

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY

THE BULLETIN

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

The applications in the Register are assigned codes. Once an application is received by ERMA New Zealand, a unique application code (3 letters and 5 digits) is allocated to the applications. An application can include more than one organism or substance. When a decision has been made a unique 6 digit approval code is assigned to each organism or substance approved. Organisms or substances that are declined are not allocated approval codes.

NEW ORGANISMS

NOTIFIED APPLICATIONS RECEIVED AND OPEN FOR SUBMISSIONS

There are no new organism applications which are currently open for submissions

SCHEDULED HEARINGS

Application Code: GMF03001

Applicant: New Zealand Institute for Crop and Food Research Limited

Purpose: To field test onions modified for tolerance to the herbicide glyphosate, and to evaluate their environmental impact; herbicide tolerance; agronomic performance; development as cultivars and equivalency to non-genetically modified onions

Date: Commencing on 3 November 2003

Location of Hearing: Christchurch Convention Centre, 86 Kilmore Street, Christchurch

NON-NOTIFIED APPLICATIONS RECEIVED

Application Code: GMD03062

Applicant: Canterbury Health Laboratories

Purpose: To create DNA standards for use in Real-time PCR assays to allow detection of pathogenic micro organisms (bacteria, viruses, fungi and parasites) in clinical samples

Date Application Received: 29 September 2003

Application Code: GMD03091

Applicant: University of Auckland

Purpose: To develop in containment recombinant retroviral vectors expressing genes that regulate mammalian cell growth. Vectors will be inserted into mammalian cells or the rodent brain to identify the mechanisms that regulate brain cell formation and survival

Date Application Received: 8 September 2003

Application Code: GMD03096

Applicant: University of Auckland

Purpose: To develop in containment for use in biomedical research recombinant-adenovirus associated viral vectors and genetically modified rodents and mammalian cell lines expressing transgenes that have roles or potential roles in regulating mammalian cell growth

Date Application Received: 9 September 2003

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

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ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



DECISIONS ON APPLICATIONS

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

The decision with the summarised organism descriptions and controls was published in the last issue of *Bulletin* (Issue 47). Below is the complete description as per Annex 1 in the decision. The controls are listed again here for ease of use.

Application Code: GMC03001

Applicant: The University of Otago, Genesis Research and Development Corporation and Malaghan Institute of Medical Research

Purpose: A generic application to allow for importation of laboratory mice with specific genetic modifications to be used in a range of studies of gene or cell function and as models for human diseases

Formally Received: 4 February 2003

Decision Notified: 20 August 2003

Description of Organisms:

1. Host organism

Mice (*Mus musculus* Linnaeus 1758; Family Muridae) strains, with genetic modifications that conform with the following:

The animals must be certified specific-pathogen-free and may be sourced from commercial farms, research institutes or private researchers, provided these sources carry out regular monitoring of known infectious agents.

2. Inserted construct

The strains of mice may be modified with vectors containing the following, whose introduction into the mice meet the requirements of Category A or B and do not meet Category C of the HSNO (Low Risk Genetic Modification Regulations) 1998¹:

a) Promoter, operator and other regulatory elements derived from bacterial, viral or mammalian genes. The regulatory elements used in the construction of the genetically modified mice shall be well characterised and their sequence and functions known.

b) Reporter genes (genes encoding easily assayed proteins) that do not produce proteins that are pathogenic or toxic in vertebrates (have an LD₅₀ less than 100µg/kg). The reporter genes used in the construction of the genetically modified mice shall be well characterised and their sequence and functions known.

c) Selectable marker genes The selectable marker genes used in the construction of the genetically modified mice shall be well characterised and their sequence and functions known.

d) 'Other features' including:

- i. Polyadenylation signals;
- ii. Multiple cloning sites;
- iii. Splice sites;
- iv. Secretory and targeting signals;
- v. Ribosomal binding sites and/or Kozak sequences;
- vi. Homologous recombination sites and flanking sequences;
- vii. Regulatory sequences for induced expression;
- viii. Cre/Lox recombinase system;
- ix. Intron signals;
- x. Insulator elements.

3. Donor DNA

The donor genetic material shall be DNA and may be sourced from humans (provided that the human donor DNA shall not come from Māori), vertebrates or bacteria.

The donor DNA shall not include:

- a) Genes encoding vertebrate toxins that have an LD₅₀ of less than 100 µg/kg, or high level expression of vertebrate toxins with an LD₅₀ of more than 100 µg/kg.
- b) Sequences capable of giving rise to infectious particles pathogenic to humans, animals or plants.
- c) Known genes associated with the development of transmissible spongiform encephalopathies.
- d) Genetic sequences from any New Zealand native or endemic flora and fauna, or species valued by Māori that are sourced from New Zealand.
- e) Species listed by the Convention on International Trade in Endangered Species (CITES), except where accompanied by appropriate letters of approval from the relevant agencies in the exporting and importing countries.

4. Phenotypes

The genetically modified mice covered by this application shall conform to the following requirements:

- a) The genetically modified mice shall not demonstrate evidence of enhanced reproductive success or increased breeding capacity when compared to unmodified laboratory mice and in particular:

¹ The Committee recognised that the Hazardous Substances and New Organisms (Low Risk Genetic Modification) Regulations 1998 were revoked on the 31 July 2003 and replaced by the Hazardous Substances and New Organisms (Low Risk Genetic Modification) Regulations 2003. The Committee considered that as the majority of their consideration of this application was done under the 1998 Regulations that these would apply to this decision.

- i. There shall be no evidence of a higher number of viable offspring produced per litter when compared to the unmodified strain, nor any evidence to indicate that the modifications might lead to such an increase or;
- ii. There shall be no evidence of an increased number of viable litters produced per year when compared to the unmodified strain, nor any evidence to indicate that the modifications might lead to such an increase or;
- iii. There shall be no evidence of an extended age of reproduction when compared to the unmodified strain nor any evidence to indicate that the modifications might lead to such an increase, or;
- iv. There shall be no evidence of an increased number of viable and reproductively fit offspring when compared to the unmodified strain nor any evidence to indicate that the modifications might lead to such an increase.

b) The genetically modified mice shall not demonstrate evidence of enhanced ability to survive outside of the laboratory when compared to unmodified laboratory mice and in particular:

- i. There shall be no evidence of an increase in maximum life span nor any evidence to indicate that the modifications might lead to such an increase; or,
- ii. There shall be no evidence of a decreased susceptibility to disease, nor any evidence to indicate that the modifications might lead to such an decrease; or,
- iii. There shall be no evidence of enhanced survival in atypical environments (such as increase in their ability to tolerate extreme cold, wet, or dry environments) nor any evidence to indicate that the modifications might lead to such an increase; or,
- iv. There shall be no evidence to indicate that the dietary preferences of the genetically modified mice are significantly altered nor any evidence to indicate that the modifications might lead to such an alteration.

c) There shall be no evidence to indicate that the aggressiveness of the genetically modified mice is increased nor any evidence to indicate that the modifications might lead to such an increase.

d) The genetically modified mice do not produce recombinant infectious viral particles.

Decision: Approved with Controls

ERMA Approval Code: GMC001197

Controls:

In order to satisfactorily address the matters detailed in the Third Schedule Part I: Containment controls for importing, developing or field testing of genetically modified organisms² of the HSNO Act, and other matters in order to give effect to the purpose of the HSNO Act (section 45(2)), the Authority's approval of this application is subject to the following controls:

1. To limit the likelihood of any accidental release of any organism or any viable genetic material³:

- 1.1 The person responsible for a particular research area and/or the person responsible for the operation of the containment facility shall inform all personnel involved in handling the organisms of the Authority's controls.
- 1.2 The containment facility in which the organisms are maintained shall be in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.03 Containment Facilities for Vertebrate Laboratory Animals, at Physical Containment Level 2 (PC2), as defined in AS/NZS Standard 2243.3.2002, Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities or any subsequent equivalent updated standard.
- 1.3 The training of personnel working in the facility shall be in compliance with the standards listed in control 1.2.
- 1.4 The construction and operation of the containment facilities ('the facility') in which the organisms are maintained, shall be in accordance with the relevant standards listed in control 1.2 above.
- 1.5 The maximum number of genetically modified laboratory mice in the containment facilities shall not exceed the capacity of the facilities, and/or any requirements of the relevant Animal Ethics Committee.
- 1.6 Any person importing the genetically modified laboratory mice must ensure that ERMA New Zealand has a current copy of their containment manual.

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

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

- 1.7 The containment facility shall be maintained so as to prevent escape and/or unintended/accidental release of the genetically modified mice from the containment facility. Genetically modified laboratory mice shall not come in contact with other animals other than those involved in the experiments.
- 1.8 Construction and operation of the containment facility shall comply with the requirements of the standards listed in control 1.2 relating to the prevention of unintended release of the organisms by experimenters working with the organisms. All inlets and outlets to the containment facility shall be secured to prevent ingress and egress of animals to and from the containment facility.
- 2. To exclude unauthorised people from the facility:**
- 2.1 The identification of entrances, numbers of and access to entrances, and security requirements for the entrances and the facility shall be in compliance with the standards listed in control 1.2.
- 2.2 Only authorised persons shall have access to the containment facility.
- 2.3 To exclude other organisms from the facility and to control undesirable and unwanted organisms within the facility:
- 2.4 Construction and operation of the containment facility shall comply with the requirements of the standards listed in control 1.2 relating to the exclusion of other organisms from the facility and the control of undesirable and unwanted organisms within the facility.
- 3. To prevent the possible contamination of the environment by material produced:**
- 3.1 All biological material in the containment facility shall be unambiguously identified at all times. The genetically modified laboratory mice shall be transported in secure containment to the facility which shall be operated according to the appropriate Containment Manual, and in accordance with the Australian/New Zealand Standard AS/NZS 2243.3:2002 and with MAF Regulatory Authority Standard 154.03.03: Containment Facilities for Vertebrate Laboratory Animals. Transport of the genetically modified laboratory mice shall be in accordance with the requirements of the IATA Regulations.
- 3.2 The applicant shall maintain a register of all the genetically modified laboratory mice in the containment facility, including their fate.
- 3.3 Tissue samples from the genetically modified laboratory mice that are incapable of regenerating into a whole mouse shall be kept in a micro organism containment facility in accordance with the Australian/New Zealand Standard AS/NZS 2243.3:2002 and with MAF Regulatory Authority

Standard 154.03.02: Containment Facilities for Micro organisms, and maintained under a minimum of Physical Containment Level 1 (PC1).

- 3.4 All genetically modified laboratory mice no longer required for experiments and any object or material that is derived from a genetically modified laboratory mouse material shall be incinerated in accordance with MAF Regulatory Authority Standard 154.03.03: Containment Facilities for Vertebrate Laboratory Animals.
- 3.5 Standard import requirements under the Biosecurity Act will be adhered to during importation and quarantine testing of the genetically modified laboratory mice. Shipping materials will be labeled and destroyed as bio-hazardous materials by incineration.
- 4. To control the effects of any accidental release or escape of an organism:**
- 4.1 Construction and operation of the containment facility shall comply with the requirements of the standards listed in control 1.2 relating to controlling the effects of any accidental release or escape of an organism.
- 4.2 If for any reason a breach of containment occurs, the facility Supervisor, MAF Biosecurity Authority and ERMA New Zealand shall be notified immediately the event is noticed (and at least within 24 hours of the breach being detected).
- 4.3 In the event of any breach of containment of the organisms, the contingency plan for the attempted retrieval or destruction of any viable material of the organism that has escaped shall be implemented immediately. The contingency plan shall be included in the containment manual in accordance with the requirements of standards listed in control 1.2.
- 5. Inspection and monitoring requirements for containment facilities:**
- 5.1 The operation of the containment facilities shall comply with the requirements contained in the standards listed in control 1.2 relating to the inspection and monitoring requirements for containment facilities.
- 5.2 The Authority, or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time. To ensure that all mice are accounted for regular monitoring of mice shall be conducted in accordance with MAF Regulatory Authority Standard 154.03.03: Containment Facilities for Vertebrate Laboratory Animals with a full animal inventory at least monthly.
- 5.3 The containment manual shall be updated, as necessary, to address the implementation of the controls imposed by this approval, in accordance with the Standards listed in control 1.2.

6. Additional controls

- 6.1 Any person proposing to import any new strain of genetically modified laboratory mice must, before doing so, submit to the Chief Executive of ERMA New Zealand a written statement specifying: a unique identifier for the strain; a description of the genetic modification and information showing conformity with the organism description of this decision. The importer must obtain a written statement from ERMA New Zealand verifying conformity with the scope of this approval and provide this to MAF Biosecurity Authority when, or prior to, making an application to import any genetically modified laboratory mouse strain under this approval.
- 6.2 If any traits unexpectedly occur that fall outside of the organism description this shall be notified to ERMA New Zealand and MAF Biosecurity Authority immediately the trait becomes apparent.
- 6.3 This approval does not authorise the creation of new strains of mice. For example, the crossing of genetically modified laboratory mice with other genetically modified mice laboratory. If such crosses are to be made at some future date they will need to apply for either IBSC or ERMA New Zealand approval depending on their risk status.

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

Application Code: GMC03003

Applicant: Institute of Environmental Science and Research (ESR)

Purpose: Importation of *Acinetobacter calcoaceticus* BD413 (*chr::KGT*) (naturally rifampicin resistant) as a tool for research on horizontal transfer of genes from modified plants to soil bacteria

Formally Received: 7 July 2003

Decision Notified: 5 September 2003

Description of Organisms: *Acinetobacter calcoaceticus* BD413 (*chr::KGT*) Rp^r

The scope of the organism subject to the approval is limited to *Acinetobacter calcoaceticus* BD413 (*chr::KGT*) Rp^r where the bacterial chromosome was stably transformed with the gene cassette KTG. This cassette contains the *nptII* gene (conferring kanamycin resistance), the *aadB* gene (conferring gentamicin resistance at very low levels, if at all) and a partial, and therefore

non-expressed, *cryIVB* gene (a delta endotoxin from *Bacillus thuringiensis* var. *morrisoni*).

Decision: Approved with Controls

ERMA Approval Code: GMC001197

Controls:

In order to satisfactorily address the matters detailed in the Third Schedule Part I: Containment controls for importing, developing or field testing of genetically modified organisms⁴ of the HSNO Act, and other matters in order to give effect to the purpose of the HSNO Act (section 45(2)), the Authority's approval of this application is subject to the following controls:

1. To limit the likelihood of any accidental release of any organism or any viable genetic material⁵:

- 1.1 The person responsible for a particular research area and/or the person responsible for the operation of the containment facility shall inform all personnel involved in the handling of the organisms of the Authority's controls.
- 1.2 The containment facility in which the organisms are maintained shall be registered by the Ministry of Agriculture and Forestry (MAF) Biosecurity Authority in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02: Containment facilities for Microorganisms at Physical Containment Level: 2 (PC2) as defined in AS/NZS Standard 2243.3.2002: Safety in Laboratories, Part 3: Microbiological aspects and containment facilities.
- 1.3 The construction and operation of the containment facilities ('the facility') in which the organisms are maintained, shall be in accordance with the relevant standards listed in 1.2 above.

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 1.2 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 1.2 relating to the exclusion of other organisms from the facility and the control of undesirable and unwanted organisms within the facility.

⁴ Bold headings refer to Matters to be Addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms, specified in the Third Schedule of the HSNO Act 1996.

⁵ Viable Genetic Material is biological material that can be resuscitated to grow into tissues or organisms. It can be defined to mean biological material capable of growth even though resuscitation procedures may be required, eg when organisms or parts thereof are sublethally damaged by being frozen, dried, heated, or affected by chemical.

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

- 4.1 Construction and operation of the containment facility shall comply with the requirements of the standards listed in control 1.2 relating to the prevention of unintended release of the organisms by experimenters working with the organisms.

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

- 5.1 Construction and operation of the containment facility shall comply with the requirements of the standards listed in control 1.2 relating to controlling the effects of any accidental release or escape of an organism.
- 5.2 If for any reason a breach of containment occurs, the facility Supervisor⁶, MAF Biosecurity Authority and ERMA New Zealand shall be notified immediately the event is noticed (and at least within 24 hours of the breach being detected).
- 5.3 In the event of any breach of containment of the organisms, the contingency plan for the attempted retrieval or destruction of any viable material of the organism that has escaped shall be implemented immediately. The contingency plan shall be included in the containment manual in accordance with the requirements of standards listed in control 1.2.

6. Inspection and monitoring requirements for containment facilities:

- 6.1 The operation of the containment facilities shall comply with the requirements contained in the standards listed in control 1.2 relating to the inspection and monitoring requirements for containment facilities.
- 6.2 The Authority, or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.
- 6.3 The containment manual shall be updated, as necessary, to address the implementation of the controls imposed by this approval, in accordance with MAF/ERMA New Zealand Standards listed in control 1.2.

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

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

DELEGATED AUTHORITY

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

Application Code: GMD03090

Applicant: Fonterra Research

Purpose: Small-scale experiments using non-pathogenic *Escherichia coli*, dairy lactic acid bacteria or yeast strains modified with selected fruit flavour enzymes to test if these enzymes can act on dairy substrates to produce novel and desirable flavours

Formally Received: 4 September 2003

Decision Notified: 18 September 2003

Description of Organisms:

1. *Escherichia coli* strain K12 or B derivatives
2. *Saccharomyces cerevisiae*
3. *Pichia pastoris*
4. *Lactococcus lactis*
5. *Lactobacillus brevis*
6. *Lactobacillus bulgaricus*
7. *Lactobacillus casei*
8. *Lactobacillus fermentum*
9. *Lactobacillus helveticus*
10. *Lactobacillus johnsonii*
11. *Lactobacillus lactis*
12. *Lactobacillus plantarum*
13. *Lactobacillus rhamnexus*
14. *Lactobacillus paracasei*
15. *Lactobacillus acidophilus*

as modified by:

1. non-conjugative plasmid vectors containing DNA from species within the genera *Malus* (including apple), *Actinidia* (including kiwifruit), *Vaccinium* (including blueberry) and *Arabidopsis* (wildcress), and excluding any species native to New Zealand or subject to CITES and excluding any genes known to encode toxins for vertebrates;
2. selectable antibiotic resistance marker genes;
3. origins of replication derived from bacterial or yeast plasmids;
4. promoters/terminators or other short DNA sequences that modify transcription or translation sourced from bacteriophages, yeast or bacteria;
5. Bacterial transposons excluding any genes known to encode toxins for vertebrates;

⁶ An Inspector appointed under the Biosecurity Act

6. DNA sequences that encode for the anchoring of proteins to cell surfaces or secretion of proteins outside the cell.

Decision: Approved with Controls

ERMA Approval Code: GMD002782 — GMD002796

Controls:

In order to provide for the matters detailed in Part 1 of the Third Schedule of the HSNO Act, Containment controls for importation, development and field testing of genetically modified organisms⁷, the approved organisms are subject to the following controls:

1. To limit the likelihood of any accidental release of any organism or any viable genetic material⁸:

- 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 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 154.03.02⁹: Containment Facilities for Micro organisms, at laboratory Physical Containment Level 1 (PC1) for organisms with category A genetic modifications or Physical Containment Level 2 (PC2) for organisms with a category B genetic modifications.
 - b) Australian New Zealand Standard AS/NZS 2243.3:2002 Safety in Laboratories: Part 3: Microbiological aspects of containment and facilities.
- 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 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 containment occurs, the facility Supervisor¹⁰, MAF Biosecurity Authority and ERMA New Zealand shall be notified immediately the event is noticed (and at least within 24 hours of the breach being detected)
- 5.3 In the event of any breach of containment of the organism, the contingency plan for the attempted retrieval or destruction of any viable material of the organisms that have escaped shall be implemented immediately. The contingency plan shall be included in the containment manual in accordance with the requirements of standards listed in 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 Bold headings refer to Matters to be Addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms, specified in the Third Schedule of the HSNO Act 1996.

⁸ Viable Genetic Material is biological material that can be resuscitated to grow into tissues or organisms. It can be defined to mean biological material capable of growth even though resuscitation procedures may be required, e.g. when organisms or parts thereof are sublethally damaged by being frozen, dried, heated, or affected by chemical.

⁹ Any equivalent updated standard as endorsed by MAF Biosecurity Authority

¹⁰ An Inspector appointed under the Biosecurity Act

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.

8. Additional control:

8.1 No products or cultures containing genetically modified organisms or material shall be tasted or consumed (ie eaten) by any person.

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

Applicant: University of Otago

Application Code: GMD03092

Purpose: To investigate the function of genes from the baculoviruses and tetraviruses, allowing the investigation of how these genes might affect the interaction between a virus and its host
Update of GMO00/UO011

Formally Received: 18 July 2003

Decision Notified: 5 August 2003

Organism Unique Identifier and Institute Code:
Autographica californica (GMO03/UO013)

Description of Organism: *Autographica californica* (Nucleopolyhedrovirus (AcMNPV) polyhedrin-minus strains) modified with non-conjugative fusion protein expression plasmids; RdRp cDNAs from: Human poliovirus (Genus Enterovirus; Family Picornaviridae), *Nudaurelia capensis* beta virus, *Thosea asigna* virus, *Euprosterina elaeasa* virus, *Nudaurelia capensis* virus, *Heliocoverpa* (Heliothis) stunt virus, Providence virus

Containment: PC1

Decision: Approved with Controls

ERMA Approval Code: GMD002797

Organism Unique Identifier and Institute Code:
Escherichia coli (Migula 1895) Castellani and Chalmers 1919 (GMO03/UO013)

Description of Organism: *Escherichia coli* (strain K12 derivatives) modified with non-conjugative fusion protein expression plasmids; RdRp cDNAs from: Human poliovirus (Genus Enterovirus; Family Picornaviridae), *Nudaurelia capensis* beta virus, *Thosea asigna* virus, *Euprosterina elaeasa* virus, *Nudaurelia capensis* virus, *Heliocoverpa* (Heliothis) stunt virus, Providence virus

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD002798

Applicant: University of Otago

Application Code: GMD03093

Purpose: To study genome structure variation and gene expression in New Zealand native coralline algae
Update of GMO99/UO007

Formally Received: 11 August 2003

Decision Notified: 29 August 2003

Organism Unique Identifier and Institute Code:
Escherichia coli (Migula 1895) Castellani and Chalmers 1919 (GMO03/UO009)

Description of Organism: *Escherichia coli* (strain K12 or B derivatives) modified with non-conjugative plasmids; DNA from coralline algae (order: *Corallinales*)

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD002778

Application Code: GMD03094

Purpose: To modify the *ccpA* gene of the *Streptococcus equi* subsp. *zooepidemicus* in order to study the expression of Zif and ZooA
Update of GMO02/UO036

Formally Received: 22 August 2003

Decision Notified: 29 August 2003

Organism Unique Identifier and Institute Code:
Escherichia coli (Migula 1895) Castellani and Chalmers 1919 (GMO03/UO021)

Description of Organism: *Escherichia coli* (strain K12 derivatives) modified with non-conjugative plasmids such as pWV01-Ts derivatives and pJRS233; DNA fragments from the *ccpA* region of the *Streptococcus equi* subsp. *Zooepidemicus* genome, and erythromycin gene from pVA388

Containment: PC1

Decision: Approved with Controls

ERMA Approval Code: GMD002776

Description of Organism: *Streptococcus equi* subsp. *Zooepidemicus* modified with non-conjugative plasmids such as pWV01-Ts derivatives and pJRS233; erythromycin gene from pVA388

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD002777

Applicant: University of Auckland

Application Code: GMD03095

Purpose: To develop Gene function studies and therapeutic strategies for Type 1 diabetes

Formally Received: 2 September 2003

Decision Notified: 4 September 2003

Organism Unique Identifier and Institute Code:
Escherichia coli (Migula 1895) Castellani and Chalmers 1919 (GMO03/UA022)

Description of Organism: *Escherichia coli* (K12 and B conjugative strains) as modified by non-conjugative cloning plasmids and retroviral plasmids (pMSCV and pEQPAM3) with human (*Homo sapiens*), rat (*Rattus rattus*, *Rattus norvegicus*) and mouse (*Mus musculus*) genes encoding:

- a. T cell Receptors
- b. GM-CSF, G-CSF and related cytokines
- c. Interleukins
- d. Luciferase, beta galactosidase and fluorescent reporter genes from Jellyfish (*Aequoria victoria*) sea pansy (*Renilla reniformis*) and (*Discosoma* spp)
- e. Mouse (*Mus musculus*) PGK promoter, IRES and 2A elements

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD002779

Organism Unique Identifier and Institute Code:
Homo sapiens cell lines (GMO03/UA022)

Description of Organism: *Homo sapiens* cell lines as modified by non-conjugative cloning plasmids and retroviral plasmids (pMSCV and pEQPAM3) with human (*Homo sapiens*), rat (*Rattus rattus*, *rattus norvegicus*) and mouse (*Mus musculus*) genes encoding:

- a. T cell Receptors
- b. GM-CSF, G-CSF and related cytokines
- c. Interleukins
- d. Luciferase, beta galactosidase and fluorescent reporter genes from Jellyfish

(*Aequoria victoria*) sea pansy (*Renilla reniformis*) and (*Discosoma* spp)

e. Mouse (*Mus musculus*) PGK promoter, IRES and 2A elements

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD002780

Organism Unique Identifier and Institute Code:
Mus musculus (Linnaeus 1758)
(GMO03/UA022)

Description of Organism: *Mus musculus* cell lines as modified by non-conjugative cloning plasmids and retroviral plasmids (pMSCV and pEQPAM3) with human (*Homo sapiens*), rat (*Rattus rattus*, *rattus norvegicus*) and mouse (*Mus musculus*) genes encoding:

- a. T cell Receptors
- b. GM-CSF, G-CSF and related cytokines
- c. Interleukins
- d. Luciferase, beta galactosidase and fluorescent reporter genes from Jellyfish (*Aequoria victoria*) sea pansy (*Renilla reniformis*) and (*Discosoma* spp)
- e. Mouse (*Mus musculus*) PGK promoter, IRES and 2A elements

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD002781

Applicant: University of Otago

Application Code: GMD03098

Purpose: To develop strains of *Pseudomonas*, *Rhizobium*, *Terrabacter* and *Rhodococcus* species which are able to degrade the environmental pollutant biphenyl using the bph operon from *Terrabacter* sp. Strain DDE-1

Formally Received: 22 August 2003

Decision Notified: 8 September 2003

Organism Unique Identifier and Institute Code:
Pseudomonas aeruginosa (GMO03/UO015)

Description of Organism: *Pseudomonas aeruginosa* modified with non-conjugative plasmid; *Terrabacter bph* operon

Containment: PC2

Category: B

Decision: Approved with Controls

ERMA Approval Code: GMD002802

Organism Unique Identifier and Institute Code:
Pseudomonas fluorescens (GMO03/UO015)

Description of Organism: *Pseudomonas fluorescens*
modified with non-conjugative plasmid;
Terrabacter bph operon
Containment: PC1
Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD002803

Organism Unique Identifier and Institute Code:
Pseudomonas putida (GMO03/UO015)

Description of Organism: *Pseudomonas putida*
modified with non-conjugative plasmid;
Terrabacter bph operon
Containment: PC1
Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD002804

Organism Unique Identifier and Institute Code:
Rhodococcus erythropolis (GMO03/UO015)

Description of Organism: *Rhodococcus erythropolis*
modified with non-conjugative plasmid;
Terrabacter bph operon
Containment: PC1
Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD002805

Organism Unique Identifier and Institute Code:
Sinorhizobium meliloti (GMO03/UO015)

Description of Organism: *Sinorhizobium meliloti*
modified with non-conjugative plasmid;
Terrabacter bph operon
Containment: PC1
Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD002806

Organism Unique Identifier and Institute Code:
Terrabacter species (GMO03/UO015)

Description of Organism: *Terrabacter* species
modified with non-conjugative plasmid;
Terrabacter bph operon
Containment: PC1
Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD002807

Applicant: University of Auckland

Application Code: GMD03100

Purpose: To identify genetic determinants of
ecological performance in *Pseudomonas*
fluorescens and *Pseudomonas putida*

Formally Received: 5 July 2003

Decision Notified: 22 September 2003

Organism Unique Identifier and Institute Code:
Escherichia coli (Migula 1895) Castellani
and Chalmers 1919 (GMO03/UA016)

Description of Organism: *Escherichia coli*
(conjugative strains) as modified by non-
conjugative vectors including nonconjugative
transposon vectors carrying transposon Tn5,
Tn10 and ISphoA/hah) and fragments of
genomic DNA from *Pseudomonas*
fluorescens (strain SBW 25) and
Pseudomonas putida (strain KT2440)
Containment: PC1
Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD002799

Organism Unique Identifier and Institute Code:
Pseudomonas fluorescens (GMO03/UA016)

Description of Organism: *Pseudomonas fluorescens*
(strain SBW 25) as modified by non-
conjugative vectors including nonconjugative
transposon vectors carrying transposon Tn5,
Tn10 and ISphoA/hah) and fragments of
genomic DNA from *Pseudomonas*
fluorescens (strain SBW 25) and
Pseudomonas putida (strain KT2440)
Containment: PC1
Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD002800

Description of Organism: *Pseudomonas putida* (strain KT2440) as modified by non-conjugative vectors including non-cojugative transposon vectors carrying transposon Tn5, Tn10 and ISphoA/hah) and fragments of genomic DNA from *Pseudomonas fluorescens* (strain SBW 25) and *Pseudomonas putida* (strain KT2440)

Containment: PC1

Category: A

Decision: Approved with Controls

ERMA Approval Code: GMD00280

Amendment:

The amendment relates to adding Malaghan Institute of Medical Research as an applicant as was originally intended

AMENDMENTS TO APPROVALS

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

The following amendment to an approval was made by the Authority on 13 August 2003

Application code: GMD02078

Applicant: Genesis Research and Development Corporation Limited

Purpose: To develop in containment Tobacco mosaic virus, Narcissus mosaic virus, Rye grass mosaic virus, Watermelon mosaic virus, Tamarillo mosaic virus, Zucchini yellow mosaic virus and Tobacco rattle virus vectors to aid assignment of plant gene function

ERMA Approval Code: GMD002585 — GMD002608

Original Control:

2.4 Genes that provide resistance to antibiotics vancomycin and penicillin shall not be used.

Amended Control:

2.4 The applicant shall only use selectable marker genes that confer resistance to any of the following agents: ampicillin, tetracyclin, spectinomycin, chloramphenicol, streptomycin, kanamycin, hygromycin and glufosinate ammonium.

The following amendment to an approval was made by the Authority on 15 September 2003

Application Code: GMD00006

Applicants: Otago University and Malaghan Institute of Medical Research

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

ERMA Approval Code: GMD000411 to GMD000444

HAZARDOUS SUBSTANCES**NOTIFIED APPLICATIONS RECEIVED AND OPEN FOR SUBMISSIONS****Application Code:** HSR03029**Applicant:** Scotts Australia Pty Limited**Purpose:** To obtain approval for the import of the hazardous substance Defender Home Garden Ready for Use - Nature's own Pyrethrum Insect Spray for the control of ants, aphids, caterpillars, thrips and certain other insects on garden plants**Date Application Received:** 23 September 2003**Date Publicly Notified:** 3 October 2003**Date Submissions Close:** 17 November 2003**Application Code:** HSR03030**Applicant:** Scotts Australia Pty Limited**Purpose:** To obtain approval for the import of Defender Bug-B-Gon Insect Spray for Indoor and Outdoor Plants for the control of aphids, caterpillars, thrips, mealy bug, whitefly, cutwork, other bugs and mites on indoor and outdoor trees, shrubs and flowering plants**Date Application Received:** 15 September 2003**Date Publicly Notified:** 19 September 2003**Date Submissions Close:** 3 November 2003**Application Code:** HSR03034**Applicant:** Bayer New Zealand**Purpose:** To import Advantix K9, a veterinary medicine for dogs**Date Application Received:** 29 August 2003**Date Publicly Notified:** 11 September 2003**Date Submissions Close:** 22 October 2003**Application Code:** HSR03035**Applicant:** Jurox New Zealand Limited**Purpose:** To import for release Prolet, an anti-inflammatory and analgesic product for use in companion animals. It triggers some HSNO thresholds for toxicity and possibly has other hazardous properties**Date Application Received:** 1 September 2003**Date Publicly Notified:** 15 September 2003**Date Submissions Close:** 28 October 2003**Application Code:** HSR03038**Applicant:** Rohm and Haas New Zealand Limited**Purpose:** To seek approval for SmartFresh Activator Solution, which is to be used with SmartFresh SmartTabs as part of an application system, to release its active ingredient, 1-MCP, for agricultural purposes**Date Application Received:** 12 September 2003**Date Publicly Notified:** 17 September 2003**Date Submissions Close:** 31 October 2003**NOTIFIED APPLICATIONS - WITHDRAWN****Application Code:** HSR03017**Applicant:** New Zealand Business Council for Sustainable Development**Purpose:** To reassess clopyralid-based herbicides used to control weeds in turf, from which mown vegetation is composted. Unchanged residue in this green waste severely affects plants grown in such media**Date Application Withdrawn:** 2 October 2003**NON-NOTIFIED APPLICATIONS RECEIVED****Application Code:** HSC02015**Applicant:** DuPont (NZ) Limited**Purpose:** To import into containment for field testing a new agricultural chemical for use in contained cropping situations (crop 1, crop2, crop3, crop 4). DPX65Z3F will be tested at various water concentrations ranging from 1 to 40% dilutions in water**Date Application Received:** 22 September 2003**Application Code:** HSC03005**Applicant:** Dow AgroSciences**Purpose:** To use in containment for the purpose of field testing the hazardous substances (6.4A and 9.1C) DASNZ001/03SG, DASNZ002/03SL and DAS003/03SL to assess their ability to control weeds in pastures**Date Application Received:** 24 September 2003

Application Code: HSC03012

Applicant: Bayer New Zealand Limited

Purpose: To field test the substances BCS005-03, BCS006-03 and BCS007-03 to assess the efficacy and phytotoxicity

Date Application Received: 1 September 2003

Application Code: HSC03013

Applicant: Pest-Tech Limited

Purpose: To assess the cost effectiveness of two new anticoagulant baits for the control of possums in replicated field trials, to obtain data on toxicant levels used, residues in possums, cost-effectiveness of each bait formulation, and regulatory toxicology

Date Application Received: 11 September 2003

Application Code: HSC03014

Applicant: United Phosphorus Limited Australia

Purpose: To import a limited quantity of QuickPHlo-R Granules for use in a trial to generate performance data for the product in support of registration of the product

Date Application Received: 30 September 2003

Application Code: HSR03039

Applicant: HAS Expertise Limited

Purpose: To import J44.01, a cleaning product which has been assessed as mildly irritating to the skin and eyes and slightly toxic to aquatic organisms (algae)

Date Application Received: 17 September 2003

DECISIONS ON APPLICATIONS

The Environmental Risk Management Authority reached a decision on the following applications:

Application Code: HSR03010

Applicant: Monsanto Australia Limited

Purpose: To import and manufacture for release, Roundup Transorb™, for use as a herbicide for the control of weeds in non-selective situations

Formally Received: 4 March 2003

Decision Notified: 1 September 2003

Identifier for Substance: Roundup Transorb™

Classification: 6.1D, 6.3B, 9.1A

Decision: Approved with Controls

ERMA Approval Code: HSR000074

Controls:

Control Code ¹¹	Regulation ¹²	Explanation ¹³
Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 - Ecotoxic Property Controls		
E1	Regulations 32 — 45	Limiting exposure to ecotoxic substances
E2	Regulations 46 — 48	Restrictions on use within application area
E5	Regulations 5(2), 6	Requirements for keeping records of use
E6	Regulation 7	Requirements for equipment used to handle hazardous substances
E7	Regulation 9	Approved Handler requirements This control applies to any application of the substance within 8 metres of water where water is defined under ‘environmental medium’ in the Hazardous Substances (class 6, 8 and 9 controls Regulations 2001 and would include, but not be limited to, ponds, lakes, rivers, streams, drains, marine foreshores etc.
E8	Regulation 10	Restrictions on the carriage of hazardous substances on passenger service vehicles
Hazardous Substances (Identification) Regulations 2001		
I1	Regulations 6, 7, 32 — 35, 36 (1) — (7)	The Identification Regulations prescribe requirements with regard to identification of hazardous substances in terms of: <ul style="list-style-type: none"> - information that must be ‘immediately available’ with the substance (priority and secondary identifiers). This information is generally provided by way of the product label - documentation that must be available in the workplace, generally provided by way of MSDS - signage at a place where there is a large quantity of the substance. General identification requirements

¹¹ 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 ERMA New Zealand website www.ermanz.govt.nz/resources and is also contained in the ERMA New Zealand *User Guide to the Controls Regulations*.

¹² 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.

¹³ These explanations are for guidance only. Refer to the cited Regulations for the formal specification, and for definitions and exemptions.

I3	Regulation 9	Priority identifiers for ecotoxic substances
I9	Regulation 18	Secondary identifiers for all hazardous substances
I11	Regulation 20	Secondary identifiers for ecotoxic substances
I16	Regulation 25	Secondary identifiers for toxic substances
I19	Regulations 29 — 31	Alternative information in certain cases
I21	Regulations 37 — 39, 47 — 50	Documentation required in places of work
I23	Regulation 41	Specific documentation requirements for ecotoxic substances
I28	Regulation 46	Specific documentation requirements for toxic substances
I29	Regulations 51 — 52	Duties of persons in charge of places with respect to signage
Hazardous Substances (Packaging) Regulations 2001		
P1	Regulations 5, 6, 7(1), 8	General packaging requirements
P3	Regulation 9	Packaging requirements for substances packed in limited quantities
P13	Regulation 19	Packaging requirements for toxic substances
P15	Regulation 21	Packaging requirements for ecotoxic substances
PG3	Schedule 3	This schedule provides the test methods for packaging required to be tested in accordance with this schedule. The tests in Schedule 3 correlate to the packaging requirements of UN Packing Group III (UN PGIII).
Hazardous Substances (Disposal) Regulations 2001		
D4	Regulation 8	Disposal requirements for toxic substances
D5	Regulation 9	Disposal requirements for ecotoxic substances
D6	Regulation 10	Disposal requirements for packages
D7	Regulations 11, 12	Disposal information requirements
D8	Regulations 13, 14	Disposal documentation requirements
Hazardous Substances (Emergency Management) Regulations 2001		
EM1	Regulations 6, 7, 9 — 11	Level 1 emergency management information: General requirements
EM6	Regulation 8(e)	Information requirements for toxic substances
EM7	Regulation 8(f)	Information requirements for ecotoxic substances
EM8	Regulations 12 — 16, 18 — 20	Level 2 emergency management information requirements
EM11	Regulations 25 — 34	Level 3 emergency management requirements – emergency response plans
EM12	Regulations 35 — 41	Level 3 emergency management requirements – secondary containment
EM13	Regulation 42	Level 3 emergency management requirements – signage
Hazardous Substances (Personnel Qualification) Regulations 2001		
AH1	Regulations 4 — 6	Approved Handler requirements (including Test Certificate and qualification requirements)

Application Code: HSR02028

Applicant: Air New Zealand

Purpose: To import for use a high temperature marking ink for airmotive gas turbine components.

Formally Received: 3 June 2003

Decision Notified: 15 September 2003

Identifier for Substance: Markem 6893 White

Classification: 3.1B, 6.1E, 6.3A, 6.4A, 6.5A, 6.5B, 6.6B, 6.7A, 6.8B, 6.9B, 9.1A

Decision: Approved with Controls

ERMA Approval Code: HSR000075

Controls:

Control Code ¹⁴	Regulation ¹⁵	Explanation ¹⁶
Hazardous Substances (Classes 1 to 5 Control Regulations) Regulations 2001 - Flammable Property Controls		
F1	Regulation 7	General test certification requirements for Markem 6893 White
F2, T7, E8	Regulation 8 (Classes 1 — 5), regulation 10 (Classes 6 — 9)	General public transportation restrictions and requirements for Markem 6893 White
F3	Regulation 55	General limits on flammable substances
F5	Regulations 58 — 59	Requirements regarding hazardous atmosphere zones for flammable liquids (3.1)
F6	Regulations 60 — 70	Requirements to prevent unintended ignition of Markem 6893 White
F11	Regulation 76	Segregation of incompatible substances
F12	Regulations 77 — 78	General requirement for hazardous substance locations for Markem 6893 White
F14	Regulation 81	Test certification requirements for facilities where Markem 6893 White is present
F16	Regulation 83	Controls on transit depots where flammable substances are present
F17	Regulations 84 — 85	Requirements to control adverse effects of intended ignition of Markem 6893 White, including requirements for protective equipment and clothing
Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 -Toxic Property Controls		
T2	Regulations 29, 30	Controlling exposure in places of work
T4, E6	Regulation 7	Requirements for equipment used to handle Markem 6893 White

¹⁴ 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 ERMA New Zealand website www.ermanz.govt.nz/resources and is also contained in the ERMA New Zealand *User Guide to the Controls Regulations*.

¹⁵ 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.

¹⁶ These explanations are for guidance only. Refer to the cited Regulations for the formal specification, and for definitions and exemptions.

Hazardous Substances (Identification) Regulations 2001		
		<p>The Identification Regulations prescribe requirements with regard to identification of hazardous substances in terms of:</p> <ul style="list-style-type: none"> - information that must be ‘immediately available’ with the substance (priority and secondary identifiers). This information is generally provided by way of the product label - documentation that must be available in the workplace, generally provided by way of MSDS - signage at a place where there is a large quantity of the substance.
I1	Regulations 6, 7, 32 — 35, 36(1) — (7)	- General identification requirements
I3, I5, I8	Regulations 9, 11, 14	Priority identifiers for Markem 6893 White
I9	Regulation 18	Secondary identifiers for all hazardous substances
I11, I13, I16	Regulations 20, 22, 25	Secondary identifiers for Markem 6893 White
I17	Regulation 26	Use of Generic Names
I18	Regulation 27	Use of Concentration Ranges
I19	Regulations 29 — 31	Alternative information in certain cases
I21	Regulations 37 — 39, 47 — 50	Documentation required in places of work
I23, I25, I28	Regulations 41, 43 and 46	Specific documentation requirements for Markem 6893 White
I29	Regulations 51 — 52	Duties of persons in charge of places with respect to signage
I30	Regulation 53	Advertising Markem 6893 White
Hazardous Substances (Packaging) Regulations 2001		
P1	Regulations 5, 6, 7(1), 8	General packaging requirements
P3, P5, P13, P15	Regulations 9, 11, 19, 21	Packaging requirements for Markem 6893 White
PG2	Schedule 2	This schedule provides the test methods for packaging required to be tested in accordance with this schedule. The tests in Schedule 2 correlate to the packaging requirements of UN Packing Group II (UN PGII).
Hazardous Substances (Disposal) Regulations 2001		
D2, D4, D5	Regulations 6, 8 and 9	Disposal requirements for Markem 6893 White
D6	Regulation 10	Disposal requirements for packages
D7	Regulations 11, 12	Disposal information requirements
D8	Regulations 13, 14	Disposal documentation requirements
Hazardous Substances (Emergency Management) Regulations 2001		
EM1	Regulations 6, 7, 9 — 11	Level 1 emergency management information: General requirements
EM4, EM6, EM7	Regulation 8(c), (e) and (f)	Additional information requirements for Markem 6893 White

EM8	Regulations 12 — 16, 18 — 20	Level 2 emergency management information requirements
EM9	Regulation 17	Extra content for Markem 6893 White
EM10	Regulations 21 — 24	Fire extinguishers
EM11	Regulations 25 — 34	Level 3 emergency management requirements – emergency response plans
EM12	Regulations 35 — 41	Level 3 emergency management requirements – secondary containment
EM13	Regulation 42	Level 3 emergency management requirements – signage
Hazardous Substances (Personnel Qualification) Regulations 2001		
AH1	Regulations 4 — 6	Approved Handler requirements (including test certificate and qualification requirements)

Application Code: TNS03003

Applicant: DefLog International Pty Limited

Purpose: To tranship through Tauranga, smokeless powder (UN 0160, 1.1C) destined for the USA from Australia

Formally Received: 5 September 2003

Decision Notified: 5 September 2003

Identifier for Substance: Smokeless powder UN 0160, 1.1C

Decision: Approved with Controls

ERMA Approval Code: TNS000022

Controls:

- This approval for multiple shipments that comply with these controls is valid until 31 December 2003.
- The Multimodal Dangerous Goods Form applicable to each shipment shall be provided to ERMA New Zealand prior to each shipment arriving at Tauranga.
- Each shipment shall consist of no more than one 20 ft container containing smokeless powder (Class 1.1C, UN 0160) with a gross weight not exceeding 15,000 kg (NEQ not exceeding 14,000 kg).
- The consignment(s) shall comply with all of the relevant provisions of the IMDG Code for explosives of this type. (Smokeless powder, UN 0160, 1.1C)
- The explosives shall be removed from the ship on arrival (first cargo movement), stored in the transit area for class 1.1C containers at the Port of Tauranga and reloaded on the ship immediately before departure (last cargo movement).
- The container must be sealed and not opened whilst in the transit area unless deemed necessary in response to an emergency.

- The vessel shall be worked in accordance with the approved Port of Tauranga operational programme for Class 1 containers and the Port of Tauranga Harbour Master's instructions.
- In the event of any emergency occurring the ship's master shall act in accordance with the Harbour Master's instructions
- A contingency plan to deal with any such emergency must be in place.
- Any significant incident must be reported to ERMA New Zealand, Environment BOP (The Harbour Master), Maritime Safety Authority and to OSH.
- Non-compliance with any of these controls shall terminate this approval

Application Code: TNS03008

Applicant: P & O Nedlloyd

Purpose: To tranship explosives of class 1.4B through Auckland en route from Germany to Australia

Formally Received: 1 September 2003

Decision Notified: 10 September 2003

Identifier for substance: Detonators, electric for blasting, UN 0255, class 1.1B

Decision: Approved with Controls

ERMA Approval Code: TNS000023

Controls:

- The consignment shall comply with all the relevant provisions of the IMDG code for explosives of the type involved in this shipment. In addition, the following additional controls are stipulated:
- Handling and storage of the consignment is to be in accordance with 'The handling of Explosives at the Port of Auckland and Onehunga Guidelines'.

- The container is to be discharged by shore crane to the Explosive Barge and moved to the Explosives Anchorage. No other work is to be conducted in the vessel until such time as the detonators are removed from it.
- The barge will return to the terminal, immediately prior to the vessel sailing, for the shore crane to lift the container back on to the vessel.
- While in transit in New Zealand, the container must be sealed and not opened unless deemed necessary in response to an emergency.

DELEGATED AUTHORITY

The Environmental Risk Management Authority reached a decision on the following applications:

Application Code: HSC03004

Applicant: Syngenta Crop Protection Limited

Purpose: To import into containment the fungicide NZF1 to conduct small scale 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

Formally Received: 24 July 2003

Decision Notified: 2 September 2003

Identifier for Substance: NZF1

Decision: Approved with Controls

ERMA Approval Code: HSC000046

Controls:

1. The trials shall be undertaken in accordance with the information contained within the applicant's application and with a field protocol (including the identification of the trial sites) written at the start of each trial season. The field protocol shall be approved by ERMA New Zealand before the trial commences.
2. Notwithstanding the requirements of control 1 above, the trials shall comply with controls 3 to 26 below.
3. The maximum quantity of NZF1 that shall be imported is 50 litres.
4. The trials may be carried out at a location that is not defined until an infestation of the target pest has been found, provided the applicant;
 - i. has permission from the owner of the land to carry out the trial.
 - ii. notifies ERMA New Zealand of the locations as per control 21.
5. The trial sites shall be chosen so as to prevent any of the substance entering any surface water or groundwater system.

6. An adequate buffer zone shall be maintained between the trial site and any building where people live or work.
7. Access to the trial sites shall be by permission of the Trial Director¹⁷ 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.
8. NZF1 shall be imported and stored in accordance with the Code of Practice for the Management of Agrichemicals NZS8409:1999.
9. The substance shall be securely packed and stored 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.
10. The transportation of the substance shall comply with The Land Transport Rule: Dangerous Goods 1999.
11. 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.
12. The personnel applying the substance to the crops shall be able to demonstrate that they have the qualifications necessary to carry out the trial. One way of demonstrating this would be the holding of an appropriate Growsafe certification.
13. Special attention shall be paid to the avoidance of drift beyond the boundary of the trial sites. Sufficient buffer zones must be maintained to ensure that commercial produce does not come into contact with the NZF1 spray.
14. No produce from within the trial site (including the buffer zone) shall be consumed by people or animals or offered for sale.
15. Produce from within the trial site (including the buffer zone) 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 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. The 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 shall be returned to Syngenta Crop Protection Limited for secure storage in an exempt laboratory, exported or degraded to a non-hazardous substance. (Note that once the trials are complete the substance does not have an 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 diluted with water, sand or earth, and then spread over a marked and designated non-crop and non-grazed area within the trial site.
 20. A record shall be kept of all use of the substance. This record shall cover all matters referred to in Regulation 6 of the Hazardous Substances (Class 6, 8 and 9 Controls) Regulations.
 21. Occupational Safety and Health, Head Office [Attn. HSNO Project Manager (OSH) or equivalent position] and ERMA New Zealand shall be informed in writing of the location, start, and completion of the trials. The OSH project manager shall be informed at least three working days prior to application at specific sites.
 22. Appropriate safety precautions necessary to provide safeguards against the substance's ecotoxic properties, acute toxic properties and skin irritant properties shall accompany the substance at all stages of its lifecycle.
 23. Relevant first aid measures for immediate action pending medical attention shall accompany the substance at all stages of its lifecycle.
 24. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities and trial sites at any reasonable time.
 25. 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.
 26. The trial must be completed within five years of the date of this approval.
-

Application Code: HSC03006

Applicant: Bayer New Zealand Limited

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

Formally Received: 28 July 2003

Decision Notified: 2 September 2003

Identifier for Substance: Impulse

Decision: Approved with Controls

ERMA Approval Code: HSC000045

Controls:

1. The trials shall be undertaken in accordance with the Project Plan and Management Plan, which accompanied the application. Modifications of the Project Plan or Management Plan may be approved in writing by ERMA New Zealand providing that they comply with the following controls.
2. Notwithstanding the requirements of control 1 above, the trials shall also comply with the following controls.
3. The trials may be carried out at a location that is not defined until an infestation of the target pest has been found, provided the applicant;
 - i. has permission from the owner of the land to carry out the trial.
 - ii. notifies ERMA New Zealand of the locations as per control 21.
4. The trial sites shall be chosen so as to prevent any of 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 Director¹⁸ 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.
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.

¹⁸ 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.

9. The substance shall be mixed, diluted and prepared in any other way prior to application in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409.
10. The substance shall be securely packed in suitable containers that comply with the Hazardous Substances (Packaging) Regulations 2001, and shall be labelled in accordance with the Hazardous Substances (Identification) Regulations 2001. A MSDS shall accompany each shipment.
11. The substance shall be transported in accordance with good practice. This may require compliance with the Land Transport Rule: Dangerous Goods 1999.
12. The substance shall be applied by way of hand-held/operator-worn equipment, using hydraulic pressure or compressed CO₂ or air on plots specifically designated and marked for each treatment, in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409. Special attention shall be paid to the minimisation of spray drift, and in particular to the avoidance of drift beyond boundaries agreed with the owner of the trial site.
13. The personnel applying the substance to the crops shall be able to demonstrate that they have the qualifications necessary to carry out the trial. One way of demonstrating this would be the holding of an appropriate Growsafe certification.
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. The 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 shall be returned to Bayer New Zealand Ltd for secure storage in an exempt laboratory, exported or degraded to a non-hazardous substance. (Note that once the trials are complete the substance does not have an 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 will be placed into sealed containers and disposed of at an appropriate waste disposal facility (which may include a landfill), subject to the facility's waste acceptance policy.
20. A record shall be kept of all use of the substance. This record shall cover all matters referred to in Regulation 6 of the Hazardous Substances (Class 6, 8 and 9 Controls) Regulations.
21. Occupational Safety and Health, Head Office [Attn. HSNO Project Manager (OSH) or equivalent position] and ERMA New Zealand shall be informed in writing of the location, start, and completion of the trials. The OSH project manager shall be informed at least three working days prior to application at specific sites.
22. 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.
23. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities and trial sites at any reasonable time.

Application Code: HSC03007

Applicant: Syngenta Crop Protection Limited

Purpose: To import into containment fungicidal compounds of the chemical class of 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

Formally Received: 8 August 2003

Decision Notified: 26 September 2003

Identifier for Substance: OPA1, OPA2, OPA3, OPA4, OPA5, OPA6, OPA7, OPA8, OPA9, OPA10 and OPA11

Decision: Approved with Controls

ERMA Approval Code: HSC000054 to HSC000064

Controls:

1. The trials shall be undertaken in accordance with the information contained within the application and attached field protocol.
2. Notwithstanding the requirements of control 1 above, the trials shall comply with controls 3 to 26 below.
3. The maximum quantity of each substance that shall be imported is 0.1 litres (100 mL).
4. The trials may be carried out at a location that is not defined, provided the applicant;

- i has permission from the owner of the land to carry out the trial.
 - ii notifies ERMA New Zealand of the locations as per control 21.
5. The trial sites shall be chosen so as to prevent any of the substances entering any surface water or groundwater system.
 6. Trial sites shall be located to prevent any building where people live or work being exposed to the substance.
 7. Access to the trial sites shall be by permission of the Trial Director¹⁹ or owner of the property on which it is located. The trial site boundaries shall be clearly marked and distinctly visible from outside the trial site throughout the life of the trials. The primary access points shall be signed indicating that unauthorised access is not allowed, that the site is subject to a trial, and that the crops should not be removed or disturbed.
 8. The substances shall be imported and stored in accordance with the Code of Practice for the Management of Agrichemicals NZS8409:1999.
 9. The substances shall be securely packed and stored 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.
 10. The transportation of the substances shall comply with any requirements under the Land Transport Rule: Dangerous Goods 1999.
 11. The substances shall be applied by way of hand-held/operator-worn equipment, using hydraulic pressure or compressed CO₂ or air on plots specifically designated and marked for each treatment, in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409.
 12. The personnel applying the substances to the crops shall be able to demonstrate that they have the qualifications necessary to carry out the trial. One way of demonstrating this would be the holding of appropriate Growsafe certification.
 13. Special attention shall be paid to the avoidance of drift beyond the boundary of the trial sites. Sufficient buffer zones must be maintained to ensure that commercial produce does not come into contact with the substances.
 14. No produce from within the trial site (including the buffer zone) shall be consumed by people or animals or offered for sale.
 15. Produce from within the trial site (including the buffer zone) 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 within the trial site.
 17. The 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 within the trial site.
 18. Surplus substances remaining at the end of the trials shall be returned to Syngenta Crop Protection Ltd for secure storage in an exempt laboratory, exported or degraded to a non-hazardous substance. (Note that once the trials are complete the substances do not have an approval to be present in New Zealand except in an exempt laboratory).
 19. Any accidental spillage of the unmixed substances or spray mixes shall be diluted with water, sand or earth, and then spread over a marked and designated non-crop and non-grazed area within the trial site.
 20. A record shall be kept of all use of the substances. This record shall cover all matters referred to in Regulation 6 of the Hazardous Substances (Class 6, 8 and 9 Controls) Regulations.
 21. Occupational Safety and Health, Head Office [Attn. HSNO Project Manager (OSH) or equivalent position] and ERMA New Zealand shall be informed in writing of the location, start, and completion of the trials, at least three working days prior to commencement of the trials. The OSH project manager shall be informed at least three working days prior to application at specific sites. Notification can be by fax or email.
 22. Information of the appropriate safety precautions necessary to provide safeguards against the substances' ecotoxic properties shall accompany each substance at all stages of its lifecycle. This shall include information on the appropriate protective clothing that is to be used.
 23. Information on the relevant first aid measures for immediate action pending medical attention shall accompany the substances at all stages of their lifecycle.

¹⁹ The Trial Director is the individual appointed by the applicant to be responsible for the overall conduct of the trial in accordance with the trial protocols and approval controls.

24. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities and trial sites at any reasonable time.
25. 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.
26. This approval expires on 31 August 2005.

Application Code: HSC03008

Applicant: Bayer New Zealand Limited

Purpose: To field test the substances BCS001-03, BCS002-03, BCS003-03 and BCS004-03 to assess the efficacy and phytotoxicity

Formally Received: 4 August 2003

Decision Notified: 16 September 2003

Identifier for Substance: BCS001-03, BCS002-03, BCS003-03 and BCS004-03

Decision: Approved with Controls

ERMA Approval Code: HSC000047 to HSC000050

Controls:

1. The trials shall be undertaken in accordance with the information contained in the application. Modifications of the Project Plan or Management Plan may be approved in writing by ERMA New Zealand providing that they comply with the following controls.
2. Notwithstanding the requirements of control 1 above, the trials shall comply with the following controls.
3. The substances shall be transported and stored 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.
4. The substances shall be transported in accordance with good practice. This may require compliance with the Land Transport Rule: Dangerous Goods 1999.
5. The substances shall be stored in a secure and enclosed laboratory at Bayer New Zealand's Christchurch premises. Access to the treatment facility shall be limited to personnel authorised by the Trial Director²⁰.
6. The GROWSAFE Code of Practice for the Management of Agrichemicals, NZS8409:1999 shall be followed.
7. The substances shall be applied to the seeds, by GROWSAFE accredited personnel, in an enclosed laboratory at Bayer New Zealand's Christchurch premises. The substances shall only be taken to the trial sites in the form of treated seed.
8. Only sufficient material to treat the appropriate amount of seed shall be removed from the container.
9. Treated seed shall be weighed out into plot sized amounts, bagged and labelled before being transported to the trial site.
10. Only sufficient seed for each trial will be taken to the trial site.
11. All seed shall be sown and covered with soil.
12. Personnel applying the substance to the seeds shall wear appropriate protective clothing, as specified by the Safety Data Sheet.
13. Personnel handling the treated seed shall wear rubber gloves.
14. Equipment used for treating the seed will be triple rinsed after use and the rinsate disposed of over a non-cropping, non-grazed area. Any surplus treatment mixture will be further diluted and disposed of as above.
15. All surplus substances shall be held in original containers and stored in the company's laboratory until after such time as the products are registered for use. If the products are not registered this surplus shall be returned to the country of origin.
16. All sample containers, once empty, shall be triple rinsed. The rinsate will then be disposed of over a non-cropping, non-grazed area, and the container shall be disposed of in an appropriate waste disposal facility (which may include a landfill), subject to the facility's waste acceptance policy.
17. Any spillage of the substances shall be contained, prevented from entering waterways, and absorbed with earth, sand, clay or other absorbent material. The material shall then 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. Any spillage of the treated seed shall be contained, collected and disposed of similarly.
18. To minimise the effects of any accidental release of the substances, the container labels shall carry appropriate safety precautions and relevant first aid measures for immediate action pending medical attention. A copy of the Safety Data Sheet shall accompany the substances to the seed treatment facility.
19. Should accidental release and exposure occur, normal precautions shall be followed, as detailed in the Safety Data Sheet.

²⁰ 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 approved controls.

20. The trial sites shall be chosen so as to prevent any of the substances entering any surface water or groundwater system.
21. Access to the trial sites shall be by permission of the Trial Director 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.
22. The trial sites shall be fenced to prevent access by stock.
23. At the completion of the trial, field trial plots shall be cultivated, and pot trials shall be allowed to dry off, and disposed of in a compost system or spread over ground that will be cultivated. No seed produce shall enter the human or animal food chain, and treated seed shall not be sold.
24. A record shall be kept of all use of the substances by the Trial Director. This record shall cover all matters referred to in Regulation 6 of the Hazardous Substances (Class 6, 8 and 9 Controls) Regulations.
25. Occupational Safety and Health, Head Office [Attn. HSNO Project Manager (OSH) or equivalent position] and ERMA New Zealand shall be informed in writing of the location, start, and completion of the trials. The OSH project manager shall be informed at least three working days prior to application at specific sites.
26. 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.
27. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities and trial sites at any reasonable time.

Application Code: HSC03009

Applicant: Bayer New Zealand Limited

Purpose: To field test the substances Galmano, Galmano Plus to assess their efficacy and phytotoxicity

Formally Received: 14 August 2003

Decision Notified: 25 September 2003

Identifier for Substance: Galmano and Galmano Plus

Decision: Approved with Controls

ERMA Approval Code: HSC000052 to HSC000053

Controls:

1. The trials shall be undertaken in accordance with the information contained in the application. Modifications of the Project Plan or Management Plan may be approved in writing by ERMA New Zealand providing that they comply with the following controls.
2. Notwithstanding the requirements of control 1 above, the trials shall comply with the following controls.
3. The substances shall be transported and stored 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.
4. The substances shall be transported in accordance with good practice. This may require compliance with the Land Transport Rule: Dangerous Goods 1999.
5. The substances shall be stored in secure facilities in the enclosed laboratory at Bayer New Zealand's Christchurch premises, in accordance with good practice. This would generally be achieved by compliance with the Code of Practice for the Management of Agrichemicals NZS8409. Access to the treatment facility shall be limited to personnel authorised by the Trial Director²¹.
6. The substances shall be prepared and applied to the seed in accordance with good practice. This would generally be achieved by compliance with the Code of Practice for the Management of Agrichemicals NZS8409. The substances shall be applied to the seeds by suitably qualified personnel (for example, GROWSAFE accredited) in an enclosed laboratory at Bayer New Zealand's Christchurch premises. The substances shall only be taken to the trial sites in the form of treated seed.
7. Only sufficient material to treat the appropriate amount of seed shall be removed from the container.
8. Treated seed shall be weighed out into plot sized amounts, bagged and labelled before being transported to the trial site.
9. Only sufficient seed for each trial shall be taken to the trial site.
10. All seed shall be sown and covered with soil.
11. Personnel applying the substance to the seeds shall wear appropriate protective clothing, as specified by the Safety Data Sheet.
12. Personnel handling the treated seed shall wear rubber gloves.

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 approved controls.

13. Equipment used for treating the seed shall be triple rinsed after use and the rinsate disposed of over a non-cropping, non-grazed area. Any surplus treatment mixture shall be further diluted and disposed of as above.
14. Surplus substances remaining at the end of the trials shall be returned to Bayer New Zealand Ltd for secure storage in an exempt laboratory, exported or degraded to a non-hazardous substance. (Note that once the trials are complete the substances do not have an approval to be present in New Zealand except in an exempt laboratory).
15. All substance containers, once empty, shall be triple rinsed. The rinsate will then be disposed of over a non-cropping, non-grazed area, and the container shall be disposed of in an appropriate waste disposal facility (which may include a landfill), subject to the facility's waste acceptance policy.
16. Any spillage of the substances shall be contained, prevented from entering waterways, and absorbed with earth, sand, clay or other absorbent material. The material shall then 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. Any spillage of the treated seed shall be contained, collected and disposed of similarly.
17. To minimise the effects of any accidental release of the substances, the container labels shall carry appropriate safety precautions and relevant first aid measures for immediate action pending medical attention. A copy of the Safety Data Sheet shall accompany the substances to the seed treatment facility.
18. Should accidental release and exposure occur, normal precautions shall be followed, as detailed in the Safety Data Sheet.
19. The trial sites shall be chosen so as to prevent any of the substances entering any surface water or groundwater system.
20. Access to the trial sites shall be by permission of the Trial Director 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 sites shall be secured by stock proof fencing to exclude grazing animals for the duration of the trial.
22. At the completion of the trial, field trial plots shall be cultivated, and pot trials shall be allowed to dry off, and disposed of in a compost system or spread over ground that will be cultivated. No seed produce shall enter the human or animal food chain, and treated seed shall not be sold.
23. A record shall be kept of all use of the substances by the Trial Director. This record shall cover all matters referred to in Regulation 6 of the Hazardous Substances (Class 6, 8 and 9 Controls) Regulations.
24. Occupational Safety and Health, Head Office [Attn. HSNO Project Manager (OSH) or equivalent position] and ERMA New Zealand shall be informed in writing of the location, start, and completion of the trials. The OSH project manager shall be informed at least three working days prior to application at specific sites.
25. 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.
26. The Authority, or its authorised agent or properly authorised enforcement officers, may inspect the facilities and trial sites at any reasonable time.

Application Code: HSC03010

Applicant: Bayer New Zealand Limited

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

Formally Received: 14 August 2003

Decision Notified: 19 September 2003

Identifier for Substance: Eagle

Decision: Approved with Controls

ERMA Approval Code: HSC000051

Controls:

1. The trials shall be undertaken in accordance with the Project Plan and Management Plan, which accompanied the application. Modifications of the Project Plan or Management Plan may be approved in writing by ERMA New Zealand providing that they comply with the following controls.
2. Notwithstanding the requirements of control 1 above, the trials shall also comply with the following controls.
3. The trials may be carried out at a location that is not defined until an infestation of the target pest has been found, provided the applicant;
 - i. has permission from the owner of the land to carry out the trial.

- ii. notifies ERMA New Zealand of the locations as per control 21.
4. The trial sites shall be chosen so as to prevent any of 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 Director²² 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.
 7. The trial sites shall be secured by stock proof fencing to exclude grazing animals for the duration of the trial.
 8. The substance shall be stored in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409.
 9. The substance shall be mixed, diluted and prepared in any other way prior to application in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409.
 10. The substance shall be securely packed in suitable containers that comply with the Hazardous Substances (Packaging) Regulations 2001, and shall be labelled in accordance with the Hazardous Substances (Identification) Regulations 2001. A 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. 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. One way of demonstrating this would be the holding of an appropriate Growsafe certification.
 14. No sprayed produce shall be consumed by people or animals or offered for sale. Grazing stock shall be kept out of the trial sites for six weeks following spraying.
 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. The equipment used shall be rinsed after use with the appropriate detergent or decontaminant, and rinsate disposed of within the trial site by being sprayed over a marked and designated non-crop and non-grazed area at the site.
 18. Surplus substance remaining at the end of the trials shall be returned to Bayer New Zealand Ltd for secure storage in an exempt laboratory, exported or degraded to a non-hazardous substance. (Note that once the trials are complete the substance does not have an 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 will be placed into sealed containers and disposed of at an appropriate waste disposal facility (which may include a landfill), subject to the facility's waste acceptance policy.
 20. A record shall be kept of all use of the substance. This record shall cover all matters referred to in Regulation 6 of the Hazardous Substances (Class 6, 8 and 9 Controls) Regulations.
 21. Occupational Safety and Health, Head Office [Attn. HSNO Project Manager (OSH) or equivalent position] and ERMA New Zealand shall be informed in writing of the location, start, and completion of the trials. The OSH project manager shall be informed at least three working days prior to application at specific sites.
 22. 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.

²² 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.

23. The Authority, or its authorised agent or properly authorised enforcement officers, may inspect the facilities and trial sites at any reasonable time.

Application Code: HSR03036

Applicant: Jurox New Zealand Limited

Purpose: To import for release an anthelmintic for use in ruminants. The product triggers acute oral toxicity, skin and eye irritation, skin sensitisation, reproductive/developmental toxicity, and aquatic and terrestrial invertebrate ecotoxicity thresholds

Formally Received: 1 September 2003

Decision Notified: 17 September 2003

Identifier for Substance: Closamec

Classification: 6.1E, 6.5B, 6.8B, 9.1A, 9.4B

Decision: Approved with Controls

ERMA Approval Code: HSR000076

Controls:

Control Code ²³	Regulation ²⁴	Explanation ²⁵
Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001		
T1	Regulations 11 — 27	Limiting exposure to toxic substances
T4, E6	Regulation 7	Requirements for equipment used to handle hazardous substances
T5	Regulation 8	Requirements for protective clothing and equipment
T7, E8	Regulation 10	Restrictions on the carriage of hazardous substances on passenger service vehicles
E1	Regulations 32 — 45	Limiting exposure to ecotoxic substances
E5	Regulations 5(2), 6	Requirements for keeping records of use
Hazardous Substances (Identification) Regulations 2001		
		<p>The Identification Regulations prescribe requirements with regard to identification of hazardous substances in terms of:</p> <ul style="list-style-type: none"> - information which must be ‘immediately available’ with the substance (priority and secondary identifiers). This information is generally provided by way of the product label - documentation that must be available in the workplace, generally provided by way of MSDS - signage at a place where there is a large quantity of the substance.
I1	Regulations 6, 7, 32 — 35, 36(1) — (7)	General identification requirements
I3	Regulation 9	Priority identifiers for ecotoxic substances
I8	Regulation 14	Priority identifiers for certain toxic substances
I9	Regulation 18	Secondary identifiers for all hazardous substances

23 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 ERMA New Zealand website www.ermanz.govt.nz/resources and is also contained in the ERMA New Zealand *User Guide to the Controls Regulations*.

24 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.

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

I11	Regulation 20	Secondary identifiers for ecotoxic substances
I16	Regulation 25	Secondary identifiers for toxic substances
I17	Regulation 26	Use of Generic Names
I18	Regulation 27	Use of Concentration Ranges
I19	Regulations 29 — 31	Alternative information in certain cases
I21	Regulations 37 — 39, 47 — 50	Documentation required in places of work
I23	Regulation 41	Specific documentation requirements for ecotoxic substances
I28	Regulation 46	Specific documentation requirements for toxic substances
I29	Regulations 51 — 52	Duties of persons in charge of places with respect to signage
I30	Regulation 53	Advertising toxic substances
Hazardous Substances (Packaging) Regulations 2001		
P1	Regulations 5, 6, 7(1), 8	General packaging requirements
P3, P13, P15, PG3	Regulations 9, 19, 21, Schedule 3	Packaging requirements
Hazardous Substances (Disposal) Regulations 2001		
D4, D5	Regulations 8, 9	Disposal requirements
D6	Regulation 10	Disposal requirements for packages
D7	Regulations 11, 12	Disposal information requirements
D8	Regulations 13, 14	Disposal documentation requirements
Hazardous Substances (Emergency Management) Regulations 2001		
EM1, EM6, EM7	Regulations 6, 7, 8(e), 8(f), 9 — 11	Level 1 emergency management information requirements
EM8	Regulations 12 — 16, 18 — 20	Level 2 emergency management information requirements
EM11	Regulations 25 — 34	Level 3 emergency management requirements – emergency response plans
EM12	Regulations 35 — 41	Level 3 emergency management requirements – secondary containment
EM13	Regulation 42	Level 3 emergency management requirements – signage

Application Code: HSR03037

Applicant: Gro-Chem New Zealand Limited

Purpose: To import THIN-IT S for use as a thinning agent in horticultural applications

Formally Received: 11 September 2003

Decision Notified: 26 September 2003

Identifier for Substance: THIN-IT S

Classification: 6.1E, 6.3B, 6.4A, 9.1D

Decision: Approved with Controls

ERMA Approval Code: HSR000077

Controls:

Control Code ²⁶	Regulation ²⁷	Explanation ²⁸
Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 - Toxic Property Controls		
T7	Regulation 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		
E6	Regulation 7	Requirements for equipment used to handle hazardous substances
Hazardous Substances (Identification) Regulations 2001		
		<p>The Identification Regulations prescribe requirements with regard to identification of hazardous substances in terms of:</p> <ul style="list-style-type: none"> • information that must be ‘immediately available’ with the substance (priority and secondary identifiers). This information is generally provided by way of the product label • documentation that must be available in the workplace, generally provided by way of MSDS • signage at a place where there is a large quantity of the substance.
I1	Regulations 6, 7, 32 — 35, 36(1) — (7)	General identification requirements
I8	Regulation 14	Priority identifiers for certain toxic substances
I9	Regulation 18	Secondary identifiers for all hazardous substances
I11	Regulation 20	Secondary identifiers for ecotoxic substances
I16	Regulation 25	Secondary identifiers for toxic substances
I19	Regulations 29 — 31	Alternative information in certain cases
I21	Regulations 37 — 39, 47 — 50	Documentation required in places of work
I28	Regulation 46	Specific documentation requirements for toxic substances
I29	Regulations 51 — 52	Duties of persons in charge of places with respect to signage
I30	Regulation 53	Advertising and toxic substances
Hazardous Substances (Packaging) Regulations 2001		
P1	Regulations 5, 6, 7(1), 8	General packaging requirements
P3	Regulation 9	Packaging requirements for substances packed in limited quantities
P13	Regulation 19	Packaging requirements for toxic substances
Hazardous Substances (Disposal) Regulations 2001		
D4	Regulation 8	Disposal requirements for toxic substances
D5	Regulation 9	Disposal requirements for ecotoxic substances
D6	Regulation 10	Disposal requirements for packages

26 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 ERMA New Zealand website www.ermanz.govt.nz/resources and is also contained in the ERMA New Zealand *User Guide to the Controls Regulations*.

27 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.

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

D7	Regulations 11, 12	Disposal information requirements
D8	Regulations 13, 14	Disposal documentation requirements
Hazardous Substances (Emergency Management) Regulations 2001		
EM1	Regulations 6, 7, 9 — 11	Level 1 emergency management information: General requirements
EM6	Regulation 8(e)	Information requirements for toxic substances
EM7	Regulation 8(f)	Information requirements for ecotoxic substances
EM8	Regulations 12 — 16, 18 — 20	Level 2 emergency management information requirements
EM11	Regulations 25 — 34	Level 3 emergency management requirements – emergency response plans
EM12	Regulations 35 — 41	Level 3 emergency management requirements – secondary containment
EM13	Regulation 42	Level 3 emergency management requirements – signage

AMENDMENTS TO APPROVALS

There have been no minor or technical amendments under Section 67A of the HSNO Act during this period.

TEST CERTIFIERS

The Chief Executive of the Environmental Risk Management Authority, acting under delegated power from the Authority, reached a decision on the following application on 12 September 2003

Applicant: Anthony Lealand

**Address: Firework Professionals Limited,
PO Box 19912, Christchurch**

Decision: Approved

ERMA Approval Code: TST000040

Requirements for which a Test Certificate may be issued:

- Containers securing class 1 substances for use in pyrotechnic displays and special effects
- Locations where class 1 substances for use in pyrotechnic displays and special effects are present
- The detonation or deflagration of class 1 substances in pyrotechnic displays and special effects in darkness
- The level of blast overpressure and heat radiation in the detonation or deflagration of class 1 substances in pyrotechnic displays and special effects
- Outdoor pyrotechnic displays
- The transfer of class 1 substances for use in pyrotechnic displays and special effects in darkness
- Locations where minor amounts of class 2, 3, 4 and 5.1 substances are present for use in pyrotechnic displays and special effects

- **Approved Handlers in Control of:**
 - Class 1 substances in pyrotechnic displays and special effects
 - The detonation or deflagration of class 1 substances in pyrotechnic displays and special effects
 - Outdoor pyrotechnic displays
 - The disposal of unfired pyrotechnics
 - Indoor pyrotechnic displays
 - The transfer of class 1 substances for use in pyrotechnic displays and special effects from one type of transport to another
 - Class 1 substances for use in pyrotechnic displays and special effects being transported by road
 - Minor amounts of Class 2, 3, 4 and 5.1 substances in pyrotechnic displays and special effects
- Safety supervisors for film, television, commercials and productions involving pyrotechnics

RECENT POLICY DECISIONS

GHS LOWERS SENSITISER LEVELS

The United Nations have recently published the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), which forms the basis of the Hazardous Substances (Minimum Degrees of Hazard) and (Classification) Regulations 2001

(www.unece.org/trans/danger/danger.htm). This document (sometimes referred to as the 'Purple Book' identifies that the cut-off level for components in mixtures for sensitisation effects has changed from the previous level of 1% to 0.1% for both skin and respiratory sensitisers. This shift was based on expert consideration of sensitisation effects at the recent OECD Joint Meeting.

ERMA New Zealand also notes that the classification of 6.9A components in mixtures can acknowledge the dose-response classification for target organ systemic effects. Therefore when a 6.9A component is present in a mixture at ≥ 1 percent and up to 10%, then a 6.9B classification is conferred to the mixture (this recognises a 'dilution' of the amount required for a 6.9A effect). When a 6.9A component is present in a mixture at ≥ 10 percent, then the mixture is considered a 6.9A substance.

These changes will be used by ERMA New Zealand staff when considering the classification of substances (both Part V applications and during Transfer).

USEFUL DATA SOURCES FOR SUBMITTING APPLICATIONS

The following databases may be useful for applicants to consult during the preparation of Part V applications. It should be stressed that this is not a complete list of data sources; applicants should also try the search engine, Google (www.google.co.nz) for further information on components.

General Information

<http://toxnet.nlm.nih.gov>

This site gives access to several databases (ChemID, HSDB, CCRIS, IRIS, DART, EMIC, GENETOX, TOXLINE)

<http://www.epa.gov/opprd001/factsheets/>

This site gives access to the EPA factsheets on several chemicals.

<http://ecb.jrc.it>

This site gives access to the European Chemical Bureau (Existing Chemicals and Classification and Labelling are useful sub-sites).

<http://www.mrw.interscience.wiley.com/pattys/>

This site gives general information on chemicals

<http://ntp-server.niehs.nih.gov/>

This site gives access to the National Toxicology Programme.

<http://chemfinder.cambridgesoft.com/>

This site gives general information on chemicals

<http://www.unece.org/trans/danger/danger.htm>

This site gives access to the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)

Pesticides

<http://cfpub.epa.gov/oppref/rereg/status.cfm?show=rereg>

This site is for USEPA Pesticide Re-registration Eligibility Documents (RED) on various pesticides

<http://www.nzfsa.govt.nz/acvm/>

This site is the list of registered pesticides (and veterinary medicines) in New Zealand

<http://www.apvma.gov.au/>

This is the Australian Regulatory Agency for assessment of Pesticide/Veterinary Medicines

Toxicity

<http://www.inchem.org>

This site gives access to the International Programme for Chemical Safety documents (factsheets, environmental health criteria, monographs and evaluations on pesticides and veterinary medicines (JECFA and JMPR), IARC summaries (International Agency for Research on Cancer))

<http://europa.eu.int/comm/food/fs/phps/pro/eva/newactive/list1en.htm>

This site gives access to the European Union new active substance evaluations

http://europa.eu.int/comm/food/fs/sfp/ph_ps/pro/eva/newactive/index.htm

This site gives access to the European Union existing active substance evaluations

<http://eudraportal.eudra.org/>

This site gives access to the European Agency for the Evaluation of Medicinal Products (EMA) – veterinary and human medicines

<http://www.nicnas.gov.au/publications/>

This site gives access to the Australian NICNAS chemical assessment reports.

Ecotoxicity

<http://www.epa.gov/ecotox/>

This site gives access to the ECOTOX database

<http://www.kemi.se/nclass/>

This site gives access to the N-class database for ecotoxic classifications.



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