

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY

THE BULLETIN

The Bulletin is published eleven times per year. It is a listing of applications being processed and the Authority's decisions as well as other activities under the Hazardous Substances and New Organisms (HSNO) Act. The public register is the official record of all applications received and any controls attached to approvals and may be viewed at our Wellington office.

Alternatively, you may view the applications and associated documents on the ERMA New Zealand website: www.ermanz.govt.nz

NEW ORGANISMS

NOTIFIED APPLICATIONS RECEIVED AND OPEN FOR SUBMISSIONS

The applications in the Bulletin are for reference only. Our public notification process includes alerts in four main daily newspapers with full information and submission forms available on our website.

To ensure that you are advised directly about applications open for public submission contact us at info@ermanz.govt.nz to be added to our interested party list. You will need to nominate the types of applications that you are interested in.

There are currently no notified applications open for submission

NON-NOTIFIED APPLICATIONS RECEIVED

There have been no applications received in this period.

DECISIONS ON APPLICATIONS

Applicant: Horticulture and Food Research Institute (HortResearch)

Application Code: NOC04002

Purpose: Importation of the Red-Banded Mango Caterpillar *Deanolis sublimbalis* (a pest of mangoes in Australia and South East Asia) to develop a synthetic pheromone for use as a monitoring tool in Australia and Papua New Guinea

Decision Notified: 13 July 2004

Description of Organisms: *Deanolis sublimbalis* (Snellen 1899)

Decision: Approved with Controls

ERMA Approval Code: NOC002285

Controls:

In order to satisfactorily address the matters detailed in the Third Schedule Part II: Containment controls for new organisms excluding genetically modified organisms¹ of the HSNO Act, and other matters in order to give effect to the purpose of the HSNO Act, the approved organism is subject to the following controls:

1. To limit the likelihood of any accidental release of any organism or any viable genetic material²:

¹ 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.

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, e.g. when organisms or parts thereof are sub lethally damaged by being frozen, dried, heated, or affected by chemical.

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

ERMA NEW ZEALAND

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- 1.1 The approved organism shall be imported into, and maintained within (subject to control 1.11 below), a containment facility which complies with these controls.
- 1.2 The construction, operation, and management of the containment facility shall be in accordance with the:
- Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.02.08. Transitional and Containment Facilities for Invertebrates.
 - Australian New Zealand Standard AS/NZS 2243:3 2002 Safety in Laboratories: Part 3: (Microbiological aspects and containment facilities).
 - Physical Containment Level 2 (PC2) requirements of the above Standards.
- 1.3 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.
- 1.4 The containment facilities shall be approved by Ministry of Agriculture and Forestry (MAF), in accordance with section 39 of the Biosecurity Act and the MAF Biosecurity Authority/ERMA New Zealand Standard 154.02.08: Containment Facilities for Invertebrates.
- 1.5 The prevention of unintended release of the organisms by experimenters working with the organisms shall be in compliance with the standards listed in control 1.2.
- Additional controls:**
- 1.6 Imported Red-Banded Mango Caterpillar (*Deanolis sublimbalis*) must be in pupal stage.
- 1.7 Pupae and moths must be kept in secure containers from which the insects cannot escape.
- 1.8 After emergence the adult male moths shall be kept separated from the adult female moths in order to prevent them from breeding.
- 1.9 Accurate counts shall be maintained of the number of imported pupae and of their fate.
- 1.10 Any parasitoides or other associated organisms, dead pupae and packaging material shall be autoclaved prior to disposal.
- 1.11 Male moths may be removed from the facility for the purpose of conducting coupled gas chromatography-electro antennogram analysis subject to double containment in secure containers. Following analysis the moths must be destroyed by autoclave prior to disposal.
- 1.12 The Operator shall promptly inform the facility Supervisor and ERMA New Zealand of any matters which may affect the long term management of the containment facility including:
- any changes within or external to HortResearch that may affect the management of the facility;
 - any event or circumstance that would affect the capacity of HortResearch to meet the requirements of the Authority's controls; and
 - changes in the use or ownership of the land on which the containment facility is located.
- 1.13 At the conclusion of the contractual arrangement with the Queensland DPI, all RBMCs held must be destroyed by autoclave prior to disposal.
- 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 1.2.
- 3. To control the effects of any accidental release or escape of an organism:**
- 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 control of the effects of any accidental release or escape of an organism.
- 3.2 If for any reason a breach³ of containment occurs the facility Supervisor⁴, MAF Biosecurity Authority and ERMA New Zealand shall promptly be notified as soon as is practicable after the event is noticed.
- 3.3 In the event of any breach of containment of the organism, 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.
- 3.4 The applicant shall comply with the requirements of the standards listed in control 1.2 relating to the maintenance of records demonstrating compliance with the MAF/ERMA New Zealand Standard 154.02.08, as required by the quality assurance programme, and documented in the containment manual.

3 For the purposes of these controls a 'breach of containment' means any interference with the containment facility or any non-compliance with Authority's controls whether an approved organism escapes from containment or not.

4 An inspector appointed under the Biosecurity Act.

4. Inspection and monitoring requirements for containment facilities:

- 4.1 The inspection and monitoring requirements for the containment facility shall be in compliance with the standards listed in control 1.2.
- 4.2 The Authority, or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.
- 4.3 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 154.02.08.

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

- 5.1 The training of personnel working in the facility shall be in compliance with the standards listed in Control 1.2.

6. Additional control

- 6.1 The applicant shall advise Te Taumutu Rūnanga and Te Rūnanga o Ngāi Tahu of the project.

Applicant: Massey University

Application Code: NOC04010

Purpose: To study the role of fungal toxins in the infection of peanut plants by the peanut leaf spot fungus *Mycosphaerella arachidis*

Decision Notified: 29 July 2004

Description of Organisms: *Mycosphaerella arachidis* (Deighton 1967)

Decision: Approved with Controls

ERMA Approval Code: NOC002286

Controls:

In order to satisfactorily address the matters detailed in the Third Schedule Part II: Containment controls for new organisms excluding genetically modified organisms⁵ of the HSNO Act, and other matters in order to give effect to the purpose of the HSNO Act, the approved organism is subject to the following controls:

1. To limit the likelihood of any accidental release of any organism or any viable genetic material⁶:

- 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 containment facilities shall be approved by Ministry of Agriculture and Forestry (MAF), and the organism shall be contained in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02: Containment Facilities for microorganisms Physical containment level 2 (PC2) and the controls set out by the Authority.

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 1.2 of this document.

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 the organism shall be in compliance with the standards listed in control 1.2 of this document.
- 3.2 In the event of any breach of containment the contingency plan for the attempted retrieval or destruction of any viable material of the organism that have escaped shall be implemented immediately. The contingency plan shall be included in the containment manual in accordance with the Standards.
- 3.3 If for any reason a breach⁷ of containment occurs the facility Supervisor⁸, MAF Biosecurity Authority and ERMA New Zealand shall be notified immediately (and at least within 24 hours of the breach being detected).

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 1.2 of this document.
- 4.2 The Authority, or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

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 1.2 of this document.

⁵ 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.

⁶ 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, e.g. when organisms or parts thereof are sub lethally damaged by being frozen, dried, heated, or affected by chemical.

⁷ For the purposes of these controls a 'breach of containment' means any interference with the containment facility or any non-compliance with Authority's controls whether an approved organism escapes from containment or not.

⁸ An inspector appointed under the Biosecurity Act.

6. Additional Controls:

- 6.1 A Class II Biological Safety Cabinet shall be used for experiments that require the handling of spores by laboratory personnel. Any equipment that comes into contact with spores shall be appropriately decontaminated.
- 6.2 Enclosed containers within the containment facility shall be used to carry out pathogenicity tests on detached leaves. Plant growth chambers shall be used if whole plants are used in the experiments with the fungus.
- 6.3 All personnel working with toxin-producing fungal cultures shall adhere to standard operating procedures to ensure that all material that may be contaminated with dothistromin toxin is adequately decontaminated (ie. by bleach or other demonstrated effective chemical method).

DELEGATED AUTHORITY

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

Applicant: Institute of Environmental Science and Research Limited (ESR)

Application Code: GMC04009

Purpose: To import into containment the cell line Vero/hSLAM (African green monkey kidney cells transfected with human measles receptor-Signaling Lymphocytic Activation Molecule) for measles virus isolation for diagnostic purposes

Decision Notified: 29 July 2004

Decision: Approved with Controls

Description of Organisms:

| Host Organism | Category of Host Organism | Modified by: | Category of Modification/ Containment level |
|--|---------------------------|---|---|
| <i>Cercopithecus aethiops</i> Linnaeus 1758 Vero cell lines | 1 | Standard non-conjugative plasmid vectors containing the human SLAM gene | A / PC1 |

ERMA Approval Code: GMC001238

Controls:

In order to provide for the matters detailed in Part I of the Third Schedule of the HSNO Act, Containment Controls for Import, Development and Field Testing of Genetically Modified Organisms, 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 material⁹:

- 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 containment facilities shall be approved by the Ministry of Agriculture and Forestry (MAF), in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02: Containment Facilities for Microorganisms and the Australia / New Zealand Standard 2243.3:2002 Safety in laboratories, Part 3: microbiological aspects and containment facilities to a minimum standard of 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 1.2 of this decision.

⁹ 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, e.g. when organisms or parts thereof are sub lethally damaged by being frozen, dried, heated, or affected by chemical.

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 1.2 of this decision.

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 organism shall be in compliance with the standards listed in control 1.2 of this decision.

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 1.2 of this decision.

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 listed in control 1.2 of this decision.

5.3 If for any reason a breach¹⁰ of containment occurs the facility Supervisor¹¹, MAF Biosecurity Authority and ERMA New Zealand shall be notified immediately (and at least within 24 hours of the breach being detected).

6. Inspection and monitoring requirements for containment facilities:

6.1 The inspection and monitoring requirements for containment facilities shall be in compliance with the standard listed in control 1.2 of this document.

6.2 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 training of personnel working in the facility shall be in compliance with the standards listed in control 1.2 of this decision.

Applicant: Forest Research Institute Limited

Application Code: GMD04076

Purpose: Project to investigate genes associated with enhancing wood quality traits; assess gene expression patterns; evaluate transgenic approaches to improve forest tree value and; enhance capabilities of functional gene testing in target plant species

Decision Notified: 29 July 2004

Decision: Approved with Controls

Description of Organisms:

| Host Organism | Category of Host Organism | Modified by: | Category of Modification/ Containment level |
|--|---------------------------|--|---|
| <i>Escherichia coli</i> (Migula 1895) Castellani & Chalmers 1919 non-pathogenic strains | 1 | Modified with standard cloning or expression plasmid vectors containing open reading frames derived from bacteria, non-pathogenic fungi, animals (excluding humans) and plants encoding either proteins or non-translated RNA sequences which are involved in: | A / PC1 |
| <i>Agrobacterium tumefaciens</i> (Smith & Townsend 1907) Conn 1942 disarmed non-pathogenic strains | | <ol style="list-style-type: none"> conferring resistance to insect pests of plants; conferring resistance to plant pathogens; | A / PC1 |

¹⁰ For the purposes of these controls a 'breach of containment' means any interference with the containment facility or any non-compliance with Authority's controls whether an approved organism escapes from containment or not.

¹¹ An inspector appointed under the Biosecurity Act.

| Host Organism | Category of Host Organism | Modified by: | Category of Modification/ Containment level |
|---|---------------------------|---|---|
| <i>Saccharomyces cerevisiae</i> Hansen 1883 | 1 | 3. responses to environmental stress (e.g. heat, cold and drought); | A / PC1 |
| <i>Arabidopsis thaliana</i> (L.) Heynh <i>in vitro</i> cultures whole plants | 1, 2 | 4. cell maintenance, cell structure, differentiation, replication, metabolism or cell wall formation; | A / PC1, B / PC2 |
| <i>Nicotiana tabacum</i> L. <i>in vitro</i> cultures whole plants | 1, 2 | 5. plant reproductive development or meristem identity and development; | A / PC1, B / PC2 |
| <i>Pinus radiata</i> D. Don <i>in vitro</i> cultures whole plants | 1, 2 | 6. wood development and structure; | A / PC1, B / PC2 |
| <i>Picea abies</i> (L.) Karst. <i>in vitro</i> cultures whole plants | 1, 2 | 7. cell communication or signalling; or plant transport processes i.e. phloem; | A / PC1, B / PC2 |
| <i>Abies nordmanniana</i> (Steven) Spach. <i>in vitro</i> cultures whole plants | 1, 2 | 8. DNA repair mechanisms and structural proteins; | A / PC1, B / PC2 |
| | | 9. gene recombination and silencing; | A / PC1, B / PC2 |
| | | AND single genes from plant viruses involved in gene silencing | A / PC1, B / PC2 |
| | | Inserted constructs will also include: | A / PC1, B / PC2 |
| | | 1. promoter and terminator sequences | |
| | | 2. reporter genes | |
| | | 3. selectable marker genes | |
| | | 4. origins of replications | |
| | | 5. multiple cloning sites | |
| | | 6. polyadenylation signals | |
| | | 7. transcription activators, enhancers, responsive elements, receptor elements | |
| | | 8. non-coding or intron sequences | |
| | | 9. ribosomal binding sites/kozak sequences | |
| | | 10. gene silencing sequences | |
| | | 11. recombination sequences | |
| | | 12. other commercially available regulatory elements | |
| | | Excluding: | |
| | | - vertebrate toxins ¹² | |
| | | - production of infectious particles | |
| | | - uncharacterised sequences from pathogenic microorganisms | |
| | | - sequences from New Zealand native flora or fauna | |
| | | - sequences from humans | |
| | | - sequences from CITES listed species without specific approval | |

12 Genes encoding vertebrate toxins that have an oral or dermal LD50 of less than 100µg/kg or genes encoding vertebrate toxins that have an oral or dermal LD50 of greater than or equal to 100 µg/kg if these genes will be expressed at levels higher than found in the organism from which they were derived.

ERMA Approval Codes: GMD003228-35**Controls:**

In order to provide for the matters detailed in Part I of the Third Schedule of the HSNO Act, Containment Controls for Import, Development and Field Testing of Genetically Modified Organisms, 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 material¹³:

- 1.1 The approved organisms shall be developed and maintained within a containment facility which complies with these controls.
- 1.2 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.
- 1.3 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 (below), and controls imposed by the Authority (as follows):

- 1.4 DNA manipulations and cloning using *Escherichia coli* and *Agrobacterium tumefaciens* and *in vitro* plant cultures:

The construction and operation of the containment facility shall be in accordance with the MAF/ERMA New Zealand Standard 154.03.02: Containment Facilities for microorganisms, and the Australian New Zealand standard AS/NZS 2243.3:2002 Safety in Laboratories: Part 3: Microbiological Aspects and Containment Facilities. Category 1 host organisms with category A genetic modifications shall be contained in a minimum of PC1 containment.

- 1.5 Maintenance of whole plants in plant house (greenhouse):

The construction and operation of the containment facility shall be in accordance with the MAF/ERMA New Zealand Standard 154.04.09: Containment Facilities for microorganisms and Australian New Zealand standard AS/NZS 2243.3:2002 Safety in Laboratories: Part 3: Microbiological Aspects and Containment Facilities shall be Category 2 host organisms with category B genetic modifications contained in a minimum of PC2 containment.

¹³ 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, e.g. when organisms or parts thereof are sub lethally damaged by being frozen, dried, heated, or affected by chemical.

¹⁴ For the purposes of these controls a 'breach of containment' means any interference with the containment facility or any non-compliance with Authority's controls whether an approved organism escapes from containment or not.

¹⁵ An inspector appointed under the Biosecurity Act.

2. To exclude unauthorised people from the facility.

- 2.1 Construction and operation of the containment facility shall comply with the requirements of the standards listed in controls 1.4 and 1.5 relating to the 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 Construction and operation of the containment facility shall comply with the requirements of the standards listed in controls 1.4 and 1.5 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 controls 1.4 and 1.5 relating to the prevention of unintended release of the organism by experimenters working with the organism.

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 controls 1.4 and 1.5 relating to controlling the effects of any accidental release or escape of an organism.
- 5.2 If for any reason a breach¹⁴ of containment occurs, the facility Supervisor¹⁵, 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 organism, 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 requirements of standards listed in controls 1.4 and 1.5.

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 controls 1.4 and 1.5 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 controls 1.4 and 1.5.
- 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 controls 1.4 and 1.5.
- 8. Additional controls:**
- 8.1 Where whole plants grown in the PC2 plant house are allowed to develop reproductive structures, such structures or whole plants will be bagged or other appropriate measures will be used to contain the pollen and subsequent seed.

Applicant: Forest Research Institute Limited

Application Code: GMC04008

Purpose: Import into containment *Trichoderma harzianum* and *Ophiostoma piceae* containing GFP for monitoring fungal susceptibility to bioactives

Decision Notified: 29 July 2004

Decision: Approved with Controls

Description of Organisms:

| Host Organism | Category of Host Organism | Modified by: | Category of Modification/ Containment level |
|--|---------------------------|--|---|
| <i>Ophiostoma piceae</i> (Münch) Syd. & P. Syd. 1919 | 1 | Standard non-conjugative expression vector containing the open reading frame of Green Fluorescent Protein (GFP) from <i>Aequorea victoria</i> and its derivatives. | A / PC1 |
| <i>Trichoderma harzianum</i> Rifai 1969 | 2 | Standard non-conjugative expression vector containing the open reading frame of Green Fluorescent Protein (GFP) from <i>Aequorea victoria</i> and its derivatives. | B / PC2 |

ERMA Approval Code: GMC001239-40

Controls:

In order to provide for the matters detailed in Part I of the Third Schedule of the HSNO Act, Containment Controls for Import, Development and Field Testing of Genetically Modified Organisms, 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 material¹⁶:**
- 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.

Genetically modified *Ophiostoma piceae*

- 1.2 The containment facilities shall be approved by the Ministry of Agriculture and Forestry (MAF), in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02: Containment Facilities for Microorganisms and the Australia / New Zealand Standard 2243.3:2002 Safety in laboratories, Part 3: microbiological aspects and containment facilities to a minimum standard of physical containment level 1 (PC1).

Genetically modified *Trichoderma harzianum*

- 1.3 The containment facilities shall be approved by the Ministry of Agriculture and Forestry (MAF), in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standard

¹⁶ 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, e.g. when organisms or parts thereof are sub lethally damaged by being frozen, dried, heated, or affected by chemical.

154.03.02: Containment Facilities for microorganisms and the Australia / New Zealand Standard 2243.3:2002 Safety in laboratories, Part 3: microbiological aspects and containment facilities to a minimum standard of physical containment level 2 (PC2).

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 standard listed in control 1.2 and 1.3 of this decision.

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 standard listed in control 1.2 and 1.3 of this decision.

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

4.1 The prevention of unintended release of organisms from containment by experimenters shall be in compliance with the standard listed in control 1.2 and 1.3 of this decision.

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 standard listed in control 1.2 and 1.3 of this decision.

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.

5.3 If for any reason a breach¹⁷ of containment occurs the facility Supervisor¹⁸, MAF Biosecurity Authority and ERMA New Zealand shall be notified immediately (and at least within 24 hours of the breach being detected).

6. Inspection and monitoring requirements for containment facilities:

6.1 The inspection and monitoring requirements for containment facilities shall be in compliance with the standard listed in control 1.2 and 1.3 of this decision.

6.2 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 training of personnel working in the facility shall be in compliance with the standard listed in control 1.2 and 1.3 of this decision.

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

Applicant: Horticulture and Food Research Institute (HortResearch Auckland)

Institute Code: (GMO04/HRA087)

Application Code: GMD04053

Purpose: To develop a new method to allow the oral delivery of protein drugs

Decision Notified: 28 April 2004

Description of Organism: *Escherichia coli* (Migula 1895) Castellani & Chalmers 1919

Escherichia coli (K12 and B strains) modified with Vector DNA: pKS and pSK Bluescript, pUC, pGEM, pLITMUS, pKK223-3, pBK-CMV, pSPORT, pDONR, pENTR, pET30 series, pGEMT easy series) or derivatives thereof, carrying ColEI replicons, ampicillin, chloramphenicol, spectinomycin, tetracycline or kanamycin resistance genes and lacZ cDNA. Donor DNA: genes encoding peptide hormones and other non-toxic proteins from humans e.g. insulin, somatrophin and amylin and known genes encoding non-toxic proteins from the following plants *Cucurbita maxima*, *Solanum tuberosum* and *Lycopersicon esculentum*.

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003217

¹⁷ For the purposes of these controls a 'breach of containment' means any interference with the containment facility or any non-compliance with Authority's controls whether an approved organism escapes from containment or not.

¹⁸ An inspector appointed under the Biosecurity Act.

Applicant: University of Auckland

Institute Code: (GMO04/UA020)

Application Code: GMD04083

Purpose: Genetic manipulation of wine yeasts

Decision Notified: 09 July 2004

Description of Organism: *Escherichia coli* (Migula 1895) Castellani & Chalmers 1919

Escherichia coli (non-pathogenic strains) modified with non self-transmissible vectors with synthetic DNA sequences (including linkers, promoter, regulatory elements and primers). Standard reporter genes. Nucleic acid sequences from non-pathogenic strains of *Escherichia coli* and non-pathogenic species of *Pseudomonas* and *Agrobacterium*. Nucleic acid from other *Saccharomyces sensu stricto* organisms. Nucleic acid from genomes of other species of common yeasts found in wine including: *Hanseniaspora uvarum*, *Torula delbreueckii*, *Candida stellata*, *Pichia fermentans*, *Issatchenkia terricola*, *Kluveromyces thermotolerans*, *Zygosaccharomyces bailii* and *Brettanomyces* species. Strains of non-*saccharomyces* yeasts used as sources of genes will be obtained from yeast culture collections and will be derived from wine.

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003218

Description of Organism: *Saccharomyces bayanus*

Saccharomyces bayanus modified with non self-transmissible vectors with Synthetic DNA sequences (including linkers, promoter, regulatory elements and primers). Standard reporter genes. Nucleic acid sequences from non-pathogenic strains of *Escherichia coli* and non-pathogenic species of *Pseudomonas* and *Agrobacterium*. Nucleic acid from other *Saccharomyces sensu stricto* organisms. Nucleic acid from genomes of other species of common yeasts found in wine including: *Hanseniaspora uvarum*, *Torula delbreueckii*, *Candida stellata*, *Pichia fermentans*, *Issatchenkia terricola*, *Kluveromyces thermotolerans*, *Zygosaccharomyces bailii* and *Brettanomyces* species. Strains of non-*saccharomyces* yeasts used as sources of genes will be obtained from yeast culture collections and will be derived from wine.

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003219

Description of Organism: *Saccharomyces cariocanus*

Saccharomyces cariocanus modified with non self-transmissible vectors with Synthetic DNA sequences (including linkers, promoter, regulatory elements and primers) standard reporter genes. Nucleic acid sequences from non-pathogenic strains of *Escherichia coli* and non-pathogenic species of *Pseudomonas* and *Agrobacterium*. Nucleic acid from other *Saccharomyces sensu stricto* organisms. Nucleic acid from genomes of other species of common yeasts found in wine including: *Hanseniaspora uvarum*, *Torula delbreueckii*, *Candida stellata*, *Pichia fermentans*, *Issatchenkia terricola*, *Kluveromyces thermotolerans*, *Zygosaccharomyces bailii* and *Brettanomyces* species. Strains of non-*saccharomyces* yeasts used as sources of genes will be obtained from yeast culture collections and will be derived from wine.

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003220

Description of Organism: *Saccharomyces cerevisiae*

Saccharomyces cerevisiae modified with non self-transmissible vectors with Synthetic DNA sequences (including linkers, promoter, regulatory elements and primers) standard reporter genes. Nucleic acid sequences from non-pathogenic strains of *Escherichia coli* and non-pathogenic species of *Pseudomonas* and *Agrobacterium*. Nucleic acid from other *Saccharomyces sensu stricto* organisms. Nucleic acid from genomes of other species of common yeasts found in wine including: *Hanseniaspora uvarum*, *Torula delbreueckii*, *Candida stellata*, *Pichia fermentans*, *Issatchenkia terricola*, *Kluveromyces thermotolerans*, *Zygosaccharomyces bailii* and *Brettanomyces* species. Strains of non-*saccharomyces* yeasts used as sources of genes will be obtained from yeast culture collections and will be derived from wine.

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003221

Description of Organism: *Saccharomyces kudriavzevii*

Saccharomyces kudriavzevii modified with non self-transmissible vectors with Synthetic DNA sequences (including linkers, promoter, regulatory elements and primers) standard reporter genes. Nucleic acid sequences from non-pathogenic strains of *Escherichia coli* and non-pathogenic species of *Pseudomonas* and *Agrobacterium* Nucleic acid from other *Saccharomyces* sensu stricto organisms. Nucleic acid from genomes of other species of common yeasts found in wine including: *Hanseniaspora uvarum*, *Torula delbreueckii*, *Candida stellata*, *Pichia fermentans*, *Issatchenkia terricola*, *Kluveromyces thermotolerans*, *Zygosaccharomyces bailii* and *Brettanomyces* species. Strains of non-*saccharomyces* yeasts used as sources of genes will be obtained from yeast culture collections and will be derived from wine.

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003222

Description of Organism: *Saccharomyces mikatae*

Saccharomyces mikatae modified with non self-transmissible vectors with Synthetic DNA sequences (including linkers, promoter, regulatory elements and primers) standard reporter genes. Nucleic acid sequences from non-pathogenic strains of *Escherichia coli* and non-pathogenic species of *Pseudomonas* and *Agrobacterium*. Nucleic acid from other *Saccharomyces* sensu stricto organisms. Nucleic acid from genomes of other species of common yeasts found in wine including: *Hanseniaspora uvarum*, *Torula delbreueckii*, *Candida stellata*, *Pichia fermentans*, *Issatchenkia terricola*, *Kluveromyces thermotolerans*, *Zygosaccharomyces bailii* and *Brettanomyces* species Strains of non-*saccharomyces* yeasts used as sources of genes will be obtained from yeast culture collections and will be derived from wine.

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003223

Description of Organism: *Saccharomyces paradoxus*

Saccharomyces paradoxus modified with non self-transmissible vectors with Synthetic DNA sequences (including linkers, promoter, regulatory elements and primers) standard reporter genes. Nucleic acid sequences from non-pathogenic strains of *Escherichia coli* and non-pathogenic species of *Pseudomonas* and *Agrobacterium*. Nucleic acid from other *Saccharomyces* sensu stricto organisms. Nucleic acid from genomes of other species of common yeasts found in wine including: *Hanseniaspora uvarum*, *Torula delbreueckii*, *Candida stellata*, *Pichia fermentans*, *Issatchenkia terricola*, *Kluveromyces thermotolerans*, *Zygosaccharomyces bailii* and *Brettanomyces* species Strains of non-*saccharomyces* yeasts used as sources of genes will be obtained from yeast culture collections and will be derived from wine.

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003224

Description of Organism: *Saccharomyces pastorianus*

Saccharomyces pastorianus modified with non self-transmissible vectors with Synthetic DNA sequences (including linkers, promoter, regulatory elements and primers) standard reporter genes. Nucleic acid sequences from non-pathogenic strains of *Escherichia coli* and non-pathogenic species of *Pseudomonas* and *Agrobacterium*. Nucleic acid from other *Saccharomyces* sensu stricto organisms. Nucleic acid from genomes of other species of common yeasts found in wine including: *Hanseniaspora uvarum*, *Torula delbreueckii*, *Candida stellata*, *Pichia fermentans*, *Issatchenkia terricola*, *Kluveromyces thermotolerans*, *Zygosaccharomyces bailii* and *Brettanomyces* species Strains of non-*saccharomyces* yeasts used as sources of genes will be obtained from yeast culture collections and will be derived from wine.

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003225

Applicant: University of Otago

Institute Code: (GMO03/UO005)

Application Code: GMD03076

Purpose: To reintroduce cloned and characterised *Mycobacterium smegmatis* genes involved in acid resistance back into *Mycobacterium smegmatis* for complementation and functional analysis experiments.
Update of GMO99/UO014 and GMO00/UO031

Decision Notified: 23 June 2003

Description of Organism: *Escherichia coli* (Migula 1895) Castellani & Chalmers 1919

Escherichia coli strain K12 derivatives modified with *Escherichia coli*/*Mycobacterium smegmatis* shuttle vectors such as pPR23-32 or plasmid pLITMUS; *Mycobacterium smegmatis* DNA sometimes disrupted with resistance markers aphA-3 or IS1096::kan

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003226

Description of Organism: *Mycobacterium smegmatis*

Mycobacterium smegmatis modified with *Escherichia coli* /*Mycobacterium smegmatis* shuttle vectors such as pPR23-32 or plasmid pLITMUS; *Mycobacterium smegmatis* DNA sometimes disrupted with resistance markers aphA-3 or IS1096::kan

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003227

Applicant: University of Otago

Institute Code: (GMO03/UO038)

Application Code: GMD04065

Purpose: To determine whether genetically modified spider-mites (*Tetranychus urticae*) or

inseparable gut bacteria residing in this species are generated during feeding experiments in which these animals are fed genetically modified plants

Decision Notified: 31 May 2004

Description of Organism: *Tetranychus urticae* (Koch)

Tetranychus urticae (Two spotted Spider Mite) and inseparable endosymbiont gut bacteria modified with DNA from French beans (*Phaseolus vulgaris*) and potatoes (*Solanum tuberosum*) that may contain a modified version of the cry1Ac9 gene from *Bacillus thuringiensis* and a Kanamycin resistance gene

Containment: PC2 plant

Category: B and

Containment: PC3

Invertebrate Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003214

Applicant: University of Otago

Institute Code: (GMO04/UO006)

Application Code: GMD04072

Purpose: To investigate *Bacillus* species strain TA2.A1 genes that are involved in enabling this bacterium to grow at high pH and temperature
Update of GMO00/UO070

Decision Notified: 10 June 2004

Description of Organism: *Escherichia coli* (Migula 1895) Castellani & Chalmers 1919

Escherichia coli (strain K12 derivatives) modified with non-conjugative vectors; DNA library of *Bacillus* species strain TA2.A1; *Escherichia coli* K12 DNA

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003215

Applicant: University of Otago

Institute Code: (GMO04/UO012)

Application Code: GMD04077

Purpose: *Escherichia coli* modified with material from *Trichosurus vulpecula*, developed to provide tools for functional genomic

studies that elucidate the biological role(s) of genes involved in epithelial function.
Update of GM003/UO031

Decision Notified: 29 June 2004

Description of Organism: *Escherichia coli* (Migula 1895) Castellani & Chalmers 1919

Escherichia coli strain K12 or B derivatives modified with Phagemid vector; Australian brushtail possum (*Trichosurus vulpecula*) genes involved in epithelial transport.

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003216

DEEMED APPROVALS

In accordance with section 55 of the Hazardous Substances and New Organisms Amendment Act 2003, ERMA New Zealand has received notice that the following applicant(s) are holding genetically modified human cell(s) as indicated:

Applicant: Institute of Environmental Science and Research Limited

Date Notification Received: 02 April 2004

Organism Description and ERMA New Zealand Approval Code:

Unique Identifier: *Homo sapien* cell line MCF7 ERE Luc

Nature and Range of the Genetic Modification:
Homo sapien cell line human breast carcinoma cell line (MCF7) stably transfected with estrogen receptor-controlled luciferase gene.

Containment Facility: PC1

Category of Host Organism: Category 1

Category of Genetic Modification: Category A

Approval Code: PRE000751

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Controls:

In considering all the matters to be addressed detailed in the Third Schedule Part I Containment Controls for Importing, Developing or Field Testing of Genetically Modified Organisms of the HSNO Act, the 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 microorganisms and
 - b) The Australian/New Zealand Standard (AS/NZS) 2243.3:2002 Safety in Laboratories: Part 3: Microbiological aspects and containment facilities, at Physical Containment Level 1 (PC1).
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.
3. All approved organism culture products and associated materials shall be autoclaved or incinerated before being disposed of.
4. If for any reason a breach¹⁹ of containment occurs the applicant shall notify the facility Supervisor²⁰ 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.

Applicant: Wallaceville Animal Research Centre

Date notification received: 10 May 2004

Organism Description and ERMA New Zealand Approval Code:

Unique Identifier: *Homo sapien* 293H cell line mouse GDF9

Nature and Range of the Genetic Modification:
Homo sapien 293H cell line expressing mouse growth differentiation factor 9 (GDF9)

Containment Facility: PC1

Category of Host Organism: Category 1

Category of Genetic Modification: Category A

Approval Code: PRE000754

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¹⁹ For the purposes of these controls a 'breach of containment' means any interference with the containment facility or any non-compliance with Authority's controls whether an approved organism escapes from containment or not.

²⁰ An inspector appointed under the Biosecurity Act.

Unique Identifier: *Homo sapien* 293H cell line ovine GDF 9
Nature and Range of the Genetic Modification:
Homo sapien cell line expressing ovine GDF9
Containment Facility: PC1
Category of host Organism:Category 1
Category of Genetic Modification: Category A
Approval Code: PRE000755

Unique Identifier: *Homo sapien* 293H cell line Bovine BMP 15
Nature and Range of the Genetic Modification:
Homo sapien cell line expressing ovine bone morphogenetic protein 15 (BMP 15 aslo known as GDF9B)
Containment Facility: PC1
Category of Host Organism: Category 1
Category of Genetic Modification: Category A
Approval Code: PRE000756

Unique Identifier: *Homo sapien* 293H cell line mouse BMPRII
Nature and Range of the Genetic Modification:
Homo sapien 293H cell line expressing mouse BMP receptor type II (BMPRII) extracellular domain (Histag)
Containment Facility: PC1
Category of Host Organism: Category 1
Category of Genetic Modification: Category A
Approval Code: PRE000757

Unique Identifier: *Homo sapien* 293H cell line mouse BMPRII pTGP
Nature and Range of the Genetic Modification:
Homo sapien 293H cell line expressing mouse BMP receptor type II (BMPRII) extracellular domain (Histag), pTGP expression vector
Containment Facility: PC1
Category of Host Organism: Category 1
Category of Genetic Modification: Category A
Approval Code: PRE000758

Unique Identifier: *Homo sapien* 293T cell line mouse GDF9
Nature and Range of the Genetic Modification:
Homo sapien 293T cell line expressing mouse GDF9

Containment Facility: PC1
Category of Host Organism: Category 1
Category of Genetic Modification: Category A
Approval Code: PRE000759

Unique Identifier: *Homo sapien* 293T cell line rat BMP15
Nature and Range of the Genetic Modification:
Homo sapien 293T cell line expressing rat BMP15
Containment Facility: PC1
Category of Host Organism: Category 1
Category of Genetic Modification: Category A
Approval Code: PRE000760

Unique Identifier: *Homo sapien* 293T cell line chimeric mouse ovine GDF9
Nature and Range of the Genetic Modification:
Homo sapien 293T expressing chimeric mouse ovine GDF9
Containment Facility: PC1
Category of Host Organism: Category 1
Category of Genetic Modification: Category A
Approval Code: PRE000761

Unique Identifier: *Homo sapien* 293T cell line chimeric rat ovine BMP15
Nature and Range of the Genetic Modification:
Homo sapien 293T experssing chimeric rat ovine BMP15 (with and without his tag and with 3 flag tag)
Containment Facility: PC1
Category of Host Organism: Category 1
Category of Genetic Modification: Category A
Approval Code: PRE000762

Unique Identifier: *Homo sapien* 293T cell line chimeric rat human BMP15
Nature and Range of the Genetic Modification:
Homo sapien 293T chimeric rat human BMP15 (with his tag)
Containment Facility: PC1
Category of Host Organism: Category 1
Category of Genetic Modification: Category A
Approval Code: PRE000763

Unique Identifier: *Homo sapien* 293T cell line chimeric mouse GDF9, ovine BMP15

Nature and Range of the Genetic Modification:
Homo sapien 293T expressing chimeric mouse GDF9, ovine BMP15

Containment Facility: PC1

Category of Host Organism: Category 1

Category of Genetic Modification: Category A

Approval Code: PRE000764

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Unique Identifier: *Homo sapien* cell line, 293T expressing human GDF9

Nature and Range of the Genetic Modification:
Homo sapien cell line, 293T expressing human GDF9

Containment Facility: PC1

Category of Host Organism: Category 1

Category of Genetic Modification: Category A

Approval Code: PRE000765

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Unique identifier: *Homo sapien* cell line, 293T expressing human BMP15

Nature and range of the genetic modification:
Homo sapien cell line, 293T expressing human BMP15

Containment Facility: PC1

Category of Host organism: Category 1

Category of Genetic Modification: Category A

Approval Code: PRE000766

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Controls:

In considering all the matters to be addressed detailed in the Third Schedule Part I Containment Controls for Importing, Developing or Field Testing of Genetically Modified Organisms of the HSNO Act, the 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 Microorganisms and
 - b) The Australian/New Zealand Standard (AS/NZS) 2243.3:2002 Safety in Laboratories: Part 3: Microbiological aspects and containment facilities, at Physical Containment Level 1 (PC1).

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.
3. All approved organism culture products and associated materials shall be autoclaved or incinerated before being disposed of.
4. If for any reason a breach²¹ of containment occurs the applicant shall notify the facility Supervisor²² 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.

Applicant: University of Auckland

Date notification received: 08 June 2004

Organism Description and ERMA New Zealand Approval Code:

Unique Identifier: *Homo sapien* cell line HT-29 colon

Nature and Range of the Genetic Modification:
Homo sapien cell line transfected with (pcDNA3.1) containing human TNF gene and CMV promoter.

Containment Facility: University of Auckland

Category of Host Organism: 1

Category of Genetic Modification: A

Approval Code: PRE000752

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Unique Identifier: *Homo sapien* cell line NZM2 melanoma

Nature and Range of the Genetic Modification:
Homo sapien NZM2 melanoma cell line transfected with vector (pcDNA3.1) containing human TNF gene and CMV promoter.

Containment Facility: University of Auckland

Category of Host Organism: 1

Category of Genetic Modification: A

Approval Code: PRE000753

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²¹ For the purposes of these controls a 'breach of containment' means any interference with the containment facility or any non-compliance with Authority's controls whether an approved organism escapes from containment or not.

²² An inspector appointed under the Biosecurity Act.

Controls:

In considering all the matters to be addressed detailed in the Third Schedule Part I Containment Controls for Importing, Developing or Field Testing of Genetically Modified Organisms of the HSNO Act, the 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 Microorganisms and
 - b) The Australian/New Zealand Standard (AS/NZS) 2243.3:2002 Safety in Laboratories: Part 3: Microbiological aspects and containment facilities, at Physical Containment Level 1 (PC1).
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.
3. All approved organism culture products and associated materials shall be autoclaved or incinerated before being disposed of.
4. If for any reason a breach²³ of containment occurs the applicant shall notify the facility Supervisor²⁴ 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.

AMENDMENTS 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 lateration is minor in effect or corrects a minor or technical error.

Applicant: Horizon2 Partnership Limited

Application Code: GMD99031

Purpose: To study gene integration efficiencies and subsequent expression in *Pinus radiata*

Decision Amendment Date: 29 June 2004

Decision Amended: Decision was amended to change the name of the applicant from Carter Holt Harvey Forest Genetics Limited to Horizon2 Partnership Limited

Applicant: Horizon2 Partnership Limited

Application Code: GMD99087

Purpose: To transform *Pinus radiata* D. Don with ScFv and nptII for the purposes of determining if ScFv can confer *Dothistroma pini* resistance to conifer

Decision Amendment Date: 29 June 2004

Decision Amended: Decision was amended to change the name of the applicant from Carter Holt Harvey Forest Genetics Limited to Horizon2 Partnership Limited

Applicant: Horizon2 Partnership Limited

Application Code: GMD99098

Purpose: To amplify the vector constructs in *Escherichia coli* to which will then be used to transform *Pinus radiata* to gain a better understanding of the flowering process in plants

Decision Amendment Date: 29 June 2004

Decision Amended: Decision was amended to change the name of the applicant from Carter Holt Harvey Forest Genetics Limited to Horizon2 Partnership Limited

Applicant: Horizon2 Partnership Limited

Application Code: GMD99099

Purpose: Transformation of *Pinus radiata* D. Don with genes from Arabidopsis, *Escherichia coli* and *Pinus radiata* for the purposes of reducing strobili formation and producing plants that are reproductively incompetent or impaired

Decision Amendment Date: 29 June 2004

Decision Amended: Decision was amended to change the name of the applicant from Trees and Technology Limited to Horizon2 Partnership Limited

Applicant: Horizon2 Partnership Limited

Application Code: GMD00202

Purpose: The purpose is to understand the effect of lignin genes on wood and fibre formation

²³ For the purposes of these controls a 'breach of containment' means any interference with the containment facility or any non-compliance with Authority's controls whether an approved organism escapes from containment or not.

²⁴ An inspector appointed under the Biosecurity Act.

and quality in *Pinus radiata*. It will also lead to a greater understanding of the lignin pathway

Decision Amendment Date: 29 June 2004

Decision Amended: Decision was amended to change the name of the applicant from Carter Holt Harvey Forest Genetics Limited to Horizon2 Partnership Limited

Applicant: Horizon2 Partnership Limited

Application Code: GMD00203

Purpose: To test the efficiency of different promoters on gene expression levels and to find out what expression patterns are produced as a result of using different promoters in *Pinus radiata*

Decision Amendment Date: 29 June 2004

Decision Amended: Decision was amended to change the name of the applicant from Carter Holt Harvey Forest Genetics Limited to Horizon2 Partnership Limited

Applicant: Horizon2 Partnership Limited

Application Code: GMD00349

Purpose: To allow studies of gene expression and phenotype modification in radiata pine and tobacco. Modified *Agrobacterium tumefaciens* generated are exclusively for the use of the bacteria to modify selected target plant tissue

Decision Amendment Date: 29 June 2004

Decision Amended: Decision was amended to change the name of the applicant from Carter Holt Harvey Forest Genetics Limited to Horizon2 Partnership Limited

Applicant: Horizon2 Partnership Limited

Application Code: GMD01004

Purpose: To use tree-tobacco (*Nicotiana glauca*) as a model plant for investigation of the genetic basis of wood composition, and to gain understanding of the effect of altered levels of cellulose synthesis in *Eucalyptus* species
Update of GMO00/FC003

Decision Amendment Date: 29 June 2004

Decision Amended: Decision was amended to change the name of the applicant from Trees and Technology Limited to Horizon2 Partnership Limited

Applicant: Horizon2 Partnership Limited

Application Code: GMD01036

Purpose: *Escherichia coli* will be used to provide DNA suitable for modification of *Agrobacterium tumefaciens* and subsequently used for the modification of *Pinus radiata* or tobacco for the study of gene function

Decision Amendment Date: 29 June 2004

Decision Amended: Decision was amended to change the name of the applicant from Carter Holt Harvey Forest Genetics Limited to Horizon2 Partnership Limited

Applicant: Horizon2 Partnership Limited

Application Code: GMD01173

Purpose: To modify *Pinus radiata* with cDNA from plants, animals and microorganisms
Update of GMO00/CH001

Decision Amendment Date: 29 June 2004

Decision Amended: Decision was amended to change the name of the applicant from Carter Holt Harvey Forest Genetics Limited to Horizon2 Partnership Limited

Applicant: Horizon2 Partnership Limited

Application Code: GMD01174

Purpose: To study factors influencing transgene expression by modifying *Pinus taeda* with genes and promoters isolated from plants, animals and microorganisms

Decision Amendment Date: 29 June 2004

Decision Amended: Decision was amended to change the name of the applicant from Carter Holt Harvey Forest Genetics Limited to Horizon2 Partnership Limited

Applicant: Horizon2 Partnership Limited

Application Code: GMD02016

Purpose: Genetic transformation of *Eucalyptus* species and interspecific hybrids with gene constructs designed to increase the quantity of cellulose deposited in plant cell walls, to gain understanding of the effect this has on wood properties

Decision Amendment Date: 29 June 2004

Decision Amended: Decision was amended to change the name of the applicant from Trees and Technology Limited to Horizon2 Partnership Limited

Applicant: Horizon2 Partnership Limited

Application Code: GMD04031

Purpose: Improvement of selected, high-value strains of *Eucalyptus* bred for plantation forestry, to better meet the requirements of foresters and pulp mills in regions overseas where *Eucalyptus* is a primary source of fibre
Update of GMD03132.

Decision Amendment Date: 29 June 2004

Decision Amended: Decision was amended to change the name of the applicant from Carter Holt Harvey Forest Genetics Limited to Horizon2 Partnership Limited and control 1.5a amended to PC2 from PC1

Applicant: Horizon2 Partnership Limited

Application Code: GMD01164

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

Decision Amendment Date: 06 July 2004

Decision Amended: Decision was amended to change the name of the applicant from Trees and Technology Limited to Horizon2 Partnership Limited

Applicant: Horizon2 Partnership Limited

Application Code: GMD00350

Purpose: To understand the effect and function of genes from various sources in *Pinus radiata*

Decision Amendment Date: 29 July 2004

Decision Amended: Decision was amended to change the name of the applicant from Carter Holt Harvey Forest Genetics Limited to Horizon2 Partnership Limited

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

Applicant: University of Otago

Institute Code: GMO04/UO012

Application Code: GMD03120

Purpose: Inactivate genes associated with production and regulation of, or immunity to, bacteriocin like inhibitory substances in *Streptococcus salivarius*, *Streptococcus uberis*, *Streptococcus mutans* and *Lactococcus lactis* using transposon mutagenesis
Update of GMO00/UO44

Decision Amendment Date: 22 June 2004

Decision Amended: To add the following additional control to the decision document:
“*Streptococcus uberis* cannot be modified with DNA containing a gene conferring resistance to an antibiotic, such as beta-lactam antibiotic, used for clinical or veterinary treatment of infections caused by *Streptococcus uberis*.”

HAZARDOUS SUBSTANCES

NOTIFIED APPLICATIONS AND PUBLIC SUBMISSIONS

The applications in the Bulletin are for reference only. Our public notification process includes alerts in four main daily newspapers with the full information and submission forms available on our website.

To ensure that you are advised directly about applications open for public submission contact us at info@ermanz.govt.nz to be added to our interested party list. You will need to nominate the types of applications that you are interested in.

Applicant: Merial New Zealand Limited

Application Code: HSR04031

Purpose: To import or manufacture Previcox Hi-Select Cox-2 Flavoured Tablets: Pain and Inflammation Control for Dogs, a new non-steroidal anti-inflammatory drug (NSAID) of the 'coxib' class

Date Formally Received: 05 July 2004

Date Publicly Notified: 12 July 2004

Date Submissions Close: 23 August 2004

Applicant: Cairns Slane

Application Code: HSR04015

Purpose: To import ThermaCELL Mosquito Repellent for use as an insect repellent strictly for outdoor use and not for agricultural or horticultural purposes

Date Formally Received: 11 May 2004

Date Publicly Notified: 19 July 2004

Date Submissions Close: 30 August 2004

NON-NOTIFIED APPLICATIONS RECEIVED

Applicant: Mattersmiths Holdings Limited

Application Code: HSR04036

Purpose: To import or manufacture SureBor, a timber preservative to be used on wood at industrial sites only

Date Formally Received: 09 July 2004

Applicant: ERMA New Zealand

Application Code: RES04001

Purpose: To determine whether there are grounds for reassessment of registered pesticides containing hydrogen cyanamide (520-530 g/litre). These substances are used as plant growth regulators in kiwifruit and some pipfruit

Date Formally Received: 13 July 2004

Applicant: BASF New Zealand

Application Code: HSC04016

Purpose: To import for field testing various substances to assess their ability to control damaging organisms in plants

Date Formally Received: 16 July 2004

Applicant: Syngenta Crop Protection Limited

Application Code: HSC04017

Purpose: To import into containment, fungicidal compounds of the chemical class Heterocyclic Amides (OPA), to conduct small-scale contained field trials to provide information for the development of these compounds

Date Formally Received: 19 July 2004

Applicant: Fort Dodge New Zealand Limited

Application Code: HSC04015

Purpose: To import into containment two anthelmintic formulations to test their efficacy against natural parasite infections in cattle and to obtain residue data

Date Formally Received: 21 July 2004

Applicant: Taranaki Nuchem Limited

Application Code: HSC04018

Purpose: To field trial in containment, a substance, TNL 2036, in various ratio of 3 actives and formulation types so that data can be produced on the most effective ratio of actives to control weeds in pastoral crops

Date Formally Received: 22 July 2004

DECISIONS ON APPLICATIONS

Applicant: Akzo Nobel Coatings Limited

Application Code: HSR04006

Purpose: To import Interline 984 Part B for use with Interline 984 Part A to produce a two pack epoxy tank-lining material

Decision Notified: 14 July 2004

Decision: Approved with Controls

Identifier for Substance: Interline 984 Part B

Classification: 3.1C flammable liquid, 6.1D acute oral toxicant, 6.1C acute inhalational toxicant, 8.2C skin corrosive, 8.3A eye corrosive, 6.5B contact sensitiser, 6.9B target organ toxicant, 9.1B aquatic toxicant, 9.2C soil toxicant, 9.3C terrestrial vertebrate toxicant

ERMA Approval Code: HSR000127

Controls:

| Control Code ²⁵ | Regulation ²⁶ | Explanation ²⁷ |
|---|----------------------------|---|
| Hazardous Substances (Classes 1 to 5 Control Regulations) Regulations 2001 - Flammable Property Controls | | |
| F1 | 7 | General test certification requirements for Interline 984 Part B |
| F3 | 55 | General limits on flammable substances 500 litres (in closed containers greater than 5 litres) 1500 litres (in closed containers up to and including 5 litres) |
| F5 | 58–59 | Requirements regarding hazardous atmosphere zones for Interline 984 Part B |
| F6 | 60–70 | Requirements to prevent unintended ignition of Interline 984 Part B |
| F11 | 76 | Segregation of incompatible substances |
| F12 | 77–78 | General requirement for hazardous substance locations for flammable substances |
| F14 | 81 | Test certification requirements for facilities where classes 2.1.1, 2.1.2 or 3.1 substances are present |
| F16 | 83 | Controls on transit depots where flammable substances are present |
| Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 - Toxic Property Controls | | |
| T2 | 29, 30 | Controlling exposure in places of work |
| T3 | 5(1), 6 | Requirements for keeping records of use |
| T4, E6 | 7 | Requirements for equipment used to handle Interline 984 Part B |
| T5 | 8 | Requirements for protective clothing and equipment |
| T6 | 9 | Approved handler requirements |
| T7, F2, E8 | 8, 10 | Restrictions on the carriage of Interline 984 Part B on passenger service vehicles |
| Hazardous Substances (Identification) Regulations 2001 | | |
| I1 | 6, 7, 32–35, 36 (1)–(7) | General identification requirements |
| I2 | 8 | Priority identifiers for corrosive substances |

²⁵ Note: The numbering system used in this column relates to the coding system used in the ERMA New Zealand Controls Matrix. This links the hazard classification categories to the regulatory controls triggered by each category. It is available from the ERMA New Zealand website www.ermanz.govt.nz/resources and is also contained in the *ERMA New Zealand User Guide to the Controls Regulations*.

²⁶ These Regulations form the controls applicable to this substance. Refer to the cited Regulations for the formal specification, and for definitions and exemptions. The accompanying explanation is intended for guidance only.

²⁷ These explanations are for guidance only. Refer to the cited Regulations for the formal specification, and for definitions and exemptions.

| | | |
|---|----------------|---|
| I3 | 9 | Priority identifiers for ecotoxic substances |
| I5 | 11 | Priority identifiers for flammable substances |
| I8 | 14 | Priority identifiers for Interline 984 Part B |
| I9 | 18 | Secondary identifiers for all hazardous substances |
| I10 | 19 | Secondary identifiers for corrosive substances |
| I11 | 20 | Secondary identifiers for ecotoxic substances |
| I13 | 22 | Secondary identifiers for flammable substances |
| I16 | 25 | Secondary identifiers for toxic substances |
| I17 | 26 | Use of Generic Names |
| I18 | 27 | Use of Concentration Ranges |
| I19 | 29–31 | Alternative information in certain cases |
| I20 | 36(8) | Durability of information for class 6.1 substances |
| I21 | 37–39, 47–50 | Documentation required in places of work |
| I22 | 40 | Specific documentation requirements for corrosive substances |
| I23 | 41 | Specific documentation requirements for ecotoxic substances |
| I25 | 43 | Specific documentation requirements for flammable substances |
| I28 | 46 | Specific documentation requirements for toxic substances |
| I29 | 51–52 | Duties of persons in charge of places with respect to signage |
| I30 | 53 | Advertising corrosive and toxic substances |
| Hazardous Substances (Packaging) Regulations 2001 | | |
| P1 | 5, 6, 7 (1), 8 | General packaging requirements |
| P3 | 9 | Packaging requirements for substances packed in limited quantities |
| P5, P13, P14, P15 | 11, 19, 20, 21 | Packaging requirements |
| PG3 | Schedule 3 | This schedule provides the test methods for packaging required to be tested in accordance with this schedule. The tests in Schedule 3 correlate to the packaging requirements of UN Packing Group III (UN PGIII). |
| Hazardous Substances (Disposal) Regulations 2001 | | |
| D2 | 6 | Disposal requirements for flammable substances |
| D4, D5 | 8, 9 | Disposal requirements for toxic, corrosive and ecotoxic substances |
| D6 | 10 | Disposal requirements for packages |
| D7 | 11, 12 | Disposal information requirements |
| D8 | 13, 14 | Disposal documentation requirements |
| Hazardous Substances (Emergency Management) Regulations 2001 | | |
| EM1 | 6, 7, 9–11 | Level 1 emergency management information: General requirements |
| EM2 | 8(a) | Information requirements for corrosive substances |
| EM6 | 8(e) | Information requirements for toxic substances |
| EM7 | 8(f) | Information requirements for ecotoxic substances |

| | | |
|--|---------------|---|
| EM8 | 12–16, 18, 20 | Level 2 emergency management information requirements |
| EM9 | 17 | Extra content for flammable substances |
| EM10 | 21–24 | Fire extinguishers |
| EM11 | 25–34 | Level 3 emergency management requirements – emergency response plans |
| EM12 | 35–41 | Level 3 emergency management requirements – secondary containment |
| EM13 | 42 | Level 3 emergency management requirements – signage |
| Hazardous Substances (Personnel Qualification) Regulations 2001 | | |
| AH1 | 4–6 | Approved Handler requirements (including test certificate and qualification requirements) |

Applicant: Ministry of Agriculture and Forestry - Head Office

Application Code: HSR04011

Purpose: To import DDVP insecticide strip to be used in the national fruit fly surveillance programme

Decision Notified: 13 July 2004

Decision: Approved with Controls

Identifier for Substance: DDVP Insecticide Strip

Classification: 6.1B acute inhalation toxicant, with lesser oral (6.1D) and dermal (6.1E) effects, 6.5B skin sensitizer, 6.7B carcinogenic, 6.9A target organ systemic toxicant (neurotoxic effects), 9.1A highly toxic to aquatic environment, 9.3A ecotoxic to terrestrial vertebrates, 9.4A ecotoxic to terrestrial invertebrates

ERMA Approval Code: HSR000126

Controls:

| Control Code ²⁸ | Regulation ²⁹ | Explanation ³⁰ |
|---|--------------------------|---|
| Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 - Toxic and Ecotoxic Property Controls | | |
| T1 | 11–27 | Limiting exposure to toxic substances |
| T3, E5 | 5(1), 5(2), 6 | Requirements for keeping records of use |
| T4, E6 | 7 | Requirements for equipment used to handle hazardous substances |
| T5 | 8 | Requirements for protective clothing and equipment |
| T6 | 9 | Approved handler requirements. This control only applies to the users of DDVP Insecticide Strip |
| T7, E8 | 10 | Restrictions on the carriage of hazardous substances on passenger service vehicles |
| E7 | 9 | Approved handler requirements |
| Hazardous Substances (Identification) Regulations 2001 | | |
| I1 | 6, 7, 32–35, 36 (1)–(7) | General identification requirements |
| I3 | 9 | Priority identifiers for ecotoxic substances |

²⁸ Note: The numbering system used in this column relates to the coding system used in the ERMA New Zealand Controls Matrix. This links the hazard classification categories to the regulatory controls triggered by each category. It is available from the ERMA New Zealand website www.ermanz.govt.nz/resources and is also contained in the *ERMA New Zealand User Guide to the Controls Regulations*.

²⁹ These Regulations form the controls applicable to this substance. Refer to the cited Regulations for the formal specification, and for definitions and exemptions. The accompanying explanation is intended for guidance only.

³⁰ These explanations are for guidance only. Refer to the cited Regulations for the formal specification, and for definitions and exemptions.

| | | |
|--|----------------|---|
| I8 | 14 | Priority identifiers for certain toxic substances |
| I9 | 18 | Secondary identifiers for all hazardous substances |
| I11 | 20 | Secondary identifiers for ecotoxic substances |
| I16 | 25 | Secondary identifiers for toxic substances |
| I17 | 26 | Use of Generic Names |
| I18 | 27 | Use of Concentration Ranges |
| I19 | 29–31 | Alternative information in certain cases |
| I20 | 36(8) | Durability of information for class 6.1 substances |
| I21 | 37–39, 47–50 | Documentation required in places of work |
| I23 | 41 | Specific documentation requirements for ecotoxic substances |
| I28 | 46 | Specific documentation requirements for toxic substances |
| I29 | 51–52 | Duties of persons in charge of places with respect to signage |
| I30 | 53 | Advertising toxic substances |
| Hazardous Substances (Packaging) Regulations 2001 | | |
| P1 | 5, 6, 7 (1), 8 | General packaging requirements |
| P3 | 9 | Packaging requirements for substances packed in limited quantities |
| P13 | 19 | Packaging requirements for toxic and ecotoxic substances |
| PG2 | Schedule 2 | This schedule provides the test methods for packaging required to be tested in accordance with this schedule. The tests in Schedule 2 correlate to the packaging requirements of UN Packing Group II (UN PGII). |
| Hazardous Substances (Disposal) Regulations 2001 | | |
| D4 | 8 | Disposal requirements for toxic and corrosive substances |
| D6 | 10 | Disposal requirements for packages |
| D7 | 11, 12 | Disposal information requirements |
| D8 | 13, 14 | Disposal documentation requirements |
| Hazardous Substances (Emergency Management) Regulations 2001 | | |
| EM1 | 6, 7, 9–11 | Level 1 emergency management information: General requirements |
| EM6 | 8(e) | Information requirements for toxic substances |
| EM7 | 8(f) | Information requirements for ecotoxic substances |
| EM8 | 12–16, 18–20 | Level 2 emergency management information requirements |
| EM11 | 25–34 | Level 3 emergency management requirements – emergency response plans |
| EM13 | 42 | Level 3 emergency management requirements – signage |
| Hazardous Substances (Personnel Qualification) Regulations 2001 | | |
| AH1 | 4–6 | Approved Handler requirements (including test certificate and qualification requirements) |
| Hazardous Substances (Tracking) Regulations 2001 | | |
| TR1 | 4(1), 5, 6 | General tracking requirements |

Additional Controls (section 77A)

DDVP Insecticide Strip shall only be imported by the Ministry of Agriculture and Forestry and shall only be used in outdoor insect traps for the fruit fly surveillance programme.

The size of each DDVP Insecticide Strip shall be restricted to 2.6 g with a total dichlorvos content no greater than 22% by weight.

Applicant: Koppers Arch Wood Protection (New Zealand) Limited

Application Code: HSR04020

Purpose: To manufacture Copper Naphthenate Formulations Type 3 and Type 4, for the preservation of timber

Decision Notified: 26 July 2004

Decision: Approved with Controls

Identifier for Substance: Copper Naphthenate Formulation Type 3 and Copper Naphthenate Formulation Type 4

Classification:

| Hazardous Property | Copper Naphthenate Formulation Type 3 | Copper Naphthenate Formulation Type 4 |
|--|---|---|
| Flammability | 3.1C | 3.1D |
| Acute toxicity (oral) | 6.1E (aspiration) | 6.1E (aspiration) |
| Skin irritation | 6.3A | 6.3A |
| Eye irritation | 6.4A | 6.4A |
| Skin/respiratory sensitisation | 6.5A/6.5B to not triggering (concentration ranges span classification) | 6.5A/6.5B to not triggering (concentration ranges span classification) |
| 9.1A and 9.1B (concentration ranges span classification) | 9.1A to 9.1B (concentration ranges span classification) | 9.1A to 9.1B (concentration ranges span classification) |
| Terrestrial Invertebrates Ecotoxicity | 9.4B to 9.4C to not triggering (concentration ranges span classification) | 9.4B to 9.4C to not triggering (concentration ranges span classification) |

ERMA Approval Code: HSR000128-9

Controls:

| Control Code ³¹ | Regulation ³² | Explanation ³³ |
|---|--------------------------|---|
| Hazardous Substances (Classes 1 to 5 Control Regulations) Regulations 2001 - Flammable Property Controls | | |
| F1 | 7 | General test certification requirements for Copper Naphthenate Formulation Type 3 |
| F3 | 55 | General limits on flammable substances |
| F5 | 58–59 | Requirements regarding hazardous atmosphere zones for Copper Naphthenate Formulation Type 3 |
| F6 | 60–70 | Requirements to prevent unintended ignition of Copper Naphthenate Formulations Type 3 and Type 4 |

31 Note: The numbering system used in this column relates to the coding system used in the ERMA New Zealand Controls Matrix. This links the hazard classification categories to the regulatory controls triggered by each category. It is available from the ERMA New Zealand website www.ermanz.govt.nz/resources and is also contained in the *ERMA New Zealand User Guide to the Controls Regulations*.

32 These Regulations form the controls applicable to this substance. Refer to the cited Regulations for the formal specification, and for definitions and exemptions. The accompanying explanation is intended for guidance only.

33 These explanations are for guidance only. Refer to the cited Regulations for the formal specification, and for definitions and exemptions.

| | | |
|--|-------------------------|---|
| F11 | 76 | Segregation of incompatible substances |
| F12 | 77–78 | General requirement for hazardous substance locations for flammable substances |
| F14 | 81 | Test certification requirements for facilities where Copper Naphthenate Formulation Type 3 is present |
| F16 | 83 | Controls on transit depots where flammable substances are present |
| Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 - Toxic Property Controls | | |
| T2 | 29, 30 | Controlling exposure in places of work |
| T4, E6 | 7 | Requirements for equipment used to handle Copper Naphthenate Formulations Type 3 and Type 4 |
| T5 | 8 | Requirements for protective clothing and equipment |
| T7 | 10 | General public transportation restrictions and requirements for Copper Naphthenate Formulations Type 3 and Type 4 |
| Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 - Ecotoxic Property Controls | | |
| E1 | 32–45 | Limiting exposure to ecotoxic substances |
| E3 | 49 | Controls relating to protection of terrestrial invertebrates e.g. beneficial insects |
| E5 | 5(2), 6 | Requirements for keeping records of use |
| Hazardous Substances (Identification) Regulations 2001 | | |
| I1 | 6, 7, 32–35, 36 (1)–(7) | General identification requirements |
| I3 | 9 | Priority identifiers for ecotoxic substances |
| I5 | 11 | Priority identifiers for flammable substances |
| I8 | 14 | Priority identifiers for Copper Naphthenate Formulations Type 3 and Type 4 |
| I9 | 18 | Secondary identifiers for all hazardous substances |
| I11 | 20 | Secondary identifiers for ecotoxic substances |
| I13 | 22 | Secondary identifiers for flammable substances |
| I16 | 25 | Secondary identifiers for toxic substances |
| I17 | 26 | Use of Generic Names |
| I18 | 27 | Use of Concentration Ranges |
| I19 | 29–31 | Alternative information in certain cases |
| I21 | 37–39, 47–50 | Documentation required in places of work |
| I23 | 41 | Specific documentation requirements for ecotoxic substances |
| I25 | 43 | Specific documentation requirements for flammable substances |
| I28 | 46 | Specific documentation requirements for toxic substances |
| I29 | 51–52 | Duties of persons in charge of places with respect to signage |
| I30 | 53 | Advertising corrosive and toxic substances |

| Hazardous Substances (Packaging) Regulations 2001 | | |
|---|----------------|---|
| P1 | 5, 6, 7 (1), 8 | General packaging requirements |
| P3 | 9 | Packaging requirements for substances packed in limited quantities |
| P5, P13, P15 | 11, 19, 21 | Packaging requirements for Copper Naphthenate Formulations Type 3 and Type 4 |
| PG3 | Schedule 3 | This schedule provides the test methods for packaging required to be tested in accordance with this schedule. The tests in Schedule 3 correlate to the packaging requirements of UN Packing Group III (UN PGIII). |
| Hazardous Substances (Disposal) Regulations 2001 | | |
| D2 | 6 | Disposal requirements for flammable substances |
| D4, D5 | 8, 9 | Disposal requirements for toxic and corrosive substances |
| D6 | 10 | Disposal requirements for packages |
| D7 | 11, 12 | Disposal information requirements |
| D8 | 13, 14 | Disposal documentation requirements |
| Hazardous Substances (Emergency Management) Regulations 2001 | | |
| EM1 | 6, 7, 9–11 | Level 1 emergency management information: General requirements |
| EM6 | 8(e) | Information requirements for toxic substances |
| EM7 | 8(f) | Information requirements for ecotoxic substances |
| EM8 | 12–16, 18–20 | Level 2 emergency management information requirements |
| EM9 | 17 | Extra content for flammable and oxidising substances and organic peroxides |
| EM10 | 21–24 | Fire extinguishers |
| EM11 | 25–34 | Level 3 emergency management requirements – emergency response plans |
| EM12 | 35–41 | Level 3 emergency management requirements – secondary containment |
| EM13 | 42 | Level 3 emergency management requirements – signage |
| Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004 | | |
| <p>Regulations 4 to 43 where applicable</p> <p>The Hazardous Substances (Tank Wagon and Transportable Containers) Regulations 2004 shall be varied to the effect that all road tank-wagons intended to carry Copper Naphthenate Formulations Type 3 and Type 4, shall have compartments designed and constructed to a size (water capacity, excluding ullage) no greater than 10,000 litres.</p> | | |
| Additional Controls (section 77A) | | |
| <p>Copper Naphthenate Formulations Type 3 and Type 4 shall only be used as agents in the preservation treatment of timber.</p> <p>The controls relating to stationary container systems, set out in Schedule 8 of the New Zealand Gazette notice of Thursday, 25 March 2004, Issue Number 35, shall apply, notwithstanding clause (1)(1) of the schedule.</p> | | |

The controls relating to secondary containment, set out in Schedule 9 of the New Zealand Gazette notice of Thursday, 25 March 2004, Issue Number 35, shall apply, notwithstanding clause (1)(1) of the schedule.

The controls relating to adverse effects of unintended ignition of class 2 and class 3.1 hazardous substances, set out in Schedule 10 of the New Zealand Gazette notice of Thursday, 25 March 2004, Issue Number 35, shall apply, notwithstanding clause (1)(1) of the schedule.

DELEGATED AUTHORITY

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

Applicant: Bayer New Zealand

Application Code: HSC04010

Purpose: To field test the substances BCS009-04 and BCS012-04 to assess the efficacy and phytotoxicity

Decision Notified: 12 July 2004

Decision: Approved with Controls

Identifier for Substance: BCS009-04 and BCS012-04

ERMA Approval Code: HSC000093-4

Controls:

1. The trials shall be undertaken in accordance with the Project Plan and Management Plan, which accompanied the application. Modifications of the Project Plan or Management Plan may be approved in writing by ERMA New Zealand providing that they comply with the following controls.
2. Notwithstanding the requirements of control 1 above, the trials shall also comply with the following controls.
3. The trials may be carried out at a location that is not defined until an infestation of the target pest has been found, provided the applicant;
 - has permission from the owner of the land to carry out the trial; and
 - notifies ERMA New Zealand of the locations as per control 22.
4. The trial sites shall be chosen so as to prevent the substances entering any surface water or groundwater system.
5. The trial sites shall be located to prevent any building where people live or work being exposed to the substances.

6. Access to the trial sites shall be by permission of the Trial Director³⁴ or owner of the property on which it is located. The trial site boundaries shall be clearly marked and distinctly visible from outside the trial site throughout the life of the trials. The primary access points shall be signed indicating that unauthorised access is not allowed, that the site is subject to a trial, and that the crops should not be removed or disturbed.
7. The trial sites shall be secured by stock proof fencing to exclude grazing animals for the duration of the trial.
8. The substances shall be stored in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409.
9. The substances shall be mixed, diluted and prepared in any other way prior to application in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409.
10. The substances shall be securely packed in suitable containers that comply with the Hazardous Substances (Packaging) Regulations 2001, and shall be labelled in accordance with the Hazardous Substances (Identification) Regulations 2001. A MSDS shall accompany each shipment.
11. The substances shall be transported in accordance with good practice. This may require compliance with the Land Transport Rule: Dangerous Goods 1999.
12. The substances shall be applied by way of hand-held/operator-worn equipment, using hydraulic pressure or compressed CO₂ or air on plots specifically designated and marked for each treatment, in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409. Special attention shall be paid to the minimisation of spray drift, and in particular to

³⁴ The Trial Director is the individual appointed by the applicant to be responsible for the overall conduct of the trial in accordance with the Management Plan and approval controls.

the avoidance of drift beyond boundaries agreed with the owner of the trial site.

13. The personnel applying the substances to the crops shall be able to demonstrate that they have the qualifications necessary to carry out the trial. Ways of demonstrating this would include the holding of an appropriate Growsafe certification or an Approved Handler qualification.
14. No sprayed produce shall be consumed by people or animals or offered for sale.
15. Sprayed produce shall be disposed of by ploughing in, by mulching or by burial at an approved landfill (not to be diverted to any composting operation).
16. The amount of spray prepared shall be adequate for the trial site, but if there is any surplus spray mix it shall be disposed of within the trial site by being further diluted and sprayed over a marked and designated non-crop and non-grazed area at the site.
17. Any equipment used shall be rinsed after use with the appropriate detergent or decontaminant, and rinsate disposed of within the trial site by being sprayed over a marked and designated non-crop and non-grazed area at the site.
18. Surplus substances remaining at the end of the trials shall be returned to Bayer New Zealand Ltd for secure storage in an exempt laboratory, exported or degraded to a non-hazardous substance (note that once the trials are complete the substances do not have approval to be present in New Zealand except in an exempt laboratory).
19. Any accidental spillage of the unmixed substances or spray mix shall be contained, prevented from entering waterways, and absorbed with an appropriate absorbent material. This material shall be placed into sealed containers and disposed of at an appropriate waste disposal facility (which may include a landfill), subject to the facility's waste acceptance policy.
20. A record shall be kept of all use of the substances. These records shall cover all matters referred to in Regulation 6 of the Hazardous Substances (Class 6, 8 and 9 Controls) Regulations.
21. Information on appropriate safety precautions necessary to provide safeguards against the substance's ecotoxic and toxic properties shall accompany the substances at all stages of their lifecycle. This shall include information on the appropriate protective clothing that is to be used and relevant first aid measures for immediate action pending medical attention.

22. Occupational Safety & Health, Head Office [Attn. HSNO Project Manager (OSH) or equivalent position] and ERMA New Zealand shall be informed in writing (by letter, fax or email) of the location, start, and completion of the trials. Notifications shall include the following details:

| Substance name | BCS009-04 |
|---------------------------|----------------|
| ERMA Application number | HSC04010 |
| ERMA Approval number | HSC000093 |
| ERMA Applications Advisor | Claire O'Hehir |

| Substance name | BCS009-04 |
|---------------------------|----------------|
| ERMA Application number | HSC04010 |
| ERMA Approval number | HSC000094 |
| ERMA Applications Advisor | Claire O'Hehir |

23. If for any reason a breach of containment occurs, the Trial Director shall notify OSH and ERMA New Zealand within 24 hours of the breach being detected. It is suggested that if a breach in containment results in contamination of a waterway, the relevant iwi authorities be advised.
24. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities and trial sites at any reasonable time.
25. This approval remains in place for the term of any concurrent approval required under the Agricultural Compounds and Veterinary Medicines Act 1997, to a maximum of five years.
26. The maximum total quantity that shall be imported under this approval is 10L of BCS009-04 and 10L of BCS012-04.

Applicant: Industrial Research Limited**Application Code: HSC04006**

Purpose: To manufacture in containment a developmental pharmaceutical product with low mammalian toxicology but no available ecotoxicology data and transfer of materials to research facilities overseas and in New Zealand for further evaluation

Decision Notified: 12 July 2004

Decision: Approved with Controls

Identifier for Substance: IRL Glycotherapeutic 0005

ERMA Approval Code: HSC000096

Controls:

1. The facilities where the substance will be synthesised shall comply with the Hazardous Substances (Exempt Laboratories) Regulations 2001. Compliance with these regulations will cover the matters to be addressed by the containment controls for hazardous substances contained in Schedule 3, Part III, of the HSNO Act.
2. The substance shall be shipped only to the facilities which have been identified in the application.
3. A maximum of 2.5 kilograms of the substance shall be manufactured for use in toxicology trials, and a maximum of 15 kilograms of the substance shall be manufactured for use in clinical trials.
4. Synthesis shall take place within the facilities at Industrial Research Limited (IRL) as identified in the application.
5. All personnel carrying out the synthesis and packaging of the substance shall wear appropriate personal protective equipment.
6. Handling of the substance shall be in accordance with good laboratory practice. Any spillage of the substance shall be cleaned up with appropriate absorbent material. The used absorbent material shall be securely packaged and retained in the IRL facility until it has been rendered non-hazardous prior to disposal.
7. The substance shall be stored in the IRL facility until it is exported or despatched to the pharmaceutical formulator. Only authorised personnel shall be allowed into the IRL facility, which has access controlled by electronic security systems and is itself located within a controlled access site.
8. The substance shall be packaged for transportation in a container within a container (secondary containment) and that secondary container shall be sufficient to control any release if the primary container should leak. The containers shall comply with the Hazardous Substances (Packaging) Regulations 2001, and shall be labelled in accordance with Regulation 11 of the Hazardous Substances (Exempt Laboratories) Regulations 2001. A Safety Data Sheet shall accompany each shipment.
9. The substance shall be transported in accordance with good practice. This may require compliance with the Land Transport Rule: Dangerous Goods 1999.
10. If for any reason a breach of containment occurs, the Manager: GSF Facility shall notify OSH (HSNO Project Manager) and ERMA New Zealand (Beth Dye) within 24 hours of the breach being detected. It is suggested that if a breach in containment results in contamination of a waterway, the relevant iwi authorities be advised of the contamination and the measures taken in response.
11. The Authority, or its authorised agent or properly authorised enforcement officers, may inspect the facility at any reasonable time.

Applicant: Bayer New Zealand**Application Code: HSC04011**

Purpose: To field test the substance BCS011-04 to assess the efficacy and phytotoxicity

Decision Notified: 12 July 2004

Decision: Approved with Controls

Identifier for Substance: BCS011-04

ERMA Approval Code: HSC000095

Controls:

1. The trials shall be undertaken in accordance with the Project Plan and Management Plan, which accompanied the application. Modifications of the Project Plan or Management Plan may be approved in writing by ERMA New Zealand providing that they comply with the following controls.
2. Notwithstanding the requirements of control 1 above, the trials shall also comply with the following controls.
3. The trials may be carried out at a location that is not defined until an infestation of the target pest has been found, provided the applicant;
 - has permission from the owner of the land to carry out the trial; and
 - notifies ERMA New Zealand of the locations as per control 22.
4. The trial sites shall be chosen so as to prevent the substance entering any surface water or groundwater system.

5. The trial sites shall be located to prevent any building where people live or work being exposed to the substance.
6. Access to the trial sites shall be by permission of the Trial Director³⁵ or owner of the property on which it is located. The trial site boundaries shall be clearly marked and distinctly visible from outside the trial site throughout the life of the trials. The primary access points shall be signed indicating that unauthorised access is not allowed, that the site is subject to a trial, and that the crops should not be removed or disturbed.
7. The trial sites shall be secured by stock proof fencing to exclude grazing animals for the duration of the trial.
8. The substance shall be stored in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409.
9. The substance shall be mixed, diluted and prepared in any other way prior to application in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409.
10. The substance shall be securely packed in suitable containers that comply with the Hazardous Substances (Packaging) Regulations 2001, and shall be labelled in accordance with the Hazardous Substances (Identification) Regulations 2001. A MSDS shall accompany each shipment.
11. The substance shall be transported in accordance with good practice. This may require compliance with the Land Transport Rule: Dangerous Goods 1999.
12. The substance shall be applied by way of hand-held/operator-worn equipment, using hydraulic pressure or compressed CO₂ or air on plots specifically designated and marked for each treatment, in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409. Special attention shall be paid to the minimisation of spray drift, and in particular to the avoidance of drift beyond boundaries agreed with the owner of the trial site.
13. The personnel applying the substance to the crops shall be able to demonstrate that they have the qualifications necessary to carry out the trial. Ways of demonstrating this would include the holding of an appropriate Growsafe certification or an Approved Handler qualification.
14. No sprayed produce shall be consumed by people or animals or offered for sale.
15. Sprayed produce shall be disposed of by ploughing in, by mulching or by burial at an approved landfill (not to be diverted to any composting operation).
16. The amount of spray prepared shall be adequate for the trial site, but if there is any surplus spray mix it shall be disposed of within the trial site by being further diluted and sprayed over a marked and designated non-crop and non-grazed area at the site.
17. Any equipment used shall be rinsed after use with the appropriate detergent or decontaminant, and rinsate disposed of within the trial site by being sprayed over a marked and designated non-crop and non-grazed area at the site.
18. Surplus substance remaining at the end of the trials shall be returned to Bayer New Zealand Ltd for secure storage in an exempt laboratory, exported or degraded to a non-hazardous substance (note that once the trials are complete the substance does not have approval to be present in New Zealand except in an exempt laboratory).
19. Any accidental spillage of the unmixed substance or spray mix shall be contained, prevented from entering waterways, and absorbed with an appropriate absorbent material. This material shall be placed into sealed containers and disposed of at an appropriate waste disposal facility (which may include a landfill), subject to the facility's waste acceptance policy.
20. A record shall be kept of all use of the substance. This record shall cover all matters referred to in Regulation 6 of the Hazardous Substances (Class 6, 8 and 9 Controls) Regulations.
21. Information on appropriate safety precautions necessary to provide safeguards against the substance's ecotoxic and toxic properties shall accompany the substance at all stages of its lifecycle. This shall include information on the appropriate protective clothing that is to be used and relevant first aid measures for immediate action pending medical attention.
22. Occupational Safety & Health, Head Office [Attn. HSNO Project Manager (OSH) or equivalent position] and ERMA New Zealand shall be informed in writing (by letter, fax or

³⁵ The Trial Director is the individual appointed by the applicant to be responsible for the overall conduct of the trial in accordance with the Management Plan and approval controls.

email) of the location, start, and completion of the trials. Notifications shall include the following details:

| Substance name | BCS011-04 |
|---------------------------|----------------|
| ERMA Application number | HSC04011 |
| ERMA Approval number | HSC000095 |
| ERMA Applications Advisor | Claire O’Hehir |

23. If for any reason a breach of containment occurs, the Trial Director shall notify OSH and ERMA New Zealand within 24 hours of the breach being detected. It is suggested that if a breach in containment results in contamination of a waterway, the relevant iwi authorities be advised.
24. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities and trial sites at any reasonable time.
25. This approval remains in place for the term of any concurrent approval required under the Agricultural Compounds and Veterinary Medicines Act 1997, to a maximum of five years.
26. The maximum total quantity of BCS011-04 that shall be imported under this approval is 15 kg.

Applicant: Bayer New Zealand

Application Code: HSC04012

Purpose: To field test the substances BCS010-04 and BCS013-04 to assess the efficacy and phytotoxicity

Decision Notified: 13 July 2004

Decision: Approved with Controls

Identifier for Substance: BCS010-04 and BCS013-04

ERMA Approval Code: HSC000097-8

Controls:

1. The trials shall be undertaken in accordance with the Project Plan and Management Plan, which accompanied the application. Modifications of the Project Plan or Management Plan may be approved in writing by ERMA New Zealand providing that they comply with the following controls.
2. Notwithstanding the requirements of control 1 above, the trials shall also comply with the following controls.

3. The trials may be carried out at a location that is not defined until an infestation of the target pests has been found, provided the applicant;
 - has permission from the owner of the land to carry out the trial; and
 - notifies ERMA New Zealand of the locations as per control 22.
4. The trial sites shall be chosen so as to prevent the substances entering any surface water or groundwater system.
5. The trial sites shall be located to prevent any building where people live or work being exposed to the substances.
6. Access to the trial sites shall be by permission of the Trial Director³⁶ or owner of the property on which it is located. The trial site boundaries shall be clearly marked and distinctly visible from outside the trial site throughout the life of the trials. The primary access points shall be signed indicating that unauthorised access is not allowed, that the site is subject to a trial, and that the crops should not be removed or disturbed.
7. The trial sites shall be secured by stock proof fencing to exclude grazing animals for the duration of the trial.
8. The substances shall be stored in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409.
9. The substances shall be mixed, diluted and prepared in any other way prior to application in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409.
10. The substances shall be securely packed in suitable containers that comply with the Hazardous Substances (Packaging) Regulations 2001, and shall be labelled in accordance with the Hazardous Substances (Identification) Regulations 2001. A MSDS shall accompany each shipment.
11. The substances shall be transported in accordance with good practice. This may require compliance with the Land Transport Rule: Dangerous Goods 1999.
12. The substances shall be applied by way of hand-held/operator-worn equipment, using hydraulic pressure or compressed CO2 or air on plots specifically designated and marked for each treatment, in accordance with good practice. This would generally be achieved through

³⁶ The Trial Director is the individual appointed by the applicant to be responsible for the overall conduct of the trial in accordance with the Management Plan and approval controls.

compliance with the Code of Practice for the Management of Agrichemicals NZS8409. Special attention shall be paid to the minimisation of spray drift, and in particular to the avoidance of drift beyond boundaries agreed with the owner of the trial site.

13. The personnel applying the substances to the crops shall be able to demonstrate that they have the qualifications necessary to carry out the trial. Ways of demonstrating this would include the holding of an appropriate Growsafe certification or an Approved Handler qualification.
14. No sprayed produce shall be consumed by people or animals or offered for sale.
15. Sprayed produce shall be disposed of by ploughing in, by mulching or by burial at an approved landfill (not to be diverted to any composting operation).
16. The amount of spray prepared shall be adequate for the trial site, but if there is any surplus spray mix it shall be disposed of within the trial site by being further diluted and sprayed over a marked and designated non-crop and non-grazed area at the site.
17. Any equipment used shall be rinsed after use with the appropriate detergent or decontaminant, and rinsate disposed of within the trial site by being sprayed over a marked and designated non-crop and non-grazed area at the site.
18. Surplus substances remaining at the end of the trials shall be returned to Bayer New Zealand Ltd for secure storage in an exempt laboratory, exported or degraded to a non-hazardous substance (note that once the trials are complete the substances do not have approval to be present in New Zealand except in an exempt laboratory).
19. Any accidental spillage of the unmixed substances or spray mix shall be contained, prevented from entering waterways, and absorbed with an appropriate absorbent material. This material shall be placed into sealed containers and disposed of at an appropriate waste disposal facility (which may include a landfill), subject to the facility's waste acceptance policy.
20. A record shall be kept of all use of the substances. These records shall cover all matters referred to in Regulation 6 of the Hazardous Substances (Class 6, 8 and 9 Controls) Regulations.
21. Information on appropriate safety precautions necessary to provide safeguards against the substances' ecotoxic and toxic properties shall accompany the substances at all stages of their

lifecycles. This shall include information on the appropriate protective clothing that is to be used and relevant first aid measures for immediate action pending medical attention.

22. Occupational Safety & Health, Head Office [Attn. HSNO Project Manager (OSH) or equivalent position] and ERMA New Zealand shall be informed in writing (by letter, fax or email) of the location, start, and completion of the trials. Notifications shall include the following details:

| Substance name | BCS010-04 |
|---------------------------|----------------|
| ERMA Application number | HSC04012 |
| ERMA Approval number | HSC000097 |
| ERMA Applications Advisor | Claire O'Hehir |

| Substance name | BCS013-04 |
|---------------------------|----------------|
| ERMA Application number | HSC04012 |
| ERMA Approval number | HSC000098 |
| ERMA Applications Advisor | Claire O'Hehir |

23. If for any reason a breach of containment occurs, the Trial Director shall notify OSH and ERMA New Zealand within 24 hours of the breach being detected. It is suggested that if a breach in containment results in contamination of a waterway, the relevant iwi authorities be advised.
24. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities and trial sites at any reasonable time.
25. This approval remains in place for the term of any concurrent approval required under the Agricultural Compounds and Veterinary Medicines Act 1997, to a maximum of five years.
26. The maximum total quantity that shall be imported under this approval is 5L of BCS010-04 and 5kg BCS013-04.

Applicant: Bayer New Zealand

Application Code: HSC04013

Purpose: To field test the substance BCS007-04 to assess the efficacy and phytotoxicity

Decision Notified: 13 July 2004

Decision: Approved with Controls

Identifier for Substance: BCS007-04

ERMA Approval Code: HSC000099

Controls:

1. The trials shall be undertaken in accordance with the Project Plan and Management Plan, which accompanied the application. Modifications of the Project Plan or Management Plan may be approved in writing by ERMA New Zealand providing that they comply with the following controls.
2. Notwithstanding the requirements of control 1 above, the trials shall also comply with the following controls:
3. The trials may be carried out at a location that is not defined until an infestation of the target pest has been found, provided the applicant;
 - has permission from the owner of the land to carry out the trial; and
 - notifies ERMA New Zealand of the locations as per control 22.
4. The trial sites shall be chosen so as to prevent the substance entering any surface water or groundwater system.
5. The trial sites shall be located to prevent any building where people live or work being exposed to the substance.
6. Access to the trial sites shall be by permission of the Trial Director³⁷ or owner of the property on which it is located. The trial site boundaries shall be clearly marked and distinctly visible from outside the trial site throughout the life of the trials. The primary access points shall be signed indicating that unauthorised access is not allowed, that the site is subject to a trial, and that the crops should not be removed or disturbed.
7. The trial sites shall be secured by stock proof fencing to exclude grazing animals for the duration of the trial.
8. The substance shall be stored in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409.
9. The substance shall be mixed, diluted and prepared in any other way prior to application in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409.
10. The substance shall be securely packed in suitable containers that comply with the Hazardous Substances (Packaging) Regulations 2001, and shall be labelled in accordance with the Hazardous Substances (Identification) Regulations 2001. A MSDS shall accompany each shipment.
11. The substance shall be transported in accordance with good practice. This may require compliance with the Land Transport Rule: Dangerous Goods 1999.
12. The substance shall be applied by way of hand-held/operator-worn equipment, using hydraulic pressure or compressed CO₂ or air on plots specifically designated and marked for each treatment, in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409. Special attention shall be paid to the minimisation of spray drift, and in particular to the avoidance of drift beyond boundaries agreed with the owner of the trial site.
13. The personnel applying the substance to the crops shall be able to demonstrate that they have the qualifications necessary to carry out the trial. Ways of demonstrating this would include the holding of an appropriate Growsafe certification or an Approved Handler qualification.
14. No sprayed produce shall be consumed by people or animals or offered for sale.
15. Sprayed produce shall be disposed of by ploughing in, by mulching or by burial at an approved landfill (not to be diverted to any composting operation).
16. The amount of spray prepared shall be adequate for the trial site, but if there is any surplus spray mix it shall be disposed of within the trial site by being further diluted and sprayed over a marked and designated non-crop and non-grazed area at the site.
17. Any equipment used shall be rinsed after use with the appropriate detergent or decontaminant, and rinsate disposed of within the trial site by being sprayed over a marked and designated non-crop and non-grazed area at the site.

³⁷ The Trial Director is the individual appointed by the applicant to be responsible for the overall conduct of the trial in accordance with the Management Plan and approval controls.

18. Surplus substance remaining at the end of the trials shall be returned to Bayer New Zealand Ltd for secure storage in an exempt laboratory, exported or degraded to a non-hazardous substance (note that once the trials are complete the substance does not have approval to be present in New Zealand except in an exempt laboratory).
19. Any accidental spillage of the unmixed substance or spray mix shall be contained, prevented from entering waterways, and absorbed with an appropriate absorbent material. This material shall be placed into sealed containers and disposed of at an appropriate waste disposal facility (which may include a landfill), subject to the facility's waste acceptance policy.
20. A record shall be kept of all use of the substance. This record shall cover all matters referred to in Regulation 6 of the Hazardous Substances (Class 6, 8 and 9 Controls) Regulations.
21. Information on appropriate safety precautions necessary to provide safeguards against the substance's ecotoxic properties shall accompany the substance at all stages of its lifecycle. Safety glasses, gloves and protective clothing shall be worn when handling the substance throughout the lifecycle.
22. Occupational Safety & Health, Head Office [Attn. HSNO Project Manager (OSH) or equivalent position] and ERMA New Zealand shall be informed in writing (by letter, fax or email) of the location, start, and completion of the trials. Notifications shall include the following details:

| Substance name | BCS007-04 |
|---------------------------|----------------|
| ERMA Application number | HSC04013 |
| ERMA Approval number | HSC000099 |
| ERMA Applications Advisor | Claire O'Hehir |

23. If for any reason a breach of containment occurs, the Trial Director shall notify OSH and ERMA New Zealand within 24 hours of the breach being detected. It is suggested that if a breach in containment results in contamination of a waterway, the relevant iwi authorities be advised.
24. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities and trial sites at any reasonable time.

TEST CERTIFIERS

The Chief Executive of the Environmental Risk Management Authority, acting under delegated power from the Authority, reached decisions on the following applications. The full requirements and limitations for the following Test Certifiers is available on our public register or website.

Applicant: Robert Storrie

Region: Canterbury

Decision: Approved with Limitations

Date of Approval: 08 July 2004

ERMA Approval Code: TST000012

Applicant: Michael Sarfaiti

Region: Southland

Decision: Approved with Limitations

Date of Approval: 14 July 2004

ERMA Approval Code: TST000078

Applicant: Adrian Hodgkinson

Region: Canterbury

Decision: Approved with Limitations

Date of Approval: 19 July 2004

ERMA Approval Code: TST000079

Applicant: Patrick Seaman

Region: Auckland

Decision: Approved with Limitations

Date of Approval: 19 July 2004

ERMA Approval Code: TST000080

Applicant: Iain Hamilton

Region: Wellington

Decision: Approved with Limitations

Date of Approval: 21 July 2004

ERMA Approval Code: TST000081

INQUIRIES INTO INCIDENTS AND EMERGENCIES

From time to time the Authority may conduct inquiries, under the HSNO Act 1996, into incidents relating to hazardous substances or new organisms. The Bulletin provides a summary list of inquiries in progress, and inquiries completed. The results of major inquiries will be published in special reports available in an ERMA Inquiry publication series. The results of minor inquiries will not be published but will be available on request.

INQUIRIES COMPLETED

2003-04 Financial Year.

1. The Authority has completed an inquiry into an incident of vandalism at the Forest Research Institute's GMO plant field test site, Rotorua (May 2003). ERMA New Zealand was notified that a hole had been cut in the boundary fence of the site containing GM *Pinus radiata*. No damage was done to the site, other than the fence, which was repaired immediately upon discovery by staff.

The inquiry concluded that it was extremely unlikely that any genetically modified plant material was removed from the site. No immediate adverse effects to human health and safety, or the environment were identified. The inquiry recommended a review of security measures for field tests.

2. The Authority has completed an inquiry into the contended illegal importation of the plant species *Pogonatherum paniceum* (baby bamboo) for sale by an Auckland plant nursery (May 2003). The plants had been imported under one name and labelled in the nursery under another. No approval for the release of the plant species under the HSNO Act had been issued. As part of the investigation, MAF seized all known stock of *Pogonatherum paniceum* from plant nurseries supplied throughout the country.

The inquiry concluded that the release of *Pogonatherum paniceum* within New Zealand was very unlikely to present significant risks to the environment, or human health.

3. The Authority has completed an inquiry into the importation of two varieties of sweetcorn grown commercially in New Zealand in the 2002-03 season. This incident involved the importation and release of two new GMO's without HSNO Act approval and triggered an incursion response by MAF, and subsequent post harvest monitoring of affected sites. It was established that the GM content in the two varieties was inadvertent.

The inquiry concluded that the magnitude of any adverse environmental and human health

effects would be very low, because the GM constructs identified occurred naturally in the environment and have been determined to be safe for animal and human consumption. As a result of this incident MAF conducted a review of the competency of MAF-accredited GM testing facilities.

4. The Authority has completed an inquiry into compliance concerns with a GM plant research project within a plant laboratory at Genesis Research & Development Corporation Limited, Auckland (June 2003). Initially there were concerns that GM plants were not adequately isolated in the facility, and that the laboratory had not been appropriately fumigated. However, it was subsequently ascertained that the research had not entered the transgenic stage, so these issues did not constitute non-compliance with control requirements.

The inquiry concluded that no new organisms were involved in the incident and no risks were therefore posed by new organisms. A training programme reviewing laboratory management procedures was undertaken by Genesis.

5. The Authority has completed an inquiry of the disappearance of a 9 month old Cotton top tamarin monkey from Wellington Zoo (March 2003). The family of Cotton top tamarin monkeys were under "psychological" style containment (i.e. free-range in trees, but containment based on physical and behavioural factors, such as fear of open spaces). There has been no direct resolution to the whereabouts of the monkey but it is thought most likely that the monkey ended up in an enclosure of a hostile animal and was killed and consumed.

It was concluded that the release of one Cotton top tamarin monkey would present a low risk to the New Zealand environment as the local surroundings of the Wellington Zoo are not abundant with food that meets the dietary requirements of the monkey, and it is unlikely that it would survive.

6. The Authority has completed an inquiry into the escape of an Asian elephant from Auckland Zoo (January 2004). *Burma*, a 21 year old, female, Asian elephant used a large log in her outdoor enclosure at Auckland Zoo to compromise and inactivate the single wire electric fence and negotiate a path through the dry moat of the Elephant exhibit. The Elephant then proceeded to the gate at the zoo's rear, where a member of the public sighted the elephant attempting to push through the gate that accessed Western Springs Park. Upon notification, staff quickly located the elephant in the upper region of the pine forest adjacent to Western Springs Park and escorted her to the Elephant Exhibit.

The inquiry concluded that no adverse effects to human health and safety, or the environment occurred as a result of this breach of containment. Auckland Zoo acted quickly to rectify key structural containment issues within the elephant enclosure and in addition, longer-term measures to bolster containment are being instigated.

7. The Authority has completed an inquiry into compliance concerns with a GM plant research project at Otago University (March 2004), identified during a routine MAF audit. The inquiry concluded that no adverse effects to human health and safety, or the environment occurred. The University addressed operational procedures immediately, whilst structural refurbishment is taking place at the facility to meet the requisite containment standard.
8. The Authority has completed an inquiry into the importation of two consignments of *Zea mays* seed containing genetically modified constructs (2004). MAF suspended the accreditation of Biogenetic Services Ltd, a facility that performs testing for detection and quantification of GM in maize seed for sowing that is imported in to New Zealand. MAF retested consignments of seed material tested by Biogenetic Services Ltd that were shipped to New Zealand since January 2003. With the return of positive results for GM constructs in two consignments, MAF undertook an incursion response to retrieve seeds not already planted, and to monitor the harvesting and processing of those fields sown with *Zea mays* seed. This incident represents a distinct case of inadvertent importation and release of a new organism under the Hazardous Substances and New Organisms (HSNO) Act 1996.

The inquiry concluded that no adverse effects to human health and safety, or the environment occurred. GM elements were detected at below 0.05 percent, under the Australian/New Zealand Joint Food Standards Code a one percent threshold of unintended presence for approved GM constructs is allowable for human consumption.

MAF Biosecurity Authority has recently reviewed the GM testing protocols for seed for sowing with the main change to the protocols being: the mandatory requirement for polymerase chain reaction (PCR) testing to be qualitative, i.e. the test is designed to indicate the presence or absence of GM seeds, but not the concentration of GM seeds in the consignment; and for testing certificated to be current (testing performed in the current year or one year previous).

9. The Authority has completed an inquiry into compliance concerns with a GM potato field test site at Crop & Food Research, Lincoln (April 2004). During a post-harvest inspection, MAF reported that three potato plants were found several metres outside the boundary of one of the trial sites. The plants found were identified as buffer plants (non GM) used in the field test and were thought to have been dragged away from the containment site by the cultivation method used.

The inquiry concluded that no immediate effects to human health and safety, or the environment occurred as a result of this incident. ERMA New Zealand recommended that the post trial monitoring period for volunteers should be extended for another 12 months, and the area monitored should be extended to include the containment location and a zone surrounding land in which the volunteer plants were found. Issues arising from this incident surrounding interpretation and writing of controls will be incorporated by ERMA New Zealand into the crafting of controls for future plant field test decisions.

