

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.

Applicant: West Coast Ragwort Control Trust

Application Code: NOR05002

Purpose: Approval is sought by the West Coast Ragwort Control Trust to import for release two new moths, *Cochylis atricapitana* (Tortricidae) and *Platyptilia isodactyla* (Pterophoridae), for the biological control of the pasture weed ragwort

Date Publicly Notified: 15 July 2005

Date Submissions Close: 26 August 2005

NON-NOTIFIED APPLICATIONS RECEIVED

Applicant: Photonz Corp Limited

Application Code: NFM05002

Purpose: Photonz Corporation Limited is developing nutritional products from naturally occurring micro-algae. The purpose of the present application is to seek approval for the Company to conduct liquid cultures of 24 microalgal species at volumes above ten litres

Date Formally Received: 01 July 2005

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: Victoria University of Wellington

Application Code: GMD05048

Purpose: Production of recombinant eukaryotic initiation factor 4AI, II and III for investigations into the molecular pharmacology of the toxin pateamine A

Decision Notified: 05 July 2005

Decision: Approved with Controls

Description of Organisms:

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

ERMA NEW ZEALAND

PO Box 131 Wellington

Phone: +64 4 916 2426 Fax: +64 4 914 0433

Email: info@ermanz.govt.nz

Website: www.ermanz.govt.nz

Host organism	Category of host organism	Modified by:	Category of modification/containment level
<i>Escherichia coli</i> (Migula 1895) Castellani and Chalmers 1919 Non-pathogenic laboratory strains	1	Standard <i>Escherichia coli</i> cloning and expression plasmid vectors containing standard and commercially available selection markers and protein purification tags (e.g. 6-His) with full or partial DNA sequences encoding the eukaryotic Initiation Factor 4A (eIF4AI, II and III) derived from <i>Mus musculus</i>	A/PC1

ERMA Approval Code: GMD003832

BCH Number: 9788

Controls:

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

- 1.1 The approved organism 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 organism 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 The construction and operation of the containment facility shall be in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02²: 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, under a minimum of Physical Containment level 1 (PC1).

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 control 1.4 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 control 1.4 relating to the exclusion of other organisms from the facility and the control of undesirable and unwanted organisms within the facility.

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

- 4.1 Construction and operation of the containment facility shall comply with the requirements of the standards listed in control 1.4 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 control 1.4 relating to controlling the effects of any accidental release or escape of an organism.

1 Viable Genetic Material is biological material that can be resuscitated to grow into tissues or organisms. It can be defined to mean biological material capable of growth even though resuscitation procedures may be required, e.g. when organisms or parts thereof are sub-lethally damaged by being frozen, dried, heated, or affected by chemical.

2 Or any updated Standard endorsed by ERMA New Zealand or MAF Biosecurity New Zealand.

- 5.2 If for any reason a breach of containment occurs, the facility Supervisor, MAF Biosecurity New Zealand and ERMA New Zealand shall be promptly notified as soon as it is practicable.
- 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 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 1.4.
- 6. Inspection and monitoring requirements for containment facilities.**
- 6.1 The operation of the containment facilities shall comply with the requirements contained in the standards listed in control 1.4 relating to the inspection and monitoring requirements for containment facilities.
- 6.2 The Authority, or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.
- 6.3 The containment manual shall be updated, as necessary, to address the implementation of the controls imposed by this approval, in accordance with the standards listed in control 1.4.
- 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 1.4.

Applicant: Cawthron Institute Trust Board

Application Code: GMD04104

Purpose: DNA sequences from marine molluscs will be introduced into standard laboratory strains of: *Escherichia coli*, *Saccharomyces cerevisiae* or *Pichia pastoris* to aid research into marine mollusc physiology and genetics

Decision Notified: 15 July 2005

Decision: Approved with Controls

Description of Organisms:

Host organism	Category of host organism	Modified by:	Category of modification/containment level
1) <i>Escherichia coli</i> (Migula 1895) Castellani & Chalmers 1919 non-pathogenic laboratory strains	1	Standard cloning and bacterial or yeast expression plasmid vectors containing PCR amplification products and genomic DNA from marine molluscs (Phylum Mollusca) sourced from the northern region of the South Island. There will be no expression of known or putative vertebrate toxin genes.	A / PC1

Host organism	Category of host organism	Modified by:	Category of modification/containment level
2) <i>Pichia pastoris</i> (Guillierm.) Phaff strain GS115 (his4), SMD1168 (his4, pep4) and other similar commercially available strains	1	Standard cloning and yeast expression plasmid vectors containing PCR amplification products and genomic DNA from marine molluscs (Phylum Mollusca) sourced from the northern region of the South Island. There will be no expression of known or putative vertebrate toxin genes.	A / PC1
3) <i>Saccharomyces cerevisiae</i> (Meyen ex E.C. Hansen 1883) strain INVSc1 and other commercially available strains	1	Standard cloning and yeast expression plasmid vectors containing PCR amplification products and genomic DNA from marine molluscs (Phylum Mollusca) sourced from the northern region of the South Island. There will be no expression of known or putative vertebrate toxin genes.	A / PC1

ERMA Approval Code: GMD003846 - 48

BCH Number: 9859 - 61

Controls:

1. To limit the likelihood of any accidental release of any organism or any viable genetic material. ³

- 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 construction and operation of the containment facility in which the organisms are maintained, shall be in accordance with the:
 - a) MAF/ERMA New Zealand Standard 154.03.02: Containment Facilities for Micro-organisms, at laboratory Physical Containment Levels 1 (PC1).⁴

- b) Australian New Zealand Standard AS/NZS 2243.3:2002 Safety in Laboratories: Part 3: Microbiological aspects of containment and facilities, except for the deviations specified in the Standard referred to in (a).

- 1.4 The facility shall be approved and registered by MAF as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard 154.03.02, and controls imposed by the Authority.

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 control 1.3 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 control 1.3 relating to the

³ 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.

⁴ Or any equivalent updated Standard endorsed by ERMA New Zealand or MAF Biosecurity New Zealand.

exclusion of other organisms from the facility and the control of undesirable and unwanted organisms within the facility.

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

4.1 Construction and operation of the containment facility shall comply with the requirements of the standards listed in control 1.3 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 control 1.3 relating to controlling the effects of any accidental release or escape of an organism.

5.2 If for any reason a breach of containment⁵ occurs, the facility Supervisor, MAF Biosecurity New Zealand 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 control 1.3.

6. Inspection and monitoring requirements for containment facilities.

6.1 The operation of the containment facilities shall comply with the requirements contained in the standards listed in control 1.3 relating to the inspection and monitoring requirements for containment facilities.

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

6.3 The containment manual shall be updated, as necessary, to address the implementation of the controls imposed by this approval, in accordance with the standards listed in control 1.3.

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

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

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

Applicant: Horticulture and Food Research Institute (HortResearch Auckland)

Institute Code: GMO05/HRA091

Application Code: GMD05062

Purpose: To maintain plant DNA clones in *Escherichia coli* in containment for extraction of DNA and to produce proteins for preliminary tests of their function. Update of GMO03/HRA079

Decision Notified: 14 April 2005

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

Escherichia coli (non pathogenic strains K12 or B derivatives) modified with standard sub-cloning vectors and inducible protein expression vectors containing plant DNA from *Petunia hybrida* and 21 additional kiwifruit species. Standard sub-cloning vectors and inducible protein expression vectors containing genes from *Erwinia herbicola*, *Rhobacter capsulatus*, *Synechococcus sp.* involved in the biosynthesis of carotenoid compounds

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003842

Applicant: Horticulture and Food Research Institute (HortResearch Auckland)

Institute Code: GMO05/HRA093

Application Code: GMD05064

Purpose: Yeast expression to determine the function of plant and fungal genes. Update of GMO00/HRA038

Decision Notified: 14 April 2005

⁵ For the purposes of these controls a 'breach of containment' means any interference with the containment facility or any non-compliance with the Authority's controls whether an approved organism escapes from containment or not.

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

Escherichia coli (K12 and B strains) modified with:

Vector DNA: pESC-series, Donor DNA from: *Nicotiana tabacum*, *Nicotiana benthamiana*, *Petunia hybrida*, *Arabidopsis thaliana*, *Lycopersicon esculentum*, *Actinidia deliciosa*, *Actinidia chinensis*, *Actinidia arguta*, *Actinidia eriantha*, *Vaccinium corybosum*, *Vaccinium ashei*, *Vaccinium angustifolium*, *Vaccinium macrocarpon*, *Malus domestica* and *Botrytis cinerea*

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003843

Description of Organism: *Saccharomyces cerevisiae* Hansen 1883

Saccharomyces cerevisiae (strains including YPH 499) modified with:

Vector DNA: pESC-series, Donor DNA from: *Nicotiana tabacum*, *Nicotiana benthamiana*, *Petunia hybrida*, *Arabidopsis thaliana*, *Lycopersicon esculentum*, *Actinidia deliciosa*, *Actinidia chinensis*, *Actinidia arguta*, *Actinidia eriantha*, *Vaccinium corybosum*, *Vaccinium ashei*, *Vaccinium angustifolium*, *Vaccinium macrocarpon*, *Malus domestica* and *Botrytis cinerea*

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003844

Applicant: Horticulture and Food Research Institute (HortResearch Auckland)

Institute Code: GMO05/HRA092

Application Code: GMD05069

Purpose: Determination of plant gene function from ESTs and genomic clones, characterisation of regulatory elements controlling plant gene expression and the development of new plant varieties. Update of GMO01/HRA053

Decision Notified: 14 April 2005

Description of Organisms: *Agrobacterium tumefaciens* (Smith & Townsend 1907) Conn 1942

Agrobacterium tumefaciens (disarmed strains (LBA4404, AGL0, AGL1, EHA101, EHA105 or GV3101)), containing standard plant transformation vectors based on pART27, pCAMBIA-series, pNOVO22 or pRK290 containing cDNA or genomicDNA derived plant genes from defined plant species with regulatory elements and reporter genes and/or carotenoid cleavage dioxygenase genes of mouse or rat origin

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003866

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

Escherichia coli (K12 or B derivatives) containing standard DNA cloning vectors, carrying ColeI replicons, specified antibiotic resistance and/or the lacZ gene and cDNA or genomic DNA derived plant genes from defined plant species with regulatory elements and reporter genes and/or carotenoid cleavage dioxygenase genes of mouse or rat origin or plant transformation vectors based on pART27, pCAMBIA-series, pNOVO22 or pRK290 containing cDNA or genomic DNA derived plant genes from defined plant species with regulatory elements and reporter genes and/or carotenoid cleavage dioxygenase genes of mouse or rat origin

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003868

The following approved organisms are modified with:

Modification: modified with standard plant transformation vectors based on pART27, pCAMBIA-series, pNOVO22 or pRK290 containing cDNA or genomic DNA derived plant genes from defined plant species with regulatory elements and reporter genes and/or carotenoid cleavage dioxygenase genes of mouse or rat origin

Description of Organisms: *Actinidia arguta*
(enclosed tubs with no reproductive
structures) modified

Containment: PC1

Category: A

Actinidia arguta (whole plants not
enclosed and/or with reproductive
structures) modified

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003862

Description of Organism: *Actinidia chinensis*
(enclosed tubs with no reproductive
structures)

Containment: PC1

Category: A

Actinidia chinensis (whole plants not
enclosed and/or with reproductive
structures)

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003863

Description of Organism: *Actinidia deliciosa*
(enclosed tubs with no reproductive
structures) modified

Containment: PC1

Category: A

Actinidia deliciosa (whole plants not
enclosed and/or with reproductive
structures) modified

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003864

Description of Organism: *Actinidia eriantha*
(enclosed tubs with no reproductive
structures) modified

Containment: PC1

Category: A

Actinidia eriantha (whole plants not
enclosed and/or with reproductive
structures) modified

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003865

Description of Organism: *Arabidopsis thaliana* (L.)
Heynh (1842) (enclosed tubs with no
reproductive structures) modified

Containment: PC1

Category: A

Arabidopsis thaliana (L.) Heynh (1842)
(whole plants not enclosed and/or with
reproductive structures) modified

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003867

Description of Organism: *Lycopersicon esculentum*
(enclosed tubs with no reproductive
structures) modified

Containment: PC1

Category: A

Lycopersicon esculentum (whole plants not
enclosed and/or with reproductive
structures) modified

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003869

Description of Organism: *Malus domestica*
(enclosed tubs with no reproductive
structures) modified

Containment: PC1

Category: A

Malus domestica (whole plants not
enclosed and/or with reproductive
structures) modified

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003870

Description of Organism: *Nicotiana benthamiana*
(enclosed tubs with no reproductive
structures) modified

Containment: PC1

Category: A

Nicotiana benthamiana (whole plants not
enclosed and/or with reproductive
structures) modified

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003871

Description of Organism: *Nicotiana tabacum*
(enclosed tubs with no reproductive
structures) modified Containment: PC1

Category: A

Nicotiana tabacum (whole plants not
enclosed and/or with reproductive
structures) modified Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003872

Description of Organism: *Petunia hybrida*
(enclosed tubs with no reproductive
structures) modified Containment: PC1

Category: A

Petunia hybrida (whole plants not enclosed
and/or with reproductive structures)
modified

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003873

Description of Organism: *Vaccinium angustifolium*
(enclosed tubs with no reproductive
structures) modified

Containment: PC1

Category: A

Vaccinium angustifolium (whole plants not
enclosed and/or with reproductive
structures) modified

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003874

Description of Organism: *Vaccinium ashei*
(enclosed tubs with no reproductive
structures) modified Containment: PC1

Category: A

Vaccinium ashei (whole plants not
enclosed and/or with reproductive
structures) modified

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003875

Description of Organism: *Vaccinium corybosum*
(enclosed tubs with no reproductive
structures) modified Containment: PC1

Category: A

Vaccinium corybosum (whole plants not
enclosed and/or with reproductive
structures) modified

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003876

Description of Organism: *Vaccinium macrocarpon*
(enclosed tubs with no reproductive
structures) modified

Containment: PC1

Category: A

Vaccinium macrocarpon (whole plants not
enclosed and/or with reproductive
structures) modified

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003877

Applicant: Landcare Research
New Zealand Limited

Institute Code: GMO05/HRA094

Application Code: GMD05063

Purpose: To isolate specific genes from New
Zealand saprobic fungi by transforming
Escherichia coli bacteria so these genes
can be further characterised through
DNA sequencing

Decision Notified: 15 July 2005

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

Escherichia coli (K12 and B strains) modified with:

pCR 4-TOPO and pCR 3.1 cloning vectors from Invitrogen. Donor DNA from New Zealand native saprobic fungi from families such as Ascomycota, Basidiomycota and Zygomycota

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003845

Applicant: Massey University

Institute Code: GMO05/MU003

Application Code: GMD05058

Purpose: To clone genes for indole-diterpene biosynthesis from *Penicillium* spp. into *Escherichia coli* to determine the gene organisation and sequence

Decision Notified: 26 May 2005

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

Escherichia coli (non-pathogenic strains) modified with non-conjugative vectors containing genomic DNA fragments coding for enzymes for indole-diterpene biosynthesis or cDNA of the same from *Penicillium graminicola*, *Penicillium janthinellum*, *Penicillium simplicissimum*, *Penicillium crustosum* and *Penicillium melinii*

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003841

BCH Number: 9904

Applicant: Massey University

Institute Code: GMO05/MU005

Application Code: GMD05059

Purpose: To study the function of genes involved in biomolecule biosynthesis and related to biofilm formation and stress tolerance. Update of GMO04/MU001

Decision Notified: 26 May 2005

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

Escherichia coli (K12 derivatives) modified with non-conjugative vectors containing standard reporter genes and *Pseudomonas aeruginosa* DNA encoding characterised genes for biomolecule biosynthesis relevant to biofilm formation and *Escherichia coli* (K12 derivatives) modified with replicative, conjugative vectors containing standard reporter genes and *Pseudomonas aeruginosa* DNA encoding characterised genes for biomolecule biosynthesis relevant to biofilm formation

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003833

BCH Number: 9909

Description of Organism: *Pseudomonas aeruginosa*

Pseudomonas aeruginosa (strain PA01) modified with non-replicative and replicative conjugative vectors containing standard reporter genes and *Pseudomonas aeruginosa* DNA encoding characterised genes for biomolecule biosynthesis relevant to biofilm formation. (Vectors will not carry resistance genes for antibiotics currently used for clinical or veterinary treatment of *Pseudomonas* infections)

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003834

BCH Number: 9910

Applicant: Massey University

Institute Code: GMO05/MU004

Application Code: GMD05065

Purpose: To establish functional complementation systems in *Schizosaccharomyces pombe*, *Saccharomyces cerevisiae* and *Aspergillus nidulans* for the analysis of fungal endophyte and *Penicillium* sp. genes required for environmental sensing, signalling and gene expression

Decision Notified: 01 July 2005

Description of Organisms: *Aspergillus nidulans*

Aspergillus nidulans modified with:
Episomal vectors containing genomic DNA fragments carrying genes involved in environmental sensing, signalling and gene expression or cDNA of the same from *Schizosaccharomyces pombe*, *Saccharomyces cerevisiae*, *Epichloe typhina*, *Epichloe festucae*, *Neotyphodium lolii*, *Penicillium paxilli* or *Aspergillus nidulans*, as well as luciferase (firefly), green fluorescent protein (jelly fish), β -galactosidase (*Escherichia coli lacZ*) and β -glucuronidase (*Escherichia coli GUS*) reporter genes

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003853

BCH Number: 9905

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

Escherichia coli (non-pathogenic strains) modified with non-conjugative vectors containing genomic DNA fragments carrying genes involved in environmental sensing, signalling and gene expression or cDNA of the same from *Schizosaccharomyces pombe*, *Saccharomyces cerevisiae*, *Epichloe typhina*, *Epichloe festucae*, *Neotyphodium lolii*, *Penicillium paxilli* or *Aspergillus nidulans*, as well as luciferase (firefly), green fluorescent protein (jelly fish), β -galactosidase (*Escherichia coli lacZ*) and β -glucuronidase (*Escherichia coli GUS*) reporter genes

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003854

BCH Number: 9906

Description of Organism: *Saccharomyces cerevisiae* Hansen 1883

Saccharomyces cerevisiae modified with:
Episomal vectors containing genomic DNA fragments carrying genes involved in environmental sensing, signalling and gene expression or cDNA of the same from *Schizosaccharomyces pombe*,

Saccharomyces cerevisiae, *Epichloe typhina*, *Epichloe festucae*, *Neotyphodium lolii*, *Penicillium paxilli* or *Aspergillus nidulans*, as well as luciferase (firefly), green fluorescent protein (jelly fish), β -galactosidase (*Escherichia coli lacZ*) and β -glucuronidase (*Escherichia coli GUS*) reporter genes

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003855

BCH Number: 9907

Description of Organism: *Schizosaccharomyces pombe*

Schizosaccharomyces pombe modified with:

Episomal or integration vectors containing genomic DNA fragments carrying genes involved in environmental sensing, signalling and gene expression or cDNA of the same from *Schizosaccharomyces pombe*, *Saccharomyces cerevisiae*, *Epichloe typhina*, *Epichloe festucae*, *Neotyphodium lolii*, *Penicillium paxilli* or *Aspergillus nidulans*, as well as luciferase (firefly), green fluorescent protein (jelly fish), β -galactosidase (*Escherichia coli lacZ*) and β -glucuronidase (*Escherichia coli GUS*) reporter genes

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003856

BCH Number: 9908

Applicant: Massey University

Institute Code: GMO05/MU007

Application Code: GMD05068

Purpose: To determine organisation of the cytoskeleton in *Epichloe festucae* and *Neotyphodium lolii* grass endophytes by introducing constructs containing green fluorescent protein and domains from rat and human that preferentially label the cellular compartments

Decision Notified: 12 July 2005

Description of Organisms: *Epichloe festucae*

Epichloe festucae modified with:
Filamentous fungal vectors containing genomic DNA fragments or cDNA from *Escherichia coli*, *Aequorea victoria* (GFP), *Aspergillus nidulans* (fungal promoters and terminators), *Homo sapiens* (human talin domain), and *Rattus rattus* (rat 2,6-sialyl transferase domain)

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003859

BCH Number: 9911

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

Escherichia coli (non-pathogenic strains) modified with non-conjugative vectors containing genomic DNA fragments or cDNA from *Escherichia coli*, *Aequorea victoria* (GFP), *Aspergillus nidulans* (fungal promoters and terminators), *Homo sapiens* (human talin domain), and *Rattus rattus* (rat 2,6-sialyl transferase domain)

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003860

BCH Number: 9912

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Description of Organism: *Neotyphodium lolii*

Neotyphodium lolii modified with:
Filamentous fungal vectors containing genomic DNA fragments or cDNA from *Escherichia coli*, *Aequorea victoria* (GFP), *Aspergillus nidulans* (fungal promoters and terminators), *Homo sapiens* (human talin domain), and *Rattus rattus* (rat 2,6-sialyl transferase domain)

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003861

BCH Number: 9913

Applicant: Massey University

Institute Code: GMO05/MU001

Application Code: GMD05070

Purpose: To allow mutations associated with malignant hyperthermia in New Zealand families to be tested and confirmed as being causative of the disease

Decision Notified: 07 July 2005

Description of Organisms: *Cricetulus griseus*

Cricetulus griseus (cell lines) modified with:

Non-conjugative plasmid mammalian expression vectors containing human cDNA for the ryanodine receptor

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003849

BCH Number: 9901

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

Escherichia coli (non-pathogenic strains) modified with:

Non-conjugative plasmid cloning and expression vectors containing human cDNA for the ryanodine receptor

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003850

BCH Number: 9900

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Description of Organism: *Homo sapiens* (Linnaeus 1758)

Homo sapiens (cell lines) modified with:

Non-conjugative plasmid mammalian expression vectors containing human cDNA for the ryanodine receptor

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003851

BCH Number: 9902

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Description of Organism: *Mesocricetus auratus*

Mesocricetus auratus (cell lines)
modified with:

Non-conjugative plasmid mammalian
expression vectors containing human
cDNA for the ryanodine receptor

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003852

BCH Number: 9903

Applicant: Massey University

Institute Code: GMO05/MU002

Application Code: GMD05057

Purpose: To transform *Escherichia coli* with
recombinant plasmids containing the
control region of the mitochondrial
genome of the Antarctic silver fish,
Pleuragramma antarcticum, for
sequencing purposes

Decision Notified: 26 May 2005

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

Escherichia coli (non-pathogenic strains)
modified with non-conjugative cloning
vectors and mitochondrial DNA from
Pleuragramma antarcticum (Antarctic
silver fish)

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003840

BCH Number: 9899

Applicant: Massey University

Institute Code: GMO05/MU006

Application Code: GMD05067

Purpose: To determine in *Saccharomyces cerevisiae*
the effects of various genes on gene
transcription, translation and post-
translational modifications

Decision Notified: 14 July 2005

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

Escherichia coli (non-pathogenic strains)
modified with:

Viral or plasmid vectors for protein
expression and purification from
Escherichia coli, integrative and non-
integrative vectors to knock out or knock
in genes involved in transcriptional,
translational (protein biosynthesis) and
post-translational regulation sourced from
non-pathogenic micro-organisms; viruses,
such that the single genes or gene
constructs do not comprise more than two
thirds of the virus genome; are not
infectious (self-replicating); and are not
complemented to become infectious in any
organism or cell culture; animals
(excluding humans) and plants; also
includes gene regulatory elements, epitope
tags, reporter and selectable marker genes;
modifications shall exclude human DNA,
DNA from native flora or fauna, DNA
sourced from pathogenic organisms,
vertebrate toxin producing genes or
CITES-listed species

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003857

BCH Number: 9948

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Description of Organism: *Saccharomyces
cerevisiae* Hansen 1883

Saccharomyces cerevisiae modified with
integrative and non-integrative plasmid or
viral vectors to knock out or knock in
genes involved in transcriptional,
translational (protein biosynthesis) and
post-translational regulation sourced from
non-pathogenic micro-organisms; viruses,
such that the single genes or gene
constructs do not comprise more than two
thirds of the virus genome; are not
infectious (self-replicating); and are not
complemented to become infectious in any
organism or cell culture; animals
(excluding humans) and plants; also
includes gene regulatory elements, epitope
tags, reporter and selectable marker genes;
modifications shall exclude human DNA,
DNA from native flora or fauna, DNA
sourced from pathogenic organisms,
vertebrate toxin producing genes or
CITES-listed species

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003858

BCH Number: 9949

Applicant: University of Auckland

Institute Code: GMO05/UA009

Application Code: GMC05010

Purpose: To import category A genetically modified human cell lines for biomedical research

Decision Notified: 20 June 2005

Description of Organisms: *Homo sapiens* (Linnaeus 1758) cell lines

Homo sapiens (cell lines), excluding cell lines derived from persons of Māori descent and cell lines that contain infectious virus, as modified with standard cloning and expression vectors.

These vectors will include some or all of the classes of gene regulatory elements listed below:

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. Intron sequences
9. Ribosomal binding sites/kozak sequences
10. Other commercially available regulatory elements

These vectors may contain promoter, operator, and enhancer sequences and/or terminator sequences derived from bacterial, vertebrate or invertebrate genes, or from mammalian, insect or bacterial viruses. Genetic material shall not include:

1. Genes encoding vertebrate toxins with an oral or dermal LD50 of less than 100g/kg
2. Over-expression of vertebrate toxins (at levels higher than that occurring in

the organism from which they are derived) with an oral or dermal LD50 greater than or equal to 100g/kg

3. Sequences that will produce particles able to infect humans, animals, or plants
4. Uncharacterised sequences from pathogenic micro-organism
5. Sequences from New Zealand native fauna
6. Sequences derived directly from Māori
7. Sequences from CITES species without specific approval

Modified with cloning and expression vectors containing genomic DNA or cDNA from mammals (including humans) encoding genes involved in regulating mammalian growth, development, metabolism, homeostasis, control of cell division and reproduction.

Inserted constructs will also include:

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. Intron sequences
9. Ribosomal binding sites/kozak sequences
10. Other commercially available regulatory elements

This includes both sense and anti-sense constructs including nucleotide deletions and substitutions as well as RNA interference sequences

Excluding:

Genes encoding

- Vertebrate toxins
- Infectious particles or transducing sequences

Also excluding DNA derived from:

- New Zealand native flora or fauna

- DNA derived from Māori
- CITES species without specific approval

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMC001280

BCH Number: 9947

Applicant: University of Auckland

Institute Code: GMO05/UA010

Application Code: GMC05011

Purpose: To import selected strains of *Drosophila* with 'enhancer traps' (i.e. Standard reporter genes linked to promoters of developmental genes) to demonstrate the genetic control of development in teaching laboratories

Decision Notified: 15 July 2005

Description of Organisms: *Drosophila melanogaster*

Drosophila melanogaster modified by transgenic 'enhancer traps' inserted in-frame with developmental gene promoters including those for hedgehog, engrailed and decapentaplegic.

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMC001281

BCH Number: 9932

Applicant: University of Auckland

Institute Code: GMO05/UA017

Application Code: GMD05072

Purpose: Genetic analysis of gap function constituents

Decision Notified: 22 July 2005

The following approved organisms are modified with:

Modification:

1. Standard *Escherichia coli*, *Saccharomyces cerevisiae* and *Pichia pastoris* cloning and expression vectors, most of which are non-conjugative but definitely not self transmissible.

- Standard mammalian, chicken and insect cell expression vectors.

- Replication deficient AAV and retroviral viral vectors used to transform mammalian cell lines only. Note also that this approval is only to use the vectors obtained either commercially or from colleagues to transform cells and this is not an application to produce these vectors.

2. Genes sourced from man (*Homo sapiens*), mouse (*Mus musculus*, *Mus spretus*), rat (*Rattus norvegicus*, *Rattus rattus*) and chicken (*Gallus gallus*) (both sense and anti-sense constructs including nucleotide deletions and substitutions as well as RNA interference sequences) encoding:

- Molecules involved in cell-cell adhesion, development, patterning, with particular reference to tight junctions and sensory organs

To include genes encoding:

- Proteins involved in coagulation and its control
- Chaperone proteins and proteins involved in post-translational processing and protein folding
- Signalling molecules associated with development, patterning and cell-cell junctions
- Signal transduction molecules and receptors
- Anti-Apoptotic proteins
- Transcriptional factor proteins
- Proteins involved in translation
- Regulatory sequences
- Transcriptional and promoter elements associated with all of the above sets of gene families (with particular reference to proteins involved in glucose, protein and lipid metabolism)
- cDNA and genomic library inserts involved in regulating glucose, protein and lipid metabolism, not fitting into the above categories

To also include genetic elements encoding protein variants with deletions, multiple amino acid repeats or those proteins variants that may misfold.

To also include cDNA sequences encoding protein tags or fusion constructs (including fluorescent and reporter marker proteins) to determine transgene localisation or aid protein purification (including His tags, GFP, FLAG and GST fusion proteins and c-myc tags) (from a variety of sources including *Aqueora vitoria* and *Discoma* spp).

And sequences encoding enzymes for assay (e.g. thymidine kinase, U6 RNA polymerase)

Due to the nature of the study the following exceptions will apply:

- Genes will not encode toxins with an LD50 < 100µg/kg
- Sequences will not produce particles able to infect human, animals or plants
- Genes will not be derived from CITES derived species.

Human genes will not be derived from persons of Māori descent

Description of Organism: *Canis familiaris* (Linnaeus 1758) (cell lines) modified
Containment: PC1 with extra controls
Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003878

BCH Number: 9914

Description of Organism: *Cercopithecus aethiops* (cell lines) modified
Containment: PC1 with extra controls
Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003879

BCH Number: 9915

Description of Organism: *Cricetulus griseus* (cell lines) modified
Containment: PC1 with extra controls
Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003880

BCH Number: 9916

Description of Organism: *Cricetulus cricetus* (cell lines) modified
Containment: PC1 with extra controls
Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003881

BCH Number: 9917

Description of Organism: *Drosophila melanogaster* (cell lines) modified

Containment: PC1 with extra controls

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003882

BCH Number: 9918

Description of Organism: *Escherichia coli* (Migula 1895) Castellani & Chalmers 1919 (non pathogenic laboratory adapted, auxotrophic strains) modified

Containment: PC1 with extra controls

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003883

BCH Number: 9919

Description of Organism: *Gallus gallus* (cell lines) modified

Containment: PC1 with extra controls

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003884

BCH Number: 9920

Description of Organism: *Homo sapiens* (Linnaeus 1758) (cell lines) modified

Containment: PC1 with extra controls

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003885

BCH Number: 9921

Description of Organism: *Mesocricetus auratus* (cell lines) modified

Containment: PC1 with extra controls

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003886

BCH Number: 9922

Description of Organism: *Mus musculus* Linnaeus 1758 (cell lines) modified

Containment: PC1 with extra controls

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003887

BCH Number: 9923

Description of Organism: *Mus spretus* Latase (cell lines) modified

Containment: PC1 with extra controls

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003888

BCH Number: 9924

Description of Organism: *Pichia pastoris* (non pathogenic laboratory adapted strains) modified

Containment: PC1 with extra controls

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003889

BCH Number: 9925

Description of Organism: *Rattus norvegicus* (Berkenhout, 1796) (cell lines) modified

Containment: PC1 with extra controls

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003890

BCH Number: 9926

Description of Organism: *Rattus rattus* Linnaeus (cell lines) modified

Containment: PC1 with extra controls

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003891

BCH Number: 9927

Description of Organism: *Saccharomyces cerevisiae* Hansen 1883 (non pathogenic laboratory strains) modified

Containment: PC1 with extra controls

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003892

BCH Number: 9928

Description of Organism: *Spodoptera frugiperda* (cell lines) modified

Containment: PC1 with extra controls

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003893

BCH Number: 9929

Description of Organism: *Trichoplusia ni* (cell lines) modified

Containment: PC1 with extra controls

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003894

BCH Number: 9930

Applicant: University of Otago

Institute Code: GMO05/UO017

Application Code: GMD05060

Purpose: To assess whether baculoviruses can be used as an alternative to deliver differentiation-specific genes into stem cells derived from adult sheep

Decision Notified: 06 June 2005

Description of Organism: *Autographa californica nucleopolyhedrovirus*

Autographa californica nucleopolyhedrovirus (polyhedrin negative strains) modified with non-conjugative plasmids and baculovirus transfer vectors such as pAcUW51; reporter genes, human (non-Māori) and ovine DNA encoding growth factors

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003835

BCH Number: 9942

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

Escherichia coli (strain K12 and B derivatives) modified with non-conjugative plasmids and baculovirus transfer vectors such as pAcUW51; reporter genes, human (non-Māori) and ovine DNA encoding growth factors

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003836

BCH Number: 9943

Description of Organism: *Homo sapiens* (Linnaeus 1758)

Homo sapiens (cell lines) modified with non-conjugative plasmids and baculovirus transfer vectors such as pAcUW51; AcMNPV polyhedrin negative DNA; reporter genes, human (non-Māori) and ovine DNA encoding growth factors

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003837

BCH Number: 9944

Description of Organism: *Ovis aries*

Ovis aries (mesenchymal stem cells from adults) modified with non-conjugative plasmids and baculovirus transfer vectors such as pAcUW51; AcMNPV polyhedrin negative DNA; reporter genes, human (non-Māori) and ovine DNA encoding growth factors

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003838

BCH Number: 9945

Description of Organism: *Spodoptera frugiperda*

Spodoptera frugiperda (Sf-9 or Sf-21 cell lines or thier derivatives) modified with non-conjugative plasmids and baculovirus transfer vectors such as pAcUW51; AcMNPV polyhedrin negative DNA; reporter genes, human (non-Māori) and ovine DNA encoding growth factors

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD003839

BCH Number: 9946

Applicant: University of Otago

Institute Code: GMO05/UO018

Application Code: GMD05071

Purpose: To interbreed ERMA-approved strains of genetically modified laboratory mice to be used in a range of studies of gene or cell function and as models for human diseases

Decision Notified: 12 July 2005

Description of Organism: *Mus musculus* Linnaeus, 1758

Mus musculus, (genetically modified mouse strains imported / developed under ERMA approvals such as GMC03001) interbred to generate new strains of mice. No new vector or donor DNA will be used

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD003895

BCH Number: 9931

AMENDMENTS TO APPROVALS

Applicant: AgResearch Limited

Institute Code: GMO01/ARPN007s67A

Application Code: GMD01147

Purpose: Gene function determination in: plant development, floral regulation, stress physiology, pathogen resistance, pathogen response, fungal symbiotic relationships, secondary metabolite biosynthesis, lipid metabolism, carbohydrate biosynthesis, gene regulation

Decision Amendment Date: 17 June 2005

Amendment: To make a minor amendment to the decision to specify the genetic modification, to specify that the approval is limited to non-pathogenic strains of micro-organisms and to specify the appropriate containment standards for the organisms.

HAZARDOUS SUBSTANCES

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 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@erманz.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: Dow AgroSciences

Application Code: HSR05067

Purpose: To manufacture a pesticide GF-1744 for the sole purpose of export to another country

Date Publicly Notified: 08 July 2005

Date Submissions Close: 19 August 2005

**Applicant: CIBA Specialty Chemicals
New Zealand Limited**

Application Code: HSR05063

Purpose: To import and manufacture Irgazone 997, a novel, non-staining p-phenylene diamine (PPD) antioxidant, antiozonant and antifatigue agent for vulcanised rubber applications

Date Publicly Notified: 13 July 2005

Date Submissions Close: 24 August 2005

Applicant: Bomac Laboratories Limited

Application Code: HSR05074

Purpose: To manufacture and release for use a broad-spectrum wormer for the treatment and control of internal and external parasites in pigs

Date Publicly Notified: 29 July 2005

Date Submissions Close: 09 September 2005

Applicant: Jurox New Zealand Limited

Application Code: HSR05082

Purpose: To import and release for use an anthelmintic for use in cattle

Date Publicly Notified: 29 July 2005

Date Submissions Close: 09 September 2005

Applicant: Grace (New Zealand) Limited

Application Code: HSR05044

Purpose: To manufacture and import a concrete admixture for use in concrete structures

Date Publicly Notified: 29 July 2005

Date Submissions Close: 09 September 2005

NON-NOTIFIED APPLICATIONS RECEIVED

Applicant: BASF New Zealand

Application Code: HSC05014

Purpose: To import into containment, for field trials, the substance BNZ0605 to assess its efficacy and phytotoxicity

Date Formally Received: 30 June 2005

Applicant: Bayer New Zealand Limited

Application Code: HSC05015

Purpose: To field test the substance BCS005-05 to assess the efficacy and phytotoxicity

Date Formally Received: 08 July 2005

Applicant: Dow AgroSciences

Application Code: HSC05016

Purpose: To import into containment GF-1674 for the purpose of field testing to assess its ability to control weeds in crops

Date Formally Received: 13 July 2005

Applicant: Dow AgroSciences

Application Code: HSC05017

Purpose: To import into containment EF-1343 for the purpose of field testing to assess its ability to control weeds in crops

Date Formally Received: 13 July 2005

Applicant: Syngenta Crop Protection Limited

Application Code: HSC05018

Purpose: To import into containment a range of agrochemical adjuvants, for use in small scale contained field trials to provide information for development of selected fungicides in combination with these adjuvants

Date Formally Received: 14 July 2005

Applicant: Syngenta Crop Protection Limited

Application Code: HSC05019

Purpose: To import into containment fungicidal compounds of the chemical class of Heteroaromatic Amides (ARYAM) for use in small-scale contained field trials to provide information for development of these compounds

Date Formally Received: 14 July 2005

Applicant: Syngenta Crop Protection Limited

Application Code: HSC05020

Purpose: To import into containment fungicidal compounds of the chemical class of Heteroaromatic Amides (ARYAM) for use in small-scale contained field trials to provide information for development of these compounds

Date Formally Received: 14 July 2005

Applicant: Syngenta Crop Protection Limited

Application Code: HSC05021

Purpose: To import into containment fungicidal compounds of the chemical class of Biheterocyclic Amines (AMBI) formulated in a standard way. The intention is to conduct small-scale contained field trials to provide information for development of these compounds

Date Formally Received: 14 July 2005

Applicant: Syngenta Crop Protection Limited

Application Code: HSC05022

Purpose: To import into containment fungicidal compounds of the chemical class Biheterocyclic Amines (AMBI) formulated in the standard way. The intention is to conduct small-scale contained field trials to provide information for the development of these compounds

Date Formally Received: 14 July 2005

Applicant: Syngenta Crop Protection Limited

Application Code: HSC05023

Purpose: To import into containment fungicidal compounds of the chemical class Heterocyclic Amides (OPA) in different mixture formulations. The intention is to conduct small-scale contained field trials to provide information for development of these compounds

Date Formally Received: 14 July 2005

Applicant: Syngenta Crop Protection Limited

Application Code: HSC05024

Purpose: To import into containment fungicidal compounds of the chemical class Heterocyclic Amides (OPA) in different formulations. The intention is to conduct small-scale contained field trials to provide information for development of these compounds

Date Formally Received: 14 July 2005

Applicant: Syngenta Crop Protection Limited

Application Code: HSC05025

Purpose: To import into containment fungicidal compounds of the chemical class Heterocyclic Amides (OPA) in different formulations. The intention is to conduct small-scale contained field trials to provide information for the development of these compounds

Date Formally Received: 14 July 2005

Applicant: Novartis New Zealand Limited

Application Code: HSR05014

Purpose: To import two formulations, ANZ-04 and ANZ-11 as ready-to-use, spray-on ectoparasiticides containing an insect growth regulator (pyrimidine group), for use on sheep as a preventative against blowfly strike

Date Formally Received: 15 July 2005

Applicant: Syngenta Crop Protection Limited

Application Code: HSC05026

Purpose: To import into containment NZF4 to conduct field trials to evaluate whether the substance is suitable for use in New Zealand agriculture and horticulture and to provide data for a future application for approval for release

Date Formally Received: 19 July 2005

Applicant: Syngenta Crop Protection Limited

Application Code: HSC05027

Purpose: To import in containment fungicidal compounds of the chemical class Heterocyclic Amides (OPA) formulated in a standard way. The intention is to conduct small-scale contained field trials to provide information for development of these compounds

Date Formally Received: 22 July 2005

Applicant: Millennium Microbes Limited

Application Code: HSR05013

Purpose: To approve Vertikil and Vertiblast, biocides containing the fungi *Verticillium lecanii*

Date Formally Received: 12 July 2005

DECISIONS ON APPLICATIONS

Applicant: Dow AgroSciences

Application Code: HSR05031

Purpose: To import and release the formulated QUINTEC for use on crops for the control of powdery mildew

Decision Notified: 15 July 2005

Decision: Approved with Controls

Identifier for Substance: Quintec

Classification: 6.5B Skin Sensitisation, 6.9B Target Organ Toxicity, 9.1A Aquatic Ecotoxicity

ERMA Approval Code: HSR001671

Controls:

Control Code ⁶	Regulation ⁷	Explanation ⁸
Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Toxic Property Controls		
T1	11–27	Limiting exposure to Quintec
T4, E6	7	Requirements for equipment used to handle Quintec
T5	8	Requirements for protective clothing and equipment
T7	10	Restrictions on the carriage of hazardous substances on passenger service vehicles
Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Ecotoxic Property Controls		
E2	11–27	Restrictions on use within application area
E5	5(2), 6	Requirements for keeping records of use
Hazardous Substances (Packaging) Regulations 2001		
I1	6, 7, 32–35, 36 (1)–(7)	General identification requirements
I3	9	Priority identifiers for ecotoxic 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

⁶ 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 HSNO Control Regulations*.

⁷ 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.

⁸ These explanations are for guidance only. Refer to the cited Regulations for the formal specification, and for definitions and exemptions.

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
I28	46	Specific documentation requirements for toxic substances
I29	51–52	Duties of persons in charge of places with respect to signage
Hazardous Substances (Packaging) Regulations 2001		
P1	5, 6, 7 (1), 8	General packaging requirements
P3	9	Packaging requirements for substances packed in limited quantities
P15	21	Packaging requirements for Quintec
PG3	Schedule 3	This schedule describes the (minimum) packaging requirements that must be complied with for this substance. The tests in Schedule 3 correlate to the packaging requirements of UN Packing Group III (UN PGIII).
PS4	Schedule 4	This schedule describes the (minimum) packaging requirements that must be complied with for this substance.
Hazardous Substances (Disposal) Regulations 2001		
D4, D5	8,9	Disposal requirements for toxic 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
EM12	35–41	Level 3 emergency management requirements – secondary containment
EM13	42	Level 3 emergency management requirements – signage

Applicant: GE Infrastructure, Water and Process Technologies

Application Code: HSR05033

Purpose: To import Fuelsolv FMG2960, a fireside deposit and corrosion inhibitor for use in coal fired boilers

Decision Notified: 15 July 2005

Decision: Approved with Controls

Identifier for Substance: Fuelsolv FMG2960

Classification: 3.1D Flammable Liquid, 6.1E Acute Toxicant, 6.3B Skin Irritant, 6.4A Eye Irritant, 6.5B Skin Sensitiser, 6.7B Carcinogen, 6.9B Target Organ Systemic Toxicant, 9.1A Aquatic Ecotoxicant

ERMA Approval Code: HSR001670

Controls:

Control Code ⁹	Regulation ¹⁰	Explanation ¹¹
Hazardous Substances (Classes 1 to 5 Control Regulations) Regulations 2001 – Flammable Property Controls		
F6	60–70	Requirements to reduce the likelihood of unintended ignition of class 2.1.1, class 2.1.2 and class 3.1 substances
F11	76	Segregation of incompatible substances
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 hazardous substances
T5	8	Requirements for protective clothing and equipment
T7 and F2	10 and 8	Restrictions on the carriage of hazardous substances on passenger service vehicles
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
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

⁹ 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 HSNO Control Regulations*.

¹⁰ 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.

¹¹ These explanations are for guidance only. Refer to the cited Regulations for the formal specification, and for definitions and exemptions.

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
Hazardous Substances (Packaging) Regulations 2001		
P1	5, 6, 7 (1), 8	General packaging requirements
P3	9	Packaging requirements for substances packed in limited quantities
P15 and P13	21 and 19	Packaging requirements for Fuelsolv FMG2960
PG3	Schedule 3	This schedule describes the (minimum) packaging requirements that must be complied with for this substance when packaged in quantities of 5 L or more. The tests in Schedule 3 correlate to the packaging requirements of UN Packing Group III (UN PGIII).
PS4	Schedule 4	This schedule describes the (minimum) packaging requirements that must be complied with for this substance when packaged in quantities of less than 5 L.
Hazardous Substances (Disposal) Regulations 2001		
D2, D4, D5	6, 8, 9	Disposal requirements for Fuelsolv FMG2960
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
EM12	35–41	Level 3 emergency management requirements – secondary containment
EM13	42	Level 3 emergency management requirements – signage
Tank Wagon and Transportable Containers Controls		
<p>Regulations 4 to 43 were applicable</p> <p>The Hazardous Substance (Tank Wagons and Transportable Containers) Regulations 2004 prescribe a number of controls relating to tank wagons and transportable containers and must be complied with as relevant.</p>		

Section 77A Controls	
	<p>Fuelsolv FMG2960 shall not be used in domestic premises.</p> <p>The controls relating to stationary container systems and secondary containment, as set out in Schedules 8 and 9 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice (New Zealand Gazette Issue No 35, 26 March 2004, as amended by Issue No. 128, 1 October 2004, shall apply to this substance, notwithstanding clause 1(1) of those schedules.</p> <p>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, as amended by the New Zealand Gazette Notice of Friday, 1 October 2004, Issue Number 128, shall apply, as applicable, notwithstanding clause 1 of the schedule.</p>

Applicant: Taranaki Nuchem Limited

Application Code: HSR05039

Purpose: To import, manufacture and release Cobra™, an agricultural fungicide for the control of blights in potatoes

Decision Notified: 15 July 2005

Decision: Approved with Controls

Identifier for Substance: Cobra™

Classification: 6.1B Acute Toxicant, 6.3B Skin Irritant, 8.3A Eye Corrosive, 6.5B Skin Sensitiser, 6.7B Carcinogen, 6.9A Target Organ Systemic Toxicant, 9.1A Aquatic Ecotoxicant, 9.2B Soil Ecotoxicant, 9.3B Terrestrial Vertebrate Ecotoxicant

ERMA Approval Code: HSR001672

Controls:

Control Code ¹²	Regulation ¹³	Explanation ¹⁴
Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Toxic Property Controls		
T3 and E5	5, 6	Requirements for keeping records of use
T4 and E6	7	Requirements for equipment used to handle hazardous substances
T5	8	Requirements for protective clothing and equipment
T6 and E7	9	Approved handler requirements
T7	10	Restrictions on the carriage of hazardous substances on passenger service vehicles
Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Ecotoxic Property Controls		
E1	32–45	Limiting exposure to ecotoxic substances
E2	46–48	Restrictions on use within application area

12 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 HSNO Control Regulations*.

13 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.

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

Hazardous Substances (Packaging) Regulations 2001		
I1	6, 7, 32–35, 36 (1)–(7)	General identification requirements
I2	8	Priority identifiers for corrosive substances
I3	9	Priority identifiers for ecotoxic substances
I8	14	Priority identifiers for certain toxic substances
I9	18	Secondary identifiers for all hazardous substances
I10	19	Secondary identifiers for corrosive 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
I22	40	Specific documentation requirements for corrosive substances
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 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
P13, P14, P15	19, 20, 21	Packaging requirements for toxic substances
PG2	Schedule 2	This schedule describes the (minimum) packaging requirements that must be complied with for this substance. The tests in Schedule 2 correlate to the packaging requirements of UN Packing Group II (UN PGII).
PS4	Schedule 4	This schedule describes the (minimum) packaging requirements that must be complied with for this substance.
Hazardous Substances (Disposal) Regulations 2001		
D4, D5	8, 9	Disposal requirements for Cobra™
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
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 (Personal Qualifications) Regulations 2001		
AH1	4–6	Approved Handler requirements
Tank Wagon and Transportable Containers Controls		
Regulations 4 to 43 were applicable		
The Hazardous Substance (Tank Wagons and Transportable Containers) Regulations 2004 prescribe a number of controls relating to tank wagons and transportable containers.		

Applicant: Osmose New Zealand

Application Code: HSR05034

Purpose: To manufacture a timber preservative containing copper and didecyl dimethyl ammonium chloride for use in New Zealand and for export

Decision Notified: 22 July 2005

Decision: Approved with Controls

Identifier for Substance: ALKALINE COPPER QUAT

Classification: 6.1D Oral Toxicant, 6.1E Inhalational Toxicant, 6.5A Respiratory Sensitiser, 6.5B Skin Sensitiser, 6.8B Reproductive/Developmental Toxicant, 6.9B Target Organ Toxicant, 8.1A Metallic Corrosive, 8.2C Skin Corrosive, 8.3A Eye Corrosive, 9.1A Aquatic Eco-toxicant, 9.3C Terrestrial Vertebrate Eco-toxicant

ERMA Approval Code: HSR001674

Controls:

Control Code ¹⁵	Regulation ¹⁶	Explanation ¹⁷
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 hazardous substances
T5	8	Requirements for protective clothing and equipment
T7	10	Restrictions on the carriage of hazardous substances on passenger service vehicles
Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Ecotoxic Property Controls		
E2	32–45	Limiting exposure to ecotoxic substances
Hazardous Substances (Identification) Regulations 2001		
I1	6, 7, 32–35, 36 (1)–(7)	General identification requirements
I2	8	Priority identifiers for corrosive substances
I3	9	Priority identifiers for ecotoxic substances
I8	14	Priority identifiers for certain toxic substances
I9	18	Secondary identifiers for all hazardous substances
I10	19	Secondary identifiers for corrosive substances
I11	20	Secondary identifiers for ecotoxic substances
I16	25	Secondary identifiers for toxic substances
I29	51-52	Duties of persons in charge of places with respect to signage
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
I28	46	Specific documentation requirements for toxic substances

15 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 HSNO Control Regulations*.

16 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.

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

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
P13, P14, P15	19, 20, 21	Packaging requirements for Alkaline Copper Quat
PG3	Schedule 3	This schedule describes the (minimum) packaging requirements that must be complied with for this substance when packaged in quantities of more than 1 L. The tests in Schedule 3 correlate to the packaging requirements of UN Packing Group III (UN PGIII).
PS4	Schedule 4	This schedule describes the (minimum) packaging requirements that may be complied with for this substance when packaged in quantities equal to or less than 1 L.
Hazardous Substances (Disposal) Regulations 2001		
D4, D5	8, 9	Disposal requirements for Alkaline Copper Quat
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
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

Tank Wagon and Transportable Containers Controls

The Hazardous Substance (Tank Wagons and Transportable Containers) Regulations 2004 prescribe a number of controls relating to tank wagons and transportable containers.

Section 77A Controls

Alkaline Copper Quat shall only be used as an agent in the preservation treatment of timber at industrial sites.

The controls relating to stationary container systems and secondary containment, as set out in Schedules 8 and 9 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice (New Zealand Gazette Issue No. 35, 25 March 2004, Issue Number 35, as amended by Issue No. 128, 1 October 2004), shall apply to this substance, notwithstanding clause 1(1) of those schedules.

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: HaS Expertise Limited

Application Code: HSR05062

Purpose: To obtain approval for the importation of J69.01 for use as a cross-linker in the powder coating industry

Decision Notified: 08 July 2005

Decision: Approved with Controls

Identifier for Substance: J69.01

Classification: 6.4A eye irritant

ERMA Approval Code: HSR001668

Controls:

Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Toxic Property Controls		
T4	7	Requirements for equipment used to handle hazardous substances
T7	10	Restrictions on the carriage of hazardous substances on passenger service vehicles
Hazardous Substances (Identification) Regulations 2001		
I1	6, 7, 32–35, 36 (1)–(7)	General identification requirements
I9	18	Secondary identifiers for all hazardous substances
I16	25	Secondary identifiers for toxic substances
I19	29–31	Alternative information in certain cases
I21	37–39, 47–50	Documentation required in places of work

I28	46	Specific documentation requirements for 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 substances
PS4	Schedule 4	This schedule describes the (minimum) packaging requirements that must be complied with for this substance.
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
EM8	12–16, 18–20	Level 2 emergency management information requirements

Applicant: Dow AgroSciences

Application Code: HSR05068

Purpose: To import for release a fungicidal formulation for the control of powdery mildew on grapes

Decision Notified: 11 July 2005

Decision: Approved with Controls

Identifier for Substance: Systhane 200 EW

Classification: 6.1E Acute toxicant, 6.3B Mild skin irritant, 6.4A Eye irritant, 6.8B Reproductive/developmental toxicant, 6.9B Target organ toxicant, 9.1B Aquatic toxicant, 9.2D Soil toxicant, 9.3C Terrestrial vertebrate toxicant

ERMA Approval Code: HSR001667

Controls:

Control Code¹⁸	Regulation¹⁹	Explanation²⁰
Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Toxic Property Controls		
T1	11–27	Limiting exposure to toxic substances
T2	29, 30	Controlling exposure in places of work
T4, E6	7	Requirements for equipment used to handle hazardous substances
T5	8	Requirements for protective clothing and equipment
T7	10	Restrictions on the carriage of Systhane 200 EW on passenger service vehicles
Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Ecotoxic Property Controls		
E1	32–45	Limiting exposure to ecotoxic substances
E2	46–48	Restrictions on use within application area
Hazardous Substances (Identification) Regulations 2001		
I1	6, 7, 32–35, 36 (1)–(7)	General identification requirements
I3	9	Priority identifiers for ecotoxic substances
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
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 (Identification) Regulations 2001		
D4, D5	8, 9	Disposal requirements for toxic substances

18 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 HSNO Control Regulations*.

19 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.

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

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
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		
Regulations 4 to 43 where applicable		
Additional Controls under section 77A		
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.		

Applicant: Bayer New Zealand Limited

Application Code: HSC05012

Purpose: To field test the substance BCS002-05 to assess the efficacy under New Zealand conditions

Decision Notified: 13 July 2005

Decision: Approved with Controls

Identifier for Substance: BCS002-05

ERMA Approval Code: HSC000158

Controls:

- 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.
- Notwithstanding the requirements of control 1 above, the trials shall also comply with the following controls:
 - The trials shall 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 location as per control 22.
 - The trial sites shall be chosen so as to prevent the substance entering any surface water or groundwater system.
 - The trial sites shall be located to prevent any building where people live or work being exposed to the substance.
 - Access to the trial sites shall be by permission of the Trial Director²¹ 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 unauthorized access is not allowed, that the site is subject to a trial, and that the crops should not be removed or disturbed.

²¹ 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.

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 NZS8409:2004.
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 NZS8409:2004.
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 Safety Data Sheet 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 NZS8409:2004. 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 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 triple rinsed after use with an 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 Limited in original containers for secure storage in an exempt laboratory, or disposed of via an external commercial incineration company, (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 2001.
21. Information on appropriate safety precautions necessary to provide safeguards against the substance's toxic and 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 and 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	BCS002-05
ERMA Application number	HSC05012
ERMA Approval number	HSC00158
ERMA Applications Advisor	Emma Doust

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 BCS002-05 that shall be imported under this approval is 6 L.

Applicant: Connovation Limited

Application Code: HSR05072

Purpose: To manufacture Feratox 500 g/kg for use in the control of possums

Decision Notified: 18 July 2005

Decision: Approved with Controls

Identifier for Substance: Feratox® 500 g/kg

Classification: 6.1B Acute Toxicant, 6.3B Skin Irritant, 6.4A Eye Irritant, 6.5B Skin Sensitiser, 6.8B Reproductive/Developmental Toxicant, 6.9A Target Organ/Systemic Toxicant, 9.1A Aquatic Ecotoxicant, 9.2A Soil Ecotoxicant, 9.3A Terrestrial Vertebrate Ecotoxicant, 9.4A Terrestrial Invertebrate Ecotoxicant

ERMA Approval Code: HSR001673

Controls:

Control Code ²²	Regulation ²³	Explanation ²⁴
Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Toxic Property Controls		
T1	11–27	Limiting exposure to Feratox® 500 g/kg
T2	29, 30	Controlling exposure in places of work
T3, E5	5(1), 6, 5(2), 6	Requirements for keeping records of use
T4, E6	7	Requirements for equipment used to handle Feratox® 500 g/kg
T5	8	Requirements for protective clothing and equipment
T6, E7	9	Approved handler requirements
T7	10	Restrictions on the carriage of hazardous substances on passenger service vehicles
T8		Controls on Vertebrate Poisons

22 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 HSNO Control Regulations*.

23 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.

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

Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 – Ecotoxic Property Controls		
E1	32–45	Limiting exposure to Feratox® 500 g/kg
E2	46–48	Restrictions on use within application area
E3	49	Controls relating to protection of terrestrial invertebrates e.g. beneficial insects
E4	50–51	Controls relating to protection of terrestrial vertebrates
Hazardous Substances (Identification) Regulations 2001		
I1	6, 7, 32–35, 36 (1)–(7)	General identification requirements
I3	9	Priority identifiers for ecotoxic substances
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 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
P13, P15	19, 21	Packaging requirements for toxic substances
PG2	Schedule 2	This schedule describes the (minimum) packaging requirements that must be complied with for Feratox® 500 g/kg when packaged in quantities of more than 0.5 kg. The tests in Schedule 2 correlate to the packaging requirements of UN Packing Group II (UN PGII).

PS4	Schedule 4	This schedule describes the minimum packaging requirements that must be complied with for this substance when packaged in quantities equal to or less than 0.5 kg.
Hazardous Substances (Disposal) Regulations 2001		
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
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
Hazardous Substances (Tracking) Regulations 2001		
TR1	4(1), 5, 6	General tracking requirements
Section 77A Controls		
<p><i>The new controls relating to Vertebrate Toxic Agents, set out in Schedule 3 of the Hazardous Substances (Vertebrate Toxic Agents) Transfer Notice 2004, 29 October 2004, Issue Number 141, shall apply.</i></p> <p>The wording of the new controls given below may be different to that in the Hazardous Substances (Vertebrate Toxic Agents) Transfer Notice (New Zealand Gazette, Issue No. 141). This is because the controls in the transfer notice are written to apply to more than one substance at a time. For Feratox® 500 g/kg, the wording has been simplified to apply solely to this substance. Nonetheless, this simplification has not changed the meaning or the requirements as set out in the Vertebrate Toxic Agents Transfer Notice.</p>		

<p>Clause 2</p>	<p>Packaging of substances for sale for vertebrate pest control</p> <p>(1) No person may pack this substance for sale for vertebrate pest control unless the package is marked with a unique identifier.</p> <p>(2) The unique identifier marked on the container must comply with regulation 35 and regulation 36 of the Hazardous Substance (Identification) Regulations 2001.</p> <p>(3) For the purposes of regulation 35(3)(c) of those regulations, the unique identifier is a secondary identifier.</p> <p>(4) In this clause package means the smallest package in which the substance is sold.</p>
<p>Clause 3</p>	<p>Permissions required for application or use of certain substances</p> <p>(1) No person may apply or otherwise use this substance on land administered or managed by the Department of Conservation unless the person first obtains a permission from the Authority.</p> <p>(2) No person may apply or otherwise use this substance in a catchment area from which water is drawn for human consumption or in any other area where a risk to public health may be created if the substance is applied or used unless the person first obtains a permission from the Authority.</p> <p><i>Note: The ERMA Authority has delegated the giving of such a permission in the case of subclause (1) to the Department of Conservation (DOC), and, in the case of subclause (2) to the Ministry of Health. Persons wishing to apply this substance where a permission is required should contact the regional DOC office or the Ministry of Health.</i></p>
<p>Clause 4</p>	<p>Licences required for possession of certain substances</p> <p>(1) No person may possess this substance unless the person has a licence from the Authority that is obtained before the person takes possession of the substance.</p> <p>(2) Despite subclause (1), a person who does not have a licence may possess this substance if –</p> <p>(a) the person is under the immediate supervision of a person who has a licence in accordance with this clause; or</p> <p>(b) the person is deemed to comply with Regulation 9 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 by regulation 9A of those regulations (as inserted by Schedule 2 of the Vertebrate Toxic Agents Transfer Notice, which is reproduced in Part B of this document).</p> <p><i>Explanation: The licence referred to in subclause (1) is a Controlled Substances Licence. For information on how to obtain this licence contact a test certifier who can certify for Vertebrate Toxic Agents.</i></p>

<p>Clause 7</p>	<p>Lost, spilt, or unintended application of substance</p> <p>If this substance is applied other than in the intended application area, or is lost or spilt, the person who is in possession of the substance at the time that it was misapplied, lost, or spilt must report the nature and quantity of the substance within 24 hours of the substance being misapplied, lost, or spilt to–</p>
	<ul style="list-style-type: none"> (a) if a permission was granted in accordance with clause 3 (above) to apply or otherwise use the substance, the person who granted the permission; and (b) the officer in charge of the nearest police station to which the person has access; and (c) the nearest Medical Officer of Health or the Medical Officer of Health in whose region the substance was misapplied, lost, or spilt; and (d) each owner or occupier of land on which the substance may have been misapplied, lost, or spilt; and (e) the person on whose behalf the substance is being applied.
<p>Clause 8</p>	<p>Unauthorised persons to stay clear of application area of certain substances</p> <ul style="list-style-type: none"> (1) A person who is not lawfully assisting in the application or use of this substance must not remain in the vicinity of the application or use of the substance (as the case may be). (2) An enforcement officer may order a person who contravenes subclause (1) to immediately leave the area in which the substance is being applied or used.

Applicant: BASF New Zealand

Application Code: HSC05013

Purpose: To field test the substance BNZ0505 to assess the efficacy and phytotoxicity

Decision Notified: 28 July 2005

Decision: Approved with Controls

Identifier for Substance: BNZ0505

ERMA Approval Code: HSC000159

Controls:

1. The trials shall be undertaken in accordance with the Management Plan, which accompanied the application. Modifications of the 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, only if the applicant;
 - has permission from the owner of the land to carry out the trial; and
 - notifies ERMA New Zealand of the location 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 Director ²⁵ 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 trial sites shall be signed indicating that unauthorized access is not allowed, that the site is subject to a trial, and that the crops should not be removed or disturbed.
7. In any location where it is possible for grazing animals to access the trial site, 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 the Code of Practice for the Management of Agrichemicals NZS8409:2004.
9. The substance shall be mixed, diluted and prepared in any other way prior to application in accordance with the relevant sections of the Code of Practice for the Management of Agrichemicals NZS8409:2004.
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 Safety Data Sheet shall accompany each shipment.
11. The substance shall be transported in compliance with any relevant requirements of 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 the Code of Practice for the Management of Agrichemicals NZS8409:2004. 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 appropriate Growsafe certification or an Approved Handler qualification. They should also be aware of the Management Plan and the controls in place in order to adequately manage the substance.
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.

²⁵ 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.

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 BASF New Zealand Limited for secure storage in an exempt laboratory, exported or degraded to non-hazardous substances (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 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 (Classes 6, 8 and 9 Controls) Regulations 2001.
21. Information on appropriate safety precautions necessary to provide safeguards against the substance's toxic and ecotoxic properties shall accompany the substance at all stages of its lifecycle. Personal protective equipment shall be worn when handling the substance throughout the lifecycle.
22. Occupational Safety and 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	BNZ0505
ERMA Application number	HSC05013
ERMA Approval number	HSC00159
ERMA Applications Advisor	Emma Doust

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 the substance that shall be imported or manufactured under this approval is 6.0 litres.

AMENDMENTS TO APPROVALS

Applicant: Yates New Zealand Limited

Application Code: HSR05057

Purpose: To approve the import or manufacture of Yates Rose Gun, a ready-to-use liquid containing 0.1g/L taufluvinate and 0.05g/L myclobutanil for use as an all-purpose combination insecticide and fungicide spray for roses and ornamentals

Decision Amendment Date: 28 July 2005

Amendment: To amend a reference to an incorrect classification and amend the controls to those prescribed for a 9.1B classification

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: Wayne Mowbray

Region: Wellington

Decision: Approved with Limitations

Date of Approval: 14 July 2005

ERMA Approval Code: TST000127

Applicant: David Manktelow

Region: Hawkes Bay

Decision: Approved with Limitations

Date of Approval: 14 July 2005

ERMA Approval Code: TST000126

FEES AND CHARGES REVISION

The Fees and Charges Schedule has been reviewed (dated 1 August 2005). Changes relate mainly to containment applications, reduced fees for hazardous substance applications that meet the risk reduction criteria, and a fixed fee for auditing of delegated authority for new organisms. New fees were introduced for grounds for reassessment, applications for group standards, amendments of transfer notices for hazardous substances, and statutory determinations.

Copies of the Fees and Charges Schedule is available on our website

<http://www.ermanz.govt.nz/about/fees.asp>

POLICY UPDATE

Two new sections have been added to the policy document Interpretations and Explanations of Key Concepts (Protocol 3 series 2). These are entitled *Use of Ribonucleic Acid (RNA) Interference Technology* and *Development of a GMO and Use of antisense oligonucleotides and peptide nucleic acids (PNAs)*. The sections can be viewed in full through our website

<http://www.ermanz.govt.nz/resources/publications/pdfs/ER-PR-03-14.pdf>





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