genes from *Schizosaccharomyces pombe, Arabidopsis thaliana* or *Homo sapiens*

Spodoptera frugiperda 21 modified with pBacPAK8 or pBacPAK9 containing PNGase genes from *Schizosaccharomyces pombe, Arabidopsis thaliana* or *Homo sapiens*

Decision: Approved with controls (PC2)

Applicant: Massey University

Institution application code: GMO02/MU012

Purpose: To isolate and characterise fungal genes involved in plant pathogenesis

ERMA Approval code(s): GMD002309-2311

Description of organism: *Escherichia coli* (K12 or B derivatives) modified with non-conjugative plasmids containing *Glomerella cingulata, Venturia inaequalis* or *Magnaporthe grisea* genes

Escherichia coli (standard disarmed strains such as K12 or B derivatives) modified with non-conjugative plasmids containing *Glomerella cingulata, Venturia inaequalis* or *Magnaporthe grisea* genes

Pichia pastoris modified with integrative plasmids containing *Glomerella cingulata, Venturia inaequalis* or *Magnaporthe grisea* genes

Decision: Approved with controls (PC1 and PC2)

HAZARDOUS SUBSTANCES

NON NOTIFIED APPLICATIONS RECEIVED

Application Code: HSC02010

Applicant: BOC Gases (New Zealand) Limited

Purpose: To research and develop a completely automated pesticide application system for enclosed environments like greenhouses

Date Application Received: 20 September 2002

DECISIONS ON APPLICATIONS

The Environmental Risk Management Authority reached a decision on the following application on 27 September 2002

Application code: TNS02002

Applicant: Exel Australia Pty Limited

Purpose: To tranship class 1.4C and 1.3G explosives through New Zealand

Description of Substances: Cartridges, Power Device Aerial Flares

Classifications: 1.4C and 1.3G

Decision: Approved with Controls

ERMA Approval Code: TNS000008 – TNS000009

Controls:

- The consignment shall comply with all the relevant provisions of the IMDG code for explosives of the type involved in this shipment UN No. 0276 and UN No. 0093.

- The explosives are to be stored on board in Tauranga.
- The container of explosives must be stored in part of the ship not affected by work being carried out on other containers.
- While in transit in New Zealand, the container must be sealed and not opened unless deemed necessary in response to an emergency.

TEST CERTIFIERS

The Chief Executive of the Environmental Risk Management Authority, acting under delegated power from the Authority, reached a decision on the following application on 6 September 2002

Application Code: TST01002

Applicant: Rex Alexander

Address: 29 Fortune Street
Dalmore
Dunedin

Decision: Approved with Controls

ERMA Approval Code: TST000009

Requirements for which a test certificate may be issued, and limitations

Facilities, locations etc:

Locations and zones where class 2 to 5 substances are present.

Approved handlers in control of:

Handlers in control of the manufacture, storage, importation, transportation, use in manufacturing, emergency management and disposal of class 2 to 5, 6, 8 and 9 substances.

Limitations:

Limitation: this approval excludes handlers in control of tankwagons.

The Chief Executive of the Environmental Risk Management Authority, acting under delegated power from the Authority, reached a decision on the following applications on 10 September 2002

Application Code: TST02016

Applicant: Nicola Cuff

Address: 16 Nephin Place
Howick
Auckland

Decision: Approved with Controls

ERMA Approval Code: TST000010

Requirements for which a test certificate may be issued, and limitations

Approved handlers in control of:

- Handlers in control of substances of classes 2.1.1A, 2.1.2A, 3.1A, 3.1B, 4.3A, 4.3B, 5.1.1, 5.1.2, 5.2, 6, 8 and 9 in manufacturing and distribution facilities.
- Handlers in control of the ground application of agrichemicals.
- Handlers in control of the farm use of animal remedies.

Application Code: TST01003

Applicant: Bruce Evans

Address: Evatech
P O Box 3568
Richmond
Nelson

Decision: Approved with Controls

ERMA Approval Code: TST000011

Requirements for which a test certificate may be issued, and limitations

Facilities, locations etc:

Hazardous substance locations or zones where substances of classes 3.1, 4.1.1, 4.3 and 5.1.1 are present.

Approved handlers in control of:

- Handlers in control of substances of classes 3.1, 4.1.1, 4.3, 5.1.1, 6.1, 6.7A, 8.2A, 9.1A, 9.2A, 9.3A, 9.4A in places of manufacture, storage and distribution.
- Handlers in control of the ground application of agrichemicals.
- Handlers in control of the farm use of animal remedies.

Limitations:

- Limitation: This approval excludes fixed bulk containers.
- Limitation: 'Agrichemicals' has the meaning given in the latest version of NZS 8409.